Contents

Special Audit Report on the requirement, procurement, supply, distribution and regulation of medicines in the years 2022 & 2023.

Executive Summary

The COVID-19 epidemic outbreak, spanning from 2020 to 2021, followed by the economic crisis experienced between 2022 and 2023, had an adverse impact on multiple sectors in Sri Lanka. Accordingly, it was possible to recognize both in audit and in social discourses in the country that the said problematic status exerted a significant impact on the health sector as well. The periodical cabinet memorandum presented by the Minister of Health revealed a shortage of medicines in the Country, while the adverse repercussions of dispensing substandard drugs to patients were sparked by discussions through the media and other social dialogues from time to time. Given the backdrop provided above, this report was issued subsequent to comprehensive inspections conducted in terms of powers vested in me under Section 13 of the Audit Act No.19 of 2018, following extensive discussions on the matter in question.

Following the approval for the Cabinet Memorandum submitted by the Minister of Health in September and October 2024 for emergency purchase of drugs citing that the available medicine stock was insufficient, suppliers were selected using both the Expression of Interest (EOI) method and the Unsolicited Proposal method. By this time, the health sector had received US$ 200 million under the Indian Credit Line and the Ministry of Finance had introduced more lenient procurement guidelines specifically tailored for this emergency procurement.

Although suppliers were selected under any of the method specified above, due to appointment of an evaluation committee alone without appointing a Technical Evaluation Committee to assess drug suppliers, required drugs had been purchased without valuation on the quality to be considered based on advanced technical aspects. Furthermore, according to the National Medicines Regulatory Authority Act No.05 of 2015, all medicines should be registered with the Authority and the Authority reserves the right to issue Waiver of Registration –WOR certificates only in specific and crucial circumstances. Further, the Authority charges a fee for these certificates as specified in the directives outlined in Extraordinary Gazette No. 2052/33 dated 05 January 2018 and those certificates which are issued by levying a fee had been issued under an accelerated mechanism, deviating from the

recognized procedure. The Chief Executive Officer, instead of following the established procedure of evaluation through a Technical Evaluation Committee, had personally granted approval, thus deviating from the Authority's primary objective. Similarly, the Authority had assigned its responsibility for ensuring the quality of medicines to another party.

Even though necessary arrangements were put in place to purchase 285 items of medicines through the Expression of Interest (EOI) method and 38 items of medicines through the unsolicited proposals in these emergency purchases, at the time of determining the required quantity, no attention had been focused on the stocks of medicines to be received under the orders placed following normal procedure. Accordingly, steps had not been taken to make optimal decisions considering the working capital requirements. Therefore, certain medicines had been received in excess of the requirement during that period. Although arrangements were made to purchase certain medicines as emergency purchases at significantly higher prices compared to those purchased through the normal method, these emergency stocks were still not received even after the arrival of stocks ordered through the normal process.

Moreover, controversy has emerged concerning specific drugs procured under emergency purchases. One such drug, Human Immunoglobulin IV 5-6g, was observed to be counterfeit according to the Medicines Regulatory Authority's documents. Also, Isolez Biotech Pharma AG Ltd, the supplier of the drug, claimed to have imported and supplied this substandard drug from India. However, according to information from the Import and Export Controller and the Sri Lankan Customs, it was observed that the company had not imported the relevant drug. The Indian manufacturing company mentioned by the supplying company has also confirmed that they did not supply this drug. Taking all these facts into account, the audit could not confirm that this drug, (supplied as a pharmaceutical product) was not illegally manufactured in Sri Lanka by this company, in violation of the provisions of the National Medicines Regulatory Authority Act.

It was observed that the relevant parties failed to fulfill their responsibility for conducting quality testing of medicines before purchasing/providing and distributing them to patients, despite the sensitive nature of these items, which are critical to human life. Furthermore, due to the failure in the proper evaluation and completion of the drug files submitted by the suppliers to the National Medicines Regulatory Authority for registration within the stipulated 300-day period, there arose a shortage of formal suppliers to supply medicines. Consequently, orders had been placed with unregistered suppliers, relying on the letters of

Waiver of Registration. Furthermore, the audit could not ascertain that the evaluations were conducted properly and impartially due to the fact that the evaluations of certain medicines were completed swiftly in less than a period of two days, thus extraordinarily shortening the evaluation timeframe.

During the economic crisis in the country, there was a tendency to utilize the limited local currency for imported goods without fully leveraging the provisions available under the Indian Credit Line at concessional terms. It was accordingly observed to the audit that attention had not been paid to the possible working capital challenges and foreign exchange challenges in the country.

Accordingly, it was observed by that a crisis situation had arisen in the health sector during the years 2022-2023 due to the lack of proper management in the health sector, absence of sound coordination between the institutions that carry out related tasks, lack of confirmation that the information necessary to make correct and rational decisions has been provided, and the absence of a proper stock control system.

However, some recommendations are given along with the following recommendations with a view to avoiding/ preventing these situations from occurring in future and for detailed information and written confirmations, please refer to volume I and annexures.

(i) To investigate and initiate legal action against those who endangered the sick people by importing substandard medicines.

(ii) To minimize, as much as possible, the issue of certificates of Waiver of Registration.

(iii) To Develop the National Drugs Quality Control Laboratory in line with international standardization level.

(iv) To take immediate action to blacklist the companies/ institutions involved in the substandard medical supplies.

(v) To devise a system for expediting and follow-up the affairs of drugs registration by the National Medicines Regulatory Authority.

(vi) To maintain a proper liaison between the institutions involved in the drug supply network.

01. Background and Nature of the Issuance of Report

Various sectors of Sri Lanka had been adversely affected by the economic crisis that occurred with the Covid epidemic of the year 2020 and the last quarter of the year 2021. It was revealed that due to the lack of foreign exchange in the country and the rapid devaluation of the rupee against the Dollar along with the rapid depreciation of foreign reserves, it had an impact on the health sector as well. Also in that situation, there was a considerable discussion in the society about the shortage of medicines in the country and the medicines issued to the patients were not in required standard and the prices of the medicines were rising rapidly.

In this situation, this report was issued after prolonged examination of these matters under the authority given to me by section 13 of the Audit Act No. 19 of 2018.
The draft of Volume I submitted with this report and the draft audit observations related to the fraudulent supply of substandard drugs by two suppliers have not been answered as the date of this report and due to that it was considered that those observations have been accepted and included in this report.

When referring to this report, it should refer to paragraph 6 and 7.5 to 7.11 for an understanding of the procurement of medicines, cabinet approvals for the emergency procurement process and amendments to the medicine procurement guidelines, intervention of the Ministry of Health and the National Medicines Regulatory Authority for emergency procurement and to understand about the medicine regulation. Paragraph 7 indicates all the observations related to this report and only the observations related to 05 drugs are included from 7.14 to 7.18. It should refer the volume I for observations relating to other 73 drugs. Also refer to annexures for detailed information and written confirmations. The recommendations of this report were mentioned by the paragraph No.08.

02. Methodologies Followed to Prepare the Report

2.1 Examining the Registers, Books and Reports

(i) National Medicines Regulatory Authority Act, No. 05 of 2015.

(ii) National Audit Act, No. 19 of 2018.

(iii) Cabinet Memoranda, cabinet decisions and observations of the Ministry of Finance relating to maintaining uninterrupted medical supplies during the period of crisis between 2020 and 2023.

(iv) Circulars of the Ministry of Finance and emergency Procurement Guidelines.

(v) Circulars relating to the quality-failed medical supplies issued by the Director of Medical Supplies issued in the years 2021, 2022, and 2023.

(vi) Procurement Guidelines 2007 relating to pharmaceuticals and medical devices.

(vii) Procurement Guidelines 2022 relating to pharmaceuticals and medical devices (those Guidelines came into effect on 01 January 2023 replacing the Procurement Guidelines 2007 relating to pharmaceuticals and medical devices)

(viii) Financial Regulations of the Democratic Socialist Republic of Sri Lanka.

(ix) The Manual on Management of Drugs issued in the year 1987 and amended in the year 2008.

(x) Board Papers of the Board of Directors of the National Medicines Regulatory Authority, reports of the Committees for evaluating medicines, reports of the sub-committees relating to waiver of registration, reports of the Committees relating to safety and risk evaluation committee minutes of the Pricing Committee of the National Medicines Regulatory Authority, dossiers on medicines, certificates for waiver of registration, files of the National Medicines Quality Assurance Laboratory.

(xi) Files relating to the Indian credit line, Minutes of the meetings of sub-committees on medicines relating to Indian credit line, files relating to emergency purchases, reports of Pricing Committees relating to emergency purchases, Procurement files of the State Pharmaceuticals Corporation, Board Papers of the Board of Directors, clearance files of the Wharf Division.

(xii) Files relating to procurements made under Expressions of Interest.

(xiii) Information relating to Customs clearance collected through the Department of Customs and Import and Export Control Department, information obtained from information system of the Office of the Registrar of Companies relating to

establishment of companies, and information retrieved from the Department of Inland Revenue.

(xiv) Files and payment vouchers of the Medical Supplies Division relating to orders of pharmaceuticals.

(xv) Information retrieved from PRONTO and Swarstha software used to administer the process of medical supplies.

2.2 Other Methodologies

(i) Analyzing the information collected by Government hospitals through various sources with respect to the said process.

(ii) Holding discussions with top level management of the institutions such as, Ministry of Health, Production, Supply and Regulation of Pharmaceuticals Unit, Medical Supplies Division, National Medicines Regulatory Authority, State Pharmaceuticals Corporation, and State Pharmaceuticals Manufacturing Corporation. Collecting information from officers of the Treasury responsible for implementing the Indian Credit Line, and officers of the Health Sector Enhancement Project – HSEP implemented under financial assistance of the Asian Development Bank.

(iii) Physical inspection of the premises of National Medicines Quality Assurance Laboratory.

03. Scope of Audit

A sample audit test was conducted with respect to the progress in the utilization of financial assistance including the Indian credit line received in favor of medical supplies to Government hospitals and productivity of emergency purchase of medicines made by deviating from standard Procurement process using such financial assistance, and the regulatory mechanism for the pharmaceuticals so supplied.

Objectives of the audit

The objective of this special audit is to examine the measures taken for fulfillment of the medicine requirement in the period of crisis arisen in 2022 due to the shortage of foreign reserves and other matters, whether the emergency procurements carried there

and inspection of the regulation of the process of providing the medicines with quality to the patients.

04. Limitation to the Scope

It is stressed that my scope was subject to the following restrictions when reaching conclusions through observations pointed out in this report.

(i) The original files relating to the emergency procurements were taken into the custody of Criminal Investigation Department whilst the audit was in progress.

(ii) Some of the explanations relating to the procurements could not be obtained due to reasons such as, the Chief Accounting Officer of the Ministry of Health, Additional Secretary of the Production, Supply and Regulation of Pharmaceuticals Unit, Deputy Director General of the Medical Supplies Division, Director of Medical Supplies, Deputy Director of Medical Supplies, Assistant Director of Medical Supplies (Pharmaceuticals) and Accountant of Medical Supplies were in remand custody due to court proceedings, and the medical officer of the Production, Supply and Regulation of Pharmaceuticals Unit, being the Head of that Unit, had not returned after proceeding abroad.

(iii) Not carry out / get it done the independent quality assurance tests further to the quality assurance certificates obtained by relevant authorized officers for verification the quality of medicines.

(iv) Not obtain the independent verifications further to the decisions/recommendations of the relevant Technical Evaluation Committees in relation to the technical facts of the medicines.

(v) Not verify the accuracy/ reliability of the data obtained through new Swarstha Information System.

(vi) There had been cases, where specific confirmations had not been received regarding the draft audit observations owing to taking action as mentioned below by the Secretary of the Ministry in replying to the draft of this report, and it is observed as a matter that needs further attention in the future as to

whether it had been an act of deliberately avoiding any disadvantageous situation.

(vii) In the provision of written replies to the draft report of this report issued on 29 December 2023 by the Secretary of the Ministry of Health, the Secretary had informed the audit that "although action had been taken to provide complete replies as much as possible, there may be incomplete replies as primary officers related to the matters pointed out in this report are in remand custody and unavailability of certain documentary information.

(viii) Even though the Secretary of Health had informed that he expected to provide complete replies through the replies provided to the relevant audit queries by giving a general concise reply for the observations made by examining a sample of 75 medicines in the draft report mentioned in the aforementioned paragraph, replies had not been given even though a period of over 02 months had elapsed since the issue of many audit queries.

(ix) As legal proceedings were in progress with respect to the draft audit observations on the supply of quality failed medicines by a supplier in a fraudulent manner, and some of the officers were in the custody of the court, it was informed that a complete reply would be given once those activities were finalized, and it was informed that an internal audit would be conducted in relation to another company and a report would be issued.

05. Deciding on Samples

A sample comprising of 78 medicines was selected in order to examine the process, in which estimates for medicines are prepared, orders are placed, and supplying such medicines to the Medical Supplies Division and distribution, by taking into account one or some of the matters, out of 06 risky fields identified such as, shortages of medicines during the years 2022 and 2023, emergency purchase of medicines, import of medicines upon waiver of registration, import of medicines under Indian credit line, quality failure of medicines, and patients experiencing serious adverse reactions and the items of medicines that were in the limelight of electronic and print media during 2022 and 2023 were also included in this sample.

06. The Procedure

6.1 Information on the medicines in short supply and deficit in foreign exchange deficit in the year 2022.

According to the register on position of the supply of medicines prevailed at that period furnished by the Secretary to the then, State Ministry of Production, Supply and Regulation of Pharmaceuticals to the Audit, it was identified that 311 (Annexure 01) items of medicines remained out of stocks as at 13 May 2022. The Secretary to the, State Ministry of Production, Supply and Regulation of Pharmaceuticals informed the Secretary to the Ministry of Health on 22 April 2022 (Annexure 02) that there existed a financial requirement of US $ 13.2 million in respect of foreign letters of credit pending at banks and letters of credit to be presented to the banks due to foreign exchange deficit. Furthermore, as per the information presented to the Audit by the State Pharmaceuticals Corporation, a total of Rs. 4,278.82 million (Annexure 03) remained payable as at 20 April 2022 with respect to the medical supplies ordered form the local market by the State Pharmaceuticals Corporation and the letters of credit pending at People's Bank and Bank of Ceylon relating to local suppliers. The State Pharmaceuticals Corporation furnished information to the Audit stating that there existed a financial liability of Rs. 23,123 million (Annexure 04) as at 25 May 2022 comprising the sum of Rs. 7,135 million relating to the issue of letters of credit on the orders placed by the State Pharmaceuticals Corporation, to be paid to the suppliers and clearance activities, and the sum of Rs. 15,988 million for the settlement of overdrafts obtained on medical supplies.

6.2 Measures taken by the State Ministry of Production, Supply and Regulation of Pharmaceuticals for the supply of medicines in shortage during the year 2022.

6.2.1 The Ministry of Health, State Ministry of Production, Supply and Regulation of Pharmaceuticals, Medical Supplies Division, State Pharmaceuticals Corporation of Sri Lanka, and State Pharmaceuticals Manufacturing Corporation had taken action to utilize the following financial assistance in order to make payments to the suppliers of medicine and purchase on priority the items of medicine that could not be supplied due to foreign exchange deficit during the first quarter of the year 2022. As per the information of the Treasury, emergency purchase of medical supplies had been facilitated using the following foreign grants.

Table No. 01 – Foreign Credit Assistance Schemes

Contributing Agent/Country	Provision
	(US $ Million)
Indian credit line	360.0*
Asian Development Bank Assitance (ADB-HSEP/AIIB)	166.0
World Bank Credit Assistance (WB)	48.0
Donations from China	22-25
Other agents (WHO, UNFPA)	2.0

* Sums of US $ 200 million and US $ 35 million had been granted in 02 instances under the Indian credit line and the other provision had been allocated later.

6.2.2 Approval had been given as mentioned in Table 02 below on 06 April 2022 by the Sub-committee established under the Drug manufacturing, supply, and regulation unit that the financial assistance of US $ 200 million granted in the first instance under the Indian credit line be used to purchase the medical supplies provided for Government hospitals through the Medical Supplies Division, make purchases with a view to making available the medicines at pharmacies functioning under the State Pharmaceuticals Corporation, purchase ingredients for the State Pharmaceuticals Manufacturing Corporation to manufacture medicines, and import medicines by private sector and local manufacturers in view of availability of medicines at the market. In this process, a sub-committee on medicines is established for Indian credit line under the Ministry of Health and the invoices selected by that Committee are sent to the High Commission of India through the Indian credit line facility center established under the Ministry of Finance. Once the relevant approvals are received, the amount required to open the letters or credit should be deposited in LKR in an account of the Treasury by the importers.

Table No. 02: Sector to Which Financial Grants had been Allocated as at 06 April 2022 and Maximum Credit Limits

Sector to Which Financial Grants had been Allocated	Maximum Limit of granting Loans
	(US $ Million)
For State Pharmaceuticals Corporation	126
For Osusala	
For State Pharmaceuticals Manufacturing Corporation	04
For local manufacturers	25
For Suppliers of the private sector	45
Total	200

6.2.3 It was stated as per the Minutes of the meetings of the sub-committee on Indian credit line dated 29 August 2022 that invoices for 1,372 items worth US $ 109 million had been approved and presented by the sub-committee utilizing credits from India as mentioned above. It was also stated that approval of the Indian Credit Line Facility Coordination Unit –ICFCU of the Ministry of Finance and the High Commission of India had been given on 584 invoices therefrom worth US $ 68 million. Accordingly, the said value represented 34 per cent of the credit amounting to US $ 200 million that had been initially allocated for the health sector. Particulars are as follows.

Table No. 03 – Financial assistance approved by the sub-committee of the Indian Credit Line as at 29 August 2022.

Sector to Which Financial Grants had been Allocated	Maximum Limit of Granting Financial Assistance	Value of Financial Assistance Approved
	(US $)	(US $)
State Pharmaceuticals Corporation	114,990,000	24,044,243
To procure by importing through the State Pharmaceuticals Corporation		242,288
For Osusala		13,028,077
For State Pharmaceuticals Manufacturing Corporation	4,000,000	3,765,680
For local manufacturers	25,000,000	13,244,885
For the suppliers of private sector	55,010,000	55,005,841
Sri Lanka State Trading Corporation	1,000,000	-
	200,000,000	109,331,014

Table 04 – Progress of utilizing Indian Credit Line as at 21.10.2022

	Amount approved by the medicines sub-committee on Indian credit line as at 2022.08.29	No. of invoices approved by the sub-committee as at 2022.08.29		Value of invoices approved by the High Commission of India as at 2022.08.26	No. of invoices approved by the Indian High Commission as at 2022.08.26		Amount deposited by the importers in the Treasury Account as at 2022.08.26	No. of invoices through which funds had been deposited in the Treasury account by the importers as at 2022.08.26		Value of orders received as at 2022.10.21	No. of invoices through which orders had been received as at 2022.10.21
	(US $)			(US $)			(US $)			(US $)	
SPC (DHS)	24,044,243	398		9,899,985	113		53,244	04		4,654,693	50
Import & supply (SPC)	242,288	08		171,438	06		0	0			
Osusala	13,028,077	322		3,344,524	109		108,087	07		870,144	47
SPMC	3,765,680	22		1,555,120	08		373,500	01		1,781,780	05
Local Manufactures	13,244,885	236		5,644,303	92		608,631	12		-	-
Private sector suppliers	55,005,841	386		47,595,611	256		15,843,765	77		-	-
	109,331,014	1,372		68,210,981	584		16,987,227	101		7,306,617	102

6.2.4 According to the Minutes of the meetings of the sub-committee on Indian credit line dated 19 May 2023, the following Table gives the values approved by the sub-committee as at 19 May 2023 after a period of 09 months since 29 August 2022.

Table 05- Financial assistance approved as at 19 May 2023.

Sector to which the assistance had been allocated	Maximum limit on assistance	Amount of assistance approved
		(US $)
Purchase of medicines for the Medical Supplies Division through State Pharmaceuticals Corporation (SPC-DHS)		72,346,466
Importing and supplying through the State Pharmaceuticals Corporation	116,954,957	280,038
Importing and supplying through the Medical Supplies Division		2,105,155
To the Medical Supplies Division		4,490,377
For Osusalas		37,802,989
To purchase ingredients for the State Pharmaceuticals Manufacturing Corporation.	3,908,580	3,908,580
For local manufacturers	12,773,403	12,773,403
For the suppliers of private sector	73,817,031	69,878,047
Receipt of US $ 35 million as additional provision on 2022.11.29	27,546,028	-
	235,000,000	203,585,055

6.2.5 However, the action had been taken to purchase medical supplies worth Rs. 29,575 million from final quarter of the year 2022 up to third quarter of the year 2023 under emergency procurements through calling for Expression of Interest (EOI) and Unsolicited Proposals.

6.3 Role of the National Medicines Regulatory Authority in respect of regulating Medicines in Sri Lanka

The National Medicines Regulatory Authority Act had become effective on 25 June 2015 as per the Gazette Notification No. 1920/28 published on that date (Annexure 06) in terms of Section 01 of the National Medicines Regulatory Authority Act, No. 05 of 2015 (Annexure 05) giving powers to the National Medicines Regulatory Authority to be responsible for registration, licensing, production, import and other matters relating to medicines, medical instruments, and borderline products, and control and conduct of clinical tests. It is the vision of the Authority to increase patient access to quality-assured medicinal products whilst the mission of the Authority is protecting and improving public health by ensuring medicinal products available in the country and meet applicable standards of safety, quality and efficacy. Objectives of the Authority directly related to the regulation of medicines and key activities are as follows (Annexure 07).

(i.) Ensure the availability of efficacious, safe and good quality medicines, to the general public at affordable prices.

(ii.) Function as the central regulator for all matters connected with the registration, licensing, cancellation of registration or licensing, pricing, manufacture, importation, storage, transport, distribution, sale, advertising and disposal of medicines.

(iii.) Ensure that all activities related to registration, licensing and importation of medicines, are carried out in a transparent, sustainable and equitable manner.

(iv.) Encourage the manufacturing of good quality medicines in Sri Lanka with a view to assuring the availability of essential medicines at affordable prices.

(v.) Promote the safe and rational use of medicines by health care professionals and consumers.

(vi.) Recommend appropriate amendments to relevant laws pertaining to medicines.

(vii.) Educate the general public, health care professionals and all stakeholders on medicines.

(viii.) Regulate the promotion and marketing of medicines.

(ix.) Regulate the availability of medicines in the country.

(x.) Conduct post marketing surveillance on quality, safety and adverse reaction of the medicines.

(xi.) Regulate all matters pertaining to the conduct of clinical trials in Sri Lanka.

6.4 Key Divisions, Committees and Functions thereof on the Regulation of Medicines

(i) Medicines Regulatory Division – MRD

Coordinating with the Authority relating to the regulation and control of all the matters pertaining to medicines, and assisting the Authority.

(ii) National Medicines Quality Assurance Laboratory – NMQAL

Conducting tests on medicines furnished with requests for registration, medicines added when imported to the country, medicines furnished by consumers along with complaints, medicines identified by the Authority during the post marketing survey, and other medicines presented by the Authority with respect to some other reasons.

(iii) Medicines Evaluation Committee – MEL

Conducting technical evaluation on medicines presented for registration by specifying the benefits, risks, quality, efficacy, safety, requirement, price, and economic analysis; and, submission of a report in that connection to the Authority.

(iv) Medicines Evaluation Subcommittee – MESC

Approving or amending when necessary the report prepared by the Medicines Regulatory Division by taking into account the quality, safety, and efficacy of the medicine thereby presenting recommendations, and presenting such recommendations to the Medicines Evaluation Committee.

(v) Waiver of Registration Subcommittee –WORSC

To make recommendations in terms of Section 109 of the National Medicines Regulatory Authority Act, No. 05 of 2015 (Annexure 08) by considering the applications received by the Authority for waiver of registration, emergency situations, and other special reasons; and, granting permission and informing the Medicines Evaluation Committee in that connection.

(vi) Pricing Committee – PC

Assisting the Authority in collecting information and data affecting the process of deciding on the price of a medicine, making recommendations to the Authority with respect to introductory price of a medicine, maximum retail price, and means of revising the price, and informing the Authority on price variations of a medicine. Overseeing the fluctuation of price of a medicine.

(vii) Safety and Risk Evaluation Subcommittee –SAFRESC

Means-ends analysis in view of ensuring efficiency of the safety of medicines, evaluation of risks, risk management, investigation of cases, communicating on crisis situations when necessary, and providing technical assistance for management.

(viii) Recall Management Committee

In the event of problems caused by medicines, making recommendations to the Authority for recalling such medicines.

6.5 Cabinet Approvals received on Emergency Purchases made during Covid Pandemic and Foreign Exchange Crisis, and Amendments made to the Procurement Guidelines.

6.5.1 Following the Section 16 (i) of Note No. 20/0694/201/016 (Annexure 09) to the Cabinet presented by the then President on 01 April 2020 with respect to the procurement of essential items during the Covid-19 pandemic, it was decided on 09 April 2020 that provisions in Supplementary 35 of Procurement Manual be further simplified in liaison with the National Procurement Commission in view of facilitating a hassle-free emergency procurement process in the wake of Covid-19 pandemic thereby issuing a simplified version of Procurement Guidelines and the Director General of the Department of Public Finance had been informed in that connection (Annexure 10). As per the said Cabinet Decision, action had been taken by the Secretary to the Treasury through the Circular No. PFD/PMD/149/000/2020-02 dated 09 April 2020 (Annexure 11) to further relax the provisions in Supplementary 35 of the Procurement Manual 2006 at the time of executing the emergency procurements relating to Covid-19. However, through the Letter No. PFD/PMD/149/000/2020-02 (Annexure 12) dated 12 October 2020 replacing the letter of the Secretary to the Treasury dated 09 April 2020, provision had been made for even more waivers under Supplementary 35 of the Procurement Manual 2006 relating to emergency purchases on Covid-19. Instructions had been further given in that letter to the effects that, the Procurement Guidelines so amended would be effective only for a temporary period, the relevant Procurement Committee and the procurement entity should assure transparency and responsibility while ensuring maximum value for the entity by following the waivers given to the Procurement Guidelines, and the waivers so given should be considered only for emergency purchases directly related to the Covid-19 pandemic.

6.5.2 Furthermore, concessions such as, enhancing the powers vested in the Procurement Committees, reduction of bid security relating to calling for bids and reordering process to 0 per cent, and temporary suspension of main procurement plan and appeal process for emergency procurements, had been made through the Procurement Guidelines that had been amended specifically in view of Covid-19 pandemic. However, it was further stated

that the evaluation process of the Procurement Committee and the procurement entity should be done attentively.

6.5.3 Approval had been given at the Cabinet meeting (Annexure 14) held on 03 May 2021 for the Cabinet Memorandum No. 21/0791/309/040 (Annexure 13) presented on 01 May 2021 by the then Minister of Health under the title "Enhancing the PCR capacity during the third wave of Covid-19" Meanwhile, a new Guideline, titled "COVID 19 Emergency Procurement Process – CEPP" had been issued through the Letter No. PFD/PMD/COVID19/Guide/21 dated 13 May 2021 (Annexure 15) by the Secretary to the Treasury based on Cabinet Decision Nos. 01 April 2020 and 03 May 2021.

6.5.4 Having mentioned in Annexure 01 to the Cabinet Memorandum considering the emergency situation in the country that the decisions taken by the Emergency Procurement Committee relating to the emergency situation in the country would be informed to the Cabinet monthly whilst the fairness of this process would be verified by the internal audit of the procurement entity, the said Guideline mentioned in paragraph 6.5.3 above had been presented to the Cabinet seeking covering approval. It had been decided at the meeting of the Cabinet held on that day that covering approval be given thereon (Annexure 17).

6.5.5 It was stated therein that deficiencies in the existing procurement process would be addressed in the wake of Covid-19 outbreak, the standard competitive bidding process mentioned in the Government Procurement Guidelines-2006 would be deviated, the COVID 19 Emergency Procurement Committee – CEPC would be established, that Committee would replace the Cabinet appointed Procurement Committees (SCAPC, CAPC, CANPC), and instructions of technical experts would be sought relating to emergency purchases as no Technical Evaluation Committees would be appointed.

6.5.6 Furthermore, the relevant Minister / State Minister should be informed on the procurements assigned by this Committee, and the relevant Minister should justify the requirement of items so procured thereby presenting a monthly report containing information such as items purchased, supplier and value to the Cabinet seeking covering approval. The Guideline further stated that the Internal Auditor of the procurement entity

should supervise the procurement process thus reporting at the end of the procurement that the process was fair and productive.

6.5.7 The Cabinet Memorandum No. 22/0734/540/001 (Annexure 18) presented by the Minister of Health on 30 May 2022 titled "Purchase of essential medicines, medical instruments, and accessories during the period of crisis" sought approval to further maintain the Covid-19 Emergency Procurement Committee established under Procurement Guidelines on 13 May 2021 by expanding its scope in view of strengthening the process of purchasing medicines and instruments during the period of crisis. The Minister of Finance, Economic Stabilization and National Policies had given approval for proposals in the Memorandum through observations (Annexure 19) made on 01 June 2022, and having included provisions similar to Guidelines in the emergency procurement process relating to Covid-19, new Guidelines were made for emergency procurements of the health sector with respect to the period June – December 2022. At the meeting of the Cabinet held on 06 June 2022, it had been decided that the Secretary to the Treasury be authorized to promptly issue the Guidelines with respect to the emergency procurement process of the health sector mentioned in Annexure A to the observations made by the Minister of Finance, Economic Stabilization and National Policies whilst ordering the Secretary to the Ministry of Health to purchase the essential medicines and medical instruments by following the said Guidelines. (Annexure 20).

6.5.8 In order to address the shortage of essential medicines and medical instruments occurred due to issues that take place in executing the existing procurement process during the period of crisis, Guidelines had been prepared and presented with respect to the Health Sector Emergency Procurement Process- HSEPP in accordance with Letter No. PFD/PMD/Health/HSEPP/01/2022 (Annexure 21) of the Secretary to the Ministry of Health dated 16 June 2022 thereby giving approval to the procurement entities of the Government health sector to make procurements by deviating from the standard competitive bidding process during the period from June 2022 to 31 December 2022.

6.5.9 The Health Sector Emergency Procurement Committee – HSEPC had been appointed to purchase emergency medicines and medical instruments. It was stated that the said Committee would replace the Cabinet appointed procurement committees

(SCAPC/CAPC/CANPC) mentioned in the handbooks and Circulars related to Procurement Guidelines -2006 and instructions of the technical experts would be sought as Technical Evaluation Committees would not be appointed with respect to emergency purchases. The Minister of Health should be informed on the procurements assigned by this Committee as well, and the Minister of Health should justify the requirement of items so procured thereby presenting a monthly report containing information such as items purchased, supplier and value to the Cabinet seeking covering approval. As in the aforementioned Covid-19 emergency procurement process, the Internal Auditor of the procurement entity should supervise and report on the procurement process to ensure fairness and productivity.

6.5.10 According to Paragraph 2.2 of the new Guidelines, composition of the Health Sector Emergency Procurement Committee was as follows.

Secretary, Ministry of Health	Chairman
Director General or similar position, Ministry of Finance	Member
Head of the procurement entity or his nominee	Member

6.5.11 As Per Paragraph 2.3 of the new Guidelines, either of the direct contract method, single source selection, or shopping method would be followed for procurements based on the emergency situation. Making procurements from local manufacturers had been encouraged, had the Health Sector Emergency Procurement Committee been satisfied with the standard and quality of the items.

6.5.12 Similarly, it had been requested to extend the emergency procurement process again up to 30 June 2023 by the Cabinet memorandum No.23/0302/640/005 dated 31 January 2023 (Annexure 22) submitted by the Minister of Health to procure the urgent essential medicines, medical equipment and accessories amidst economic crisis situation. As per the observations of the Minister of Finance, Economic Stabilization and National Policies on 06 February 2023 related thereto, it had been indicated that the Minister of Finance had observed that there were delays in the procurement plans and the procurement process due to weak procurement plans and weak coordination prevailing among the

institutions in taking into account many requests made to the Ministry of Finance by the Ministry of Health in relation to the implementation of the price variations and unsolicited proposals. Further, as per the approval granted by the cabinet of ministers on 12 January 2011, it had been also proposed to appoint the Procurement Planning Committee for Medicines with immediate effect. However, the Minister of Finance had mentioned that there was no objection in relation to the proposal noted in the above memorandum considering the continuous supply of medicines (Annexure 23) and at the cabinet meeting held on 13 February 2023, the approval had been granted by emphasizing to pay the attention to the observations of the Minister of Finance. (Annexure 24)

6.5.13 In order to avoid the shortage of items during the period of crisis until the usual procurement process becomes optimally established, the Minister of Health had again presented a Cabinet Memorandum No.23/1223/640/022 on 19 June 2023 (Annexure 25) requesting approval to extend the validity period of guidelines for emergency procurement process of the health sector up to 31 December 2023. However, the observations such as, not only the cost of procurement would be increased due to the use of provisions for emergency purchase of medicines and other medical supplies but the best practices for procurement process would be deviated, had been made by the Minister of Finance on 28 June 2023 in that connection thereby requesting that when the validity period of emergency procurement guidelines are extended, the conditions relating to procurement timeframe, bid security, and performance securities should also be amended by the Chief Accounting Officer of the Ministry under consent of the National Procurement Commission.(Annexure 26)

6.5.14 The approval of the Cabinet of Ministers had been granted for the proposal indicated in the memorandum taking into consideration further explanations given by the Minister of Health at that meeting on the observations of the Minister of Finance, Economic Stabilization and National Policies at the cabinet meeting held on 04 July 2023 related thereto and the proposal indicated in the memorandum. (Annexure 27) At that meeting, the powers has been conferred on the Secretary to the President to be appointed a committee consisting with the experts in the relevant field in order to submit a report

with the recommendations after studying 05 facts noted in the cabinet decision to the Cabinet of Ministers within a period of one month.

6.6 Intervention of the Ministry of Health for Emergency Procurement Process

6.6.1 It had been informed to Deputy Director General of the Medical Supplies Division by the Chairman of Indian Credit Line Subcommittee on 01 September 2022 that the action should be taken to amend the date of receipt of all items expected to be imported under Indian Credit Line before 31 January 2023 and submit the new orders which can be obtained under Indian Credit Line to the State Pharmaceuticals Corporation.(Annexure 28)

6.6.2 It was informed by the letter dated 22 September 2022 (Annexure 29) sent by Additional Secretary of Production, Supply and Regulation of Pharmaceuticals Division to Deputy Director General of Medical Supplies Division that it had been decided at the meeting held with the Minister of Health to procure the medicines which had the stock level less than one month from the private suppliers under Indian Credit Line. Accordingly, it had been also informed to submit the orders the State Pharmaceuticals Corporation as emergency procurements adequate for the period of 03 months and since the procurement process of the State Pharmaceuticals Corporation was delay up to 02 months, numbers of orders were ordered without considering the orders scheduled to be receipt at that time.

6.6.3 It had been informed to submit orders to the State Pharmaceuticals Corporation by writing down a note in the letter indicated in above 6.6.2 paragraph by Deputy Director General of Medical Supplies on 23 September 2022.As per the instructions of the Additional Secretary shown in above paragraph, the orders had been submitted for 182 medicine items worth of Rs.4,150.11 million to the State Pharmaceuticals Corporation without taking into account the pending orders for the period of 03 months under Indian Credit Line for the medicine items on which the stock level had less than one month by the letter of Deputy Director General of Medical Supplies No.2022/SPC/V/P/ 09/2022 dated 26 September 2022 i.e.03 days after.(Annexure 30)

6.6.4 The solutions had been proposed to avoid the acute medical supplies shortage in the government health institutions, cancel the Indian Credit Line at the end of year, to be utilized that Credit Line before that period, grant permission to the import agents in the private sector to import the medical supplies under the approval of the National Medicines Regulatory Authority as the emergency procurements by utilizing its remaining funds, procure medical supply stocks from them adequate for 03 months and follow the prevailing method for price determination itself used by the Pricing Committee of the Ministry for that by the cabinet memorandum No.22/1523/610/018 dated 26 September 2022 (Annexure 31) submitted by former Minister of Health with an objective of maintaining a continuous medical supplies service in Sri Lanka. In addition, the Minister of Health had submitted to the Cabinet of Ministers that the items not registered in the National Medicines Regulatory Authority under 3.3 of the memorandum should be subject to a Waiver of Registration process properly in order to minimize the delay of imports amidst the crisis situation as a proposed solution. The approval of the cabinet of ministers had been sought for the following facts from said memorandum.

(i) To grant permission to the import agents in the private sector to import the medical supplies under the National Medicines Regulatory Authority as emergency procurements by utilizing the remaining funds under Indian Credit Line (ICL) based on urgent requirement of the Medical Supplies Division,

(ii) To grant the approval to the Medical Supplies Division to procure the medical supplies adequate for 03 months from the private import agents who import the medical supplies by using Indian Credit Line (ICL) subject to the prevailing procurement mechanism determined by the Pricing Committee of the Ministry of Health

The Cabinet of Ministers who had considered this matter had granted the approval for said 02 proposals on 03 October 2022. (Annexure 32)

6.6.5 As per the decision of the meeting held between the Minister of Health and the suppliers of medicines on 22 September 2022 on import and supply of vital and essential medicines for the period of 03 months under Indian Credit Line, the approval for the documents for calling of Expression of Interest prepared for inviting the suppliers to import and supply of vital and essential pharmaceuticals had been requested from the Secretary of Health by an internal note jointly made by Additional Secretary of Production, Supply and Regulation of Medicines Division and the Medical Officer (Procurements) on 27 September 2022.Moreover, the approval of the Cabinet of Ministers had been requested to publish these documents for calling Expression of Interest in the relevant websites. Furthermore, the documents for calling Expression of Interest for procurement of 285 medicine items under 04 priority lists had been prepared and submitted for that approval of the Secretary of Ministry of Health. (Annexure 33) Accordingly, on the approval of the Secretary of Health, such documents had been published in the government electronic procurement website (PROMISE.lk) on the same day itself. It had been approved to be appointed 06 Opening Committees for Expression of Interest and 02 additional committees on that day itself by the Secretary of Health as per Annexure 33 and the relevant letters of appointment had been issued dated 28 September 2022. On 30 September 2022, an Evaluation Committee chaired by Additional Secretary and consisting with 05 members had been appointed by the Secretary of Health in relation to calling of Expression of Interest as follows.(Annexure 34)

Table No. – 06: Members of the Evaluation Committees

	Name	Designation
1.	Mrs. U.S.K. Denawatte	Additional Secretary (Administration), Ministry of Health
2.	Dr. A.T. Sudharshana	Deputy Director, Medical Supplies Division
3.	Dr.Jayanath Buthpitiya	Medical Officer (Procurements), Ministry of Health
4.	Mrs.D.H.R.N.Pemathunge	Internal Auditor, Ministry of Health **
5.	Mrs. P.D. Soleman	Assistant Director (Medicines), Medical Supplies Division

** Mrs. Pemathunge was not an Internal Auditor in the Ministry of Health at the time of appointment of this committee.

6.6.6 The Secretary of Health had been nominated as the Project Manager of this process for calling of Expression of Interest and Additional Secretary of Production, Supply and Regulatory of Medicines Division related thereto had been nominated as the second coordination officer as per above Annexure 33. It had been indicated in the document for calling of Expression of Interest that this calling of Expressions of Interest will be ended at 11.00 a.m. on 03 October 2022, intended completion date of short listing process will be performed within 02 days and intended completion date of evaluation of invitee's responses will be 07 October 2022. Similarly, it had been noted that the supplier should have a valid registered certificate in the National Medicines Regulatory Authority in order to import the medicines to Sri Lanka and the bidders who had submitted the minimum price and had no registration in the Authority considered the price factor can choose to waive the registration and it could be considered to issue the Waiver of Registration (WOR) for such bidders under the mandatory requirement of the document for calling Expression of Interest.

6.6.7 It had been mentioned that the following documents were required to waive the registration with the Expression of Interest –(EOI) documents for the suppliers who had not registered in the Authority.

i. Request letter of applicant
ii. Completed WOR application
iii. Certificate of Analysis (COA)of relevant product
iv. Certificate of Pharmaceutical Product (COPP)
v. Documents including the trade invoice

6.6.8 Meanwhile, the letters in relation to supply of essential medicines had been forwarded to the Minister of Health and Deputy Director General for Medical Supplies by a private company named Savorite Pharmaceuticals (pvt) Ltd on 21 October 2022 (Annexure 35)

and 28 October 2022 (Annexure 36) respectively and it had been proposed to procure surplus stock of 38 medicine items belonging to the company through that letter.

6.6.9 By presenting a cabinet memorandum No. 22/1523/610/024 dated 25 October 2022 related to this matter again by former Minister of Health (Annexure 37), it had been mentioned that a considerable period of time will take to import the medical supplies from the State Pharmaceuticals Corporation, the existing stocks in the Medical Supplies Division is in a risk level, stocks of 151 medicines is in zero level, the function of the surgeries will be totally inactivated in next 03 months and the Savorite Pharmaceuticals (pvt) Ltd had agreed to provide the stocks of medical supplies adequate for the period of 03 months to Sri Lanka within 45 days by using Indian Credit Line and other funding methods. The approval of the Cabinet of Ministers was sought for;

(i) To grant the permission to the Savorite Pharmaceuticals (pvt) Ltd and the other selected suppliers to import the medical supplies approved by State Pharmaceuticals Corporation adequate for the period of 03 months by utilizing the other funds including the remaining funds of Indian Credit Line and funds of Government of Sri Lanka based on the urgent situation and requirement of the medical supplies division.

(ii) To sign an agreement with the Savorite Pharmaceuticals (pvt) Ltd and other selected suppliers for making the payments as per the agreed payment plan by utilizing the funds of Indian Credit Line and other funds.

6.6.10 Accordingly, it had been informed to grant the policy approval for these proposals indicated in the memorandum and submit the observations of the Minister of Finance, Economic Stabilization and National Policies to Cabinet Subcommittee on Public Expenditure Management at the cabinet meeting held on same date. (Annexure 38) Meanwhile, the Director and the all Assistant Directors in the Medical Supplies Division that the relevant approvals of the Cabinet of Ministers had been received and submit the orders forwarded under code “V”to State

Pharmaceuticals Corporation through code “V” under the local orders of Medical Supplies Division by the letter dated 01 November 2022 sent by Deputy Director General of Medical Supplies.(Annexure 39)

6.6.11 Accordingly, in accordance with such cabinet decision dated 25 October 2022, the Minister of Finance had informed on 02 November 2022 that there was no objection for the relevant proposals subject to the following observations.(Annexure 40)

(i) To review on price and quality of the medical supplies and come to an agreement on market price, actual and fair price and quality of the medicines through Cabinet Appointed Negotiation Committee (CANC) or Health Sector Emergency Procurement Committee (HSEPC) since the proposed supplier had been selected under unsolicited basis,

(ii) To follow the medicines import process used by the medicine suppliers in the private sector under Indian Credit Line for State Pharmaceuticals Corporation for the proposed supplier by the Ministry of Health,

(iii) To come into an agreement on price and quality of the medicines between Ministry of Health and the proposed supplier prior to import

(iv) To follow the above 03 facts by the Ministry of Health if other private supplier comes forward to supply the medicines under unsolicited basis through Indian Credit Line and follow the relevant procurement guidelines by the Ministry of Health, if other funds which are not under Indian Credit Line are utilized for that,

(v) To develop a mechanism by the State Pharmaceuticals Corporation to decrease lead time spent for the procurement process,

(vi) To develop a proper monitoring and coordination mechanism among the institutions by the Ministry of Health to minimize the unnecessary delays in the procurement process,

(vii) To adhere the relevant procurement plans process by maintaining the lead time and buffer stocks by the Ministry of Health in order to avoid the shortage of the medical supplies in due course.

6.6.12 The Cabinet Subcommittee on Public Expenditure Management had forwarded the recommendations at their meeting and the approval of the cabinet of ministers had been granted for the proposals in the cabinet memorandum at the cabinet meeting held on 14 November 2022 subject to taking action as per the observations of the Minister of Finance. (Annexure 41)

6.6.13 The procurement of the medical supplies had been carried out by the Procurement Division of the Ministry of Health prior to establishment of the State Ministry of Production, Supply and Regulation of Medicines in 2020. But after cancellation of the State Ministry of Production, Supply and Regulation of Medicines on 28 April 2022, the opportunity had been provided by former Secretary of Ministry of Health to carry out the procurements related to the medical supplies through having established a Production, Supply and Regulation of Medicines Division under another Additional Secretary during 6 1/2 months up to 19 November 2022 without any assignment in writing though there was a Procurement Division under Additional Secretary in the Ministry of Health as indicated above. Subsequently, the Additional Secretary of Production, Supply and Regulation of Medicines Division had been assigned the powers by the letter dated 20 November 2022 (Annexure 42) by the Secretary of Health to carry out the procurement process related to Health Sector Emergency Procurement Committee through that division .A medical officer under him had been appointed as the head of such Procurement Division by the Additional Secretary on 21 November 2022 and the preparation of cabinet memoranda and notes to the cabinet, other activities of the procurement process and coordination activities had been assigned.(Annexure 43) But a

large number of medical supplies emergency procurements which were matter in controversy had been performed by that division at that time and the procurements had been carried out through unsolicited proposals by Additional Secretary even before entrusting the powers and the emergency procurement process had been commenced through Expression of Interest –EOI.

6.6.14 Even though relevant ministry level procurements had been performed through the Procurement Division of the Ministry of Health through the State Pharmaceuticals Corporation which acts as the procurement representative of the procurements in relation to the medical supplies distributed to the government hospitals procured by the Medical Supplies Division earlier, many emergency procurements which was in matter of controversy had been carried out through Production, Supply and Regulation of Medicines Division by adhering the Unsolicited Method and Expression of Interest (EOI) Method.

6.6.15 By indicating as per the instructions given by the Minister of Health at the meeting held on 01 December 2022 with the Secretary of Ministry of Health, Additional Secretary and Director General of Health Services, a note had been written down by the Deputy Director of Medical Supplies without a date (Annexure 44) giving instructions to take action to obtain the approvals in relation to 28 medicine items forwarded by Kausikh Therapeutics (Pvt) Ltd in India and a price quotation /invoice had been submitted with regard to 28 medicine items on 30 November 2022 to the State Pharmaceuticals Corporation by the relevant company.(Annexure 45)

6.6.16 A note to the cabinet No.22/1993/610/024-1 under captioned “maintenance of continuous medical supplies service in Sri Lanka” had been submitted again by the Minister of Health on 05 December 2022 to the Cabinet of Ministers (Annexure 46) and the approval had been sought to grant the permission to Kausikh Therapeutics (Pvt) Ltd to import the medical supplies stock approved by the State Pharmaceuticals Corporation adequate for the period of 03 months by utilizing the remaining funds of Indian Credit Line and other funds based on emergency situation and requirement of the Medical

Supplies Division for the prevention of acute shortage of medical supplies in the government medical institutions. Furthermore, the approval had been also requested by that to come into agreements with the institute for making payments as per the payment plan agreed by utilizing Indian Credit Line and other funding methods as well as the quality and price of the medical supplies. The approval of the Cabinet of Ministers had been granted for this subject to taking action in compliance with the observations submitted on 02 November 2022 by the Minister of Finance in relation to the cabinet memorandum dated 25 October 2022 at the cabinet meeting held on that day itself. (Annexure 47)

6.7 Intervention of the National Medicines Regulatory Authority for the emergency procurement process

The decisions of Board of Directors with regard to issuance of Waivers of Registration (WOR) by the National Medicines Regulatory Authority by facilitating the emergency procurement process are as follows.

Table No. – 07: Decisions taken by the Board of Directors in relation to issuance of letters for Waivers of Registration

Date of meeting of Board of Directors	Paper No. of Board of Director	Decisions of Board of Directors
Approve a special and expeditious mechanism for the procurement of medicines under ICL/ADB/WB/AIIB loan schemes on 16 September 2022	84.5.2 (Annexure 48)	Not taking responsibility by the Regulatory Authority in relation to the medicines which fail in the quality imported under this scheme and bearing the responsibility by the institute itself which acknowledges and donates

21 October 2022	84.5.2 (Annexure 49)	Not taking responsibility by the Regulatory Authority in relation to the medicines which fail in the quality imported under this scheme and bearing the responsibility by the institute itself which acknowledges and donates
18 November 2022	(84.5.2) (Annexure 50)	Not taking responsibility by the Regulatory Authority in relation to the medicines which fail in the quality imported under this scheme and bearing the responsibility by the institute itself which acknowledges and donates Any other institute approved by JICA and the Secretary
29 December 2022	87.4.9 (Annexure 51)	Not accepting the responsibility on safety, quality and efficacy of the production by NMRA
29 December 2022	87.5.1 (Annexure 52)	Not accepting the responsibility on safety, quality and efficacy of the production by NMRA

07. Observations

7.1 Utilization of Indian Credit Line

7.1.1 The progress of the utilization of the provisions received under Indian Credit Line up to 29 August 2022 and 19 May 2023 is indicated in the above paragraphs 6.2.3 and 6.2.4 respectively and the action had been taken to return US $ 160 million out of US $ 360 million received for the medicines shown in the above Chart 01 up to September 2023 to the Treasury. Furthermore, the approval had been granted by Indian Credit Line Sub Committee for 2,565 invoices worth of US $ 197 million up to 29 January 2024 as per meeting minutes of the Indian Credit Line Subcommittee. The money in Rupee value had been deposited in the Treasury Account by the suppliers in relation to 1,816 invoices worth of US $ 130 million i.e. Only for 66 percent from the value approved by the committee. Moreover, such value was only 36 percent from US $ 360 million indicated in above Table No.01 approved for the medicines. In this backdrop, it was observed that the action had been taken to procure emergency procurements by utilizing the local funds.

7.1.2 As per the answers submitted for the draft report of this report forwarded to the audit on 26 February 2024 by the Secretary of Ministry of Health, it had been informed that the relevant loan funds couldn't be effectively utilized due to the reasons such as delays in handing over the relevant files to Indian Credit Line Co-ordination Unit of the Treasury by the suppliers, delays occurred in sending the relevant documents to the importer by pertinent Indian Manufacturing Company, taking vey lengthy period of time for granting the approval to the relevant invoices by Indian High Commission in certain occasions, delays occurred in opening the letter of credit by the importers and non-commencement of the manufacturing activities by some importers until the receipt of letter of credit.

7.2 Making payments for the medicines

7.2.1 As per the information submitted to the audit by the Medical Supplies Division, an amount of Rs. 79,652.98 million should be paid to the other suppliers including State Pharmaceuticals Corporation and State Pharmaceuticals Manufacturing Corporation for the supply of medicines by the Medical Supplies Division up to 31 December 2023 and

an amount of Rs. 54,364.84 million and an amount of Rs. 13,543.31 million should be paid to the State Pharmaceuticals Corporation and State Pharmaceuticals Manufacturing Corporation respectively. Since such values as per the financial statements 2023 of such two Corporations were Rs.38, 853.76 million and Rs.2, 368.68 million respectively, a difference of Rs.26, 685.72 million had been observed in relation to the amount to be paid.

7.2.2 Even though the settlement of the debit notices sent to the Medical Supplies Division by the State Pharmaceuticals Corporation pertinent to the medical supplies should be carried out through Swastha Information System, the payments for debit notices of Rs. 20,202.74 million received from August to November 2023 had been halted even up to 29 November 2023 due to the issues of implementation of said system. In addition, due to the shortcomings such as showing the inaccurate values, not indicating the delay charges, not indicating the name of the payee in the Swastha Information System in the preparation of the vouchers for Rs. 5,678.91 million and Rs.2,297.39 million to be paid to the State Pharmaceuticals Manufacturing Corporation and local suppliers respectively from August to November 2023 pertinent to the procurements of medical supplies, such payments had not been settled even up to 29 November 2023 which was the date of audit.

7.2.3 An aggregate financial requirement of Rs.33, 342.78 million existed including Rs. 606.09 million for issuance of letters of credit for the orders in the Medical Supplies Division by the State Pharmaceuticals Corporation up to 31 December 2023, Rs.14, 120 million for payments to the suppliers (bank bills to be paid) and Rs.18, 616.64 million for the settlement of overdrafts obtained for the medical supplies. It was an increase of Rs.10, 220 million than the amount of Rs.23, 123 million which had existed before 19 months; that is 25 May 2022.

7.2.4 Rs. 145 million in relation to 11 shipping guarantees opened for the period from 2011 to 2020 had been utilized from limit of credit limit given by Bank of Ceylon up to 31 December 2023 Since the above shipping guarantees couldn’t be opened even up to the date of audit on 22 February 2024, the State Pharmaceuticals Corporation couldn’t be opened these letters of credit from this value.

7.3 Emergency Procurement Process performed in 2022 and 2023

Subsequent to making the observations on intervention of Ministry of Health, Ministry of Finance and National Medicines Regulatory Authority in order to maintain a continuous medical supplies service in Sri Lanka, the facts observed in relation to arrangement of an environment for making frauds such as how Ministry of Health, Production, Supply and Regulation of Medicines Division, Medical supplies Division, State Pharmaceuticals Corporation and National Medicines Regulatory Authority had acted in this regard, on the way of carrying out emergency procurements, severe violations of internal control methods due to neglecting the accepted procurement guidelines and taking action exceeding the cabinet decisions and weak internal control methods are shown below.

7.3.1 In accordance with the letter No PFD/PMD/Health/HSEPP/01/2022 dated 16 June 2022 issued by the Secretary of Ministry of Finance mentioned in above paragraph 6.5.8, it had been noticed that a monthly report on the items purchased from the procurements made under health sector emergency procurement process should be submitted by the Minister of Health for the covering approval of the Cabinet of Ministers by justifying the procurement requirement. But said covering approval of the cabinet of ministers which had to be taken monthly had not been obtained even up to 31 March 2024 in relation to the procurements worth of US $ 20 million and with regard to 663 health sector emergency procurements worth of Rs.21, 999 million carried out from June 2022 to November 2023.

7.3.2 Even though the Internal Auditor of the procurement entity had participated to observe the emergency procurements implemented through State Pharmaceuticals Corporation, it had not been verified at the audit that the other emergency procurements carried out by the Production, Supply and Regulation of Medicines Division had been observed. Similarly, no document had been forwarded by Internal Auditor in order to verify that an

effective process had been performed in the procurements in which he had participated as an observer and accordingly, a fair and effective process had not been ensured at the end of the procurement process. However, the Chief Internal Auditor of the Ministry of Health had stated to the audit in writing on 01 April 2024 that he had participated for the procurement committee as per the telephone call given and it had not been informed in writing to be participated as an observer of the procurement committee and submitted a report related thereto after said participation and since he had not been made aware to forward a such report, a report including the observations had not been given.

7.3.3 As per the letter sent by Additional Secretary of Production, Supply and Regulation of Medicines Division on 22 September 2022 in accordance with above paragraph No.6.6.2, it had been observed that the State Pharmaceuticals Corporation had been informed to submit the orders on 23 September 2022 by writing down a note to the staff by Deputy Director General of Medical Supplies and the orders had been submitted for the period of 03 months under Indian Credit Line for 182 medicine items worth of Rs.4,150.11 million to State Pharmaceuticals Corporation by Deputy Director General of Medical Supplies on 26 September 2022 i.e. 03 days after that as noted in paragraph No.6.6.3.But the orders had been submitted for the emergency procurements 07 days before the receipt of the approval of the Cabinet of Ministers for the cabinet memorandum presented related thereto as per above No.6.6.4. It had been also observed that the risk of occurring loss to the government had been neglected by determining to inform the orders irrespective of the pending orders, receipt of stocks on immediate dates and making emergency procurements at the higher prices.

7.3.4 It was observed that after one day of forwarding the orders worth of Rs. 4,150.11 million to the State Pharmaceuticals Corporation for 182 medicine items and submitting the cabinet memorandum indicated in above No.6.6.4 i.e. on 27 September 2022 through an internal note shown in paragraph 6.6.5 forwarded by Additional Secretary of Production, Supply and Regulation of Medicines Division to the Secretary of Health mentioning " as per the decision of the meeting held between the Minister of Health and the suppliers of medicine in relation to import and supply of vital and essential medicines for the period

of 03 months by utilizing the Indian Credit Line on 22 September 2022", the documents for calling Expression of Interest had been prepared and submitted on the approval of the Secretary of Health to procure 285 medicine items with regard to import and supply of vital and essential medicine items through Indian Credit Line 06 days before the receipt of the cabinet approval dated 03 October 2022. The medicine items such as Everolimus, Gentamicin Sulphate inj., Cefuroxime inj. which had not been included in the essential medicines list had been inserted in such increased list.

7.3.5 Furthermore, the calling of Expression of Interest had been published in the websites and the bid opening committees and the evaluation committees had been appointed by the Additional Secretary and the Secretary of Health respectively prior to receipt of the approval of the cabinet of ministers dated 03 October 2022 indicated in above paragraph 6.6.4.Similarly, it was observed that the action had been taken to open the bids on the date on which the approval of cabinet of ministers had been received itself and the action had been taken to inform it to the Ministry of Health on 05 October 2022. Further, even though it had been mentioned in this paragraph above that a meeting was held between the Minister of Health and the medicine suppliers, the information on holding such meeting had not been submitted to the audit.

7.3.6 An Evaluation Committee consisting of 05 members had been appointed by the Secretary of Health for the evaluation of 285 medicine items indicated in above 6.6.5 and it was observed that the Medical Officer who had performed duties as the head of Procurement Division had been also appointed as a member of that committee and no specialist for evaluation of the special medicines such as cancers or an expert with the technical knowledge related thereto had been appointed. Even though the Evaluation Committee had not been appointed in accordance with emergency procurement guideline, the steps should be taken to obtain the instructions from the technical experts by Health Sector Emergency Procurement Committee and it was observed that no action was taken in such manner.

7.3.7 It was observed that even though the Expression of Interest Evaluation Committee at its meetings held on 06, 07,10,11,12 and 13 October 2022 had considered the price of the medicines and stock providing timetables and the quality of the medicines had not been considered in carrying out relevant evaluations in accordance with the statement of the member of the Evaluation Committee dated 13 November 2023. Moreover, it had been informed to Additional Secretary of Production, Supply and Regulation of Medicines Division that the evaluation couldn't be carried out due to the shortcomings prevailed in the documents to be submitted in calling the expressions and it had been informed to the audit on 02 May 2024 by the Chairman of Expression of Interest Evaluation Committee that the relevant Additional Secretary had noticed to immediately select the suitable interested parties as per the delivery schedule and actual minimum price of the medicines. Accordingly, the committee had not considered on the major deviations of the procurement in relation of non-availability of the documents to be submitted by the suppliers who do not have the registration certificate of the National Medicines Regulatory Authority indicated in the evaluation criteria in calling Expressions. Accordingly, it was observed that its own evaluation process had not been independently performed by the Evaluation Committee. Similarly, even though it had been informed to submit 08 documents including the application related thereto by the suppliers who do not have registration certificate of National Medicines Regulatory Authority and the business registration in calling expressions as per above paragraph 6..6.7 and the registration of the National Medicines Regulatory Authority, Expression of Interest Opening Committee had not examined on that.

7.3.8 Due to the facts including the backlog prevailed in the medicines registration process of National Medicines Regulatory Authority and non-attention on the government medicines requirement by the Authority in the registration of medicines as per under-mentioned paragraph 7.7, there are no adequate valid registered suppliers suitable for the medicines supply requirement of the country. Many suppliers had submitted the tenders without a valid registration certificates since the opportunity had been given for the procurements under Waivers of Registration in Expression of Interest Method and the appropriate restricted conditions had not been included in the bidding documents

enabling to minimize the submission for the procurements under Waivers of Registration. Likewise, the methodology which ensures the supply of medicines with quality had been deviated through relaxing the conditions.

7.3.9 It was observed that a risk prevailed in relation to the quality of the medicines procured due to the facts such as negligence of compulsory requirement of the registration certificate of Medicines Authority which certifies whether it is a quality medicine in the medicine procurement as per 2.1 of Procurement Guideline on Medicines and Medical Supplies 2007, non-appointment of the Technical Evaluation Committees but appointment of the Evaluation Committees instead of that, not taking the instructions from the technical experts and non-examination of the documents related to quality of the medicine by the Evaluation Committees appointed.

7.3.10 As per the facts observed in above No.6.7 and following observation No 7.5 and 7.11.7 of this report under intervention of the National Medicines Regulatory Authority with regard to the emergency procurement process, the action had been taken by the Medicines Authority to issue such certificates deviation from the accepted and prevailed methodology for issuance of Waivers of Registration. Even though the Authority had issued the Waivers of Registration, it was observed in the audit that the basic objective of providing the medicines with high quality is not fulfilled due to deviation from the responsibility on quality, safety and efficacy of such medicines, entrusting the responsibility on quality, safety and efficacy of the medicines to other parties (Annexure 53) deviation from the objective indicated in subsection 3(a) of the National Medicines Regulatory Authority Act, refusal the responsibility related thereto by the parties entrusted such responsibility. (Annexure 54)

7.3.11 Accordingly, it was not verified in the audit that the relevant procurement committee and procurement entity had certified that the maximum value is given to the money of the procurement entity in transparent and responsible manner and the procurement committee and procurement entity had acted with adequate attention in the evaluation process.

7.3.12 Similarly, the EOI Evaluation Committee had recommended to award the tender with Waiver of Registration (Annexure 55) to the all responsive suppliers who do not have the registration in Medicines Authority and the Health Sector Procurement Emergency Committee at its meetings held on 13 and 18 October 2022 had decided to award the tender for 170 medicine items worth of US $ 19.8 million to the substantial responsive bidders. But the procurement committee had not taken measures to verify the quality of the medicines.

7.3.13 This Health Sector Emergency Procurement Committee shown in above paragraph 6.5.10 at the meetings held on 13 and 18 October 2022 in which a Treasury Representative is a member also had decided to procure these medicine items under Indian Credit Line or direct purchases. (Annexure 56) Accordingly, it was observed that the Health Sector Emergency Procurement Committee had acted by exceeding the cabinet decision given on 03 October 2022 by granting permission to the import agents in the private sector to import the medical supplies as emergency procurements by utilizing the remaining funds of Indian Credit Line. Accordingly, it was observed that an amount of Rs.2, 909.45 million had been paid by the local funds deviation from Indian Credit Line for the medicines procured under Expression of Interest Method and Rs.1, 267.60 million has to be paid as at 31 December 2023.

7.3.14 The Indian manufacturers had been selected for the procurements implemented through the Expression of Interest under Indian Credit Line and the orders had been awarded to above 21 suppliers informing that these orders should only be implemented under Indian Credit Line by the Secretary of Health (Annexure 57) on 20 October 2022. But the instructions had been given by Secretary of Health to be implemented the purchase orders under the following conditions by the letter No. PSRP/08/EOI/General/2022 dated 28 October 2022 of Production, Supply and Regulation of Medicines Division (Annexure 58) addressed to Director General of Medical Supplies. Accordingly, it had been informed;

- To purchase each item under Indian Credit Line or any other convenient method to both parties

- If any supplier does not submit the registration certificates, include the clear limits on the relevant responsibility
- To include the relevant conditions on performance securities and exemption of penalties for the delays
- To make payments to the suppliers within 45 days in making payments
- The ministry should take action to pay the suppliers a monthly fee i.e.3 percent for the delays occurred by the ministry party in making payments

The following facts were observed in relation to this.

(i) It was observed that the Indian Credit Line Sub Committee had been established under Production, Supply and Regulation of Medicines Division itself and since the procurement committee established under that division itself had not taken measures to submit 158 orders worth of US $ 19.1 million which should be implemented under only Indian Credit Line above mentioned to the recommendation of Indian Credit Line Sub Committee , an opportunity had been provided to avoid the implementation of these orders under Indian Credit Line.

(ii) Even though the bids had been called to carry out these procurements by only utilizing the remaining funds of Indian Credit Line, the approval had been granted by the Secretary to purchase through Indian credit Line or any other convenient method for both parties in contrary to that condition.

(iii) Through that, the action had been taken to make the payments through the local funds selected Indian suppliers, restrict the opportunity for the parties for participation fairly for this procurement, procure the medicines at higher prices and lose the opportunities to procure the other quality medicines at a competitive price.

(iv) It was observed that the Secretary of Health had taken action in a manner where the loss had occurred to the government amidst severe economic crisis through

inserting the condition such as payment of monthly fee i.e. monthly 3 percent for the delays occurred in making payments.

(v) It was observed that Deputy Director of the Medical Supplies Division who had been appointed to cover up the duties in the post of Director at that time had affixed the official frank as Director of Medical Supplies without formal appointment in issuing the purchase orders under EOI.

7.3.15 It was observed that it had been recommended by Deputy Director General of Medical Supplies and Additional Secretary of Production, Supply and Regulation of Medicines Division on 02 November 2022 to issue these purchase orders through US $,make the payments through the remaining funds of Indian credit Line 0r other sources, , issue the purchase orders subject to transfer the provisions of State Pharmaceuticals Corporation to the Medical Supplies Division and issue the purchase orders without obtaining the purchase agreements and performance securities prior to obtain the approval of the cabinet of ministers for the cabinet memorandum for import of the medical supplies by utilizing the remaining funds of the Indian Credit Line and other sources including the funds of Government of Sri Lanka indicated in above paragraph 6.6.9 submitted on 25 October 2022 and the Minister of Health had approved that on the same date itself.(Annexure 59)

7.3.16 On the approval of Health Sector Emergency Procurement Committee, the steps had been taken to make emergency procurements worth of Rs.12, 200 million for 280 medicine items through State Pharmaceuticals Corporation during July 2022- September 2023 as per the information received to the audit. Such all orders had been awarded to the above 18 companies out of 21 noted in paragraph 7.3.14. The procurement had been awarded under Waiver of Registration for 103 orders out of 280.

7.3.17 Subject to the observations given by the Minister of Finance dated 02 November 2022 for the cabinet decision submitted on 25 October 2022 as per above No.6.6.8,6.6.9 and 6.6.10, the approval of the Cabinet of Ministers had been granted on 14 November 2022 to procure the relevant procurements. In accordance with the observations of the Minister

of Finance, it had been mentioned that if other funds rather than ICL is utilized, the relevant procurement guidelines should be followed by the Ministry of Health. A method of calling Expression of Interest had not been approved through that.

7.3.18 It was observed that the orders in relation to 140 medicine items on which the stock had not been fully supplied and 12 orders for items on which the stock had been partly supplied from 158 emergency procurement purchase orders given under emergency procurement had been cancelled by the letter No.DDG/MSD/EMPU/Gen/2022 dated 06 November 2023 sent by Director of Medical Supplies.(Annexure 60) Accordingly, it was observed in the audit that the overall process carried out was not effective due to the extension of emergency procurement guideline by mentioning as very urgent procurements at several occasions and cancellation of such 140 orders finally by carrying out this process by taking efforts to give relaxations indicated in above 7.3.14 to the companies who had no registration in relation to the medicines.

7.4 Intervention of the Ministry of Health in relation to the requests received to the Minister of Health through the unsolicited proposals and relevant internal process

7.4.1 By indicating as per the instructions given at a meeting headed by former Minister of Health on 17 October 2022, a memorandum prepared with regard to the medicine items list submitted by the Indian Company shown above paragraph 6.6.8 had been forwarded to the Secretary to Health on 19 October 2022 by Acting Deputy Director of Medical Supplies (Annexure 61) The Secretary of Health had informed to Director General of Health Services to implement that under Unsolicited Procurement Procedure on 20 October (Annexure 62). Similarly, it was informed to the Minister of Health by a letter dated 21 October 2022 by the company shown in above paragraph 6.6.8 that a meeting was held between this company and the Minister of Health on that day itself and the company had surplus stocks and 38 medicine items can be provided between 45-65 days . Accordingly, it was observed that the instructions had been given by the Minister of Health to the officers to submit the relevant orders prior to 04 days of written notice of the relevant company.

7.4.2 After 04 days from the date of letter forwarded to the Minister of Health by the company on 21 October 2022 as indicated in above paragraphs 6.6.7 and 6.6.8 the Minister of Health had informed that the existing stocks in the Medical Supplies Division were in risk level, the stocks of 151 medicines were in zero level, the function of the surgeries will be totally inactivated during next 03 months , the Savorite Pharmaceuticals (Pvt) Ltd. in Gujrath in India had agreed to provide the medical supplies to Sri Lanka adequate for a period of 03 months within 45 days by utilizing the Indian Credit Line and other funds and a request had been made to grant the approval of the Cabinet of Ministers for that by the cabinet memorandum dated 25 October 2022.Two medicine lists (Vital and Essential) i.e. lists for 325 medicines on which the stock level had prevailed less than 03 months had been submitted by Annexure 1 of such cabinet memorandum and said lists had been prepared based on the information obtained on 24 October 2022 through MSMIS System. But it was observed that the attention had not been paid to the pending orders up to that date in determining the stock level of this medicine list.

7.4.3 Taking into account this memorandum, it had been decided by the Cabinet of Ministers on 26 October 2022 to grant the policy approval for such proposals and consider the observations of the Minister of Finance, Economic Stabilization and National Policies for such proposals in order to come to a final decision. In accordance with the observations of the Minister of Finance, Economic Stabilization and National Policies dated 02 November 2022,it had been recommended to come to an agreement after reviewing on price and quality through Cabinet Appointed Negotiate Committee (CANC) or Health Sector Emergency Procurement Committee and follow the method carried out by State Pharmaceuticals Corporation in Indian Credit Line and the approval of the Cabinet of Ministers had been granted on 14 November 2022 to import the medicines from the relevant company subject to the above observations.

7.4.4 Within 10 days of submission of unsolicited proposal, a letter of awarding the orders worth of US $ 4.49 million had been issued to this company by the Secretary of Health pertaining to 38 medicines on 31 October 2022.(Annexure 63) It was observed that the

relevant letter had been sent to this company by the Secretary of Health prior to obtaining the approval of Health Sector Emergency Procurement Committee and the approval had been granted to carry out these procurements under Indian credit Line or direct purchases at its meeting held on following day i.e. 01 November. Accordingly, it was observed in the audit that 38 purchase orders worth of US $ 4.49 million (approximately Rs.1.7 billion) had been issued to the pertinent company up to 05 November 2022 i.e. 09 days before the receipt of the cabinet decision dated 14 November 2022 and the company had accepted those purchase orders on that day itself.

Table No.-08: Timeframe in which the unsolicited method had been carried out

	Action taken	**Timeframe**
1	Giving instructions to prepare a memorandum pertinent to a list of medicine items forwarded by the Savorite pharmaceuticals (pvt) Ltd at a meeting headed by former Minister of Health	17.10.2022
2	Submission of aforesaid memorandum by Deputy Director who performed duties as Acting Director of Medical Supplies to the Secretary of Health	19.10.2022
3	Inform by Secretary of Health to implement the unsolicited proposals in the memorandum submitted by Deputy Director through the procurement process	20.10.2022
4	Inform by savorite Company to the Minister of Health by a letter that 38 medicine items can be provided during 45-65 days	21.10.2022.
5	Submission of the cabinet memorandum	25.10.2022
6	First cabinet decision (policy approval)	26.10.2022
7	Inform to MSD by the Secretary that the approval of the Cabinet of Ministers had been received	28.10.2020

8	Issuance of a letter for awarding the orders worth of US $ 4,490,377.5 in relation to 38 medicines by Secretary of Health to Savorite Company	31.10.2022
9	Health Sector Emergency Procurement Committee meeting	01.11.2022
10	Issuance of 38 purchase orders to the suppliers	05.11.2022
11	Giving the final decision of the Cabinet of Ministers	14.11.2022

7.4.5 It had not been verified at the audit that the prices of the medicines forwarded by the above unsolicited proposal had been analyzed having adjusted with prior SPC prices and exchange rate changes by relevant Pricing Committee as per the observations of the Minister of Finance indicated in 6.6.11(i) and (iii) or the relevant laboratory reports had been used in relation to the quality of medicines.

7.4.6 In terms of the Fee Regulation published in the Extraordinary Gazette Notification No.2052/33 dated 05 January 2018 in relation to issuance of letters for Waiver of Registration of medicines, the fee is charged by the Regulatory Authority. The registration of the Medicines Regulatory Authority had not been obtained for any medicine forwarded by the aforesaid company through the Unsolicited Proposal and the facts had been informed by Additional Secretary of Production, Supply and Regulation of Medicines Division at a meeting held on 08 December 2022 to issue WOR certificates without a fee specially to this company and the Minister of Health had informed to issue in this manner only for this occasion and not to take it as a normal usage. Accordingly, it was observed that 38 Waivers of Registration had been issued by the Regulatory Authority without evaluation on the quality of the medicine through Special Pathway.

7.4.7 Even though the facts had been provided to the Cabinet of Ministers through the cabinet memorandum dated 25 October 2022 mentioning the current existing stocks of the medical supplies were in risk level, a severe risk prevailed of creating an acute shortage of medical supplies in the country within next 03 weeks, it was expected that the function of the surgeries was totally inactivated within next 03 weeks and the medicines will be

imported from Savorite Company on the emergency situation of the Medical Supplies Division in order to avoid the acute shortage of medical supplies in the government health institutions, it was observed that 10 medicines out of 38 ordered from this company were the medicines which had not been included in the essential medicines list as per Pronto System of Medical Supplies Division and an expected amount to be incurred for that was approximately Rs.280 million.

7.4.8 It was questionable in the audit whether it was essential to purchase the medicines which had not been included in the essential medicines list from a one company under emergency procurements without checking the quality at a higher price and it was observed that the all orders provided to this company had been increased by 100 percent for another 03 months and decided to submit the orders and issued the orders for 33 items out of that at the meeting of Medicines Management Committee held on 08 December 2022 headed by Additional Secretary of Production, supply and Regulation of Medicines Division.

7.4.9 An unsolicited proposal in relation to 28 medicine items worth of US $ 537,955.12 had been also submitted by Causik Therapeautics company in India to the Minister of Health in addition to Savorite company as per above No.6.6.11 and 6.6.15 and it had been informed that the approval was granted to import 13 items indicated in the proposal forwarded by the company by the letter dated 20 December 2022 (Annexure 64) addressed to Chief Executive Officer of the relevant company and come into an agreement on price of 15 items which had higher price than standard price by the Minister of Health through a file of Production, Supply and Regulation of Medicines Division (Annexure 65). Similarly, it was also informed to utilize the remaining funds of Indian Credit Line for this requirement. But the Evaluation Committees or Pricing Committees had not been appointed at that time as per the cabinet decision dated 14 November 2022 and a request had been made to be appointed a Pricing Committee consisting with 05 members for evaluation this unsolicited proposal by Additional Secretary of Production, Supply and Regulation of Medicines Division on 03 January

2023 i.e. after 14 days from that to the Chairman of Health Sector Emergency Procurement Committee.

7.4.10 At the meeting of Medicines Management Committee headed by the Additional Secretary of Production, supply and Regulation of Medicines Division held on 19 December 2022, it had been decided to give the stocks for 28 items of this company for 06 months and the Minister of Health and the Chief Executive Officer of National Medicines Regulatory Authority had participated for an observation tour of this company in India during 21-24 December 2022. Subsequent to the facts had been revealed that this supplier was a company blacklisted by State Pharmaceuticals Corporation earlier, the process with regard to procurement of these items had not been commenced.

7.4.11 It was observed that the import of the medicines had been suspended by the Supreme Court due to the Fundamental Rights Cases No. SC/FR/65/2023 and No. SC/FR/82/2023 submitted by a civil organization and a civil organization activist in relation to 38 medicines items ordered through the above unsolicited proposal from which the responsibility had been assigned to the Director of Medical Supplies pertaining to the quality, safety and efficacy of the medicines without carrying out the evaluations by the National Medicines Regulatory Authority.

7.5 Intervention of National Medicines Regulatory Authority in relation to Emergency Procurement Process

7.5.1 It is mandatory to obtain the registration of the Medicines Regulatory Authority to import, manufacture, sell and distribute the all medicines by the Sections 58, 82 and 101 of the National Medicines Regulatory Authority Act No.05 of 2015 (Annexure 66) and the Medicines Authority shall be responsible for the quality, safety and efficacy of the medicines. But it was observed that it had been proposed to the Cabinet of Ministers that the items which do not have the registration in the Authority should be subject to a Waiver of Registration process irrespective of that. Similarly, even though the observations on issues arisen due to usage of Waiver of Registration process for the other

matters deviation from the section 109 of the National Medicines Regulatory Authority had been submitted by the audit since many years, it was observed that the attention had not been paid for that.

7.5.2 Similarly, it was observed in the audit that the relevant conditions had been relaxed by providing the opportunity to supply the medicines after obtaining the Waiver of Registration certificates by the suppliers who do not have the registration for medicines under No.3.6 of the Procurement Guidelines on new medicines and the medical equipment issued by Public Finance Circular No.1/2023 dated 13 January 2023 by the Secretary of Ministry of Finance, Economic Stabilization and National Policies, general conditions in the bidding documents in 2023 of the State Pharmaceuticals Corporation and mandatory requirements in calling the Expressions which were in controversy and no action was taken by the Authority related thereto.

7.5.3 Even though it had been proposed that the items which did not have the registration in the Medicines Regulatory Authority should be properly subject to a Waiver of Registration process before import in order to minimize the delay of the import in submission the cabinet memorandum dated 26 September 2022 by the Minister of Health as indicated in above paragraph 6.6.4, it was observed that the Waiver of Registration certificates had been issued without submission to the pertinent committee by mentioning through a special pathway via a fast track deviation from the issuing method of the Waivers of Registration certificates of National Medicines Authority subject to a formal committee approval.

7.5.4 As indicated in under-mentioned observation No.7.11.7, a method of issuing of letters for Waivers of Registration had been followed on the approval of the Chief Executive Officer through a fast track identified as the special pathway without submission for the approval of the Subcommittee in terms of the decision of the Board of Directors dated 16 September 2022 in relation to the method of issuing the letters for Waiver of Registration. The relevant approval had been granted checking only the documents which verify the order such as purchase order, indent and sales invoice without paying attention

to the factors such as price fairness, opinion of the relevant school on medicine, essentiality of medicine, existing number of registered medicines similar to that, registered condition of the medicine, registered status of the medicine, registered status of the supplier and the manufacturer and prevailing prior issues on quality (quality failures) and without evaluating the documents which verify the quality, safety and efficacy of the medicines. It was also observed that the recommendation given for carrying out the method of issuance of No Objection Letter-NOL by the Authority and before the establishment of the Authority through an independent unbiased committee at the special audit done on the process of medical supplies issued by me on 14 March 2018 in this manner itself had been neglected.

7.5.5 It had been indicated in under-mentioned observation No.7.11.7 about taking action to issue the letters for Waiver of Registration on the approval of the Chief Executive Officer exceeding the Waiver of Registration Subcommittee as noted above.

7.5.6 Similarly, even though it had been proposed to the Cabinet of Ministers that it should be properly subject to a Waiver of Registration Process as per above No.6.6.4 , the Authority had deviated its own responsibility with regard to the quality of the medicines in accordance with the Section 3(a) of the Act No.05 of 2015 informing that the National Medicines Regulatory Authority had no responsibility for the medicines which fail in the quality and import through the various proposals such as Indian Credit Line, World Bank, Asian Development Bank, Asian Infrastructure Facilities and JICA and it was unable to take the responsibility on the quality, safety and efficacy of the medicines.

7.5.7 Even though the National Medicines Regulatory Authority had issued 38 Waiver of Registration certificates (WOR) to a private company for import of 38 medicine items submitted through the unsolicited proposals in December 2022, the Authority had neglected its responsibility by forwarding the conditions that the National Medicines Regulatory Authority had not evaluated the pertinent medicines, the Authority had no responsibility on the quality, safety and efficacy of medicines due to that and the responsibility should be taken by the Director of Medical Supplies. However, the

Director of Medical Supplies had given his opinions to the audit that" since the legal framework pertaining to the quality, safety and efficacy of relevant medicines relates to the National Medicines Regulatory Authority, the Authority bears the full responsibility on issuance of Waiver of Registration certificates, the responsibility on that couldn't be borne by him and such condition had been inserted by the Authority without his agreement."

7.5.8 As indicated in under- mentioned observation No.7.11.6.4, the copy of the Director of Medical Supplies of Waiver of Registration certificate submitted to the Controller General of Imports and Exports by the Authority pertaining to the emergency procurements performed since 2022 and the procurements made under Indian Credit Line had not been sent to the Medical Supplies Division formally.. It was observed that if the relevant copies would have been received formally to the Medical Supplies Division, the Stock Control Officers were able to verify whether those certificates were true and the internal control was able to minimize the false medicines supply frauds such as Human Immunoglobulin and Rituximab which arise critical issues presently. Subsequent to happening this issue, the copy of the Director of Medical Supplies of 105 Waiver of Registration certificates had been sent to the Medical Supplies Division by Medicines Regulatory Authority on 16 October 2023.But it was further observed that the pertinent copy of other Waiver of Registration certificates issued by the Medicines Authority had not been sent to the Medical Supplies Division up to the date of audit on 31 December 2023 and as a result of that, the opportunities for making the frauds were further opened also.

7.6 Not Taking Into Account the Government Medicines Requirement in the Registration of Medicines

7.6.1 The obtaining the registration under the National Medicines Regulatory Authority is considered as a main criterion in the procurement of medicines for the government hospitals in accordance with 2.1 of Procurement Guidelines on Medicines and Medical Devices 2007 (Annexure 67) and the opportunity is provided to the procurement entities

for supply of the most appropriate medicine at a fair price through the Competitive Bidding Method due to the registration of several medicines under one Generic Name. Furthermore, a list of 1,743 medicines (Annexure 68) to be utilized by the government hospitals had been identified by the Medicines Formulary Review Committee held in 2020-2021 for the last time and a list of 312 medicines including 36 medicines on which the priority should be given in the registration,58 medicines on which number of registrations should be incrased,64 medicines to be registered under Orphan Category for rare diseases and 154 new medicines on which the registration should be included had been informed to the Medicines Regulatory Authority on 24 November 2022 by the Medical Supplies Division.(Annexure 69)

7.6.2 Similarly, a priority list of 850 medicines to be procured and utilized for the hospitals had been published by a Circular No. 01-14/2023 issued by Director General of Health Services on 04 April 2023 with an objective of minimizing the cost for the medical supplies.(Annexure 70) An amended list including 33 medicines from that priority list, 96 medicines for Orphan Category and 135 medicines which had not been registered so far had been submitted by the Director of Medical Supplies Division to the Authority on 11 April 2023 for the priority of registration at 02 incidents by the letters No.MSD/FR/QA/SEO/2023-01 and 02. (Annexure 71) But the attention of the Medicines Regulatory Authority had not been paid to the aforesaid facts and since the registration priority list for 95 medicines published in the official website of the Authority on 14 October 2020 had not been updated by timely review on the government's medicine requirement, no adequate measure was taken to encourage the above medicine registration (Annexure 72).

7.6.3 Certain medicines determined by the Medicines Formulary Review Committee cannot be entered into the health sector through non-availability of registration or minimization of the registration of essential medicines for the government hospitals and it had been noticed by Director of the Medical Supplies Division on 11 April 2023 that numerous issues had arisen in procurement of such medicines indicated in above 7.6.2. Since the registration is not available, the issues such as non-availability of verification on quality, safety and efficacy of the medicine and inability of continuous supply arise in relation to

the supply chain and it had not been verified in the audit that it did not happen to buy medicines from outside by patients and the monopoly markets were not created due to these reasons. The receipt of the expected profit of the free health to the people had not been exactly verified in the audit also. Accordingly, even though a program for promotion of the registration of such medicines should be formulated by the Authority having paid attention on government's medicine requirement, no action was taken accordingly.

7.7 Medicines Registration Process carried out by the National Medicines Regulatory Authority

7.7.1 In terms of subsection 58(1) of National Medicines Regulatory Authority Act No. 5 of 2015 (Annexure 73), no person shall manufacture or import any medicine without registering such medicine with the authority and obtain a license from the Authority therefor and said licenses should be renewed in terms of Section 64 of the Act. (Annexure 74) Accordingly, a significant number of dossiers are annually submitted to the Authority for medicines registration and renewals of the registration. In terms of the Good Regulatory Practices published by the schedule XXIII in the Medicines Registration and Granting the Licenses Regulation in the Extraordinary Gazette Notification No.2145/1 dated 14 October 2019, prepared time period for evaluation the registered dossier had been determined as 300 working days (Annexure 75) and this scheduled period of time is given for evaluation the dossier of the medicine as well as quality checking of the medicine through the National Medicines Quality Assurance Laboratory.

7.7.2 However, the quality of the all medicines submitted for the registration does not check in the laboratory by the Authority and the evaluation of the medicine is performed only by examining the documents. In this situation, the medicines registration process and the renewal of the registration process of the Authority had become backlog and the Authority had 1,565 pending dossiers up to 30 June 2023 as 1,169 new dossiers submitted for registration within 2022 and 2023 and 396 dossiers submitted for renewal of the registration. The details on this are shown in under-mentioned Table No.09 (Annexure 76).

Table No. 09 - Pending dossiers up to 30 June 2023 (related to 2022-2023)

	2022	Up to 30.06.2023	Total
Submitted for registration	693	476	1,169
Submitted for renewal of registration	189	207	396
			1,565

7.7.3 Further, due to the failure to grant registration within the target period mentioned in the aforesaid Regulation on Registration and Licensing of Medicines as stated in the paragraph 7.7.1 above, 317 files; as 98 drug files presented for registration and 219 drug files presented for renewal of registration during the period 2018 - 2021, remained with the authority for more than 1 ½ years without finishing their registration activities as at 30 June 2023.

Table 10 - Pending Dossiers as at 30 June 2023 (related to 2018 -2021)

Year	Presented for registration	Presented for renewal of registration	Total
2018	11	14	25
2019	13	12	25
2020	34	82	116
2021	40	111	151
Total	98	219	317

Accordingly, total number of Pending Dossiers; of which the registrations are not completed, remained with the authority as of 30 June 2023 was 1,882.

7.7.4. Even if the evaluation period of a Dossier has been set as 300 days as mentioned in the paragraph 7.7.1 above, it was observed that 41 dossiers out of 93 dossiers; that had been presented to the National Medicines Regulatory Authority in the year 2020 to obtain the Medicines Registration Certificate of 02 Companies consisted with two Directors with same name at same address mentioned in 7.3.16 above and another company related

thereto, had been evaluated by one Pharmacist within two days or period less than that. As per the dossier assignment register, it was confirmed to the audit that the evaluation of 17 dossiers had been done on the assignment of the then Chief Executive Officer of the Medicines Regulatory Authority. It had been confirmed by an independent expert inspection report that the said dossier had not been properly evaluated (Annexure 77).

7.7.5. It was also discovered that the pharmacist stated in paragraph 7.7.4 above who had been assigned to the Authority by the Ministry of Health had spent between 281 and 427 days for evaluating one dossier of other companies apart from the above companies in the year 2019. Similarly, according to section 8 of the Gazette mentioned in paragraph 7.7.1 above (Annexure 78), Even if the full registration can be given for a period that may be determined by the authority for a medicine after the expiry of the temporary registration period of a medicine, the full certificates for 05 years had been awarded in contrast to that for 03 companies at 35 occasions after 03 months upon the issuance of temporary certificates.

7.7.6. Accordingly, the audit does not have any guarantee to say that the companies did not come across with an advantageous circumstance by carrying out the evaluation activities for providing complete registration, executing inspections and granting approval thereto by the Chief Executive Officer within 01 and 02 days. Although more than 02 years had passed since the audit disclosed this questionable deed to the Secretary of the Ministry of Health, no investigation had been carried out, and no system had been prepared to prevent repetitions of such acts.

7.7.7 As a remedy for the drawback in the medicine registration and registration renewal processes mentioned in 7.7.2 above, the methods of Extension of Certificates and granting Approval for Consignment Clearance had been followed by the Authority. However, it was observed in the audit that the National Medicines Regulatory Authority Act and the National Medicines (Registration and Licensing of Medicines) Regulations published in the Extraordinary Gazette No. 2145/1 dated 14 October 2019 do not provide legal provisions to the Authority to extend the registration and grant clearance approvals.

It was further observed that the reviews that should be carried out on the quality, safety and efficacy of the medicines as expected by the implementation of the regulatory measures made on medicines registration and license renewal are not fulfilled through the implementation of such methods.

7.7.7.1 The authority had extended the validity period of all medicine registration certificates which were to be expired after 30 June 2019 up to 30 June 2021 (Annexure 79) and up to 31 December 2021 (Annexure 80). Subsequently, the existing registration of 618 medicines in the year 2022 and 249 medicines in the first half of the year 2023 had been extended by 5 years (Annexure 81) and the validity period of 124 temporary registration certificates had been extended by one year during the audited period (Annexure 82). Accordingly, it was observed in the audit that the registration for certain medicines had been extended by a considerable number of years in several cases. Further, the validity period of 70 out of 124 temporary registration certificates extended during the period of 2022 – 2023 had been extended by a period of 2 - 4 years in two cases. (Annexure 83)

7.7.7.2 Although it is required to obtain samples, documents or other evidence when necessary, get evaluation reports from the National Medicines Quality Assurance Laboratory and renew the registration taking relevant matters into consideration when a request is made to the Authority for renewal of registration imposed by Section 64 of the Act as mentioned in 7.7.1 paragraph above, it was observed during the audit that the regulatory provisions are violated by so extending the validity period of registration certificates and a reasonable assurance on the quality, safety and efficacy of the medicines is not provided thereby.

7.7.7.3 The Board of Directors of the Authority had given approval on 21 January 2022 (Annexure 84) to grant clearance approvals to release the consignment of medicines imported only up to 30 April 2022 from the customs due to reasons such as the registration of certain medicines being processed, the existing registration having expired and the remaining validity period of the registration certificate being short. Afterwards, the Chief Executive Officer of the Authority had presented a Board Paper on 20 May

2022 (Annexure 86) to grant medicines consignment clearance approvals misinterpreting the powers provided by Section 14(g) of the Act (Annexure 85) for granting approval to release the raw materials required in the local production of medicines, and the approval of the board of directors had been given to implement this method without delay. Accordingly, 3,202 consignment clearance approvals (Annexure 87) had been given by the Chief Executive Officer from January 2022 to 31 October 2023 and several such cases are given in Annexure 88.

7.7.7.4. A valid registration certificate provides a validity period from one to five years to import the relevant drug, and the instances where numerous clearance approvals had to be granted for the same medicine since the medicine importers miss the said permission due to non-renewal of registration caused by the inefficiency of the above-mentioned authority were observed during the audit according to the consignment clearance approval seal placed on the back of the existed registration certificates. Some examples for that are given below.

Table No.11: Granting numerous clearance approvals for the same medicine

Name of Medicine	Name of Importer	Number of Registration Certificate existed	No. of instances where stock clearance approvals had been granted
Globetasol Propionate Ointment USP 1.05%	Ceyoka (Pvt) Ltd	M-008786-PR	6
Travoprost Ophthalmic Solution USP 0.004%	Heamas Pharmaceuticals (Pvt) Ltd	M-006590-PR	6
Azithromycin Capsules USP 250mg	Heamas Pharmaceuticals (Pvt) Ltd	M-005121-PR	4
Miconazole Nitrate Cream IP 2%	Pharma Associates (Pvt)	M-008019-PR	8

	Ltd.		
Finasteride Tablets 5mg	Emerchemie NB (Ceylon) Ltd.	M-002418-FR	7
Montelukast Tablets 10mg	Morison Son & Jones	FR-067003	10

7.7.7.5 The cases of withdrawals of medicines from use, temporary suspensions of use and non-continuation of use due to complications with the quality of medicines imported under consignment clearance approvals within the period from January 2022 to October 2023 were observed according to the information provided to the audit by the Authority. The details about this matter are given below and comprehensive information is given in Annexure 89.

Year	Withdrawals of medicines from the use	Temporary suspensions of use	Non-continuation of use	Total no. of instances where complications occurred
2022	14	6	1	21
Up to 31.10.2023	14	7	1	22
Total	28	13	2	43

7.7.7.6 The function of carrying out the technical evaluation of the medicines forwarded for registration and submit a report on the benefits and risks attached to such medicines, quality, efficacy, safety, need and cost of such medicines with pharmacoeconomic analysis to the Authority as per the sub-sections 43(2)(a) and (b) of the Act (Annexure 90). Further, the responsibility of evaluating the medicines considering the need to ensure the availability of efficacious, safe and good quality medicine relevant to the healthcare needs of the public at an affordable price in terms of sub-section 59(4)(a) of the Act (Annexure 91) and the function of presenting an opinion related to the application for the renewal of registration in terms of sub-section 64(3) of the Act are vested with the Medicines Evaluation Committee. Accordingly, Even if obtaining the approval or

ratification of the Medicines Evaluation Committee for all consignment clearance approvals given for the import of medicines due to the delay in medicines registration and registration renewal process, consulting the opinion of the committee or reporting to the committee should be done, the Authority had not proceeded so. Accordingly, it was observed in the audit that consignment clearance approvals have been given regardless of the powers assigned to the Medicines Evaluation Committee regarding the registration of medicines by the Authority Act.

7.7.7.7 A formal and detailed database about the consignment clearance approvals granted by the Authority had not been maintained, and a system was not in place for cross-checking whether the clearance was actually granted by the Authority through the Automated System for Customs Data (ASYCUDA) for clearance of the concerned consignment from the port. Accordingly, the approval for clearance had been granted on the assumption that the existing registration certificate uploaded to the ASYCUDA system by the importers and the stamp of approval placed overleaf were correct as per the personal observation and judgment of the officer in the Authority having access to the ASYCUDA system.

7.7.7.8 Further, the actions had not been taken maintain a record or database on the stock of medicines cleared through the ASYCUDA system and the authority had not followed a formal and transparent system and effective internal control procedure for granting approvals for consignment clearances. Accordingly, it was observed that there was a risk for irregularities and malpractices through the adoption of such unsystematic methodologies in the importation of medicines to this country and that the entire health system may be at risk consequently.

7.7.7.9 Also, it was observed that the medicines evaluation and registration activities; which is the main task of the authority, are experiencing further drawbacks, and that the objective of ensuring that all activities related to registration, licensing and importation of medicines are carried out in a transparent, sustainable and equitable manner as expected by the Section 3 (c) of the Act among the objectives of establishing the Authority is not

fulfilled as the officers of the Medicines Regulatory Division are continuously engaged in the activities of extending registration and granting consignment clearance approvals.

7.7.8 Even if data on the quantity of medicines imported under licenses should be collected according to Sub-Section 14 (j) of the Act (Annexure 92), the Authority had not done so, and therefore the authority did not have a database on imported medicines helpful to achieve the objectives such as regulate the availability of medicines in the country as indicated in Section 3(i) of the Act.

7.7.9 According to sub-section 59(4)(b) of the Act, upon receipt of an application for the registration of a medicine, a sample of the said medicine should be submitted to the National Medicines Quality Assurance Laboratory for testing of the quality of the medicine. However, the quality testing is not done by the Authority for all medicines submitted for registration, and the medicines called Meropenam for injection, Erythromycin, Thyroxin and only some medicines based on the circumstances had been submitted to the National Medicines Quality Assurance Laboratory according to the guidelines on submitting registration samples to the laboratory dated 15 October 2019 (Annexure 93). The following particulars were further observed in this regard.

7.7.9.1 It was observed according to the particulars presented for the audit by the Authority that 1,646 out of 1,730 medicines submitted for registration from 2022 up to 30 September 2023; that is 95 percent, had not been submitted to the National Medicines Quality Assurance Laboratory for sample testing.

7.7.9.2 76 samples of medicines submitted at the time of registration had been analyzed by the National Medicines Quality Assurance Laboratory within the period from January 2022 to September 2023 and it was observed to the audit as per the particulars given to the Board of Directors by the Laboratory that 16 samples thereof or 21 percent had failed in quality. Consequently, a reasonable conclusion can be made to the effect that one out of five medicines submitted to the authority for registration may have a risk of quality and it was also observed that there may be a greater risk of quality of imported medicines

compared to the locally produced medicines since 12 of above-mentioned 16 samples which are failed in quality are imported medicines (Annexure 94). It was therefore observed in the audit that testing and verifying the quality of registered medicines are a very significant factor in meeting the objective of providing medicines with proven quality, safety and efficacy to the public.

7.7.9.3 It was observed in the audit that; even when the fact were detected to the effect that there is a risk of medicines being imported to the country without confirmation on their quality, safety and efficacy and that there are issues on the quality due to the registration of medicines without sample testing, a significant amount of those medicines have been used for patients. The instances of withdrawals of medicines from use, temporary suspensions of use, non-continuation of use and voluntary withdrawal by the importer due to the occurrence of such problems were observed by the audit over the years. A summarized description of this is given below.

Year	Withdrawals of medicines from use	Temporary suspensions of use	Non-continuation of use	Voluntary withdrawal by the importer	Total no. of instances where complications occurred
2015	19	12	1	-	32
2016	15	13	2	-	30
2017	37	20	5	1	63
2018	31	24	2	-	57
2019	38	27	-	-	65
2020	24	28	-	3	55
2021	38	15	2	1	56
2022	23	17	4	-	44
Up to 31.10.2023	23	17	1	5	46
Total	248	173	17	10	448

7.7.10 The National Medicines Regulatory Authority; which functions as the central regulator for all matters related to medicines in this country, had not fulfilled the main regulatory requirements to be achieved at the time of registration and refusal of registration of medicines. As a result, the purposes of educating the general public, health care professionals and all stakeholders on medicines as specified in the section 3 (g) among the objectives of establishing the authority have not been achieved sufficiently and that the benefits of the entire health system are deprived due to the awareness of the relevant parties. The details are given below.

7.7.10.1 According to subsection 60(2) of the Act (Annexure 95), where the Authority registers the medicine, such registration may be informed to the public by order published in the Gazette. However, the authority had not formally fulfilled this regulatory requirement. Although 7,378 medicines registered as at that time under the Authority Act were published by the Extraordinary Gazette No. 2144/20 dated 9 October 2019 (Annexure 96), no actions had been taken subsequently to gazette the details of medicines registered recently during the period of last 4 years.

7.7.10.2 Even though where the Authority refuses the registration of the medicine, the public shall be informed about such refusal by an order published in the Gazette as per the Section 61 of the Act (Annexure 97), the proceedings had not been done in a way this regulatory requirement is fulfilled within the 8 years since the establishment of the Authority.

7.7.11 The following particulars were observed in respect of the composition of Medicines Evaluation Committee, holding of its meetings and participation of members in the meetings.

7.7.11.1 Even if a Professor in Pharmacology in University of Colombo established under the Universities Act, No. 16 of 1978, nominated by the Dean of the Faculty of Medicine of the University of Colombo shall represent the Medicines Evaluation Committee in terms of sub-section 44(1)(b)(ii) of the National Medicines Regulatory Authority Act

(Annexure 98), the said regulatory requirement had not been fulfilled from the month of August 2023.

7.7.11.2 The participation of the committee members appointed for 20 Medicines Evaluation Committees held from January 2022 to August 2023 was at a low level in some cases, and the participation of the members for 9 committees was below 60 percent. The details of this are given in Annexure 99.

7.7.11.3 As specified by Section 44 of the Act (Annexure 100), the Medicines Evaluation Committee should consist of expert and scholarly members representing various segments of the health sector, and the fact that the incomplete composition of the committee and minimal participation of members can affect unfavorably on the effectiveness of the decisions taken by the committee could not be ruled out in the audit.

7.8 Price Regulation Process of Medicines

The regulatory authority had been assigned with relevant powers by the Section 118 of the National Medicines Regulatory Authority Act (Annexure 101) to regulate the price of medicines; which is a very sensitive and critical factor considered in the procurement of medicines for government needs and for public consumption. The following points were observed in this connection.

7.8.1 The authority had fixed through the gazettes the maximum retail price for 60 types of scheduled medicines including 48 types of medicines in the year 2016 for the first time and then 12 other medicines, and the said prices were being revised as per the occasion from time to time since 2019 (Annexure 102). However, no actions had been taken in the recent 4 years in addition to these 60 medicines to identify the other types of medicines widely used in this country and on which the patients have to bear the most expenses and to set a maximum retail price that does not vary according to brands.

7.8.2 A maximum procurement price was fixed by the medicine tender pricing order no. 2086/37 dated 31 August 2018 (Annexure 103) for 10 medicines and had been amended

in 2019 by substituting another medicine for one of them (Annexure 104). However, any review regarding the maximum procurement price of medicines had not been conducted subsequently by the Authority and the attention of the Authority had not been paid for the need of revising the procurement price determination order so as to include new items taking the government's pharmaceutical requirements into consideration.

7.8.3 Due to the recent increase in exchange rates within the economic crisis, the maximum retail price of scheduled medicines had been increased at two occasions during the year 2022 (Annexure 105). In each of those instances, the authority had informed the Sri Lanka Chamber of Pharmaceutical Industry (Annexure 106) and gave permission to increase the price of other medicines by a certain percentage. However, even if the actions had been taken through the most recent price revision on 15 June 2023 (Annexure 107) to reduce the maximum retail price of the 60 scheduled medicines by 16 percent (Annexure 108), the authority had not informed the Sri Lanka Chamber of Pharmaceutical Industry to reduce the prices of other medicines. This raises an issue about the transparency of the Authority regarding its price regulation and the authority has deviated from the objective of providing medicines to the public at an affordable price as expected by section 3(a) of the Act. Further, it is observed in the audit that this is an opportunity given for the pharmaceutical companies to retain the price advantage that could have been given to the public.

7.8.4 Even if the authority is entrusted with the task of determining the price of a medicine in terms of sub-sections 14(q) and 118(2) (a) (Annexure 109) of the Act, it was observed during the audit that 765 medicines are in the market without a fixed maximum retail price due to non-performance of that function properly. As the powers assigned to the Authority regarding price regulation were not positively exercised, the price demanded by the relevant companies and the maximum retail price that the Authority can give for these medicines were still at the level of discussion. Consequently, it was further observed that there is a risk of these medicines being sold at a high price in the market and this situation is an obstructive factor to achieve the objective of ensuring that medicines are provided to the public at an affordable price. The details are given below.

Table No – 12: No. of Medicines of which the Maximum Retail Price was not fixed.

Description	No. of Medicines
Not fixed the maximum retail price at the point of registration	319
Not fixed the maximum retail price at the annual import licensing	446
	765

7.8.5 In terms of sub-section 118(2) (a) of the Act, the Authority shall; in consultation with the Pricing Committee, determine the introductory price of medicines. According to the approval of the Board of Directors dated 19 May 2023 (Annexure 110), a new Pricing Committee had been appointed for this purpose with effect from 14 June 2023 (Annexure 111) as the tenure of the Pricing Committee appointed in 2021 had ended on 14 May 2023. However, the Authority had set the maximum retail price for 159 medicines on 16 June 2023 (Annexure 112) without consulting the recommendations of this pricing committee. Accordingly, it was observed during the audit that the authority has disregarded the powers of the pricing committee by setting the maximum retail price of medicines without obtaining its recommendations even if a valid price committee was in function, and this may cause a risk about the transparency of the medicine pricing system of the Authority.

7.8.6 Except for the 60 types of scheduled medicines, the maximum retail price of the rest of the medicines is recorded in the medicines registration certificate and is revised from time to time during the annual import licensing process. However, a system to communicate these maximum retail prices to the public had not been adopted by the Authority. Since the maximum retail price is always a factor related to the consumer, the public is the main party to be aware of that matter, and it is observed during the audit that the public may not get the real benefit of the maximum pricing done by the Authority exerting a firm effort if this price communication is not effectively executed. Although

the official website of the Authority can be used constructively for this purpose, it was further observed that the Authority has not paid an adequate attention to this price communication not taking actions to include the maximum retail price although all the other details such as the manufacturer, local agent, brand name of a medicine have been included therein.

7.8.7 A motion had been filed by the Sri Lanka Chamber of Pharmaceutical Industry before the court on 5 October 2021 claiming that the Authority should introduce an appropriate price formula to determine the maximum retail price of medicines. Although more than two years had passed as at 14 December 2023, the Authority had failed to prepare and approve a rational and appropriate price formula until the said date. Consequently, the court issued an interim order on 14 December 2023 to the regulatory authority to temporarily refrain from determining the price. Accordingly, it was observed during the audit that the reasonableness and accuracy of the maximum retail price set for the medicines by the Authority is at risk of being challenged.

7.8.8 According to paragraph 4 of the Pricing Regulation No. 2146/3 dated 21 October 2019 (Annexure 113), an ex officio representative of the Consumer Affairs Authority should be appointed to the Pricing Committee. However, the said appointment was not made to the new Pricing Committee appointed on 14 June 2023 and the contribution of the said representative had not been given for the 10 pricing committee meetings held in the year 2023. As a result, the said representation had not been received by the decisions taken regarding the price of 470 medicines. Even if taking decisions about the price of medicines without representation of the Consumer Affairs Authority; which operates with the objective of providing better protection to the consumer through trade and price regulation in Sri Lanka is not a positive factor in respect of the consumers of medicines, it was observed in the audit that the Authority has not given priority for the requirement of this representation. The details are given below.

Table No – 13: No. of Medicines of which the prices were fixed without the participation of the representative of the Consumer Affairs Authority

Date of Meeting	Medicines of which the price was determined at registration	Medicines of which the price was determined at annual import licensing	Total
09.08.2023	121	11	132
21.08.2023	56	127	183
21.09.2023	70	85	155
Total	247	223	470

7.8.9 Although data on consuming a drug product or a class of drug product within Sri Lanka shall be collected by the Pricing Committee according to paragraph 9 (d) of the above regulation, the proceedings had not been made accordingly. Consequently, the authority did not have a formal data system that provides a logical basis to identify new types of medicines to be included among the scheduled medicines for which a maximum retail price could be determined.

7.8.10 As per paragraph 10 of the above regulation, the holder of registration certificate or the local manufacturer of any pharmaceutical product should submit reports to the Authority every six months on the quantity of any registered pharmaceutical product, imported or supplied to the market. However, this regulatory requirement has not been fulfilled even till the audited date; 30 November 2023, and the Authority has not taken steps to introduce a suitable mechanism to obtain these reports, establish a formal data system based on relevant information and to carry out follow-ups.

7.9 Method of inspecting the quality of medicines

In accordance with subsection 39(1) of the National Medicines Regulatory Authority Act (Annexure 114), testing the quality of medicines where submitted with the application for registration, collected at the entry to the country, submitted as a complaint by users,

collected during the post marketing surveillance and submitted to the Authority on other circumstantial matters are the main task of the National Medicines Quality Assurance Laboratory. When the problems with the quality of a medicine are occurred, the Authority uses these research reports to make decisions about the use of that medicine and such decisions are a decisive factor in the health system of this country. Accordingly, following matters were observed in respect of the activities of the National Medicines Quality Assurance Laboratory which is one of main divisions of the Authority and supporting it for the regulation of the medicines.

7.9.1 An application had been submitted to the Sri Lanka Accreditation Board in the year 2020 to obtain the conformity assessment certificate on the standard of this laboratory and the accreditation board had conducted a preliminary conformity assessment on 26 November 2021. Even if a period of 02 months had been given to the Authority to complete the main deficits identified under the international standardization criteria of ISO 17025:2017 (Annexure 115), the Authority had failed to complete the relevant criteria. Although the Accreditation Board had conveyed its willingness on 17 October 2022 to give the Authority an additional opportunity for a pre-compliance assessment, the Authority had made a request on 30 June 2023 to postpone the relevant assessment because of the lack of staff in the laboratory. However, the said request had been rejected by the Accreditation Board on 26 September 2023 asking to complete and apply again as further extension could not be granted in accordance with the accreditation procedures.

7.9.1.1 Accordingly, although nearly 04 years had passed after the application was made, the Authority had not taken steps to raise the standard of the laboratory enabling to obtain the conformity assessment certificate, and the laboratory had failed to reach the international standardization level that should be in a research laboratory. Consequently, it was observed in the audit that the National Medicines Quality Assurance Laboratory may lose the benefits of accreditation such as reduced risk of false test results, reduced costs and international recognition.

7.9.1.2 Some deficiencies identified by the Accreditation Board in the pre-compliance assessment done in 2021 had not been completed even by the date of the audit, and it was

accordingly observed that the research laboratory continued to conduct its research activities outside the prescribed standardization. Some examples are given below.

(i) The scope of accreditation not updated with latest British Pharmacopoeia-BP.

(ii) Non-confirmation competencies of the staff and non-participation in Proficiency Testing-PT and Inter Laboratory Comparison-ILC so that all relevant parameters are covered.

(iii) Essential main equipment being at inoperative and maintenance level.

(iv) Nonexistence of a proper environment in the laboratory due to the inactivity of the central air-conditioning system.

7.9.2 The proposal to construct a new 23-storey building for the National Medicines Regulatory Authority and the National Medicines Quality Assurance Laboratory had not been approved on the policy decisions of the government, and subsequently the discussions had been held to have a land in Narahenpita area belonging to the Ministry of Agriculture for this purpose. However, the said proposal had also been unsuccessful due to the problems related to the removal of unpermitted dwellers. Consequently, even though the Board of Directors had decided to improve and maintain the existing laboratory as per the requirements, the following deficits and shortages existed even as of the date of audit hindering the running of an efficient laboratory service as the adequate measures were not taken.

7.9.2.1 Most of the complex equipment used for medicine analysis were very old and some equipment was inactive and beyond to be repaired. In addition, 18 items of equipment essential for the smooth operation of analytical activities in the main divisions of the laboratory were lacking. The details about this are given below Table No. 14.

Table No -14: Items of equipment essential for the laboratory.

Division	No. of items lacked	Some examples for lacked items
Biological Division	4	Dry Block heater, Vacuum Pump, Hot Plate with Magnetic Stirrer, PH meter with printer, UV-Visible Spectrophotometer, Atomic Absorption Spectrophotometer, Digital Polari meter, Water bath single raw, Centrifuge, Top Pan Balance, Heating Mantle, Stop watch
Chemical Division	8	
Microbiological Division	6	
	18	

7.9.2.2 Repairing works of 29 items in usable condition had not been completed and some items had been removed from the use for more than a year (Annexure 116). Annual calibration activities of 16 machines in use had failed to be completed on time (Annexure 117).

7.9.3 It was observed during the inspection of the laboratory premises that an atmosphere not in accordance with the standard of a national level laboratory; which issues significant test reports helpful for the regulation of medicines and may have negative effects on the test results, has been created in the National Medicines Quality Assurance Laboratory. Some of such factors are given below.

(i) The central air-conditioning system was inactive and the air-conditioners installed in some divisions were also not in function causing no temperature control in the laboratories and thereby impeding the stability of complex analytical equipment.

(ii) Disruption of inspection activities and deactivation of machines due to sudden disconnection of power and interruption of power supply to certain divisions.

(iii) Due to the increase in temperature in stores of chemical items, the chemicals which should be in solid form are dissolved and destroyed, and the chemical power decreases.

(iv) Absence of a favorable environment for tests and staff due to the lack of adequate light condition as some bulbs being inactive, fresh ventilation and adequate air circulation.

(v) Due to infiltration of rainwater into the laboratories, its ceiling, walls and certain fittings have been dilapidated; an unclean environment has been created owing to water leakage from the water distiller, water pipes and sewage pipes.

Accordingly, it was observed in the audit that no successful attempt has been made to overcome these deficiencies that have existed for years although the authority has the sufficient financial capacity.

7.9.4 The National Medicines Quality Assurance Laboratory; which was operating under the Ministry of Health, had consisted with a staff of 70 people immediately before being placed under the National Medicines Regulatory Authority in the year 2015 by the National Medicines Regulatory Authority Act, and 42 of them were the officers belonged to the staff directly involved in testing activities and takes related decisions. The following particulars were observed regarding the present staff of the laboratory.

7.9.4.1 The staff of the laboratory had been rapidly reduced since the actions were not taken to conduct timely reviews and recruit persons for the vacancies caused by the leaving of some officers from the laboratory at the time of placing under the Authority and subsequent retirements of the officers, and the staff had been reduced to 22 officers as at 31 December 2022. It was only 52 percent as compared to the staff employed at the time of transferring the laboratory to the Authority.

7.9.4.2 The new staff approved for the National Medicines Regulatory Authority on 22 August 2023 (Annexure 118) had included 54 officers who could be directly assigned to the laboratory. However, the staff of the laboratory had been reduced to 11 by the date of audit; 30 November 2023, as the related recruitments were continuously delayed. It was only 20 percent in comparison with approved staff. The details of this are given below.

Table No.-15: Particulars of the staff of the laboratory

Post	Staff as at 30.06.2015	Staff as at 31.12.2022	Staff approved on 22.08.2023	Staff as at 30.11.2023
Director	1	1	1	1
Deputy Director	1	1	-	-
Divisional Head	5	-	-	-
Medicine Analyst	8	6	20	5
Assistant Medicine Analyst	-	-	25	-
Pharmacist	27	14	-	5
Laboratory Assistant	-	-	08	-
Total	**42**	**22**	**54**	**11**

7.9.4.3 The adequate attention of the Authority had not been paid for updating the knowledge of laboratory personnel and sharing technical knowledge by providing suitable training opportunities.

7.9.5 According to the benchmarking program conducted by the World Health Organization in the year 2019, 15 major recommendations to be implemented in respect of the National Medicines Quality Assurance Laboratory had been proposed. All these recommendations provide necessary guidance to conduct the works of the laboratory in a more systematic, effective and transparent manner. However, even if 04 years had passed since those recommendations were made, no attention had been given by the Authority to steer the activities of the laboratory to a more positive path through the implementation of those recommendations. Consequently, 3 of those recommendations had not been partially implemented and 10 recommendations had not been fully implemented (Annexure 119). Some examples are given below.

(i) All environmental circumstances which may cause a direct effect on the quality of the tests shall be controlled by the laboratory and there should be a procedure therefor.

(ii) Laboratory storage system should be upgraded.

(iii) The sample management procedure should be revised; the test parameters and sample retention procedures should be implemented to maintain the specific sample storage conditions.

(iv) The operation procedure for laboratory reporting should be revised.

(v) The operation procedure should be revised by incorporating trend analysis procedures for primary and secondary reference standards.

(vi) The operation procedure should be revised to regulate safe handling, transportation, storage of chemical items and disposal of hazardous substances.

(vii) Formation, implementation and monitoring of immunization programs for laboratory staff.

(viii) The laboratory should have separate measuring rooms under controlled circumstances.

(ix) The operation procedure should be revised in order to provide clear information on specifications or criteria for external laboratories and contract procedures.

7.9.6 The laboratory had failed to issue medicine quality testing reports within the stipulated timeframe and a significant amount of pending samples of which the testing activities were not completed had been continuously piled up. Further, the research laboratory does not have enough facilities to carry out some necessary tests regarding the condition of the medicines and no positive trend in the testing activities was observed during the audit. The details are given below.

7.9.6.1 In the review of the details about the number of samples received for testing and the number of samples tested and remained pending within several periods, the progress of issuing the medicines quality inspection reports regarding the samples to be tested during

the said period had been decreased from 69 percent to 32 percent. A summary of this is given in Table No. 16 and it is observed in the audit that this situation can directly affect the delay in decisions related to the regulation of medicines due to not taking adequate measures in this connection.

Table No -16: Sample Testing Progress

	No. of samples existed at the beginning of the period	No. of samples received	No. of samples existed to be tested within the period	No. of samples tested	No. of samples existed to be tested as a percentage of samples tested
Year 2022	212	309	521	362	69
First half of the year 2023	159	199	358	165	46
From July to October 2023	193	231	424	134	32

7.9.6.2 Although the relevant test report should be issued within 90 days from the date of submitting the sample to the National Medicines Quality Assurance Laboratory as per the Paragraph 5.1 of the Operating Procedures for Quality Control in Pharmaceutical Products dated 01 April 2021(Annexure 120), the laboratory had failed to issue 220 reports; I.e. 38 percent, within the stipulated period out of 586 medicine test reports issued during the period from January 2022 to October 2023. Further, it was also observed that more than a period of one year had been spent to issue 47 reports from those.

Table No.- 17 : Particulars of test reports that couldn't be issued within 90 days

Year	Total test reports issued	Test reports failed to be issued within 90 days	
		Quantity	Percentage
2022	311	123	40%
Up to 31.10.2023	275	97	35%
Total	**586**	**220**	**38**

7.9.6.3 Although the samples of medicines should be examined and the relevant report should be sent to the court within 28 days upon the receipt of samples by the laboratory from the court as per sub-section 127 (3) of the Act (Annexure 121) and the Operating Procedures for Quality Control in Pharmaceutical Products, all the 102 such test reports issued during the period from January 2022 to October 2023 had been failed to be presented within the stipulated time. Further, it was also observed that more than a year had been spent for the issuance of 26 reports from those. Therefore, it was observed in the audit that the task of functioning as an additional approved Analyst as per the circumstances assigned to the laboratory according to the sub-section 39(1)(b) of the Act has not been effectively performed, and that this situation may affect the delay of certain judicial actions related to medicines. A summary of this is given below.

Table No-18: Particulars about research reports unable to be issued within 28 days

Year	Total test reports issued	Test reports failed to be issued within 28 days	
		Quantity	Percentage
2022	46	46	100%
Up to 31.10.2023	56	56	100%
Total	**102**	**102**	**100%**

7.9.6.4 It was observed that conducting biological and microbiological examinations of medicines is at a minimum level as the laboratory is currently lack of modern machinery, advanced technological techniques and qualified technical staff as at the audited date; 30 November 2023.

7.9.6.5 It was observed that an enough support is not received from the laboratory in terms of taking decisions on medicines, fulfilling the objectives of regulation and satisfying legal requirements due to the deficiencies such as failure to test the relevant samples and issue reports within the specified timeframe as above, the existence of a large number of pending samples of which the tests were not completed, and the lack of sufficient facilities to carry out certain essential tests.

7.9.7 As per the 39(1)(c) of the National Medicines Regulatory Authority Act, in cases where the Authority deems that the services of local or overseas laboratories are necessary for testing the quality of medicines, the task of coordinating with such laboratories is assigned to the National Medicines Quality Assurance Laboratory. A situation; where samples are not submitted to the laboratory to examine the quality of all the medicines submitted for registration, has currently been created due to the lack of necessary facilities in the laboratory, and a large number of pending samples of which the examinations have not been completed was available at the laboratory by the audited date; 30 November 2023. Despite the situation, the pharmaceutical laboratory of the Industrial Technology Institute; which is an accredited third-party laboratory for the development of the pharmaceutical sector in Sri Lanka, or other local and foreign laboratories recognized by the Authority as capable of providing testing facilities, had not been adequately utilized to test the quality of medicines.

7.9.8 Even if the research projects pertaining to quality assurance of medicines should be carried out as per the 39(1)(d) of the Act, the proceedings had not been done so by the National Medicines Quality Assurance Laboratory.

7.10 Regulation of Medicines Stores and Transportation of Medicines

The matters had been pointed out by the audit from several years regarding the weaknesses such as not keeping proper temperature in the government medicines stores, not maintaining the cold chain continuously, destruction of medicines due to storage errors, storing medicines in unsafe places and not taking proper actions on expired medicines, and the following points were observed in the course of inquiring about the role of the National Medicines Regulatory Authority.

7.10.1 Although the National Medicines Regulatory Authority is assigned with the task of issuing licenses for storage, distribution and transportation of medicines according to subsection 14(e) of the National Medicines Regulatory Authority Act No. 5 of 2015 (Annexure 122), a regulating and licensing method for Medical Supplies Division, Regional Medical Supplies Divisions, Storage of Medicines being maintained at Government Hospitals and Medical Transport Vehicles had not been adopted by the Authority.

7.10.2 The Guideline on Good Distribution Practices (GDP) dated 27 August 2021 (Annexure 123) provides a comprehensive guidance for storage and transportation of medicines through the criteria such as conditions of storage premises, obtaining medicines and methods of storing, proper storage conditions, safety arrangements, temperature control, cleanliness, responsible officers, stock control, dealing with expired stock, equipment, delivery vehicles and record keeping. Also, as per the subsection 49(3) of the Act (Annexure 124), no person shall distribute any medicine without adhering to Good Distribution Practices (GDP). However, a system to check whether the government medicines stores and transport vehicles including the medical supplies sector are being maintained in accordance with Good Distribution Practices had not been established by the Authority.

7.10.3 Accordingly, it was observed in the audit that the attention of the Authority had not been given for the need to continuous validation of the quality, efficacy and safety of medicines released into the free health system through supervising, regulating and licensing these medicines stores and transport vehicles.

7.11 Issuance of Waiver of Registration Letters by the National Medicines Regulatory Authority.

According to Section 109 of the National Medicines Regulatory Authority Act No. 5 of 2015, the Authority may grant permission in special circumstances such as to save a life, to control an outbreak of an infection or an epidemic or any other national emergency or for national security to import and supply a particular medicine in specified quantities. However, it was observed as per the following particulars that the authority had issued waiver of registration letters to import medicines without adhering to those provisions.

7.11.1 Waiver of Registration Letters had been issued for many years for the State Pharmaceutical Corporation, Medical Supplies Division and private institutes for reasons not taken under the reasons stated in the Act such as expiry of previous registration, unavailability of registered suppliers, and delay in the registration process. The details about the number of Waiver of Registration Letters so issued yearly are given below.

Table No-19: Number of Waiver of Registration Letters issued yearly

The institute to which the letter was issued	2018	2019	2020	2021	2022	Up to June 2023	**Total**
Donations or other Public Institutes	03	36	43	24	326	145	**577**
Medical Supplies Division	02	09	-	13	57	03	**84**
State Pharmaceutical Corporation	136	157	139	52	252	88	**824**
Private Sector	-	15	18	37	21	25	**116**
Total	**141**	**217**	**200**	**126**	**656**	**261**	**1,601**

7.11.2 Even if a comprehensive perusal of documents is done when a certain medicine is registered including information of the manufacturer and local agent of the relevant medicine, administrative information and prescribing information, dossier overall summary related to the medicine, documents ensuring the quality of the medicine, non-clinical study reports and clinical study reports according to the Guidelines on Registration of Medicines dated 15 October 2019 (Annexure 125), it was observed in the audit from a number of years that the medicines without an validation about its quality are imported to the country due to the issuance of the Waiver of Registration Letters by a Waiver of Registration Subcommittee (WORSC) established under the Medicines Evaluation Committee by evaluating only very limited quantity of documents and without a sample testing as stated in paragraph 7.5.4 above.

7.11.3 The instances of removal of medicines from use, temporary suspensions of use and voluntary removals by the importer was observed to the audit at 26 occasions from the year 2019 to 2023 due to problems occurred in respect of the quality of medicines imported into this country under waiver of registration approvals and the details of this are given below.

Table No-20: Instances where problems occurred in respect of the quality of medicines imported into this country under waiver of registration approvals

Year	Removal of medicines from use	Temporary suspensions of use	Voluntary removals by the importer	Total No. of instances of problems
2019	1	-	-	1
2020	-	1	-	1
2021	8	1	-	9
2022	5	-	-	5
Up to 31.10.2023	3	6	1	10
Total	**17**	**8**	**1**	**26**

Accordingly, it was observed that the medicines of which the quality is not confirmed are being imported to this country, the quality of the medicines so imported is not checked before being distributed to the hospitals, the harm caused to the patients by the use of such medicines cannot be measured and the well-being of the health sector in this country is negatively affected. Some examples of this are provided below.

(i) Even at the time where a stock of 6,000 bottles of Furosemide syrup - which is used in illness conditions such as heart, liver, kidney disease and high blood pressure - imported under a waiver of registration letter issued in the year 2020 is reported to be defective in quality, a quantity of 98 percent of the said stock have been used for the patients in public hospitals including the Lady Ridgeway Hospital for Children.

(ii) Two women had died in Peradeniya Teaching Hospital consequent to the use of Bupivacaine purchased by the Medical Supplies Division under a waiver of registration letter issued in the year 2022, and the Safety and Risk Evaluation Subcommittee (SAFRESC) held on 20 July 2023 has recommended to remove the medicine completely from the use as the patients had suffered Adverse Drug Reaction (ADR) from the use of the medicine.

7.11.4 Even though the Authority; as the only government body acting as a central regulator of medicines, has the responsibility to act in such a way as to minimize the referral of the waiver of registration letters to the Authority as much as possible being strictly based on the provisions made by subsections 58 (1) and 109 (1) of the National Medicines Regulatory Authority Act, the circumstances where the said responsibility was not fulfilled optimally were observed. Several such cases are given below.

7.11.4.1 The waiver of registration letters had been issued repeatedly by the Authority to the same applicant on several occasions as well as for the same medicine. The interest of

local agents in the registration of medicines is declined thereby and it is also observed that there is a temptation to import medicines into Sri Lanka based on the waiver of registration letters and it is not a positive trend for the health system.

7.11.4.2 Accordingly, in examining a sample of 30 importers of medicines to whom the waiver of registration letters had been issued from January 2022 to June 2023, a total of 306 waiver of registration letters had been issued to those 30 importers during the audited period, and there were cases where between 02 and 54 letters had been issued to each of those institutes. The details are given in Table No. 21.

Table No-21: Particulars of the Waiver of Registration Letters issued

	Name of the Importer	No. of Waiver of Registration Letters issued
1.	Yaden International	54
2.	Pharma Associate	28
3.	Sisili Projects Consortium Pvt Ltd	27
4.	Pharmatec (Pvt) Ltd	23
5.	ABC Parma Services Pvt Ltd	20
6.	Mansel (Ceylon) Pvt Ltd	14
7.	Sunshine Healthcare	14
8.	Tabrane Pharmaceuticals	13
9.	A Baur & Co. Ltd	12
10.	Siba Healthcare (Pvt) Ltd	11
11.	Breath Free Lanka (Pvt) Ltd	10
12.	Ravilux Co.Ltd	10
13.	Cloud Healthcare (Pvt) Ltd	7
14.	Kamazu (Pvt) Ltd	6
15.	George Steuart Health Ltd	5
16.	Markss HLC (Pvt) Ltd	5

17.	Softcare International	5
18.	Emar Pharma (Pvt) Ltd	4
19.	Junaht International (Pvt) Ltd	4
20.	Niix Holdings (Pvt) Ltd	4
21.	Novachem Lanka (Pvt) Ltd	4
22.	TMI Solutions (Pvt) Ltd	4
23.	Care Ring Pharma (Pvt) Ltd	3
24.	Imperial Life Sciences (Pvt) Ltd	3
25.	Lanka Therapeutics Pvt Ltd	3
26.	PTC Medical Pvt Ltd	3
27.	SSK Pharma (Pvt) Ltd	3
28.	Unicura International Pvt Ltd-Dehiwala	3
29.	Ceyoka (Pvt) Ltd	2
30.	P.T.C Medical Colombo 13	2
	Total	**306**

7.11.4.3 Further, waiver of registration letters had been issued to the same importer at several circumstances for importing the same medicine, and a quantity from 02 to 04 waiver of registration letters had been issued in respect of 29 medicines to 17 importers related to the above sample. Summarized details of this are given below.

Table No -22: Particulars of the issuance of waiver of registration letters to the same Importer

	Name of Importer	Name of Medicine	No. of Letters
1.	A Baur & Co. Ltd	Capecitabine Tablets 500mg	3
		Clobazam Tablets IP 10mg	4
2.	ABC Parma Services Pvt Ltd	Desferrioxamine Mesilate for Injection BP 500mg	2
3.	Breath Free Lanka	Warfarin Sodium Tablets IP 5mg	2

	(Pvt) Ltd	(WARF-5)	
4.	Emar Pharma (Pvt) Ltd	Dried Aluminium HYdroxide Gel 240mg + Magnesium Hydroxide 100mg + Light Magnesium Carbonate 60mg + Activated Dimethicone 25mg Tablets (DIOVOL)	2
5.	Kamazu (Pvt) Ltd	Amoxicillin Capsules BP 250 mg	2
		Erythromycin Stearate Tablets BP 500mg	2
6.	Lanka Therapeutics Pvt Ltd	Ruxolitinib Tablets 5mg	2
7.	Mansel (Ceylon) Pvt Ltd	Fusidic Acid 2% w/w and Hydrocortisone Acetate 1% w/w Cream (DISUF-H-Cream)	2
8.	Niix Holdings (Pvt) Ltd	Atracurium Besilate 10mg/ ml Solution for Injection/ Infusion (25mg in 2.5 ml)	2
9.	Pharma Associate	Pazopanib Tablets 200mg	2
10.	Pharmatec (Pvt) Ltd	Metoprolol Tartrate Injection 1mg/ml, 5ml	2
11.	Ravilux Co.Ltd	Etoposide Capsules 100mg	2
12.	Siba Healthcare (Pvt) Ltd	Captopril Tablets BP 25mg	2
		Gabapentin Capsules USP 100mg (RAVASTAL-100)	4
		Olanzapine Tablets USP 5mg	2
13.	Sisili Projects Consortium Pvt Ltd	Cefotaxime for Injection USP 1g	2

14.	Sunshine Healthcare	Linezolid IV Injection 200mg/100ml (Lizolid IV)	2
		Pantoprazole for IV Injection 40mg	3
15.	Tabrane Pharmaceuticals	Cyclosparin Capsules USP 50mg	2
		Olaparib Capsules 50mg	2
		Sofosbuvir INN 400mg & Ledpasvir INN 90 mg Tablets (HopSo-LP)	2
16.	TMI Solutions (Pvt) Ltd	Enoxaparin Injection 40mg in 0.4ml	2
17.	Yaden International	Chlorambucil Tablets 2mg	2
		Ergometrine Injection BP 500mcg/ml	3
		Fludrocortisone Acetate Tablets USP 100mcg	2
		Morphine Tablets 10mg	2
		Sodium Fusidate for Infusion BP 50mg	2
		Tetracosactide Injection BP 250mcg/1ml	2
	Total		**65**

7.11.5 As per sub-section 58(1) of the Act, only medicines registered under the Authority should be imported into this country. Accordingly, even though the non-issuance of waiver of registration letters and minimizing the issuance of such letters as much as possible should be done by the Authority, there were cases where waiver of registration letters had been issued even for the medicines registered under different brand names. Accordingly, for a sample of 07 selected medicines, waiver of registration letters had been issued to other importers as follows even in cases where there are between 02 and 57 registered medicines.

Table No-.23: Issuance of Waiver of Registration letters for the medicines registered under various brand names

	Name of Medicine	No. of registered medicines available	Name of institute to which the waiver of registration letters had been issued
	---	---	---
1.	Aciclovir 200mg bp tablets	19	Savorite pharmaceuticals pvt ltd
2.	Acitretin capsules bp 10mg	3	Centurion healthcare pvt ltd, india
3.	Amikacin sulphate injection bp 500mg/2ml	5	Nandani medical laboratories (pvt) ltd, india
4.	Amoxicillin capsules b.p 250mg	57	Micro labs ltd, india
5.	Atropine eye drops 1% w/v	3	DCI pharmaceuticals (pvt) ltd, india
6.	Azathioprine 50mg bp tablets	8	Siba holdings Yaden international pvt ltd
7.	Betamethasone 0.1%	2	Pharmatec pvt ltd

7.11.6 Although the importer shall be responsible; as per sub-section 109(3) of the Act, for the accountability and management of the medicine imported under the waiver of registration letters, it was observed according to 3(a) of the Act that the Authority has the prime responsibility to ensure that the efficacious, safe and good quality medicines are provided to the public. However, when waiver of registration letters were issued, the Authority had deviated from its prime responsibility of regulation assigning the responsibility for the quality, safety and efficacy of the medicine to the related Procurement and Technical Evaluation Committees on behalf of the State Pharmaceutical Corporation or to the Director when issuing on behalf of the Medical Supplies Division. The following particulars were further observed in this regard.

7.11.6.1 Even though responsibilities had been assigned to the Medical Supplies Division and the Procurement and Technical Evaluation Committees of the State Pharmaceutical Corporation as above, they had refused to accept that responsibility (Annexure 126). However, in the procurements made under the calling for expression of interest, the Health Sector Emergency Procurement Committee had not been subjected to obtaining waiver of registration letters when giving its decision.

7.11.6.2 Accordingly, a situation; where the responsibility for quality, safety and efficacy of the medicines imported into this country under the waiver of registration letters is not taken by any related party, has been created. Also, a major objective of establishing the Authority which is the responsibility of ensuring that the efficacious, safe and good quality medicines are provided to the public as per the Section 3(a) of the Act had not been effectively achieved by the Authority.

7.11.6.3 Instead of referring the originals of the waiver of registration letters for medicines issued by the Authority directly to the Controller General of Imports and Exports, the actions had been taken to give those to the relevant importers of medicines. Further, the copy of the waiver of registration letters issued on behalf of the Medical Supplies Division had not been formally forwarded to the Director of the Medical Supplies Division, and the copies of 105 waiver of registration letters issued from 02 February 2022 had been handed over at once on 16 October 2023.

7.11.6.4 The severe weaknesses such as not mentioning the date of release, not stating the name of the manufacturer, not specifying the name of the medicine waived from registration, and using two official seals by the Chief Executive Officer with and without the name in some of those copies were observed.

7.11.6.5 Even though strict internal control systems should have been implemented regarding the issuance of waiver of registration letters, it was observed that fraudulent activities have been allowed due to the aforementioned irregularities done intentionally or negligently by the Authority and activities are being done inconsistently with the objective of ensuring that all activities related to the importation of medicines in terms of 3(c) of the Act are being carried out in transparent, sustainable and fair manner.

7.11.7 The Authority had prepared a guideline (Annexure 127) dated 15 October 2019 regarding the method of issuing waiver of registration letters and in accordance with that, the approval for waiver of registration of medicines should be obtained from the relevant technical sub-committee. The Secretary of the Ministry of Health had given permission to set up a fast-track mechanism to issue waiver of registration letters for the purchase of medicines through Indian Credit Line and other foreign credit assistance projects. Accordingly, the Chief Executive Officer of the National Medicines Regulatory Authority had recommended a fast-track mechanism called as special pathway and submitted a board paper on 16 September 2022 for obtaining the approval to enable the Chief Executive Officer to issue waiver of registration letters without referring that matter to the afore-mentioned sub-committee. (Annexure 128)

7.11.7.1 The conditions of fast track mechanism, parties to implement the fast track mechanism, fees to be charged, essential documents (application and purchase order / indent / invoice) and the following procedures had been submitted by the Board paper for approval and it was observed during the audit that none of the documents or tasks that confirm the quality, safety and efficacy of the medicine had been covered by those procedures, and it had not been confirmed to the audit that any other methodology that could confirm the quality had been proposed.

- Obtaining the Application for Waiver of Registration from the Office of the Chief Executive Officer of the Authority.

- Handing over of the received applications to the concerned pharmacists.
- Obtaining the approval of the Chief Executive Officer by the Pharmacists for further activities.
- Issuance of the payment note to applicant by Management Assistant.
- Drafting of the Waiver of Registration letter by Management Assistant after receiving the payment.
- Maintenance of relevant data system and register by the Management Assistant.
- Checking of the waiver of registration letter by the pharmacists.
- Submitting the final draft letter to the signature of the Chief Executive Officer.
- Sending copies of the letter to the responsible parties concerned.

7.11.7.2 Action had not been taken to submit a risk analysis indicating the identified risks that could arise from the implementation of this fast track mechanism, likelihood of risk, its impact and risk management strategies in the board paper presented. Accordingly, it was not confirmed to the audit that attention had been paid on the possible adverse effects to the health system of this country by implementing such a system.

7.11.7.3 The proposed fast track mechanism had been approved on the facts included in the afore-mentioned Board paper without paying proper attention on the risk of challenging the major objective of establishing the National Medicines Regulatory Authority, viz, ensuring the availability of efficacious, safe and good quality medicines to the general public, by implementing such a system by the Board of Directors of the Authority.

7.11.7.4 It was not confirmed to the audit that the medicines evaluation committee or the waiver of registration sub-committee had been consulted to prepare a fast mechanism in order to ensure the quality of the medicines in the procurement of such medicines on the Waiver of Registration letters using foreign credit schemes within the economic crisis prevailed, and even the opinion of the said committees had not been obtained before the implementation of this system.

7.11.7.5 Although the waiver of registration sub-committee should meet once in every two weeks as per the guideline on issuing letters on waiver of registration of medicines, the Authority had not complied with it since earlier. Although 36 sub-committee meetings should have been held from January 2022 to June 2023, which was the audited period, only 15 meetings had been held. Furthermore, it was observed during the audit that action had not been taken to convene the relevant committee in the month of September 2022, at the time that the Board of Directors had approved this fast track mechanism.

7.11.7.6 Even though the sub-committee had focused attention on the reasonability of the price of the medicine, the opinion of the concerned college about the medicine, the essentiality of the medicine, the number of registered drugs similar to those medicines available currently, the registration status of the medicine, the registration status of the supplier and manufacturer, the existence of previous problems with the quality (quality failures) in granting the approval for waiver of registration. Waiver of registration letters had been issued without paying attention to such matters under this methodology. The details of the number of approvals issued for waiver of registration as mentioned above to the Medical Supplies Division and the State Pharmaceutical Corporation during the audited period are indicated in Table No. 24 below.

Table No -24: The details of the number of approvals on waiver of registration issued through Special Pathway system

Description	2022	Up to June 2023	Total
Total number of waiver of registration letters	**656**	**261**	**917**
to Medical Supplies Division under Special Pathway System	57	03	60
to State Pharmaceuticals Corporation under Special Pathway System	176	51	227
Total number issued under Special Pathway System	**233**	**54**	**287**
Total number of letters issued under the Special Pathway	36%	21%	31%

system as a percentage of the total number of waiver of registration letters issued

7.11.7.7 The committee members, who had participated in the emergency medicines evaluation committee held on the two days of 24 and 27 January 2023, had inquired on the issue of waiver of registration letters on the approval of the Chief Executive Officer by overriding the Waiver of Registration Subcommittee (WORSC) and had given their opinions that those members were willing to participate in emergency meetings to prevent the shortage of medicines in the country and the importance of purchasing medicines from registered suppliers after evaluating criteria such as quality, safety and efficacy, and the declaration that the Authority does not accept the responsibility for the quality, safety and efficacy of the medicines imported under the waiver of registration letters should not be included in the waiver of registration letters. Furthermore, the Secretary of the Medicines Evaluation Committee had emphasized the need to consider the principle that the manufacturer or the local agent requesting the certificate of waiver of registration should have been registered with the Authority even though the relevant medicine is not registered in Sri Lanka.

7.11.7.8 Furthermore, the 233 approvals for waiver of registration issued to the Medical Supplies Division and the State Pharmaceuticals Corporation in the year 2022 through the Special Pathway system, had been submitted to the Medicines Evaluation Committee, which had been specially met on the two dates of 24 and 27 January 2023, for obtaining the ratification. The ratification of the Committee had not been granted for 89 waiver of registration letters (Annexure 129) issued to the Medical Supplies Division for 31 types of medicines and to the State Pharmaceuticals Corporation for 58 types of medicines due to the reasons such as the medicines had not been essential, inconsistency in the dosage of the medicine, offering a higher price, possibility in purchasing from such a supplier owing to the availability of several registered medicines, local production of the medicine and non-registration of the manufacturer or local agent. In addition, ratification of the Committee had been granted with conditions for 25 waiver of registration letters (Annexure 130) issued to the Medical Supplies Division for 13 types of medicines and to the State

Pharmaceuticals Corporation for 12 types of medicines on the conditions, such as the manufacturer should be registered and the price offered should be less than the maximum retail price. Further details in this regard are as follows.

7.11.7.9 Since it is not allowed for any person to import any medicine without registering it with the Authority and without obtaining a license from the Authority in terms of sub-section 58 (1) of the National Medicines Regulatory Authority Act No. 5 of 2015, the Medicines Evaluation Committee primarily considers whether there are registered medicines in granting the approval for waiver of registration. Since there had been 01 to 21 registered medicines for 166 waiver of registration of medicines provided through the Special Pathway system, ratification of the Medicines Evaluation Committee had not been granted for 26 waiver of registration based on that reason. (Annexure 131)

7.11.7.10 Approval for waiver of registration had been granted through the Special Pathway system for the importation of 400,000 units of the antibiotic called Meropenem Injection USP 500mg, which is commonly used for infected patients, and the Medicines Evaluation Committee had not granted ratification for that as quality failures had been reported previously. In addition to this, it was observed during the audit that there had been reports on the quality failures of the medicines of the manufacturers related to 15 other medicines, for which the approval had been granted as mentioned above. (Annexure 132)

7.11.7.11 The ratification of the Medicines Evaluation Committee had not been granted for 29 medicines, such as Ofloxacin vial Eye/Ear Drops 5ml, Cinnarizine Tablets BP 25mg, Rifaximin Tablets 550mg, and Mosapride Citrate Tablets 5mg used for ear infections, haematological conditions and digestive system problems etc. for which the waiver of registration had been granted through the Special Pathway method, as they had not been included in the list of essential medicines. (Annexure 133)

7.11.7.12 Accordingly, it was observed during the audit that there is a risk of importing medicines, for which there had been no confirmation on the quality, safety, efficacy and fairness in prices, into the country and using them for patients through granting approval by the Chief Executive Officer for waiver of registration of medicines through the Special Pathway system, by overriding the Waiver of Registration Sub-committee.

7.11.8 Even though the importer shall submit routine reports on the medicine imported under waiver of registration letters in the prescribed manner to the Authority in terms of Section 109 (4) of the Act, that regulatory requirement had not been fulfilled and the Authority had not formulated a methodology to obtain these reports and maintain a database using those reports. Therefore, there was no follow-up as to whether the medicines were imported / not imported under the waiver of registration letters issued by the Authority and the compliance of the imported medicines.

7.12 Observations regarding the major orders submitted to the State Pharmaceuticals Corporation for the years 2022 and 2023.

7.12.1 The following matters were observed during the audit test check carried out in relation to the progress of the major orders submitted to the State Pharmaceuticals Corporation for the years 2022 and 2023 for the medicines related to the orders submitted for purchases carried out by calling for expression of interest and unsolicited method deviating from the standard procurement guidelines and in relation to the other major orders submitted to the State Pharmaceuticals Corporation for 80 medicines for the years 2022 and 2023 although the ministry party had submitted facts to the Cabinet that emergency purchases would be made due to the shortage of medicines in the year 2022.

7.12.1.1 Since there is a waiting period of 11 months for receiving medicines to the institution after making orders for medicines required for a certain year as decided by the Medical Supplies Division, the order should be made to the State Pharmaceuticals

Corporation at least in the month of January in the previous year. However, it was observed that the general annual order for the year 2022 related to 04 medicines and the general annual order of the year 2023 related to 07 medicines and the general annual order of the year 2024 related to 07 medicines had not been prepared by the Medical Supplies Division. (Annexure 134)

7.12.1.2 It was also observed that the Medical Supplies Division had delayed the preparation of the general annual order for the year 2022 related to 05 medicines and submission of it to the State Pharmaceuticals Corporation approximately by one month, and the Medical Supplies Division had delayed the preparation of the general annual order for the year 2023 related to 12 medicines and submission of it to the State Pharmaceuticals Corporation for a period ranging from 07 months to 11 months. (Annexure 135)

7.12.1.3 The MSMIS computer system had been used for estimating, ordering, issuing and distribution of medicines in the Ministry of Health until June 2023. However, procurement activities had been started with a delay of a period ranging from 1 month to 10 months after submitting orders as the Corporation had been waiting until 6 orders related to 6 medicines forwarded to the State Pharmaceuticals Corporation by the Medical Supplies Division through the MSMIS computer system had been communicated to the Corporation in writing as usual. (Annexure 136)

7.12.1.4 Eighteen (18) medicines remained in short supply for a period ranging from 04 months to 35 ½ months due to not preparing and executing the general annual order for the year 2022, delaying the commencement of procurement activities related to the general order by 10 months, delaying the issuance of the indent for nearly three months after selecting the supplier, the bidder had rejected the acceptance of the supply as 21 months had been spent for the procurement activities, taking 11 months to obtain the opinion of the Medical Supplies Division regarding the only bidder responded due to the poor relationship in communication between the Medical Supplies Division and the State Pharmaceuticals Corporation, cancellation of orders

and temporary suspension of orders, the certificate of the only supplier, who had obtained the NMRA certificate, had expired, a supplier, who had fulfilled the specifications of the Medical Supplies Division had not registered with the National Medicines Regulatory Authority, taking a long time unnecessarily for the procurement activities of this medicine in the years 2022 and 2023 and cancellation of the orders etc., and due to the other reasons. (Annexure 137)

7.12.1.5 There were variations between estimated amount and the actual supply from 2019 to 2023 for 06 medicine items, and it was observed that the Medical Supplies Division had not taken action to accurately forecast these estimated data according to the requirement of the medicine. (Annexure 138)

7.12.2 Not taking action in compliance with the Procurement Guidelines

7.12.2.1 Even though a performance guarantee should be obtained in accordance with Section 6 of the second part of the bid invitation document since it has been stated that suppliers are required to provide a performance guarantee to safeguard the Procurement Entity against non-performance of the contract in terms of Guideline 5.4.10 (b) of the Government Procurement Guidelines, action had not been taken to obtain a performance guarantee worth Rs. 180 million and USD 0.44 million for tenders worth Rs. 1,800 million and USD 4.43 million as it had been informed by the recommendation mentioned in the letter of the Secretary of the Ministry of Health bearing No. SH/PSRP/01/SPC/2021 dated 10 January 2023 to retain an amount of 10 percent of the value that should be paid to the supplier for up to 30 days after the completion of the supply instead of obtaining a performance guarantee. (Annexure 139)

7.12.2.2 Even though a penalty fee should be charged from the supplier for the delay in the supply of medicines according to the supply conditions specified in the purchase order, the penalty fee imposed on the delay in supply had been waived off as per the letter of the Secretary of the Ministry of Health bearing No. SH/Misc/03/2022 dated 23 November 2022. Due to the provision of such concessions, it had not possible to

take any action regarding the delay in the supply of medicines by the supplier. Even though emergency purchases had been carried out at high prices on the shortage of stock, the government had lost a sum of Rs.155.595 million and a penalty of USD 0.064 million due to not supplying within the due period. (Annexure 140)

7.12.2.3 As per 5.4.10 (b) of the Government Procurement Guidelines, the supplier shall furnish a performance guarantee of 10 percent and even though a performance guarantee that is valid for 03 months from the date of delivery of the stock should be provided within 03 days after informing the supply as per Condition No. 5 of the Conditions related to Bids in the invitation for bids, the performance guarantees worth Rs. 31.66 million given for 2 orders had not been valid. (Annexure 141)

7.12.2.4 The audit observed that the Medical Supplies Division had complicated the procurement process by issuing several orders for the same medicine without submitting orders for the same medicine at the same time in making orders by the Medical Supplies Division and the Division had lost the opportunity to reduce the unit price by procuring more units at the same time. (Annexure 142)

7.12.2.5 Even though the Medical Supplies Division had issued orders through the MSMIS system for the purchase of medicines through the State Pharmaceuticals Corporation under Order Code No. V of the Medical Supplies Division, Deputy General Manager (Import and Procurement) - Pharmaceuticals had confirmed to the audit in writing on 30 October 2023 that the said orders had not been received to the Corporation. Accordingly, action had not been taken to remove the non-executing orders from the "Swastha" data system.

7.12.2.6 Reviewing the report and recommendations of the Technical Evaluation Committee is a responsibility and a duty of the Procurement Committee in terms of Guideline 2.5.1 (f) of the Government Procurement Guidelines, and after the Procurement Committee has carefully examined the report of the Technical Evaluation Committee and has sought any required clarifications from the Technical Evaluation Committee in terms

of Guideline 8.8.1 of the Government Procurement Guidelines, action should be taken to award the contract in terms of Guideline 8.8.1 (a) of the Government Procurement Guidelines. Although the technical evaluation committee appointed by the Technical Division of the State Pharmaceuticals Corporation had evaluated the bids for the procurement, the reports containing the formally prepared recommendations had not been submitted to the procurement committee. However, the procurement committee had not taken steps to inquire about it from the technical evaluation committee. A sum of Rs.1.83 million had been paid as the allowance of the technical evaluation committee for carrying out technical evaluations from the year 2022 until 30 September 2023.

7.12.2.7 **Quantitative and important matters related to the process of preparation of estimates of medicines and ordering medicines and provision of the orders to the medical supplies division and the distribution of those medicines as observed during the audit test check carried out regarding the main orders submitted to the State Pharmaceuticals Corporation for 73 items of medicines for the years 2022, and 2023 have been included in Volume I. The Chief Accounting Officer of the Ministry had submitted incomplete answers to the audit even though the Draft report of the Auditor General had been issued to the Chief Accounting Officer on 29 December 2023 and he had been provided 01 ½ months to provide answers for the report and more than 02 months to answer the audit queries.**

7.13 **Examination of the quality of Medicines purchased in the years 2022 and 2023**

7.13.1 Matters such as the presence of broken glass pieces, visible particles, one dead cockroach and breakage of pills, colour change, non-compliance with British Pharmacopoeia specifications, death due to adverse reactions, microbial contamination etc. had been identified in certain medicines including antibiotics, medicines used for allergies, asthma, cancer, heart diseases, eye infection and kidney diseases, according to the circulars issued in 2019, 2020, 2021 and 2022 regarding the

medical supplies, which had failed the quality tests, and as a result, they had been withdrawn or withheld from the use.

(i) Medicines, surgical and laboratory materials worth Rs. 349.03 million, out of the medical supplies issued to government hospitals in the year 2022, had been withdrawn due to quality failures, and another set of medicines worth Rs.31.75 million had been withheld due to quality failures. Among them, the presence of visible particles, the presence of needle-shaped crystals on the surface of the tablet, broken tablets, change in colour, non-conformity with the British Pharmacopoeia specification, reporting of deaths of patients, etc. had been identified and they had been withdrawn and withheld from the use due to those reasons. It was further observed that there were medicines used for diabetes, cancer, infections, and kidney diseases and medicines used as pain killers, among the medical supplies that were withdrawn from use due to quality failures.

(ii) Even though this situation has been revealed by the audit for many years, efforts have not been made to mitigate this situation and medicines, surgical and laboratory materials worth Rs.2,482.12 million in relation to the year 2023 had been withdrawn from use due to quality failure, and another set of medical supplies worth Rs. 10.72 million had been withheld from the use due to quality failures. It was observed that medical supplies including medicines used for eye diseases, cancer diseases, medicines used for anesthesia and immunization had been withdrawn due to quality failures and problems such as adverse reactions to patients, death of patients, blindness etc. had occurred after using the medicines. Due to this, the expectation of preventing the supply of low-quality medicines to patients had not been fulfilled.

(iii) Four (04) Circulars had been issued in the year 2022 to discontinue only the defective items, out of the items in 04 categories related to 02 types of medicines, and only the defective medicine stocks worth Rs.2.05 million had

been withdrawn in accordance with those circulars. Since the Medical Supplies Division had not followed up the information on the balance stock quantities in the hospitals at the time the medical supplies had failed in quality, it was problematic during the audit whether the hospitals had correctly counted the defective stocks and sent them to the Medical Supplies Division.

7.13.2 It was observed for many years that majority of those medicines were reported to have been used by the patients at the time the medicines were reported to have failed in quality due to the inability of testing the quality at the National Medicines Quality Assurance Laboratory (NMQAL) operated under the National Medicines Regulatory Authority before releasing the medicines to the hospitals by the Medical Supplies Division. However, there had been no methodology of testing the quality of medicines before they were released to the hospitals even during the year 2023 to avoid such conditions in a quantitative manner.

(i) Since the facility to supply medicines is provided to the suppliers, who do not have the registration certificate of the National Medicine Regulatory Authority by issuing a Waiver of Registration - WOR letter for them without examining the qualifications of the supplier and the quality of the medicine at the time of procurement even though it had been informed to the audit that the medicines would be procured from the suppliers, who had obtained the GMP certificate, instead of testing the quality of medicines, it was observed that there is also a risk about the quality of the medicines.

(ii) Even though a small quantity of medicines were tested using the laboratory facility of the State Pharmaceuticals Corporation by the year 2023, if it is revealed that the medicines have failed the quality tests, the samples should be sent back to the National Medicines Quality Assurance Laboratory for testing them within the existing legal situation.

(iii) The Ministry of Health or the National Medicines Regulatory Authority had not taken action even during the year 2023 to use the pharmaceuticals laboratory, which had been constructed in the Industrial Technology Institute (ITI) at a cost of Rs.99 million as an independent accredited third-party laboratory for the development of the pharmaceutical sector in Sri Lanka and has been operated since 2019, for this purpose.

7.13.3 After the medical supplies procured by the Medical Supplies Division had failed the quality tests, money had not been properly recovered from the relevant suppliers and the amounts to be recovered in that manner had not been accounted. Instead of that, arrangements were made to deduct the value to be recovered only if there had been debit note values to be paid to those suppliers, and to collect from certain suppliers in installments from the bills to be paid to them in the future. Accordingly, Rs.1663 million comprised of Rs.1,046.77 million from the State Pharmaceuticals Corporation of Sri Lanka, Rs. 160.59 million from the State Pharmaceuticals Manufacturing Corporation of Sri Lanka, Rs. 84.87 million from local suppliers and Rs. 370.76 million from local manufacturers had not been recovered by the Medical Supplies Division for the medical supplies, which had failed quality tests, until 31 December 2023. Furthermore, the State Pharmaceuticals Corporation has not yet recovered a sum of Rs.1,406.48 million that should be recovered from the suppliers, and legal action would be taken for a sum of Rs.685.68 million, out of that, and taking action in relation to another Rs.165.80 million had been suspended as per the instructions of the Secretary of Health.

7.13.4 The reporting of quality failures after the release of medicines to hospitals and issuance of medicines to patients or using of medicines by patients for 100% in instances, where circulars had been issued on the medicines, which had failed the quality tests, and on the spontaneous expiration of items, before issuing orders for withdrawal or revoking medicines after conducting further tests for items, which were ordered to withhold and losing the possibility of recovering the related losses from the suppliers for expired items due to the delay in testing had been continuously revealed through the audit

reports. Nevertheless, a methodology had not been implemented to test the quality before the medical supplies were released to the hospitals to avoid such instances.

7.14 Test (SR- 01502003) on the quality failure of the medicine, Bupivacaine 0.5% + Glucose 8% used for anesthesia inj.4 ml Amp.

7.14.1 A stock of 68,750 injections of the medicine called Bupivacaine 0.5% + Glucose 8% inj.4 ml Amp used for anesthesia in surgeries had been purchased under emergency procurement on stock shortage by order No2022/MSD/V/R/P/00076 (ICL/EOI/P1/134/2022) of the Medical Supplies Division from Slim Pharmaceuticals (pvt) Ltd. at a value of R.40,738,819. This order had been issued to a company that is not a registered supplier of the National Medicines Regulatory Authority under Calling for Expression of Interest (EOI) as mentioned in the paragraph 6.6.5 above subject to obtaining a waiver of registration certificate and the stock had been received to the Medical Supplies Division on 13 February 2023.

7.14.2 A Medical Specialist of Peradeniya Teaching Hospital had complained to the Director of Hospitals on 04 April 2023 and to the National Medicines Quality Assurance Research Laboratory (NMQAL) on 06 April informing that one pregnant woman had died after using this medicine, which had been issued to national hospitals, teaching hospitals, basic hospitals and other health institutions from the date of receipt of these medicine injections consisting of 03 batch numbers to the medical supplies division and another woman had underwent Neurological Adverse Reaction. In the examination of the relevant complaints, the use of the medicine had been suspended by the Director of Medical Supplies with immediate effect in view of the serious adverse reactions caused by using the medicine.

7.14.3 According to the minutes of the meeting dated 10 April 2023 of the Safety & Risk Evaluation Sub-committee (SAFRSC) of the National Medicines Regulatory Authority, 34,705 units or 50 percent of the total stock of injections had been issued to the patients, at the time the stock of 68,750 vaccines had been identified as failed in quality tests.

Subsequently, the same product had been completely withdrawn from use by the Director of Medical Supplies on 27 July 2023. It was observed that the Medical Supplies Division had not taken adequate measures to test the quality of the medicines from the National Medicines Quality Assurance Laboratory (NMQAL) before these medicines had been released to the hospitals.

7.14.4 The National Medicines Regulatory Authority had charged a sum of USD 200 or Rs.85,496 from the company mentioned in paragraph 7.14.1 above and had issued a waiver of registration certificate on 30 December 2022 under the special pathway through the fast track mechanism without evaluating the medicine by the National Medicines Regulatory Authority as mentioned in paragraph 7.11.7 above. Accordingly, the National Medicines Regulatory Authority had charged an amount as indicated above from the supplier and issued a waiver of registration certificate and thereby had functioned by deviating from the main objective through entrusting with its responsibility to another party as indicated in paragraph 7.11.6.1 above.

7.14.5 The audit inquired as mentioned in paragraph 7.5.7 .above whether the Director of Medical Supplies takes the responsibility in relation to the quality failure of this medicine and the damage caused to the relevant patients by the use of the medicine. It was stated that it had been impossible for the Director of Medical Supplies to take the responsibility in relation to the quality of the medicines and that condition had been included without his consent.

Furthermore, the evaluation committee referred to in paragraph 7.3.6 .above had evaluated without seeking instructions of the medical specialists, in the evaluation of suppliers after calling for expression of interest, and had provided the opportunity to supply these medicines to unregistered suppliers.

Accordingly, it was observed to the audit that these institutions have failed to take responsibility/perform the duty properly in relation to this medicine, identified as failed in quality tests as per the circulars mentioned in paragraph 7.14.2 above, issued by the Medical Supplies Division.

7.15 Examination on the quality failure of the medicine called Prednisolone Acetate Eye Drop 1%, 5ml dropper Bot used for eye diseases. (SR- 00901001)

7.15.1 A stock of 500,000 vials of the medicine, Prednisolone Acetate Eye Drop, which is used after cataract surgery for eye patients, had been ordered by the order No. 2021/SPC/N/R/P/00043 of the medical supplies division and a stock of 50,000 vials worth Rs.3,631,093, out of that, had been received to the Medical Supplies Division on 03 March 2023. The stock of 50,000 units of this medicine consisted of 02 batches had been issued to 58 hospitals including Sri Lanka National Eye Hospital, Lady Ridgeway Children's Hospital and Kandy National Hospital and health institutions since 09 March 2023.

7.15.2 In this regard, the Directors of the National Eye Hospital and the Nuwara Eliya District General Hospital had lodged complaints in relation to this medicine to the National Medicines Quality Assurance Laboratory (NMQAL) on 18 April 2023 by reporting that the relevant patients got endophthalmitis after using this medicine. After investigating the complaints lodged, this medicine had been reported as failed in quality and this situation had been stated as "Sample does not conform to specifications for the sterility test" owing to the serious adverse reactions occurred to the patients and the Director of Medical Supplies Division had withdrawn this medicine from the use on 25 April 2023, after 46 days of the distribution of the medicine. However, The Deputy Director General of Medical Supplies had informed the audit by the letter No. MSD/Fin/MSB/75/2023on 29 April 2024 that 21,510 units or 43 percent of the total stock already received of this medicine had been issued to patients at the time of withdrawing this medicine. Moreover, it had also been stated that two patients of the National Eye Hospital had become completely blind due to the use of this medicine and 16 patients in the Nuwara Eliya District General Hospital had undergone allergies.

7.15.3 Adequate measures had not been taken by the Medical Supplies division or/and the National Medicines Quality Assurance Laboratory to test the quality of the medicines before issuing them to the hospitals.

7.16 Purchasing of the falsified medicine of Human Immunoglobulin IV 5-6g (SR-00603205) and Rituximab inj. Buying fake medicine 500mg in 50ml vial(SR-01205702) due to the deviation from standard procurement guidelines and the informality in the emergency procurement process

The aforementioned two medicines called Human Immunoglobulin IV 5-6g (SR-00603205) and Rituximab inj. 500mg in 50ml vial (SR-01205702) were further tested and the matters identified in that regard are given from 7.16.1 to 7.16.13 below.

7.16.1 Human Immunoglobulin IV 5-6g (SR-00603205)

7.16.1.1 Bids had been obtained from the suppliers through calling for expression of interest basis to purchase this medicine under the emergency purchases conducted as mentioned in No. 6.6.5 above as a remedy for the stock shortage in the country in the year 2022. Accordingly, the procurement had been awarded to the selected bidder, Isolez Biotech Pharma AG Ltd. by the Secretary of Health on 04 January 2023 to supply 22,500 injections at a cost of USD 2,925,000 at the rate of USD 130 per one injection. Thereafter, purchase order of the above value bearing No. 2022/MSD/V/R/P/00038 (ICL/EOI/P1/174/2022) had been issued to the supplier on 13 January 2023.

7.16.1.2 The supplier had supplied 3,985 vials worth Rs. 168.86 million, out of 22,500 injection vials, to the Medical Supplies Division during the period from May to September 2023, and the Division had paid an amount of Rs. 36.38 million to the suppliers. All the injection vials received by the Medical Supplies Division had been issued to national hospitals, teaching hospitals, provincial hospitals and regional medical supplies Divisions from 30 May 2023. It was reported to the National Medicines Regulatory Authority in September 2023 that patients in Colombo, Kandy National Hospitals and Matale and Matara District General Hospitals had serious adverse reactions after using the medicine by patients.

7.16.1.3 The Authority had discovered that patients had undergone serious adverse reactions after using this medicine and certificate of registration with the Authority or waiver of registration certificate (WOR) had not been issued for this medicine. Thereafter, as a safety measure, the use of the entire stock supplied by this supplier had been withheld with immediate effect by the Director of Medical Supplies on 03 October 2023 by declaring that the medicine had failed the quality tests. The entire stock of this medicine had been withdrawn with immediate effect in accordance with the Circular No. MSD/QP/2023/56 dated 09 October 2023 as the medicine was a falsified medicine and there had been serious adverse reactions. Thereafter, all the products supplied by this supplier had been withdrawn by the Circular No. MSD/Q/Special/2023/4 dated 18 October 2023.

7.16.1.4 When calling for expression of interest for this medicine under the emergency purchases by September 2022 as indicated in paragraph 7.16.1.1 above, the procurement activities of the general annual order submitted for the year 2022 for this medicine had been delayed for 19 months and action had not been taken to obtain the emergency purchase order presented for the year 2021. Moreover, expression of interest had been called for purchasing 22,500 injections, which had been the requirement for 03 months, as mentioned in 7.16.1.1 above, regardless of the 47,202 injections sufficient for 06 months that were scheduled to be received in relation to the general annual order submitted for the year 2021.

7.16.1.5 Since the procurement of this medicine had also been carried out on the basis of calling for expression of interest under emergency purchases as mentioned in paragraph No.6.6.3 above, it was observed even in the purchase of this medicine as indicated in observation No. 7.3 above that a monthly report under the procurement process had not been submitted by the Minister of Health for the covering approval of the Cabinet of Ministers and the internal auditor had not ensured a fair and effective process at the end of the procurement process. Furthermore, the audit could not confirm that an opportunity that could have been used optimally for another priority had not been missed by deciding to notify the order amount regardless of the stock to

be received. Moreover, it was observed that medicines had been purchased through the process of calling for expression of interest, and even though the Health Sector Emergency Purchase Committee should have sought the instructions of the technical experts, the Committee had not functioned so, and appropriate restrictive conditions were not included in the tender documents to minimize the submission of procurements under waiver of registration.

7.16.1.6 This supplier had stated in the price list of the relevant bid documents that this medicine had been of Indian origin and the manufacturer had been Livealth Bio Pharma Pvt Ltd in India, and the entire stock could be imported and supplied between 01 and 05 working days, and the supplier had stated in the same document that the raw materials had been from Livealth Bio Pharma Pvt Ltd of India and the product formulated and the contract manufacturing and market had been Isolez Biotech Pharma AG Ltd. However, attention of the evaluation committee had not been focused on this.

7.16.1.7 It had been revealed during the inspection conducted by the National Medicines Regulatory Authority in this regard that this is a falsified medicine and it had also been revealed from the confirmation made through the electronic mail by Livealth Bio Pharma, the Indian manufacturing company on 04 October 2023 that the company mentioned in the package of medicine had not manufactured or supplied this medicine. Accordingly, Isolez Biotech Pharma AG Ltd had falsely stated that it functioned as the local agent of this medicine and fraudulently used the name of the Indian company named, Livealth Bio Pharma as the manufacturer of the medicine in the relevant package of the medicine and documents including the waiver of registration certificate, and thereby attempted to prove that it was an imported medicine.

7.16.1.8 Even though the supplier had submitted a Certificate of Analysis (COA) of the medicine by stating that it had been from the quality control department of the Livehealth company, which had been stated as the manufacturer of the relevant medicine stock along with the bidding documents, the certificate of analysis had also

been confirmed as a fake certificate according to the written confirmation made by the manufacturer in India to the National Medicines Regulatory Authority.

7.16.1.9 According to a laboratory report submitted by the Medical Research Institute to the Secretary of Health on 14 November 2023, the level of IgG (Immunoglobulin) contained in the medicine was below the detection level of 5,000mg/dL, and as a result, there is a risk of infection in the patients concerned. had given Moreover, it was revealed to the audit that three samples obtained from the Colombo National Hospital had not complied with the relevant specifications during the sterility test, and that one of the three samples had not complied with the relevant specifications during the bacterial endotoxins test according to the 03 quality certificates issued by the National Medicines Quality Assurance Laboratory on 23 November 2023.

7.16.1.10 Sri Lanka Customs had informed the Chief Executive Officer of the Medicines Regulatory Authority on 17 October 2023 that such a medicine had not been imported from 01 January 2023 by the supplier and since the medicine of this supplier had not been included in the list submitted by the Controller General of Imports and Exports on 08 November 2023 on the medicines imported on waiver of Registration certificates from the year 2022 to the year 2023, it was observed that the supplier had falsely stated that the medicine would be imported and supplied in the bid documents.

7.16.1.11 As per paragraph 7.3.7 above, it was observed that the expression of interest evaluation committee had not acted independently and with maximum attention as the evaluation committee had focused only on the price and supply schedule and had not paid attention to the matters such as not submitting the other documents required to obtain the WOR. Accordingly, it was observed during the audit that the evaluation committee had not checked further regarding the contradictory facts mentioned in the bidding documents as per paragraph 7.16.1.6 above. Moreover, the Health Sector Emergency Procurement Committee had not paid attention to verifying the quality of medicines. Thereby, it was observed during the audit that the procurement committee and the

procurement entity had not functioned with maximum attention in the evaluation process.

7.16.1.12 Since it had not confirmed to the audit that this supplier company had supplied the items of medicine at any time although the company had supplied items related to chemicals to the Medical Supplies Division for many years, and since this supplier had not obtained the registration with the National Medicines Regulatory Authority, the evaluation committee had made this recommendation without ascertaining the capability of importing such medicines used for neuro patients and whether the supplier had been an authorized local agent of the relevant Indian manufacturer.

7.16.1.13 Even though the EOI Evaluation Committee had recommended to award the procurement to the relevant company with the WOR certificate as mentioned above, Secretary of Health had informed that in the event of the item is awarded to unregistered bidder, the WOR issued by NMRA should be submitted at the time of delivering the item, if not payment will not be released for the delivered item under Condition No. 07 of the letter sent through File No. PSRP/08/EOI/ACC/2022 of the Pharmaceuticals production, Supply and Regulation Division on 04 January 2023 by awarding this procurement. In the meantime, the Medical Supplies Division had issued this purchase order worth USD 2,925,000 to the supplier on 13 January 2023 without paying attention to the possibility of obtaining the WOR certificate.

7.16.1.14 The number of National Medicines Regulatory Authority had been stated as NMRA/ FA/WOR/MED/ICL/1/MSD096/23 in the WOR certificate that had been provided by the supplier at the time of delivering this stock to the Medical Supplies Division. It was observed that this number was different when compared with other WOR certificate numbers issued by the National Medicines Regulatory Authority during this period. Moreover, according to No. 88.5.1 of the report of the Board of Directors of the National Medicine Regulatory Authority dated 20 January 2023, approval had been granted to extend the validity period from 12 weeks to 06 months in all the WOR certificates, on which the medicines were imported through the Indian Credit Line

Facility to the State Pharmaceuticals Corporation and which are to be issued in the future, Accordingly, the Authority had revised that condition in the WOR certificates issued from February 2023. Although the WOR certificate in question had been issued on 17 February 2023, this condition had not been revised.

7.16.1.15 It was observed to audit that it would have been possible to identify that waiver of registration certificates had not been issued for this medicine at the time of receiving the goods, and thereby, it would have been possible to take necessary measures regarding this supplier at that time if the Medicines Regulatory Authority had made arrangements to send the copy of the Medical Supplies Division to the Division at the same time of issuing the waiver of registration certificates at the time of receiving the goods as indicated in paragraph 7.11.6.4 above, or if arrangements had been made to inquire about that and to get the relevant copies of certificates delivered to the Medical Supplies Division, Furthermore, it was observed to audit that if it was happened in that manner, it would have been possible for the patients to avoid the risky situations that had to be confronted after using this medicine.

7.16.1.16 Accordingly, although clearance is done through the Wharf Section of the Corporation and the stock is given to the Medical Supply Division in the orders procured by the Medical Supplies Division through the State Pharmaceuticals Corporation, the State Pharmaceuticals Corporation or the Medical Supplies Division do not take part in this clearance activities in these emergency purchases. Therefore, there was no methodology of checking the relevant bill of lading, customs declarations or packing list to verify that the supplier had actually imported the drugs. Accordingly, due to the weakness of this internal control, this medicine had the opportunity of entering in to the medicines supply network as a falsified medicine.

7.16.1.17 It was observed according to the minutes of the board meeting No. 84.6.1 of the National Medicines Regulatory Authority held on 16 September 2022, that discussions had been held on lodging complaints to the Criminal Investigation Department on the use of fake seals and signatures on the registration certificates and import licenses

during consignment clearance, and the possibility of applying QR codes by considering the protection of the documents and the implementation of a fool proof mechanism. It was also observed in the audit that if prompt measures had been taken in that regard, it would have been possible to prevent the submission of a WOR certificate fraudulently.

7.16.1.18 Even though the supplier concerned had made 02 requests by addressing the Deputy Director General of Medical Supplies Division and the Accountant supplies on 16 January and 28 February 2023 respectively to obtain a WOR certificate for this medicine, the Medical Supplies Division had not attended to this request as the issuance of these WOR certificates had not been a role of the Medical Supplies division. However, the supplier had submitted a WOR certificate issued dated 17 February 2023 by the National Medicines Regulatory Authority at the time of delivering the first stock of medicines to the Medical Supplies Division on 27 May 2023. It has been observed that if this WOR certificate had been issued legally and duly, there had been no need of submitting the second request by the supplier.

7.16.1.19 At the time of delivering this falsified medicine to the Medical Supplies Division, two persons had been working as its directors, and one of the directors, Hewage Sudath Janaka Fernando had submitted a letter to the Director of National Blood Transfusion Service on 27 February 2023, after the date of the fake WOR certificate with the recommendation of the Secretary of Health by making a request to purchase 1,000 litres of human blood plasma for research and development of undiscovered roles in physiological functions of human plasma and isolation of new plasma proteins from pooled plasma by fractionation process conducted by Isolez Biotech Pharma with overseas collaboration. The Director of the National Blood Transfusion Service had also appointed a committee of 5 members on 28 February 2023 to examine this situation. After that, requests were made in that regard again to the Director of Blood Transfusion Service on 16 March 2023 and on April 26 with the recommendation of the Health Secretary.

7.16.1.20 It had been stated in a report dated 03 May 2023 submitted by the Committee appointed in this regard as indicated in paragraph 7.16.1.18 above that excess human plasma had been exported by a selected bidder according to a Cabinet decision taken in the year 2015, and that a large stock of plasma could not be released for this purpose, and considering the national importance stated in the proposal, it was recommended to provide 40 litres of plasma packets per week for 09 months charging USD 44.60 per litre of plasma.

7.16.1.21 Arrangements had been made to provide plasma to an external party without confirming that plasma had not been infected by laboratory tests and that it is a formally approved research or that the research has been carried out in accordance with the Ethical Review, and recommending by the committee appointed by the Blood Transfusion Service to release blood plasma without confirming that these research activities are conducted in accordance with the Ethical Review. Furthermore, this committee had suggested to check the terrain related to the research, but the blood plasma had been issued without doing such an examination.

7.16.1.22 Since blood plasma is used for the production of this drug as per the information obtained from the internet, and the supplier had procured 21.73 litres of blood plasma and 06 blood packets during the period from the date of placing the above order to the supplier up to the date of 26 May 2023, the date of delivering the first stock of the medicine to the Medical Supplies Division, and subsequent to that date, the supplier had obtained 149.15 litres of plasma, it was problematic to the audit whether the above medicine had been manufactured in the supplier's factory including them. Accordingly, it was observed during the audit that if the supplier had manufactured this medicine at his manufacturing premises, he would have engaged in an illegal activity by violating subsection 113 (1) of the National Medicines Regulatory Authority Act.

7.16.1.23 In case such plasma and blood had been used, it is observed that the supplier had acted by deviating from Section 49 (1) and (2) of the Part III of the National Medicines

Regulatory Act as it has stated therein that no person shall import or sell any medicine that is manufactured under insanitary conditions, consists in whole or in part any foreign matter and is adulterated and no person shall manufacture any medicine without adhering to Good Manufacturing Practices (GMP).

7.16.1.24 Accordingly, it was observed that 170.88 litres of blood plasma had been issued to the concerned supplier by charging a sum of Rs. 2,460,174 by 20 November 2023. Six (06) packets of blood had been issued in addition to human plasma without obtaining a formal approval to the aforementioned supplier company, which had not engaged in the activity of treating patients, in another day subsequent to making the first request by the supplier, i.e. on 10 March 2023 by charging a sum of Rs.12,000.

7.16.1.25 This Company had stated as "Developer, Manufacturer & Supplier of Sterile Pharmaceuticals & Research Chemicals" in the letterheads of the supplier. However, it was confirmed from the information obtained from Sri Lanka Customs by the National Medicines Regulatory Authority on 17 October 2023 that this Company had imported items related to the milk production such as Vacuum Mixer for Milk Manufacturing 200L, Milk Packing Machine, Milk Storage Unit, Milk Storage Tank, Milk Sterilization Tank 200 L, Milk Making Machinery, Centrifuge for food juice industry (Machine for food juice) from the year 2017 to the year 2021. The National Medicine Regulatory Authority observed during the GMP inspection conducted on 28 April 2023 that the equipment in the company premises had not been suitable to manufacture mediicnes.. Therefore, the suspicion that the supplier had used the milk production machines imported as mentioned above to manufacture this medicine cannot be ruled out in the audit under this situation and as per the matters revealed in the audit examination.

7.16.1.26 It was also observed during the audit that a company named Ospelts Life Science Production GMBH had been established at the same residential address of Hewage Sudath Janaka Fernando according to the business registration certificates submitted to the Sri Lanka Customs, and equipment related to milk production had been among the

items imported through that company, and these companies had interlinked to each other.

7.16.1.27 A GMP inspection had been conducted by The National Medicines Regulatory Authority in the workplace of the supplier in 05 instances from the year 2013 to 2022, and the supplier had not given the requested approval to manufacture medicines on various reasons. Moreover, a GMP inspection had been conducted by the Authority in this workplace also on the days of 20 and 22 February 2023, and it had been informed to the supplier on 28 April 2023 that this workplace could not be accepted as carrying out manufacturing activities according to good manufacturing practices and that it could not be allowed to produce injections (Sterile injections). In spite of that, the supplier company had fraudulently stated in their letter heads and documents that they manufacture generic injectable finished pharmaceuticals formulations for human use with WHO/FDA/CANADIAN GMP and further manufacture Antibiotics, Antibodies, Bio chemicals enzymes, Hormones, Biotechs and it had been a GMP Sterile Pharmaceutical Production Plant, and also manufacture cancer medicines such as Carfilzomib, Ponatinib, Trastuzumab and Rituximab used for cancer patients.

7.16.1.28 Notwithstanding the circumstances, former Secretary of Health had recommended and informed by a letter No. SH/Misc/03/Medi.Equip dated 05 June 2023 to the Chief Executive Officer of the National Medicines Regulatory Authority to issue a GMP license to carry out trials on medicines such as Salbutamol, Lidocaine and Tramadol at the initial stage and to provide manufacturing approval to Isolez Biotech Pharma AG Limited under any conditions considering the situation as a national requirement.

7.16.2 Rituximab inj.500mg

7.16.2.1 The State Pharmaceuticals Corporation had placed the major order of procuring 11,600 units of the Medicine, Rituximab inj. 500mg, which had been submitted to the State Pharmaceuticals Corporation in the year 2022 by the Medical Supplies Division, to the supplier at US$59.95 per unit. The first stock of 3,500 units related to this order was

received by the Medical Supplies Division on 14 October 2022 and the stock was sufficient for 04 months. The second stock of 5,076 units of this order was received 02 months after receiving the first stock i.e. on 15 December 2022, and the third stock was received almost three months after receiving the first batch i.e. on 09 January 2023. With the receipt of the stock, the medicine was sufficient for the first 10 months of the year 2023. Accordingly, action had been taken to procure 2,250 vials of this medicine under emergency purchases from Pharma Isolez Biotech AG Ltd., which had supplied the medicine of Human Immunoglobulin IV 5-6g mentioned in 7.16.1 above, at a high price of USD 152 per injection on 10 November 2022, due to taking action on instructions not to consider stocks to be received given by the Additional Secretary of the Pharmaceutical Products, Supply and Regulatory Division and without making sufficient efforts to confirm the receipt of the stock as stated in paragraph 6.6.3 above. Even though this stock was supposed to be received within 07 days under emergency purchase, it had not been supplied until the lapse of 05 months. Accordingly, it was observed in the audit that there had been no need to procure this medicine under emergency purchases at a price, 254 percent higher than the normal order price and the loss incurred to the government due to this uneconomical transaction had been approximately Rs.65,350,342 (92.05*2200*322.7), and it was also observed during the audit that the importation of a medicine, of which the quality, safety and efficacy had not been confirmed, had been supported.

.

7.16.2.2 The supplier had fraudulently submitted documents including the name of the manufacturer in India including a WOR certificate also in supplying the stock of Rituximab vaccine and even though the supplier had indicated that this medicine had also been of Indian origin and the manufacturer had been Livealth Bio Pharma of India, and 100 percent of the medicine could be imported and supplied between 01 and 05 working days in calling for expression of interest for emergency purchase as mentioned under No. 7.16.1.6 above, it was observed in the audit that the EOI evaluation committee had not paid attention to the indication of the supplier in the lower part of the bid document that the raw materials had been from Livealth Bio Pharma Pvt Ltd of India and the Product formulated and contract manufacturing &

market had been from Isolez Biotech Pharma AG Ltd. It was further observed during the audit that no technical expert or medical specialist had been appointed to the evaluation committee and only the prices and stock delivery schedules had only been observed as per the instructions of the additional secretary, who had been in charge of the process of calling for expression of interest.

7.16.2.3 The matters mentioned in observations No. from 7.16.1.5 to 7.16.1.8 and from 7.16.1.10 to 7.16.1.15 mentioned above in relation to the purchase of Human Immunoglobulin were also observed under this medicine.

7.16.3 Similarly, it was observed during the audit that it had been indicated in the bid documents related to the medicine called Irinotecan hydrochloride trihydrate, that it had been a product of the Indian manufacturer and the medicine analysis certificates mentioned in the name of that manufacturer had been submitted falsely as indicated in No. 7.16.1.6 mentioned earlier. Even though an order had been placed for the anti-cancer medicine called Irinotecan hydrochloride trihydrate through these informal procedures, it was observed that the supplier had not provided the stocks related to that and the EOI evaluation committee had recommended to purchase 03 other medicines used for cancer, eye diseases and hemophilia patients under waiver of registration. Even though the supplier company had stated that these medicines had been of Indian origin as mentioned above, and the manufacturer had been Livealth Bio pharmaceuticals in India, and that they could import and supply 100 percent between 01 to 05 working days in calling for expression of interest under emergency purchases pertaining to these 03 items, it was observed by the audit that it had been mentioned at the lower part of the bidding document that the raw materials had been from Livealth Bio Pharma Pvt Ltd of India and the product formulated and the contract manufacturing and market had been from Isolez Biotech Pharma AG Ltd, but the EOI evaluation committee had not focussed their attention in that regard.

7.16.4 Even though orders have not yet been issued for these 03 items, it was observed during the audit that the Certificate of Analysis (COA) of the medicine indicating the name

of the manufacturer in India as the manufacturer had also been submitted along with the bid documents submitted by the company in relation to the 02 items, Docetaxel and Fluorescein sodium, during the examination conducted by the audit in accordance with a notification made by the National Medicines Regulatory Authority, the manufacturing company in India had confirmed that they had never supplied medicines to Sri Lanka, and they had no idea of Isolez Biotech Pharma or any of its promoters, and they had no dealings with such a person and the Company had further informed to cancel the registration of all the products, for which the name of the Company had been used fraudulently.

7.16.5 Accordingly, it was observed during the audit that it is more appropriate to proceed through a judicial process in this regard as criminal matters are observed regarding the supplier as to whether the 02 WOR Certificates submitted by the supplier to the Medical Supplies Division on two occasions were forged by the supplier or fraudulently supplied by the National Medicines Regulatory Authority, and about manufacturing and selling locally by stating that the medicine had been imported and supplied in the bidding documents and for falsely using the name of the manufacturer in India and submitting 05 falsified certificates of analysis in the name of the manufacturer in India along with the bidding documents.

7.16.6 In terms of Sections 124 and 125 of the National Medicines Regulatory Authority Act, any Provincial Director of Health Services, any Regional Director of Health Services, any Medical Officer of Health, any Divisional Pharmacist, any Food and Medicines Inspector can be appointed for the purposes of this Act, and an Authorized Officer, for the performance of his duties and the exercise of his powers under the Act may enter to any place and examine any such article. However, it was observed during the audit that after the manufacturing company of the above supplier had failed in the GMP quality test, there had been a risk of illegal medicine production and a follow-up mechanism had not been launched. It was observed that such loopholes had been created by enabling such misconducting companies to manufacture fake medicines as the medicine inspectors of the emergency raids division of the Authority had not been

informed to continuously inspect and follow up such manufactories, and the authorized officers had not implemented such a mechanism in cooperation with the provincial or regional authorized officers.

7.16.7 It was observed according to the information submitted to the audit that 1,732 Human Immunoglobulin vials had been remaining in hospitals and 2,253 vials (57 per cent) had been issued to patients, out of the stock of 3,985 vials of Human Immunoglobulin that had been issued to hospitals by 13 November 2023. It was observed according to the information received from 28 hospitals that this medicine had been given to 87 patients and 09 patients had Anaphylaxis Reaction and Adverse Drug Reaction - ADR. Moreover, it was observed that 104 vials of Rituximab injections had been issued to the patients and only a few hospitals has already provided information about that and according to that information, adverse reactions had not been reported from the patients.

7.16.8 Even though medical specialists are expressing opinions that patients would have to infect HIV/AIDS, Hepatitis B and Hepatitis C infections in case Human Immunoglobulin, which is a medicine produced using blood plasma, had not been produced under standard quality controls, action had not been taken to refer all the relevant patients to a special clinic and to continuously follow up the clinical status of those patients through a screening process.

7.16.9 It was observed that the information had not been revised in the PRONTO computer system used for the management of medicines in the Medical Supplies Division even though this Company, which had been an old supplier of medical supplies to the Medical Supplies Division since 2015, had been converted into a company since 02 October 2017, it had been entered in to the PRONTO system in the name of Isolez Biotech Pharma AG. Even though the supplier company had clearly informed to make payments to Isolez Biotech Pharma AG Ltd in the bidding documents in these emergency purchase orders, all payments related to this company had been made to an account named Isolez Biotech Pharma AG due to negligence. In terms of Financial

Regulations 257 and 260, it is the duty of every officer passing a voucher for payment or making payment thereon, to see that a voucher accepted for payment has been duly certified by an officer who has been authorized to do so and even though all precautions should be taken against payments to wrong parties, action had not been taken accordingly and it was observed that the internal control process had also been in a very poor condition.

7.16.10 It was observed in the audit that the Secretary of Health had made an unusual intervention due to the handling in making payments to the supplier company, by the Secretary of Health in giving instructions to give priority to the supplier for payment on three occasions, giving recommendations when the supplier receives blood plasma, when GMP is rejected and when making requests for payment in favour of the supplier.

7.16.11 The Chief Accounting Officer shall ensure that the financial planning, financial management and financial control of an audited entity are effective in terms of subsections 38(1) (b) and (c) of Part VII of the National Audit Act No. 19 of 2018. It should also ensure that an effective internal control system is developed and maintained. Also, it was observed in the audit that the above problems have arisen due to the fact that actions are taken excluding them though the previous review of the effectiveness of the system should have been done and the necessary changes should have been made to run the system effectively.

7.16.12 Even though the management was informed by the audit since more than a period of 06 years to implement a mechanism of checking the quality of the medicine before the distribution of the medicines to the hospitals, the adequate steps were not taken to date for that, consequently, it had not been possible to minimize the issuance of quality failed medicines to the patients.

7.17 The facts observed in the year 2022 by the company called PharmAce regarding the fraudulent supply of Trastuzumab 440mg and before that Ipratropium Pressurized

Inhalation, Cefotaxime injection USP 1g, Ceftriaxone Sodium for Injection BP 500mg and Furosemide Injection BP 20 mg/2 ml to the Medical Supplies Division

7.17.1 To buy 500 units of Trastuzumab 440mg vaccine, the Ministry Emergency Procurement Committee had invited open prices on 15 July 2022, and the Ministry Emergency Procurement Committee, which met on 16 August 2022, had granted the order for the purchase of 500 vaccines for Rs.26, 225,000 to the institution which had submitted the lowest price for this. The following observations are made in this regard.

7.17.1.1 The certificate of National Medicines Regulatory Authority registration submitted by the selected bidder with the bid was not a certificate issued on behalf of that company and the said registration certificate was a registration certificate issued by the National Drug Regulatory Authority to another company. This certificate also expired about 29 months ago on 17 February 2020. Although the Technical Evaluation Committee had recommended awarding the order to this institution only subject to submission of a valid registration certificate issued by the National Medicines Regulatory Authority on 29 July 2022, regardless of that, the Ministry Emergency Procurement Committee had selected the relevant bidder to award this procurement without obtaining such a valid registration certificate from the National Medicines Regulatory Authority on 16 August 2022.

7.17.1.2 Through the letter dated 24 April 2021 addressed to the Chairman of the State Pharmaceuticals Corporation by the Secretary of the State Ministry of Pharmaceuticals Production, Supply and Regulation, it was informed to stop temporarily all purchases made from these companies and their subsidiaries until further notice. Nevertheless, in relation to this procurement, the Russian manufacturing company of this medicine had informed to the Chairman of the Health Division Emergency Procurement Committee on 20 July 2022, that it has appointed a private company as the Sri Lankan official representative of its company and has delegated the authority to another local company to participate in sales and tenders on behalf of its company. The company appointed by the manufacturer as its Sri Lankan representative was the new registered name of a company whose registrations had previously been temporarily banned by the National

Medicines Regulatory Authority. But in this procurement, the decisions of the procurement committee had been given without considering the facts.

7.17.1.3 Although the life time of the product was to be 02 years as per the tender conditions, the life time of the stock offered by this bidder was 07 months and thus the medicine was left for use only for 7 months from the date of award of the order. Accordingly, the procurement entity had not taken steps to confirm that the disputed local agency had not submitted the remaining stock which was previously brought to Sri Lanka, to the medical supply department.

7.17.1.4 The procurement committee decision for purchase was given on 16 August 2022 and accordingly the State Pharmaceuticals Corporation issued the purchase order on 25 August 2022. But before this purchase order was issued i.e. on 17 August 2022, the relevant stock of medicines had been handed over to the Medical Supplies Division.

7.17.1.5 Although the Committee on Public Enterprises (COPE) had ordered the Secretary of Health on 07 July 2017 to provide all the files prepared to be submitted to the Criminal Investigation Department and to report the progress to the Committee regarding the case regarding that the Chief Executive Officer of the National Medicines Regulatory Authority issued a registration certificate before receiving the recommendation of the Medicines Evaluation Committee to grant the registration certificate from the National Medicines Regulatory Authority in the year 2016 when purchasing this drug for the medical supplies Division and the provision of false information to the court that this medicine has been approved by the Authority for a related case, 05 years have passed but there was no follow up on it.

7.17.2 According to the purchase order presented on 01 April 2016 by the Medical Supplies Division at the estimated cost of Rs.58,988,800, 130,000 units of Ipratropium Pressurized Inhalation BP 20 Mcg/Puff medicine had been purchased for a cost of Rs.91,702,000 and the following observations are made in that regard.

7.17.2.1 In connection with this procurement, tenders were invited on three occasions and in the first instance, while the indent was issued to the supplier and the letters of credit were opened, according to the notice of the Director of Medical Supplies Division and

according to the purchase appeal, the first stock which was stated to be supplied on 03 January 2017 was for 09 months and the second stock, which was to be supplied on 02 May was notified to be supplied 13 months late. But the supplier had informed on 20 January 2017 that the relevant supply cannot be delayed. It was informed on 03 April 2017 that the supplier could not supply the medicines due to a technical error in the production process after the date the supplier agreed to supply them. According to the conditions of supply of medicine presented by the Medical Supplies Division, this procurement is an urgent matter and it was informed that the procurement should be done as soon as possible by inviting limited bids and it was observed on informing that this medicine should be provided with a delay of 09 months that this supply is not a factual order on the emergency basis.

7.17.2.2 In relation to this procurement, at the time of the third bid calling, although the National Medicines Regulatory Authority's registration certificate of the supplier who had submitted the bid, had expired, the procurement committee in September 2017, subject to the conditions of retrieving the registration certificate and obtaining the registration certificate under the General Contract Agreement Act No. 03 of 1987 on 29 September, 2017 had awarded order of 130,000 units at the rate of Rs.705.40 per unit amounting to Rs.91,702,000 but according to the invoices submitted to the Sri Lanka Customs, the supplier had imported 130,000 units at Rs.14.13 per unit at expense of Rs.1,836,900 into Sri Lanka by a company not registered with the National Medicines Regulatory Authority and supplied to the medical supplies Division at a higher price of 4892 percent. The supplier had imported the manufactured medicines by a manufacturing company not mentioned in the tender documents. Also, it was observed that the prescribed rules and procedures had not been followed in releasing the drugs from the customs of an unregistered company.

7.17.2.3 Although the purchase order on 20 October 2017 was issued to the supplier, the approval of the packaging, label and government logo of the drugs should be obtained before supplying the drugs to the Medical Supply Division, but the same information had not been submitted for the approval of the Medical Supplies Division. Also, it had

taken more than a month to supply the Medical Supplies Division from the date of importation of the first batch (65000 units) pertaining to the order.

7.17.2.4 In contravention of Section 106(1) of the National Medicines Regulatory Authority Act No. 05 of 2015, the medicine imported by the supplier to the State Pharmaceuticals Corporation was imported into this country by a manufacturer other than the manufacturer mentioned in the tender documents and then the details of the manufacturer mentioned in the tender documents in the medicine packaging, had been printed illegally.

7.17.2.5 Inconsistencies were observed Between and among the sample packaging of the medicine included in the file submitted to the National Medicines Regulatory Authority for the registration of the imported medicine by the supplier and the information contained in the patient instruction leaflet contained in the medicine's packaging given to the medical supplies department and the information contained in the label of the medicine supplied and between the declarations of the local representative, compliance letters and the certificates of analysis of the respective drug submitted by the supplier to the State Pharmaceuticals Corporation under the letter heads of the manufacturing company along with the bid documents as well as in the same letter heads submitted.

7.17.2.6 Although the supplier's invoice had stated that the sample of the drug was approved by the medical supply department before the supplier imported and supplied the drug to the medical supplies Division, the changes in the packaging had not been recognized at that time and it was observed that actual samples of this medicine was not properly inspected by the Medical Supplies Division.

7.17.2.7 Considering this procurement as an urgent need, a short period of 09 days was given to submit bids, but as per the agreement, the supplier had supplied the stocks with time delays of 5 to 8 months than the agreed dates for supplying the stocks. But for these

delays No arrangements had been made to collect late charges as per clause 10 of the agreement. Further, the audit cannot rule out the suspicion that this supplier had been dealt with in favor of this supplier as an urgent need.

7.17.3 According to the order related to the purchase of 1,000,000 vials of Cefotaxime injection USP 1g issued by the Medical Supplies Division on 16 February 2016 the State Pharmaceuticals Corporation had invited international competitive bids at an estimated cost of Rs.43,070,000, on 15 March 2016. As per Technical Evaluation Committee recommendation dated 25 July 2016, the Departmental Procurement Committee had decided on 06 September 2016 to award the order of US $252,000 for 1,000,000 vials of vaccines at the rate of US $0.252 per one vial to the lowest bidder with valid registration certificate. The following facts were observed during the sample audit test conducted in this regard.

7.17.3.1 According to the letter dated 14 March 2017 from the Medical Supplies Division, the order had been canceled due to a 59 percent drop in demand for the medicine. But after about a year i.e. on 19 April 2018, as the stock of this drug has become scarce, on the basis of re-notification that the stock of drugs is required, the bid letter was issued to the bidder selected in 2016 on 23 May 2018, 1 ½ years after the expiry of the validity period of the bid. However, by that time his registration certificate from the Medicines Regulatory Authority had expired. Even though the samples and additional information required obtaining the re-registration certificate had been handed over to the relevant agencies and as the back of the expired registration certificate stated that the certificate was valid for 1,000,000 vaccine units on 01 August 2019, the permission had been granted to the Import Control Department to release 729,600 units. Although the authority had issued no-objection letters on 07 January 2020 and 17 March 2020 to release the remaining 770,400 vaccine units, the authority had failed to issue the relevant registration certificate.

7.17.3.2 The Medical Supplies Division had periodically revised the times to supply the medicines on 05 occasions in relation to the total procurement without paying attention

to the accurate forecast of the demand of the medicine and the orders to be received and the amount of orders had been increased by 50 percent on 29 January 2019. The first batch of vaccine vials related to the order received 364,800 vials on 14 February 2019, the second batch of 364,800 units on 07 October 2019, the third batch of 270,400 units on 07 January 2020 and 500,000 units on 22 April 2020. Though the order dated 30 May 2019 had been submitted to the State Pharmaceuticals Corporation on 03 June 2019 for local purchase, informing that 250,000 more vials of vaccine are required within 04 days due to the delay in the main order while the stock of medicine is due to be received, the procurement activities could not be completed within the stipulated time due to the unusual revisions made by the Medical Supplies Division in the supply schedule from time to time.

7.17.3.3 The procurement committee had decided to cancel the order offered for local purchase of 250,000 vials of vaccines and call for re-bidding citing the long lead time of the bidder who submitted the lowest price of Rs.70.70 per unit on the requirement of Medical Supplies Division. Accordingly, pursuant to a price call given for submitting bids for less than one day, the bidder registered with the National Medicines Regulatory Authority submitted Rs.540 per unit price as the procurement value exceeds the limit of the Departmental Procurement Committee, so the price was negotiated with the bidder (on the free supply of 65,000 vaccines) and the effective price of one vaccine has been agreed to be Rs.399.60 for a total value of Rs.99, 900,000. The estimated cost of a vial of vaccine is Rs.45.71 and the unit price of the first selected supplier is Rs.70.70, there was an increase of 774 percent and 465 percent respectively in the price of the selected supplier. The bidder selected in the second time had offered a unit price of Rs.255 in the first time and the procurement committee had awarded the order irrespective the fact that in the second time the bid was Rs.540 unit price had been submitted in the second time less than 2 months later. In the first call for bids, the selected bidder who offered a minimum unit price of Rs.70.70 had agreed to supply the entire stock within 45 days but it had been refused and bids had been invited again, but the selected supplier had failed to supply the drugs within 3 weeks. According to the customs note containing details regarding the import of these medicines dated 27 December 2019, an address of a different manufacturing company had been mentioned in the supplier's bid

documents. According to the inquiry made by the National Medicines Regulatory Authority on 27 February 2020 from this manufacturing company, it had confirmed that this vaccine stock was not exported to Sri Lanka by their company.

7.17.3.4 On 27 December 2019, the supplier had planned to supplies the Medical Supply Division with 20,000 vaccines that were illegally airlifted into Sri Lanka from a company not registered with the National Medicines Regulatory Authority. Also, although the name and address of the manufacturer should be mentioned on the package and main container of these medicines, the samples had been approved by the Medical Supplies Division without that information. On 02 January 2020, the Director of the Medical Supplies Division had submitted a letter to the National Medicines Regulatory Authority to accept these defective drugs due to the lack of vaccine stocks and to give instructions for labeling. Also, according to the file issued with the registration certificate of the National Medicines Regulatory Authority related to this medicine, clear differences were observed between the packaging of the registered drug that was to be given to the Medical Supplies Division and the Medicines packaging that was seized by the Food and Medicines Inspector of the National Medicines Regulatory Authority.

7.17.4 79,500 units of Ceftriaxone Sodium for Injection BP 500mg at a cost of Rs.1,488,240 had been purchased from a supplier who did not have a valid registration certificate from the National Medicines Regulatory Authority and according to the procurement documents submitted by the supplier and according to the documents submitted to the customs department at the time of import, This drug had been imported from a company that was not registered with the National Medicines Regulatory Authority without the approval of the company that was mentioned as the manufacturer of the vaccine. Also, the information that the samples of the drug were tested by the Bee Pharma laboratory in India before shipping and the file with the dossier maintained by the National Medicines Regulatory Authority related to drug registration was not submitted for audit. During the quality test conducted by the National Medicines Quality Assurance Laboratory regarding the stock supplied by the supplier to the medical supplies department, the relevant batch of stock had been informed to be

withdrawn from use due to the differences between the USP label requirement and the characteristics found in the existing labels. The amount of Rs.1, 860,300 incurred due to the supply of substandard medicines from the suspended payments of the supplier, despite the fact that the corporation had informed the supplier to refund the costs incurred for the stock removed from use due to non-compliance with the required specifications, but the supplier who did not accept it did not proceed to blacklist the supplier. But instead, a deduction of Rs.273, 598,324 had been paid to this supplier in the months of August, November and December 2022.

7.17.5 5,845,000 units of Furosemide Injection BP 20 mg/2 ml had been purchased at a Cost of Rs.35,761,504 for the Medical Supplies Division in 2016, 2017 and 2018. The following observations are made in this regard.

7.17.5.1 Due to the defects observed on receipt the stock of 99,000 doses of vaccines supplied to the Medical Supplies Division on March 7, 2017 and this said stock was not acceptable and for that, the supplier had provided the Accelerate Stability Report based on the notification given to the supplier to provide the Product Stability Report and as stated in it, the manufacturer company had informed that the related medicines were in compliance with the required standards and specifications. But it was observed during the audit that the letterhead of the letter so informed was different from the letterhead used by the manufacturing company and that this was a wrongly prepared letterhead and the procurement entity had not taken any notice of those differences although the signatures and format of the control manager were also different in the quality of vaccine analysis certificates issued by the manufacturing company from time to time in relation to the total quantity of units ordered.

7.17.5.2 According to the data of the Sri Lanka Customs Department, in relation to the above supply, the supplier had imported 3,898,900 doses of vaccines from two other import companies other than the registered drug manufacturer of the National Medicines Regulatory Authority mentioned in the bid documents and it was observed that both those companies are not registered companies of the National Medicines Regulatory Authority.

7.17.5.3 According to the test report of National Medicines Quality Assurance Laboratory (NMQAL) related to the test conducted in relation to the complaints submitted by 02 government hospitals and the Medical Supplies Division regarding this vaccine that had been supplied by the supplier, It was stated in the sterility test that the said vaccine was not in accordance with the British Pharmaceuticals Specifications and a discrepancy was observed in the vaccine sample that had been submitted to be tested and model packing of the product contained in the files submitted to the National Medicines Quality Assurance Laboratory (NMQAL) for registration. Based on the results of this test, all government hospitals and institutions had been informed to immediately remove this vaccine from use and the relevant company was informed to remove it from private shops. By the time the awareness was made, the stocks related to the years 2018 and 2019 had expired.

7.17.5.4 Although a forensic audit on behalf of the National Medicines Regulatory Authority confirmed in writing that the company did not supply any items to this supplier during the relevant period mentioned in the procurement documents and customs clearance documents as the manufacturer of the stocks related to these indents and that it has no knowledge regarding this procurement, the letters and analysis certificates in the relevant procurement file had been submitted through the letterheads of the manufacturing company. However, those letterheads were completely different from the letterheads sent to the Cosmetic Devices and Medicines Authority 10 June 2015, stating that the manufacturer had appointed the supplier as its Sri Lankan representative.

7.17.5.5 According to the physical inspection carried out in relation to the packaging obtained from the Colombo National Hospital, various differences were observed in the packaging that was left over from the stocks of this medicine issued to the Colombo National Hospital by the Model Packaging and Medical Supplies Division, which had been submitted to the National Medicines Regulatory Authority for registration.

7.17.5.6 Due to the above facts, although the supplier company had been referred to the legal department for blacklisting, the process of blacklisting had been stopped on the

grounds that there was no need to blacklist this supplier due to the fact that the amount due to the corporation had been collected for the medicines of poor quality.

7.17.5.7 Due to the irregularities mentioned in paragraphs 7.17.1 to 7.17.5 above, payment of bills due to the local representative body for the medical supplies provided by the State Pharmaceuticals Corporation to the Medical Supplies Division and the pharmacies of the State Pharmaceuticals Corporation is more than two years old. It had been suspended for some time but the payment had been made without conducting a formal investigation or formal approval and the following observations are made in that regard.

7.17.5.8 Suspended payments of Rs.248, 354,974 had been paid to the supplier in the months of August and November 2022 without obtaining the approval of the prescribed procurement committees or any other formal approval on the recommendation of the Chairman of the State Pharmaceuticals Corporation.

7.17.6 In addition, the bid price submitted by the supplier for 1729 Bevacizumab injections purchased by the State Pharmaceuticals Corporation and supplied to the Medical Supplies Division under Indenture No. LP/MSD/CPU-DHS/RQ/341/2018 from this local agency, the corporation, on the recommendation of the Secretary of the Ministry of Health, on 08 December 2022, had made the payment for the difference of Rs.25, 243,400 between the Quoted Price and the Awarded Price which was suspended to the concerned company without the approval of the relevant tender board and submitting the adequate reasons.

7.17.6.1 According to Board Decision No. 758 dated April 20, 2020, payments to suppliers recommended by the Streamline Committee should be made only within the recommended limits. Apart from the decision of the 65th committee of the same committee held on 08 June 2022 on the recommendations of the Secretary of the Ministry of Health and the Chairman of the State Pharmaceuticals Corporation, payments of Rs.248, 354,974 had been made to this company. The said committee, which was established with the aim of establishing a specific policy and a transparent

formal system for making payments to suppliers, and that function was abolished by the Board of Directors meeting No. 782 dated 03 October 2022, and no reasonable reason was observed for the abolition of that committee during the audit.

7.17.6.2 This company had subsequently changed its business name and had applied under that new business name to settle its outstanding bills. However, since the contract with the supplier corporation for the relevant medical supplies had been made under the name of the original company, the State Pharmaceuticals Corporation had released the letters of credit through the accounts in that name. Also, the company's name change was not accepted by the National Medicines Regulatory Authority. Thus, the company that made the request for payment and the company that made the payment were different from each other.

7.17.6.3 According to the letter No. SM/PSRP/01/SPC/2021 sent by the Secretary of the State Ministry of Pharmaceutical Products, Supply and Regulation to the Chairman of the State Pharmaceuticals Corporation on April 24, 2021, informing the National Drug Corporation regarding the fraudulent behavior of this supplier in the registration of medicines in violation of government rules and regulations and all purchases made from this original company and its subsidiaries be temporarily stopped until further notice, but according to the decision of the Emergency Procurement Committee dated August 16, 2022,it had accepted a bid submitted by a company named as its representative under the new company name of the original company and awarded the procurement of 1000 units of Trustuzumab 400mg injections worth Rs.54,450,000 and the sais stock of medicines had been delivered to the Division of Medical Supplies on 29 August,2022 and 12 September,2022

7.17.6.4 According to the report of the Presidential Commission of Inquiry into Corruption and Fraud believed to have taken place in government institutions from 15 January, 2015 to31 December, 2018, the cancer drug "Trastazumab" under the brand name "Hurticad" was imported into Sri Lanka through a private company. Recommendations had been made regarding the responsible officials in the health

sector related to fraud, corruption and irregularities, but the relevant authorities had not implemented any of those recommendations against those responsible officials.

7.18 **Controversial test on Ceftriaxone for inj.1g vial (SR- 00101704) due to loss of two patient lives**

2,100,000 vaccines worth Rs.75,959,792 had been purchased under the order number 2021/SPCN/R/P/00030 of this medicine which is an antibiotic medicine and 02 deaths had been reported in Peradeniya and Kegalle Teaching Hospitals after the distribution of the stock of 700,000 received in March 2023. Also, it was reported that patients in hospitals like Colombo, Kandy National Hospital, Gampaha, Kamburupitiya, Negombo and Karavanella developed allergies after using the medicine. In this regard, after testing the samples obtained from the hospitals, it was revealed that the laboratories had confirmed that there is no problem with the condition of the medicine. The Peradeniya Hospital had not arranged to send the samples to the laboratory of the group that was used for the young woman who died in the controversial Peradeniya Teaching Hospital. After the notification of the audit, the relevant samples had been sent to the laboratory but the relevant reports had not been released till the date of the audit.

08. Recommendations

8.1. The National Medicines Regulatory Authority, which was established to achieve the primary objective of providing authentic, safe and correct quality medicines to the public, had issued waiver of registration at that time through the recommendation of a technical committee. However, because of issuing waiver of registration certificates under a special pathway, deviating from the minimum method, it is recommended to investigate and take legal actions regarding the then Chief Executive Officer of the Authority who recommended the above special pathway by bringing medicines to Sri Lanka without any minimum method to confirm the quality of the medicines and putting the patients at risk and the Governing Board that approved it.(Ref:7.11.7)

8.2 In terms of the Authority Act, if there is a need to exempt suppliers from registration in emergency situations, it is recommended to issue the waiver of registration certificates in compliance with the existing rules and verifying the quality of medicines and to take necessary measures to prevent possible irregularities in the issuance of waiver of registration certificates contrary to accepted formal methods.(Ref: from 7.11.1 to 7.11.6)

8.3 It is recommended to complete the shortcomings and deficiencies of the National Medicines Quality Assurance Laboratory and improve it into an accredited international standardization level laboratory and give priority to confirm the quality of medicines used for patients by testing samples at different times of registration, importation and storage of medicines. (Ref: from 7.9.1 to 7.9.8)

8.4 It is recommended that the law enforcement agencies should take further actions against the supplier after a formal investigation into the fraudulent actions and serious endangerment of patients' lives by the supplier during the procurement process of 05 medicines including Human Immunoglobulin and Rituximab and supply of medicine stocks. (Ref: 7.16)

8.5 In calling for expression of interest and carrying out procurements of medicines on unsolicited basis including Human Immunoglobulin, it is recommended to carry out further investigations and take legal actions against those responsible for overriding Cabinet Decisions, not doing technical evaluations properly, giving recommendations to be beneficial to suppliers and prioritizing for 02 fake medicines in making payments. (Ref:7.3, 7.4, 7.16)

8.6 It is recommended that in blacklisting the companies/organizations that have made substandard medical supplies, the Secretary to the Ministry of Finance, the Registrar of Companies and the Procurement Commission should take actions to promptly blacklist through identity documents such as national identity cards or passports of the owners of those organizations in order to prevent those organizations from re-supplying medicines under other names. (Ref:7.16, 7.18, Volume I)

8.7 It is recommended to prepare an orderly program to carry out the registration activities promptly and formally in offering registration for medicines by the National Medicines Regulatory Authority by paying attention to the government's medicines requirements in order to avoid the problems due to inefficiently performing the registration process and keeping a large number of pending files and develop a system to follow up on the proper functioning of the said procedures.(Ref: 7.6.1, 7.6.2, 7.6.3 and from 7.7.1 to 7.7.11)

8.8 It is recommended to maintain the quality of medicines continuously from the time of import/manufacture of medicines to the time of use by patients by establishing appropriate system for regulating the government medicine stores and transportation of medicines.(Ref:7.10.1, 7.10.2, 7.10.3)

8.9 It is recommended to ensure that medicines are provided to the public at an affordable price by correcting the deficiencies in the system of pricing and regulating medicines. (Ref: 7.8.1 to 7.8.10)

8.10 It is recommended to establish an online computerized system that will be linked the related agencies such as Medical Supplies Division, State Pharmaceutical Corporation, Sri Lanka Customs and the Import and Export Control Department with the National Medicines Regulatory Authority so that all documents including registration and waiver of registration certificates pertaining to medicines clearance in the importation of medicines are cross-checked through an online system.(Ref:7.7.7.7, 7.7.7.8, 7.11.6.3)

8.11 It is recommended to introduce an accurate stock management system based on the reorder stock levels through a scientific method enabling to reduce the lead time for obtaining the medical supplies and forecast accurately the medicine requirement for the government hospitals, decide accurately the reorder level and maintain a reliable updated data system which provides the correct information enabling to submit the annual orders without delay in the specified time. (Ref: Volume I)

8.12 It is recommended to receive the orders forwarded to the suppliers on a specified date, charge accurately the delay charges on orders not happened in that manner, and formulate

a mechanism which verifies if the date of receipt and quantity is amended, it should be carried out on correct evaluation. (Ref: Volume I)

8.13 It is recommended to take frequent follow-up on the orders issued to the suppliers and take necessary action in relation to the orders which have less probability of receipt and no probability. (Ref: Volume I)

8.14 It is recommended to decide what medicines are in shortage taking into account not only the balance stock indicated on a specified date by the information systems but the orders to be received from the suppliers , probabilities of receipt of those orders, monthly usage of the medicine and other factors as the case may be and take action in maximum to obtain the orders to be received from the suppliers before referring to the emergency procurements and take necessary steps to immediately complete the general annual orders which had not been completed. (Ref: Volume I)

8.15 If the emergency purchases are necessary even after taking measures as above, and if such emergency purchases have been caused by the negligence or inefficiency of the officials, the disciplinary actions should be taken against those officers and the loss incurred by the government due to emergency purchases is recommended to be charged from the responsible officials. (Ref: Volume I)

8.16 Since varied problems had arisen due to the collapse of a good rapport that should be among the institutions; such as the Ministry of Health, the Medical Supplies Division and the State Pharmaceutical Corporation that carry out interconnected functions, it is recommended to take necessary steps to build a formal mechanism to establish good coordination among these institutions. (Ref: Volume I)

8.17 It was observed that an additional cost of Rs. 709,149,099 had to be borne by the government due to moving into emergency purchases without referring the whole information related to 11 medicines in the sample audit inspection as shown in detail in volume 1.Consequently, it is recommended to conduct a formal investigation to identify those responsible and recover the additional costs incurred and take disciplinary action against the officers. (Ref: Volume I)

8.18 Since it is observed that an additional cost of Rs.167,717,935 had to be borne due to the cancellation of the orders which were being accomplished related to the procurement of 04 medicines and referring to the local manufacturers of medicines in the sample audit inspection as shown in Volume I, it is recommended take appropriate measures executing further investigations and take necessary actions against the responsible parties. (Ref: Volume I)

8.19 It is recommended to review and evaluate the existing internal control procedures of the National Medicines Regulatory Authority, Medical Supplies Division and other related institutions to identify the existing shortcomings and deficiencies and establish strong internal control systems by correcting them. (Ref: from 7.6 to 7.11)

8.20 Prompt implementation of the recommendations numbered 8.1 to 8.47 mentioned in the special audit report on the medical supplies process issued by me on 14 March 2018 and even though it has been more than 06 years since those recommendations were given, it is recommended that the appropriate actions be taken against the officers who have not taken sufficient actions to implement the said recommendations. (Annexure 143)

Sgd./W.P.C. Wickramaratne
Auditor General

W. P. C. Wickramaratne
Auditor General
10 May 2024

Special Audit Report on Pharmaceuticals Requirement, Procurement, Supply, Distribution and Regulation in the Years 2022 and 2023

Volume I

(Observations on each pharmaceutical on the examination of the process from the preparation of pharmaceuticals estimates, ordering of pharmaceuticals and delivery to the Medical Supplies Division and distribution of those pharmaceuticals)

01. Meropenem Injection 1g (SR 00102102)

By supplying 1,500,000 vials of injection regarding the orders received from the State Pharmaceuticals Corporation in the years 2022 and 2023 from this pharmaceutical which is used to treat infections caused by bacteria, the debit notes of Rs.1,105,494,000 had been issued to the Medical Supplies Division. The following observations are made in respect of the procurement related to that supply.

(a) The bid of the second lowest bidder, who had offered Rs.1,395 per vials of injection in respect of the purchase of 150,000 vials of injections under order No. 2022/SPC/E/C/P/00432 of the Medical Supplies Division had been rejected, on the grounds of non-submission of the registration certificate of the National Medicines Regulatory Authority and non-availability of stock - in- hand. As the supplier who offered the third lowest price will deliver the stock within 04 weeks time frame, the order was also awarded to the Yaden International (Pvt.) Ltd. for Rs.1,400 per vial subject to submission of a valid certificate from the National Medicines Regulatory Authority. However, the supplier had supplied the stock with 56 days and 238 days delay for which the date to be supplied the pharmaceuticals with the Waiver of Registration.

(b) The Health Sector Emergency Procurement Committee had stated that there was no any stock as at 21 November 2022 in relation to the purchase of 450,000 vials of injection for Rs.1895.50 each for order No. 2022/SPC/E/C/P/00724 as an emergency purchase. However, 438,590 vials of injection had been handed over to the Medical Supplies Division on 08 November 2022 and 50,000 vials of injection on 17 November 2022 in relation to orders No. 2022/SPC/N/C/P/00044 and 2022/SPC/E/C/P/00432 respectively. Accordingly, as it is observed that nearly 488,590 units of vials of injection received during the month of November 2022 remained in the Medical Supplies Division or hospital system, it was not observed in audit that there an urgent need to purchase 450,000 vials of injection. Accordingly, it was also observed during the audit due to the fact that an emergency purchase was made even though there was sufficient quantity of pharmaceutical, a vial of injection was purchased at a price of Rs.1,075.60 under the normal order, and a vial of injection was purchased at a price of Rs.1,895.50 under the emergency purchase, resulting in a loss of approximately Rs.368,955,000 to the government. Further, even if it was agreed to supply the pharmaceutical within two weeks of receiving the Waiver of Registration with the National Medicines Regulatory Authority which was the main reason for choosing this supplier, Slim Pharmaceuticals (Pvt.) Ltd. had supplied the pharmaceuticals with a delay of 6 days and 41 days from the date to be supplied.

(c) Due to the fact that the Medical Supplies Division did not accurately identify the requirement and order the stock, one vial of injection for Rs.1,075.60 under the normal order , one vial of injection for Rs.901.20 under Indian Credit Line and one vial of injection for Rs.1,400 and for Rs.1,895.50 under emergency purchase. Similarly, various hospitals had purchased 14,450 vials of injection at high prices ranging from Rs.4,950 to Rs.9,450 per vial in the year 2022 at a cost of Rs.81,619,637 .

02. Liposomal Amphotericin B Injection 50mg (SR 00107403)

This is a pharmaceutical used to treat fungal infections. This has been done by the State Pharmaceuticals Corporation, Medical Supplies Division and foreign loan project pertaining to the years 2022 and 2023. A number of 42,800 units of this pharmaceutical had been ordered from the State Pharmaceuticals Corporation in the years 2022 and 2023. A number of 1,345 units had been received as donations in the year 2022. The following observations are made in respect of the procurement pertaining to the years 2022 and 2023.

(a) Although the order was awarded to Ceyoka (Pvt.) Ltd. for the purchase of 2,050 vials of injection under order No. 2022/SPC/E/C/P/00476 as an emergency purchase in the year 2022, the stock of 1,549 vials of injection from that had been supplied with one month delay from the date it was supposed to be supplied.

(b) The procurement had been awarded to the Slim Pharmaceuticals (Pvt.) Ltd., the fifth lowest bidder who had agreed to hand over the stock within 02 weeks after obtaining the Waiver of Registration for the procurement of 6,250 vials of injection under Order No. 2022/SPC/E/C/P/00741 for the year 2022 as an emergency purchase. Nevertheless, the supplier had taken more than a month after obtaining the Waiver of Registration to deliver the stock to the Medical Supplies Division.

(c) The second lowest bid of Rs.11,505.68 per unit had been rejected by the Procurement Committee due to making request of 30 days to supply the pharmaceutical. Nevertheless, the fifth lowest bidder, who had offered a bid of Rs.25,744.32 higher than the amount offered by the second lowest bidder, had also spent the same time period as agreed by the second lowest bidder to supply the pharmaceutical to the Medical Supplies Division.

(d) Accordingly, due to the fact that this procurement was awarded to the fifth lowest bidder Slim Pharmaceuticals (Pvt.) Ltd. without being offered the bid to the second lowest bidder, the government had incurred a loss by paying an amount of Rs.160,902,000 in excess. Also, according to the bid conditions, although the supplier had to submit samples, the Company had also not made arrangements accordingly.

03. Dried, Factor VIII fraction 200-350 IU (SR 00206101)

The following observations are made with regard to the procurement of 85,000 vials of injection through annual requirement order 2021 and 13,500 vials of injections under emergency procurement in 2023 by State Pharmaceuticals Corporation for this pharmaceutical which is used to treat for bleeding in patients with hemophilia A.

(a) Although the procurement was awarded to Baxalta GmbH to purchase 85,000 vials of injection at US$ 61 (Rs.11,407) per unit by Medical Supplies Division's annual requirement order No. 2021/SPC/N/C/P/00015 of the year 2021 dated 01 January 2020, the payments had been made with World Bank assistance due to failure of opening Letter of Credit. Even though the World Bank had informed about the payment to the Corporations on 21 April 2022, after a delay of 1 ½ months, that is on 16 June 2022, the first stock of 24,969 units had been supplied to the Medical Supplies Division.

(b) The Indent had been issued with 03 months delay after receiving the approval of the Cabinet of Ministers regarding the above order.

(c) Out of 60,031 vials of injection pertaining to the second stock of the above order a number of 4,500 vials of injection had been supplied with a 5 months delay that is 04 July 2023 and 25,500 vials of injection with 8 months delay that is 06 October 2023. The remaining quantity of 30,031 vials of injection had not been supplied to the Medical Supplies Division even as at 07 March 2024.

(d) Due to the deficiencies in the procurement process mentioned above, it was not possible to procure the quantity of vials of injection expected to be procured under the normal order as per the stipulated supply time frame. Due to this, an emergency purchase had to be resorted to and actions had been taken to purchase a number of 13,500 vials of injection from ABC Pharma Services (Pvt.) Ltd. for Rs.24,832.50 per unit under the emergency order No. 2023/SPC/E/C/P/00166 dated 07 March 2023. Accordingly, when the Indent was issued for emergency purchase, the value of one US dollar was Rs.311.23 as at 24 May 2023, and accordingly, as per the order of the year 2021, one unit of this pharmaceutical on that day (US$ 61 x Rs.311.23) was Rs.18,985.03. Accordingly, an excess payment of Rs.78,940,845 had to be incurred due to overpayment of Rs.5,847.47 for a vial of injection .

04. Phenytoin Sodium Injection 250mg / 5ml (SR 00303704)

From the orders issued by the Medical Supplies Division to the State Pharmaceuticals Corporation, the State Pharmaceutical Manufacturing Corporation and the Medical Supplies Division as 08 orders for the year 2022 and one order for the year 2023 for

the pharmaceutical requirement of the year 2022 and 2023 of this injection, 07 orders submitted for the year 2022 had been cancelled. Accordingly, this injection had been in short supply on 5 occasions from 02 December 2021 to 15 June 2023 in the warehouse of the Medical Supplies Division. The following matters were observed in this regard.

(a) Cancelling the normal order No. 2022/SPC/N/R/P/00003 dated 23 February 2021 for the purchase of 34,000 units of this pharmaceutical after 1 year and 11 months, it had been decided to purchase 24,000 injections from Yaden Laboratories (Pvt.) Ltd, a joint venture of State Pharmaceutical Corporation according to the letter of the Secretary of Ministry of Health dated 30 November 2022.

(b) The purchase order for supply of 25,000 units of this pharmaceutical has been issued to Pharmaceuticals Corporation on 09 September 2022 to receive 30 November 2022 under India Credit Line No. 2022/SPC/X/R/P/00589 due to urgent need caused by non-execution of normal order and the approval had been received on 06 October 2022 to award the tender to the lowest bidder at the ampoule value of US$ 4.25 per unit (Rs.1549.32 per unit in Sri Lanka currency). Due to delay in submission of registration certificate of NMRA again by the supplier and delay in receiving Indian Credit Line, the stock of injection had been received at the warehouse on 27 March 2023, three months delay from the due date of 31 December 2022 .

(c) The purchase order 2023/SPM/N/R/P/00044 instead of Normal Purchase Order 2022/SPC/N/R/P/00003 on 02 November 2022 had been issued by Medical Supplies Division to State Pharmaceutical Manufacturing Corporation for the purchase of 24,000 units of injections as 12,000 units each on 01 January 2023 and 01 March 2023. The State Pharmaceuticals Manufacturing Corporation had failed to supply these pharmaceuticals for those due dates and after 07 months that is on 07 July 2023, a number of 24,000 units had been purchased from Yaden Laboratory at Rs.4,600 per unit and supplied.

(d) Even though the arrangements had been made to award the order of one ampoule of the above pharmaceutical evaluated under the Indian Credit Line on 23 September 2022 to a foreign supplier Ciron Drugs Pharmaceutical at a value of Rs.1,542.32 equivalent to US$ 4.25, the order had been placed 1 1/2 months after the due date that is 02 November 2022 from Yaden Laboratory through State Pharmaceutical Manufacturing Corporation to purchase one ampoule of this pharmaceutical at a price of Rs.4600. Accordingly, in the case that the foreign exchange rate had not changed much in a short period of time (2022.09.23 US$ 1 = Rs.359.18, 2022.11.02 - US$ 1 = Rs.360.71), there was a difference of 3,058 (4600 – 1542) between the value of a unit imported

as above and the value of a unit (01 ampoule) purchased locally through the State Pharmaceutical Manufacturing Corporation (SPMC)). Accordingly, it was purchased from Yaden Laboratory through the State Pharmaceutical Manufacturing Corporation (SPMC) at a high price compared to the import price, which had been 198 per cent as compared to the import price. Accordingly, due to lack of proper procurement plan, an additional cost of Rs. 73,392,000 had to be incurred by the Medical Supplies Division for this purchase.

05. Thiamine Hydrochloride Injection 100mg/2ml Ampoule (SR 00402702)

Six orders were executed from 2021 to 2023 for the purchase of this injection, out of which 2 orders were canceled by the former Secretary of Ministry of Health. Due to these cancellations, the injection was out of stock in the Medical Supplies Division for a period of approximately one year from 06 October 2021 to 20 September 2022. The following matters are observed in this regard.

(a) Although normal order No. 2022/SPC/N/R/P/00042 dated 27 February 2021 has been submitted to the State Pharmaceuticals Corporation for the requirement of this injection in the year 2022, a re-order had been made on 01 March 2022 after one year due to its misplacement and there was a shortage of pharmaceuticals in the year 2022 due to lack of follow-up on the misplaced order.

(b) After placing this order again with the same order number on 01 March 2022 to the Corporation for the purchase of 220,000 units of injection, the m/s Ciron Drugs and Pharmaceuticals (Pvt.) Ltd. who had submitted the lowest bid at US$ 0.149 per unit (equivalent to Rs.41.72) with a total value US$ 32,780 had been awarded the contract on 05 July 2022 .

(c) Nevertheless, because of purchasing by the State Pharmaceuticals Manufacturing Corporation due to then economic crisis, by cancelling of this normal order by the letter of the Secretary of Health dated 30 November 2022, the purchase was made on 15 February 2023 seven months after the award of this normal order, at a price of Rs.175 by Yaden Laboratories, a joint venture of the State Pharmaceuticals Manufacturing Corporation.

(d) Despite there was a possibility to purchase the injections at Rs.41.72 by the order No. 2022/SPC/N/R/P/00042 related to the year 2022, the decision to procure from Yaden Laboratories, a joint venture of the State Pharmaceutical Manufacturing Corporation, had been extended to normal Order No. 2023/SPM/N/R/P/00041 for the year 2023 requirement. Accordingly, although the stock of injections was requested on 02 January 2023, one and a half months later, a number of 149,240 injections had been supplied to the Medical

Supplies Division at Rs.175 per unit and, the remaining 50,760 injection units were supplied to the Medical Supplies Division after 09 months at Rs.250 per unit on 24 September 2023. Accordingly, the injections required for the year 2022 had been received in the Warehouse of the Medical Supplies Division during the year 2023.

(e) Arrangements had been made to procure 33,000 units of injection at Rs.177 each unit of injection under emergency purchase order No. 2022/SPC/E/R/P/00479 dated 28 June 2022 also due to non-execution of normal order 19 September 2022. Based on the factor of 06 weeks to supply the injection by the lowest bidder in this procurement, it had been decided according to the decision of the Emergency Procurement Committee dated 30 August 2022 to offer 33,000 units of pharmaceutical Ampoules at a total value of Rs .177 per unit within 05 days to the Yaden International which was rejected by the Technical Evaluation Committee due to unavailability of the registration certificate from National Medicines Regulatory Authority and those injections had been received in the warehouse on 16 September 2022 .

(f) The emergency procurement which was agreed to supply in 05 days by Yaden International had spent 9 days in excess to supply these injections for this emergency procurement and, although the National Medicines Quality Assurance Laboratory (NMQAL) and the Medical Supplies Division requested to withdraw the entire batch of injections from the use by letters dated 06 April 2023 and 25 April 2023 respectively, the entire poor quality injections stock had been issued to the hospitals by 06 April 2023.

(g) Similarly, despite the supplier agreed to supply one unit of injection for US$ 0.149 (Rs. 41.72) as per Purchase Order No.2022/SPC/N/R/P/00042, canceling it and giving emergency order to another supplier for Rs. 177 equivalent to US$ 0.49 as per Purchase Order No. 2022/SPC/E/R/P/00479 and cancelling order No. 2022/SPC/N/R/P/00042 and handing over Purchase Order No. 2023/SPM/N/R/P/00041 dated 01 November 2022 for purchase through Yaden Laboratories, the joint venture of State Pharmaceutical Manufacturing Corporation, to the above 02 institutions , the Medical Supplies Division had incurred an identifiable loss of Rs. 34,527,550 .

(h) Even though it had been recommended to be awarded to US$ 0.045 per unit and total value US$ 4500 to the lowest bidder with Waiver of Registration by Invitation for Expressions of Interest for carrying out emergency procurement using remained funds under the Indian Credit Line to purchase 100,000 units on emergency purchases under Order No. 2022/MSD/V/R/P/00085, the former Secretary of Health had cancelled the order on 30 November 2022 stating that the pharmaceuticals are being supplied by a joint venture of the State Pharmaceutical Manufacturing Corporation .

(i) The information on whether the injections were procured from the local market during the shortage of injections from 06 October 2021 to 16 September 2022 was not provided to audit.

(j) Further, Although the order on 24 March 2022 was submitted to the State Pharmaceuticals Corporation as required by 30 April 2022 for the purchase of 400,000 of this pharmaceutical under Indian Credit Line on urgent requirement under Order No. 2022/SPC/X/R/P/00274, the related stock of pharmaceuticals had been received by the Medical Supplies Division on 17 and 25 February 2023 that is about 11 months delay after the order date. Accordingly, it was not possible to provide the requirement of the year 2022 in the Medical Supplies Division.

06. Fentanyl Citrate Injection 100mcg in 2ml ampoule Pharmaceutical (SR 00000301)

The following observations are made regarding this pharmaceutical, which is used as a narcotic pharmaceutical for pain relief in surgery.

(a) The normal annual order of 2022 had not been prepared and the order number 2022/SPC/X/R/P/00287 for 720,000 units of pharmaceuticals had been executed by the Medical Supplies Division and under the Indian Credit Line. A number of 360,000 units which was the first stock of the order had been supplied by the supplier to the Medical Supplies Division on 28 November 2022, and the stock had been sufficient for a period of 6 months.

(b) Even though an order of 187,500 units at a price of Rs 52.70 per unit was forwarded to the Chinese company Yichang Humanwell Pharmaceuticals Co. Ltd. on 16 November 2022 as an additional order related to the year 2021, State Pharmaceuticals Corporation had not taken steps to procure the stocks related to the order.

(c) As per observations “a” and “b” above, it was observed that there was no shortage of this pharmaceutical from December 2022 to May 2023 and there was no need to resort to emergency purchase. However, the Health Sector Emergency Procurement Committee executed the order 2022/SPC/E/R/P/00735 for the purchase of 180,000 units and forwarded the indent on 09 December 2022 to the above Chinese company at a price of Rs 162.50 per unit. The stock of pharmaceuticals had been supplied with a delay of 80 days , on 04 April 2023 beyond the scheduled date of supply of pharmaceuticals to the Medical Supplies Division on 13 January 2023. Accordingly, the loss to the government was approximately Rs. 19,767,000.

(d) By the order No. 2023/SPC/N/R/P/00037, which was submitted 7 months late for the year 2023, requirement of 300,000 units had been requested and, the Regional Procurement Committee of the State Pharmaceuticals Corporation had decided on 09 February 2023 to award the order to the Chinese pharmaceutical company Yichang Humanwell Pharmaceuticals Co. Ltd., who quoted the lowest price of Rs.42.12 for the year 2021 and emergency order for the year 2022. In spite of that, it had been informed by letter No. SH/Misc/03/2022 dated 22 February 2023 of the Secretary of the Ministry of Health that to cancel the current orders related to the above pharmaceutical and 09 other pharmaceuticals and to refrain from making quotations for those pharmaceuticals in the future, because of the second highest bidder for this order, Yaden Laboratories (Pvt.) Ltd, which submitted the price of Rs.184, is possible to manufacture and supply 9 other pharmaceuticals including this pharmaceutical locally and as those products are registered with the National Medicines Regulatory Authority. Accordingly, the order was canceled by the State Pharmaceuticals Corporation. However, at the time of issuing the above letter by the Secretary of the Ministry of Health, Yaden Laboratories (Pvt.) Ltd. was not registered with the National Medicines Regulatory Authority and only the Good Manufacturing Practices Inspection (GMP) report had been obtained from the National Medicines Regulatory Authority. As obtaining this GMP report is not considered as obtaining NMRA certificate for this pharmaceutical by the National Medicines Regulatory Authority, it was observed in audit that, stating of this local pharmaceutical manufacturing private company is capable of producing and supplying 9 other pharmaceuticals including this pharmaceutical locally and that these products are registered with the National Medicines Regulatory Authority is a misstatement of the Secretary of the Ministry of Health in his letter.

(e) Despite the order for the year 2023 was possible to be purchased at a unit price of Rs.42.12, the Price Committee, which determines the prices for purchase of pharmaceuticals and medical supplies from local suppliers, had given a price of Rs.218.83 per unit of this pharmaceutical to the local pharmaceutical manufacturing private company with a price increase of 418 per cent. However, custom documents and original documents confirming the cost documents and cost variables involved in this pricing decision were not submitted to audit.

(f) Accordingly, due to the cancellation of order No. 2023/SPC/N/R/P/00037 which had already been decided to offer a unit at a minimum price of Rs.42.12, informing that Yaden Laboratories (pvt) Ltd, which was not ready to supply the pharmaceutical by February 2023, can manufacture and supply this pharmaceutical locally, the additional cost had to be borne by the government was Rs.53,013,000.

07. Vancomycin Injection 500mg (SR 00103501)

The State Pharmaceuticals Corporation had supplied 398,000 vials of injection pertaining to the orders received from the year 2021 to 2024 and debit note valued at Rs.45,849,122.50 had been issued to the Medical Supplies Division. The following observations are made regarding these supplies.

(a) Even though the Emergency Procurement Committee of the Ministry had stated that there was a zero stock in the Medical Supplies Division and awarded the order on 21 November 2022 by Emergency Order No. 2022/SPC/E/C/P/00731 dated 03 November 2022 of the Medical Supplies Division to buy 48,000 vials of injection to Slim Pharmaceuticals which offered Rs.575 per vial as the second lowest price, 20,000 units as donation on 16 November 2022 and 70,000 units under normal order of 2021 had been received on 23 November 2022. Further, it was observed that the monthly requirement of this pharmaceutical is 18,977 units as at 15 December 2022 according to the data of the Swastha System. However, the Indent was issued on 03 January 2023 in relation to this emergency order. Further, 47,000 units had been supplied with a delay of 30 days and 1,000 units with a delay of 02 months and 05 days in relation to that indent.

(b) Further, the injection purchased for US$ 0.53 under the normal order of the year 2021 (when the pharmaceutical stock was cleared on 23 November, one US dollar was Rs.371.76 and accordingly a vial of injection was Rs. 197.03) had to be purchased at a cost of Rs.575 under the emergency purchase, an additional cost of Rs.18,142,560 had been incurred for 48,000 vials of injection.

(c) Due to failure of Medical Supplies Division to accurately identify the need and order the stock, the injection purchased for Rs.197.03 under normal order and Rs.575 under emergency purchase, had been purchased by incurring Rs.467,200 for 400 vials of injection by various hospitals at a high price ranging from Rs.1,100 to Rs.1,644 each injection.

08. Decarbazine injection 200 mg Vial (SR - 01203301)

As per the information shown on the internet, this pharmaceutical called Decarbazine belongs to the batch of pharmaceuticals known as Alkyman category. It is used to treat cancers of the lymphatic system and malignant melanoma (a type of skin cancer), and also can be used to treat other types of cancer as determined by a doctor.

(a) Order No. 2022/SPC/V/R/P/00690 had been issued for purchase of 1,500 units and despite that order, Order No. 2022/MSD/V/R/P/00074 had been issued instead. A file related to this order was not submitted for audit and it is

observed that, the two actual orders above are shown as issued orders in the system even on the date of audit.

(b) The Procurement Committee had decided to invite bids through international competitive method within the limits of the Departmental Procurement Committee for the normal order 2022 of 3,500 units. It took 17 days to deliver the order to the State Pharmaceuticals Corporation and more than 04 months to call for bids. The recommendations regarding the selection by the Technical Evaluation Committee were not formalized and specified. Likewise, according to the evaluation report, relevant members were signed without mentioning the names of them. The Procurement Committee had met and decided to award the order to Esses Pharmacy (Pvt.) Ltd. at a price of Rs.1,480 per unit subject to obtaining a valid registration certificate. It took 82 days from the meeting of the Technical Evaluation Committee to take this decision. The supplier had informed that the order could not be supplied due to the change in exchange rates. It was observed during the examination of the file that actions have not been taken regarding the failure of supplying the order from the respective supplier until a period of 05 months had elapsed. Similarly, it is observed in the audit that since the performance security amounted to Rs.518,000 had also been cancelled, it was impossible to recover the damages for the non-receipt of the relevant order from the supplier, and the Procurement Committee cannot deviate from its responsibility in this regard.

(c) The Procurement Committee had decided to cancel the aforesaid order and re-bid. Accordingly bids were invited from registered and previous suppliers. It had taken 37 days to cancel the original order and 55 days to re-invite bids after the order was cancelled. The supplier, The Esses Pharmacy (Pvt.) Ltd, which initially agreed to supply Rs.1,480 per unit, then suspended the order stating that it could not supply the pharmaceutical, had re-submitted a bid for Rs . 2,200 per unit. Although the performance bond of this institution should have been taken over and blacklisted, it was not done so. The new supplier, United Bio Tech, who agreed to provide pharmaceuticals for US$ 2.65 per unit during the second call for bids, had only been selected subject to renewal of the registration of the National Medicines Regulatory Authority, and the further work related to this order had not been done until the date of the audit. However, according to the Swastha system, this order had been stated as pharmaceutical receivable in the name of The Esses Pharmacy (Pvt.) Ltd., which was canceled in the first call for bid.

(d) As per the order No. 2022/SPC/E/R/P/00744, a number of 1,500 units of injection were to be supplied as an emergency order 2022 in a background of non-implementation of the normal order. The Procurement Committee had decided to invite bids from registered and previous suppliers within the purview of the Departmental Procurement Committee. According to the

evaluation report, a formal and specific recommendation had not been presented and the names of the relevant members were signed without mentioning them. The Procurement Committee dated 30 December 2022 had recommended awarding this order subject to obtaining the relevant registration certificate or WOR Certificate to the United Bio Tech that has submitted a unit price of US$ 5.00 out of these bids and has applied for extension of the National Medicines Regulatory Authority's registration. It had been mentioned that a Manager of the State Pharmaceuticals Corporation contacted the Director of the Medical Supplies Division and rejected this stock of pharmaceuticals, and there was need to forward a stability data report and a certificate for acceptance of stock due to temperature issue and when the matter is referred to the supplier, a letter of clarification of data has been submitted with a certificate and to make arrangements to accept this order by considering the said documents. However, this stock of pharmaceutical was received on 08 May 2023. It was problematic whether this Manager had formal authority to give a recommendation regarding such a technical matter and it was observed that a laboratory report should have been obtained regarding this matter. The audit also observed that it should be more careful regarding storage temperature of such a pharmaceutical, which is used to treat cancer of the human lymphatic system and malignant melanoma (a type of skin cancer) .

(e) Although the normal order related to the year 2023 should be placed in the month of January 2022, according to the order control form prepared on 01 June 2022, although 6,000 units should be ordered as per the order control form, 3,000 units under order No.2023/SPC/N/C/ P/00081 had been placed with a delay of about 11 months. The Procurement Committee had decided to invite bids from suppliers registered under the National Medicines Regulatory Authority. According to the Evaluation Report, a formal and specific recommendation had not been presented and the names of the relevant members were signed without mentioning them. The Procurement Committee had recommended the award of this order subject to renewal of registration to the United Bio Tech that submitted the lowest price of Rs.1,478.99 out of the orders. After issuing the order, it took approximately 120 days to evaluate the bids and almost 40 days were spent to award the order after the procurement evaluation. Although the order was granted subject to the renewal of the registration of the National Medicines Regulatory Authority and also the renewed certificate had not been included in the file, these pharmaceuticals had been provided on 11 October 2023 .

(f) As it was decided to issue only 3000 units from the normal order pertaining to the year 2023, the order No.2023/SPC/E/R/P/00143 for 1,500 units had been re-issued by the Medical Supplies Division. The Procurement Committee had recommended supplier Yaden International (Pvt.) Ltd. for this order, which

had submitted a revised price of Rs.12,800 per unit registered with the National Medicines Regulatory Authority. This stock of pharmaceuticals, which was supposed to be supplied on 30 June 2023, had not been supplied by the audited date of November 2023. This stock of pharmaceuticals, which was supposed to be supplied on 30 June 2023, had not been supplied by the audited date of November 2023. Further, according to the Swastha System, this order had not been shown as a receivable order. However, it was observed during the audit that the unit price under order No. 2023/SPC/N/C/P/00081 (within 23 days), which was done nearly before this order was Rs.1,478 and the responsible officers had not drawn attention to this. The supplier was selected and the Indent was issued at a price increase of 780 per cent within 23 days. Accordingly, if the order had been implemented under these prices, the government would have had to bear a financial loss of Rs.16,983,000.

(g) Order No. 2023/SPC/T/R/P/00146 for 1,000 units had been issued on 02 February 2023 from Medical Supplies Division. A Technical Evaluation Committee had not been appointed for the procurement and the recommendation for this purchase had been given by a price committee appointed by the Additional Secretary, Division of Pharmaceuticals, Supply and Regulation. The authority power given to the Additional Secretary to appoint a price committee could not be ascertained in the audit. Only 02 days were given to submit the prices and 61 days were spent to issue the Indent after completing the rest of the work. Accordingly, this emergency only limited the time given to submit bids. The indent was issued to the supplier, Yaden International (Pvt) Ltd, reducing the unit price of Rs.13,000 to Rs.7,000. According to the aforementioned near procurement, the unit price was Rs.1,478, and the price of Rs.7,000 was an increase of about 374 per cent. This stock had been received on 11 July 2023, and the government had to bear a financial loss of Rs.5,522,000 due to the purchase of pharmaceuticals at a higher price. Evidences were not submitted to the audit that the cover approval of the Cabinet of Ministers were obtained for this procurement decision or that a certificate from the Chief Internal Auditor was obtained that the procurement was done properly.

(h) Order No. 2023/SPC/X/R/P/00191 of 4,500 units had been decided to award the order to George Steuart Health (Pvt.) Ltd subject to receipt of valid registration certificate obtained from the National Medicines Regulatory Authority and the entity had also been recommended by the Health Sector Emergency Procurement Committee. Accordingly, the price of a unit presented by this entity as Rs.1,945.39 was agreed to reduce to Rs.1,945 by .39 cent and a performance bond had not been given. Only 02 days were given to submit the prices and 90 days were spent to issue the Indent after completing the rest of the work. Accordingly, this emergency was limited to limiting the time given to suppliers to submit bids. Evidence was not

submitted to the audit that the cover approval of the Cabinet of Ministers was obtained for this procurement decision or that a certificate from the Chief Internal Auditor was obtained that the procurement was done properly. It was problematic during the audit that although the shelf life of the pharmaceutical was stated as 24 months, it was stated as 12 months in the Indent.

(i) According to the above mentioned fact, although the required stock for this pharmaceutical for the year 2023 was predicted as 6,000 units, a normal order of 3,000 units had been issued. Due to ordering less amount pharmaceuticals, thus resorting to 02 emergency procurement cases and resorting to purchase drugs at higher prices, the government had incurred a financial loss of Rs.15,872,500 to purchase additional 5500 units.

(j) An order control form to determine the normal order quantity for the year 2024 had not been prepared even by November 29, 2023. Accordingly, no decision was reached on whether the issuing of the order will be made or not for the year 2024. In this situation, it was observed that emergency purchases may have to be resorted to in the year 2024 as well.

(k) It was shown in the Swastha System that 25,020 units of this pharmaceutical will be received on 21 November 2023. However, it was impossible to identify the way of setting of the number of units in the System.

09. Fluconazole Capsule 50mg Pharmaceutical (SR 00107101)

The following observations are made regarding this pharmaceutical, which is essential for fungal infections and antibiotic.

(a) This pharmaceutical had been purchased in the year 2022 in contrary to Section 109 of the National Medicines Regulation Act No. 05 of 2015 with WOR certificate under the Indian Credit Line for the pharmaceutical shortage occurred due to reduction of amount of units in normal order 2021 without carrying out accurate forecast and delays in procurement due to inefficiency of Medical Supplies Division and State Pharmaceuticals Corporation and due to supplier had rejected normal order 2022 and a US$ 0.028 per unit had been paid for a pharmaceutical unit, which is US$ 0.00452 more the price received for normal orders in the years 2021 and 2022. Accordingly, the State Pharmaceuticals Corporation had borne an additional cost of US$ 4,425.9 for 979,200 units.

(b) The purchase order for another order in the year 2022 had been given to the supplier on 03 November 2022 regarding this pharmaceutical and the unit price of US$ 0.0214 offered for that was lower than the prices offered for other orders in 2022. However, the order had been cancelled based on the letter No.

SH/MISC/03/ Medi.Equip issued by the Secretary of the Ministry of Health on 12 January 2023 regarding to be resorted to local pharmaceutical manufacturers.

(c) If the pharmaceuticals are purchased from a local pharmaceuticals manufacturer, a Buy Back Guarantee should be entered into according to the Decision of Cabinet of Ministers CP No. 18/1883/814/056 dated 17 October 2018, this pharmaceutical was purchased from Newgen Lanka Health Care (Pvt.) Ltd, a local pharmaceutical company in the year 2023 without entering into a Buy Back Guarantee. Due to this there was no system to recover the losses incurred to the government through the supply of pharmaceuticals with a delay of 3 to 6 months, in the year 2023 .

(d) Even though the price committee had given a price of Rs. 22.64 for a unit of this pharmaceutical in the year 2023, what cost variations were included in that price and those cost variations were not confirmed through customs documents and original documents. It was observed that the unit price given by the price committee so is almost 170 per cent higher than the price offered by foreign suppliers in the year 2022. Accordingly, the Medical Supplies Division had incurred an additional cost of Rs. 6,785,385 for 475,500 units.

10. Trastuzumab Injection 440mg (SR 01205102)

A number of 10,240 vials of injection have been supplied from this pharmaceutical which is used for breast and stomach related cancers, in relation to the orders placed to the State Pharmaceuticals Corporation in the year 2022 and debit notes valued at Rs. 655,983,655 for that had been issued to the Medical Supplies Division. The following observations are made in this regard.

(a) The approval for the purchase of 8,400 vials of the above pharmaceutical for the import of the second stock of 3,040 vials of injection for Rs.56,000 each by Order No. 2022/SPC/N/C/P/00034 dated 17 June 2021 issued by the Medical Supplies Division was delayed by 04 months and 19 days from the date of approval of the first stock order. The supply of the third stock (4,000 vials) under the said procurement was made on 06 November 2023 with a delay of 2 months from the scheduled date of 31 August 2023. Although the Letter of Credit of Rs.101,080,000 opened on 09 March 2022 related to the above order should be canceled immediately, the notice for the same was issued to the bank with a delay of about 14 months from the expiry date of the Letter of Credit.

(b) The Technical Evaluation Committee had given recommendation to a supplier with valid registration of National Medicines Regulatory Authority for procurement related to purchase order No. 2022/SPC/E/C/P/00497 of 1,000 vials of injections of Medical Supplies Division. However, without considering about it, the Advitec International (Pvt.) Ltd., which did not have a valid registration certificate of the National Medicines Regulatory Authority, was awarded the procurement to supply the above order at a price of Rs.52,450 each.

Nevertheless, Advitec International (Pvt.) Ltd. had supplied 500 vials of injections to the Medical Supplies Division before issuing the indent related to the supply and it was observed that it was a controversial situation.

(c) The supply condition of these 500 vials of injection as well as the remaining 500 vials of injection related to the order mentioned under (b) above was imposed by the Medical Supplies Division as "it should be supplied with a minimum shelf life of 24 months". However, as it was observed that the shelf life of the 1,000 vials of injection related to the order was less than 05, 06 months, the suppliers had violated the supply conditions while supplying this order.

(e) It was observed that the revising the order under (b) above as an order for 2,000 vials of injection has been done by the undated letter No. 10/2022 of the Director of Medical Supplies. As per the order, the above mentioned Advitec International (Pvt.) Ltd. was provided with the necessary opportunity to supply 1,000 more vials of injection. Accordingly, the above organization had provided a quantity of 840 vials of injection related to the second order and the shelf life of the vials of injection was also low between 02 and 03 months. The remaining 160 vials of injection pertaining to the second order had not been supplied by 07 March 2024 and the performance guarantee for supply had also expired.

(f) Ignoring the minimum unit price of Rs 60,950, the bid of an organization non-registered with the National Medicines Regulatory Authority, which had been submitted for the procurement of 3,000 vials of injections as per Order No. 2022/SPC/E/C/P/00742 of the Medical Supplies Division, it had decided to award the procurement to the second lowest bid of Rs 63,450. The Procurement Committee of the Ministry had approved the awarding of the procurement to Advitec International (Pvt) Ltd. subject to obtaining Waiver of Registration from National Medicines Regulatory Authority.

However, the application of the institution for Waiver of Registration was rejected by the National Medicines Regulatory Authority on 23 February 2023 (WOR Committee response "Not recommended by oncologists till the product is register").

Due to that refusal, bearing an additional cost of Rs.22,350,000 was temporarily avoided for order No. 2022/SPC/E/C/P/00742 .

11. Glyceryl Trinitrate Inj.50mg/10ml Pharmaceutical (SR 00203002)

The following observations are made regarding this pharmaceutical, which is injection given to facilitate blood circulation to patients and emergency treatments.

(a) The remaining 50,000 units of the normal order for the year 2021 were temporarily suspended without predicting how much the demand for this pharmaceutical has fallen due to the Covid-19 pandemic and how much will be needed in the future period and the normal order of 2022, which could have been purchased at US$ 4.9 per unit, had been cancelled.

(b) After notifying the State Pharmaceuticals Corporation to reverse the obtaining of the remaining 50,000 units of the 2021 normal order that was temporarily suspended, it had delayed almost 5 months to inform that decision to the supplier.

(c) Due to this delay, this pharmaceutical , which is an emergency injection given to heart patients, was in short supply for almost 04 months from August 2022 to 25 November 2022. Further, due to the institutional deficiencies mentioned under (a) and (b) above, emergency purchase had to be made for this pharmaceutical in the year 2022 .

(d) Thus, during the shortage period, the order No. 2022/MSD/V/R/P/00102 for 11,250 units had been given by the Health Sector Emergency Procurement Committee to a pharmaceuticals supplier on 23 November 2022 at a relatively high unit price of US$ 6.23 with the WOR certificate and the stock of pharmaceutical was received on 07 April 2023, with a four months delay of the scheduled time. However, two days after this order was given to the supplier, the amount of 29,950 units of the reactivated normal order of the year 2021 had been received by the Medical Supplies Division. Accordingly, the Medical Supplies Division had borne an additional cost of Rs 4,946,032 for 11,250 units through this purchase which was not practically an urgent need.

(e) Another order No. 2022/SPC/X/R/P/000264 had been submitted for this pharmaceutical for 30,000 units in the year 2022, and Centurion Healthcare Private Limited who is the Indian pharmaceuticals supplier introduced by the selected bidder in its bid had not been covered by the NMRA certificate submitted by the bidder. Similarly, it was not confirmed in writing that the Indian pharmaceutical company named Mercury Laboratories Limited mentioned in the NMRA certificate authorized the Indian supplier Centurion Healthcare Private Limited mentioned in the bid to sell its company's products. Accordingly, 30,000 units of pharmaceuticals related to this order had been obtained from an unconfirmed Indian supplier in the months of December 2022 and January 2023 .

12. Clarithromycin for Infusion 500 mg vial Pharmaceutical (SR 00103002)

The following observations are made regarding this pharmaceutical , which is used as an antibiotic in bacterial infection.

(a) A price of Rs. 151.16 and Rs. 190.44 had been presented for the normal annual orders executed in relation to the years 2018 and 2019 respectively and out of the remaining 159,700 units of those orders, 111,070 units were received by the Medical Supplies Division with a delay of the scheduled time and the remaining 48,630 units had not been received. Due to non-receipt and delay in receiving pharmaceuticals so, the State Pharmaceuticals Corporation had purchased 9400 units at Rs .1085.22 per unit and 5400 units at Rs. 924.04 per unit at a higher price in the years 2019 and 2020 under regional purchases. Accordingly, through this purchase, the State Pharmaceuticals Corporation had borne an additional cost of approximately Rs. 12,953,708 for 14,800 units.

(b) The normal annual order 2022 had not been prepared and, out of the stock of approximately 43,655 units received in the months of December 2020 and January 2021 in relation to the average annual order of the year 2020 and remained at the beginning of the year 2022, a stock of 15,120 units cost at Rs. 5,134,449 had expired as at 30 September 2022. After the stock had expired, although the purchase order for 25,000 units under the Indian Credit Line was placed with a supplier on 18 October 2022 with WOR certificate, the pharmaceutical stock had been not received up to 30 November 2023. Therefore, this pharmaceutical had remained in short supply for approximately 14 months from September 2022 to 30 November 2023 .

(c) The Marawila Base Hospital had purchased 50 units in 2 cases during the period of 14 months which remained in shortage at a price of Rs.5500 each, that is 413 per cent higher than the price that the State Pharmaceuticals Corporation had purchased orders for in the last three years.

(d) The normal annual order of 2023 had been submitted by the Medical Supplies Division after 10 months delay and the State Pharmaceuticals Corporation had spent more than 07 months period for procurement activities to select a supplier for it. However, the Indent had not been issued by 30 November 2023 .

(e) After deducting a stock of 60,000 units not confirmed by the MSMIS system or by the Swastha system as having an order and a stock of 70,000 units receivable on the normal annual order 2021 for which there was no possibility of receipt from the forecast requirement in the year 2024, the annual normal order 2024 had not been submitted stating that an order was not needed.

(f) Due to non-implementation of the normal annual order 2023so and non-submission of the 2024 normal annual order, the risk of this pharmaceutical being in short supply in the future period and the risk of resorting to emergency procurement could not be ruled out in the audit.

13. Dopamine Hydrochloride Injection BP 200mg/5ml (SR -00204001)

This pharmaceutical is used to correct hemodynamic imbalances caused by heart failure, shock, kidney failure and chronic heart failure. Procurement of 63,000 units of the pharmaceutical and 37,500 units under emergency purchase and 30,000 units through foreign project scheme had been made under normal order 2023 and the following observations are made in this regard.

(a) Although the Medical Supplies Division has to place the normal order with a waiting period of 11 months, due to the order which should be supplied as 33,000 units on 15 January 2023 and 30,000 units on 16 April 2023 under order No. 2023/SPC/N/R/P/00121 was sent on 24 November 2022 to the Corporation, the waiting period had limited to 1 ½ months.

(b) Due to this delay, in placing the regular order, an emergency purchase had to be resorted. Accordingly, although the order was placed to purchase 37,479 units at Rs.354.60 per unit by order No. 2023/SPC/E/R/P/00187 dated 09 March 2023 sent to the Medical Supplies Division to make an emergency purchase, the Ceyoka (Pvt.) Ltd. had supplied pharmaceuticals to the Medical Supplies Division with a delay of 21 days. Also, as a result of this injection , which could have been purchased for Rs.284.91 under the normal order, had been purchased for Rs.354.60 each under emergency purchase, a sum of 2,611,911 had been spent in excess.

(c) A number of 30,000 units had been purchased from Yaden International (Pvt.) Ltd. for US$ 3.0535 (Rs.953.72) per unit under Foreign Loan Projecct under order No. 2023/ADB/X/R/P/00021 of the Medical Supplies Division.

Although this pharmaceutical could have been purchased from Yaden International (Pvt.) Ltd. for Rs.284.91 under the normal order, it was observed that it was a 234 per cent price increase as compared to the normal order price when purchasing from foreign projects. Accordingly, a sum of Rs. 20,064,300 had been spent in excess. Also, although this supply was supposed to be made within 60 days from the date of the agreement, it had been supplied to the Medical Supplies Division with a delay of one month.

14. Tenecteplase Inj 40mg (SR 00206901)

A pharmaceutical used for emergency treatment in case of heart attack. A number of 6,000 vials of injections had been supplied in relation to the orders received in the year 2023 and , for that purpose debit notes of Rs. 915,854,940 had been issued by the State Pharmaceuticals Corporation. The following observations are made regarding the procurement of this pharmaceutical.

(a) The annual order for the year 2022 had been canceled on the basis that the stock in respect of pending orders was sufficient for the proposed period. Similarly, although the order received under the Indian Credit Line in the year 2022 had taken 15 months, the Corporation had not made sufficient arrangements to get the decision of the Standing Procurement Committee appointed by the Cabinet of Ministers.

(b) In relation to the procurement of 6,000 vials of injection under Order No. 2023/SPC/N/R/P/00071 dated 15 November 2022 in the Medical Supplies Division, even though the temperature to store the pharmaceutical is 2Co – 8Co according to the bid documents of the supplier who offered the lowest price of Rs. 83,035.01 per unit, the temperature to be stored was 28Co – 32Co as per the bid documents published for the procurement. However, the Technical Evaluation Committee had recommended that supplier without considering it. Although the Technical Evaluation Committee and the Standing Procurement Committee appointed by the Cabinet had awarded the bid, the Appeal Committee had canceled the bid based on an appeal made by a bidder. It had taken 57 days of period to inform the Corporation.

(c) Due to having to resort to emergency procurement because of deficiencies in the above procurement process, the advantage that could have been obtained by resorting to normal procurement could not be obtained and a total of Rs. 880,629,750 had been spent for the purchase of 1,500 vials of injection at Rs. 150,150 per vial by the emergency order dated 01 March 2023 and 6,000 vials of injection at Rs. 145,645.50 per vial by the emergency order dated 09 May 2023.

15. Anti Rabies Inactivated (TC) Vaccine (SR 00600204)

An injection used for Rabies. A number of 1,967,500 doses of this pharmaceutical were received as a donation on 28 September 2022 .

Despite this, the Indent was issued on 14 October 2022 for emergency procurement of 250,000 injection doses at Rs.310 per unit as per the procurement of 500,000 injection doses under order No. 2022/SPC/E/R/P/00406 .

According to this order, out of 500,000 injection doses, 250,000 doses were purchased for Rs.372.70 each as the first stock and 250,000 injection doses were purchased from the same supplier for Rs.310 each at the second time. Accordingly, initially a sum of Rs.15,675,000 had been spent in excess for 250,000 doses as Rs. 62.70 per dose.

16. Ceftriaxone Injection 500 mg (SR 00101703)

The Sri Lanka State Pharmaceuticals Corporation had supplied 27,500 vials of injections valued at Rs.25,662,547 in relation to the orders received in 2022 and 2023 for this pharmaceutical, which is used to treat bacterial infections in various parts of the body and for that purpose, the State Pharmaceuticals Corporation had issued debit notes valued at Rs.25,662,547. The following matters were observed in relation to the procurement of this pharmaceutical.

(a) Although the procurement activities for the order No. 2022/ SPC/E/R/P/00703 dated 18 October 2022 for 27,500 units submitted to the Corporation as an emergency order should be carried out by the Health Sector Emergency Procurement Committee (HSEPC) chaired by the Secretary to the Ministry of Health, this procurement had been carried out by the Departmental Procurement Committee.

(b) According to the Indent issued on 08 February 2023 regarding the procurement of 440,000 vials of injection under Order No. 2023/SPC/N/R/P/00016, a number of 150,000 units had to be supplied as the first stock on 31 May 2023 and the Eureka Life Sciences (Pvt.) Ltd. had informed on 17 May 2023 that this order is under production. However, as per Medical Supplies Division circular No. MSD/QA/DRMM-2023 dated 04 April 2023, the order had been temporarily suspended as this pharmaceutical was not in the priority list. As a result, if the supplier's trust has breached and bidders will not appear for future procurements, it will not be possible to call competitive bids due to the loss of suppliers.

17. Calcium Polystyrene Sulphonate 15g-17g powder sachet Pharmaceutical (SR 00406202)

The following observations are made regarding this essential pharmaceutical given to kidney patients.

(a) The quantity of pharmaceutical receivable at the beginning of the year 2022 had been received in the year 2023 after a delay of more than 14 months due to delays in preparation and submission of normal annual order 2022 and in carrying out the procurement .

(b) Due to this delay, this pharmaceutical remained in short supply for approximately 09 months from 01 January 2022 to 27 July 2022 and from 01 January 2023 to 08 March 2023.

(c) Two hospitals had procured 45 units at Rs.348 and 28 units at Rs.412 under local purchases during the period of shortage for a price higher than Rs.307.70 for which the normal annual order was offered.

(d) As a result of this shortage , the actual consumption had remained at a lowest of 25 per cent of its estimated requirement in the year 2022 . It is observed that this pharmaceutical had not been received sufficiently for kidney patients in the year 2022 .

(e) Although 02 orders in the year 2022 related to the same pharmaceutical had been cancelled, thus it was observed that they had remained as valid orders in the Swastha System, the stock of pharmaceuticals received in relation to one order in the year 2022 was not recorded in the Swastha System, and the stock of pharmaceuticals received in relation to another order in the year 2022 was recorded with changing of dates, the information shown by Swastha Systems about the pharmaceutical was not accurate.

18. Sodium Valproate Syrup 200mg/5ml, 100ml Pharmaceutical (SR 00304004)

The following observations are made regarding this pharmaceutical which is essential for children suffering from epilepsy.

(a) Only two suppliers had obtained the certificate of National Medicines Regulatory Authority from the year 2021 to 2023 and thus the registered certificate of one of the suppliers had expired in the year 2022, the presentation of a competitive price for this pharmaceutical had been limited.

(b) Due to poor co-ordination between Medical Supplies Division and State pharmaceuticals Corporation, the pharmaceutical was in short supply in the Medical Supplies Division for approximately 07 months from August 2021 to 09 March 2022 due to approximately 25 months spent on procurement of normal orders in 2022.

(c) Due to the failure of the National Medicines Regulatory Authority to register sufficient suppliers for the pharmaceuticals and the shortage of the pharmaceuticals so, the Indent of the order had been awarded on 10 March 2023 to the lowest bidder with WOR certificate due to comparatively higher price from the sole NMRA certificate holding supplier for order No. 2022/SPC/X/R/P/00294 of the year 2022 .

19. Calcium 500mg+ Vitamin D3 250IU Tab Pharmaceutical (SR No. 00405401)

This certificate of the sole supplier who has obtained NMRA certificate from suppliers who had submitted bids for this pharmaceutical used for patients suffering from calcium and vitamin deficiencies had expired on 12 November 2021. Without achieving the facts such as renewing the registration or registering new suppliers for this pharmaceutical or revising the specifications of the Medical Supplies Division appropriately according to the alternative pharmaceuticals available in the market if there are no suppliers, an unnecessarily long period had spent for the procurement of this pharmaceutical in the years 2021, 2022 and 2023 and that normal annual orders had been cancelled. As a result, this pharmaceutical had remained in short supply in Medical Supplies Division from 16 December 2020 to 30 November 2023, the date of audit.

20. Digoxin injection BP 500 mcg/2ml Pharmaceutical (SR 00200102)

The following observations are made regarding this pharmaceutical used in heart patients.

(a) This pharmaceutical was not available in the Medical Supplies Division for a period of 15 months in the 20 month period from January 2022 to August 2023 due to delay in preparation and submission of normal annual orders from the year 2021 to 2023 by the Medical Supplies Division, failure to accurately forecasting the amount of annual orders, delay in execution of orders submitted to the State Pharmaceuticals Corporation and spending long time in procurement. So compared to the estimated requirement of this pharmaceutical, the amount of units of pharmaceutical issued was at a lowest value ranging from 12 per cent to 38 per cent from 2021 to the end of August 2023.

(b) Purchasing of 95 units for Rs.180 per each under local purchase on 9 occasions by the 3 hospitals during the period when the pharmaceutical was in short supply was problematic in audit on the background where the pharmaceutical had been purchased by Medical Supplies Division and the State Pharmaceuticals Corporation, for a unit ranging from Rs.1,296 to Rs.9,575 in 4 cases in the years 2022 and 2023 .

(c) There was a huge variance between the prices offered by the suppliers on 04 occasions and the difference in the highest price compared to the lowest price offered was 706 per cent in the years 2022 and 2023. There, the suppliers who have obtained NMRA certificate offered a high price and the suppliers without NMRA certificate offered a very low price. The government had to bear high costs for this pharmaceutical because the Ministry of Health, the Medical Supplies Division and the State Pharmaceuticals Corporation had failed to identify the causal factors influencing the occurrence of extreme fluctuations remained in the prices, of the suppliers and to identify the measures to be taken to reduce them.

21. Protein hydrolysate Injection 100ml (SR No -00402201)

The following observations are made regarding this pharmaceutical used as a nutritional supplement for patients in the Intensive Care Unit.

(a) Only one supplier had submitted quotations for all the orders executed in the years 2022 and 2023. Instead of investigating the reasons why only one supplier appear for the orders of this pharmaceutical and taking the necessary measures so, the officers of the State Pharmaceuticals Corporation deliberately or due to negligence and inefficiency, spent a long period for procurement activities and had not implemented the normal annual orders.

(b) The unit price offered by the only bidder who had submitted bids in all those cases was a price increase of approximately 85 per cent over the Rs. 895 unit price offered for the normal order in the year 2021.

(c) This supplier had agreed on 15 May 2023 to supply Rs.1,516 units per each for the normal annual order 2022 and the pharmaceutical batch number (Batch No.) agreed to be supplied was No. 16RM6293. However, due to this pharmaceutical was removed from the priority list, the above normal annual order was canceled on 05 July 2023. However, the Health Sector Emergency Procurement Committee had decided to purchase 3000 units of the above pharmaceutical batch at a price of Rs.1662.39 per unit, that is at an additional cost of Rs.146.39 per unit by including this pharmaceutical in the priority list once again on 07 July 2023.

22. Aciclovir Tab. 200mg (SR-00107901)

A 69 per cent of the estimated pharmaceutical requirement to be supplied to the hospitals in the year 2022 had not been supplied by the Medical Supplies Division. As a result, there were zero pharmaceuticals in the warehouse since 08 November 2022. It was observed during the examination of the computerized stock ledger records that the shortage of pharmaceuticals lasted for almost 07 months, and the following facts had caused for this.

(a) Suspension of the Normal Order 2022/SPC/N/R/P/00045 issued to the State Pharmaceuticals Corporation on 25 February 2021 for the supply of 840,000 tablets in the year 2022 by the Procurement Committee on 26 October, 2021 as recommended by the Medical Supplies Division after 08 months.

(b) The Medical Supplies Division had carried out an emergency procurement on 04 November 2022 under Order No. 2022/MSD/V/R/P/00077 to procure 525,000 pharmaceuticals while the pharmaceuticals in the Medical Supplies Division were nearing zero and the supplier had failed to supply the pharmaceuticals on the expected date. Suspension of the order immediately by the Medical Supplies Division seven months after the date of placing the order that is on 03 June 2023.

(c) Although the stock of 1,000,000 tablets to be received through the procurement number 2022/SPC/X/R/P/00267 made under the Indian Credit Line for the procurement of pharmaceuticals in the year 2022 should be received as at 31 October 2022, receiving of it on 18 July 2023 almost with a delay of a year.

23. Gliclazide tab. BP 40mg (SR 00700301)

When the National Medicines Quality Assurance Laboratory (NMQAL) notified on 17 July 2023 that the 5,947,500 tablets belonging to Batch Number 3 of this pharmaceutical provided by the State Pharmaceuticals Manufacturing Corporation under purchase order No. 2022/SPM/A/R/P/00069 had failed in quality, all those pharmaceuticals had been issued to the hospitals from the Warehouse of Medical Supplies Division. However, in the testing of the quality of the pharmaceutical by a laboratory in New Delhi, India it had been confirmed by the relevant reports that the pharmaceutical had passed the relevant parameters. Accordingly, there is a controversial situation regarding the quality tests of this pharmaceutical.

24. Flucloxicillin BP 500 mg (SR 00100801)

The State Pharmaceutical Manufacturing Corporation itself accepted that 11,731,600 units of Flucloxicillin BP 500mg which was manufactured by the State Pharmaceutical Manufacturing Corporation and supplied to the Medical Supplies Division were not in accordance with the required quality and a request had been made to the Medical Supply Division to withdraw it from use. Accordingly, when these batches of pharmaceutical were withdrawn from use by the Medical Supply Division on 31 may 2023, all those pharmaceutical units had been issued to the hospitals from the warehouse of Medical Supplies Division .

25. Cefuroxime Tablet 500mg (SR 00101403)

This is a pharmaceutical given for bacterial infections occurring in different parts of the body. It was observed that there is a stock of 79,966,716 units of this pharmaceutical according to the data of the Swastha System as at 03 October 2023. It was observed that the stock is 5 times the annual estimated requirement of the year 2023 and will be sufficient for the next 09 years and 05 months.

Accordingly, when placing orders of pharmaceuticals by the Medical Supplies Division, it was observed that orders are made without adequate checks on accurate estimation and pharmaceuticals that have been ordered for a long time and have not been supplied as ordered and as a result, stocks on pharmaceutical are unnecessarily stockpile and expire.

26. Sodium Valproate Tab. 100mg (SR-00304001)

This pharmaceutical was zero in stock in the Medical Supplies Warehouse from 24 May 2022 to 11 January 2023, and 83 per cent of the estimated pharmaceuticals requirement to be supplied in 2022 was not made by the Medical Supplies Division. The following facts had affected to the shortage of pharmaceuticals in the Medical Supplies Division.

(a) The normal order No. 2022/SPC/N/R/P/00003 issued on 27 February 2021 to the State Pharmaceuticals Corporation for procurement of 22,000,000 units of pharmaceuticals during the year 2022 had been suspended by the Procurement Committee as per the recommendation of the Medical Supplies Division on 09 September 2021 after 06 months from the date of placing the order.

(b) The time frame of remaining 7,625,000 units of pharmaceutical to be supplied in the normal order (2021/SPC/N/R/P/00001) made as receivable in the year 2022 had been revised and the time frame of the pharmaceuticals are to be supplied in the months of June, August, October and November of 2022

had been amended. The supplier did not supply the pharmaceutical within the stipulated time and a questionable situation had arisen due to quality failure of a pre-procured pharmaceutical batch (S-01032). This order, which was not completed within the stipulated time, had been cancelled by the Medical Supplies Division in the year 2023 .

(c) Due to the unavailability of pharmaceuticals in the medical supplies warehouse by the end of May, the emergency order No. 2022/SPC/E/R/P/00488 had been given to the State Pharmaceuticals Corporation to purchase 1,000,000 units of pharmaceuticals at a unit cost of Rs.7.00 to meet the monthly requirement. The pharmaceuticals pertaining to this order had been received in 2023 with a 4 months of delay and the emergency procurement made at a high cost of Rs. 7,000,000 for one month's consumption had been uneconomical.

(d) The order No.2022/SPM/N/R/P/00079 had been issued by the Medical Supplies Division on 21 September 2022 for the purchase of 3,000,000 tablets unit at a cost of Rs.5.78 each from the State Pharmaceutical Manufacturing Corporation due to delay in the above emergency procurement. For that order, the order was placed 10 days before the date the pharmaceutical was to be supplied, and accordingly, sufficient and reasonable time had not been given to the Manufacturing Corporation to manufacture and supply the pharmaceutical. After the State Pharmaceutical Manufacturing Corporation started supplying the above pharmaceuticals in January 2023 and supplied 622,100 tablets, the pharmaceuticals were received by the Medical Supplies Division under the emergency procurement which was carried out at a high cost.

(e) Not even a unit of pharmaceutical had been received through the procurements for the year 2022 and, after the delay in importing and supplying pharmaceuticals through emergency procurement, the Medical Supplies Division had resorted to procure the pharmaceuticals from the local manufacturer of the government.

27. Miconazole oromucosal gel 40 g Tube/Container (SR No. 01001801)

(a) This order dated 15 February 2020, with an estimated value of Rs.4,814,370, was received by the State Pharmaceuticals Corporation on 21 February 2020 as the normal order for the year 2021. According to this order, 20,000 units on 04 January 2021 and 13,000 units on 01 June 2021 were to be supplied. For this procurement, the Corporation had invited bids on 03 May 2020 through the Global Tender and the bidding had been completed on 16 June 2020. Two bidders had appeared for this procurement and the bids were evaluated by the Technical Evaluation Committee on 06 November 2020. According to the letter of the Director of Medical Supplies dated 23 April 2020, the

Medical Supplies Division had increased the quantity of this order to 43,750 units on 21 May 2020. Accordingly, 23,750 units should have been supplied on 04 January 2021 and 20,000 units on 01 June 2021. The Departmental Procurement Committee dated 16 December 2020 had selected the bidder who had submitted the lowest price and the Procurement Committee had decided to purchase 22,000 units at a price of US$ 0.795 per unit for a total value of US$ 17,490 . The following observations are made in this regard.

(i) The agreement to award the order dated 01 January 2021 to the supplier had been accepted on 05 January 2021 and there, although the supplier had requested to waive the inspection of the sample before the shipment, the approval had not been given. The Medical Supplies Division had revised the time table of this order by the email letters dated 28 January 2021 and 02 March 2021. Accordingly, as per the Indent DHS/NV/300/2021 dated 13 May 2021, a number of 22,000 units should have been supplied by 31 July 2021. However, although the time of the order had been revised again in the letter sent by the Director of the Medical Supplies Division dated 23 June 2021, the supplier had not agreed to it, and although the stock of pharmaceuticals had been supplied to the Medical Supplies Division on 31 March 2022, the relevant National Drug Quality Assurance Laboratory report had been received in on 22 March 2023. According to the report, the Medical Supplies Division and Maharagama Cancer Hospital were informed to withdraw the pharmaceuticals immediately due to non-compliance with British pharmaceuticals specifications.

(ii) The Medical Supplies Division had distributed 17,561 packs of pharmaceuticals to government hospitals and institutions up to 18 December, 2022 even at the time of the above notification on 22 March 2023. Accordingly, although 8,198 packs of this pharmaceutical were withdrawn from use due to the failure of the quality, the remaining 13,802 packs were released for use by patients. It was further observed that the lives of the patients were put at risk by not conducting the quality tests of the pharmaceutical promptly and failure to take actions to distribute the pharmaceuticals after obtaining the test reports.

(iii) Actions had not been taken even by 08 November 2023 by the date of audit to recover an administrative charge of 25 per cent along with the total unloading cost from the supplier as per condition 3.3 of the contract in respect of the failed stock in the above condition.

(iv) Despite 22,000 units imported from the above order had to be withdrawn due to failure of quality, the Departmental Procurement Committee dated 13 October 2023 had given approval to order the remaining 21,750 units which were not yet supplied in the order, from the same supplier on the basis of pre-shipment sample testing from an independent laboratory.

(b) As per the emergency order dated 28 February 2023 with an estimated value of Rs.1,304,100 issued by the Medical Supplies Division, a number of 7,500 packs of the above pharmaceutical should have been supplied on 10 March 2023 due to non-receipt of the normal orders in the years 2022 and 2023. It was not observed that information on calling quotations for this was available in the relevant file and according to the bid invitation the date was mentioned as 15 March, 2023 and the bid closing date was 17 March 2023 and it was observed that only 03 days were given for the bid. Only one bidder had submitted the quotations for this and the Technical Evaluation Committee dated 28 March 2023 had informed that bidder to be awarded the procurement and to negotiate a reduction in the offered price. The Procurement Committee dated 12 April 2023 had decided to award the procurement to the sole bidder as the bidder had agreed to reduce the price of a pack from Rs.1,600 to Rs.1,250. Nevertheless, it was observed an increase of 619 per cent in price as compared to the estimated unit cost. In the normal order made in the year 2023, thus the price decided to buy this pack was Rs. 247.50, a price increase of 405 per cent was observed from the price of a unit of the normal order by deciding to buy pharmaceutical through an emergency order, and as a result, the additional cost to be borne was Rs. 7,518,750 .

(i) According to the Indent No. LP/DHS/EP/3736/2023 dated 12 May 2023, although this stock should have been supplied on 08 June 2023, the supplier had not obtained the Waiver of Registration of the National Medicines Regulatory Authority even by then.

(ii) During the computer system check even on 12 March 2024, the stocks related to this order had not been received. Also, as a result it was announced a stock of 22,000 packs in relation to the order of the year 2021 received on 01 April 2022 to be withdrawn from use on 22 March 2023, this pharmaceutical remained zero in stock from that date according to the Swastha System in the Medical Supplies Division and at the National Level even by the audit date of 12 March 2024.

28. Timolol Eye Drops 0.5% 5ml vial (SR No.00901702)

The normal order related to the year 2022 had not been executed and an order of 80,000 units of this pharmaceutical at an estimated cost of Rs.2,958,400 had been placed by the Medical Supplies Division on 25 March 2022. According to the order, 40,000 units were expected to be obtained by 30 April 2022 and 40,000 units by 30 June 2022 under Indian Credit Line. In the calling of bids conducted in this manner, bids were submitted by 03 institutions and the bid was awarded to the tenderer who submitted the lowest price of US$ 12,960 at the price of US$ 0.162 per unit, subject to obtaining the Waiver of Registration of the Pharmaceuticals Regulatory Authority for the pharmaceutical. The supply schedule related to this procurement had been revised by the Medical Supplies Division and the supplier had been informed in this regard through an email letter dated 08 June 2022. According to that, although 40,000 units should have been supplied immediately and the remained within 02 months, it was not possible to get the supplies accordingly. Although this procurement was done as an emergency procurement with the aim of obtaining stock immediately, the Waiver of Registration of National Medicines Regulatory Authority for the supplier had been issued on 26 September 2022. Accordingly, the Indent No. DHS/ICL/IG/296/22 dated 27 September 2022 was issued and 40,000 units of pharmaceutical should have been supplied by 30 November 2022 and 31 December 2022. However, this stock was received at the same time by the Medical Supplies Division on 30 May 2023 after a delay of 06 months from the date of requesting of the stock in that Division.

29. Nepafenac Ophthalmic Suspension 0.1per cent 3ml - 5ml vial (SR No.00903201)

Even though it was expected to receive 87,500 units of the above pharmaceutical with regard to the normal order of 2021, considering the decrease in demand for the pharmaceutical due to the Corona epidemic, it had been decided to receive only 30,000 units on 08 April, 2022 and to suspend the import of the remaining 57,500 units. It was observed that a normal order related to the year 2022 had not been executed. As per the above order dated 25 March 2022, a number of 45,000 vials of this pharmaceutical had been requested at an estimated cost of Rs.45,000,000 in anticipation of purchase under India Loan Line. Under this, 22,500 vials were expected to be received on 30 April 2022 and 22,500 vials on 30 June 2022. Tenders were invited in this regard through a newspaper advertisement and from registered Indian suppliers and only 04 days were given during the invitation of bids. Accordingly, only one bidder had submitted bids. The Technical Evaluation Committee Report dated 22 April 2022 had been given and 21 days had been spent for it from the date of opening of bids. The Departmental Procurement Committee had met on 25 April 2022 and had decided to negotiate with the sole bidder. Accordingly, since the supplier had agreed to reduce the bid price from Rs.670 to Rs.636.50 per unit, it had been decided to award the bid for US$ 95,791.50 for 45,000 units at US$ 2.1287 per unit. Indent No. DHS/ICL/AMS/186/2022 was issued on 31 December

2022 and a number of 22,500 vials had to be supplied on 31 October 2022 and 22,500 on 31 December 2022. However, the related vials of pharmaceutical were received by the Medical Supplies Division on 30 May 2023 after a delay of 07 months. The following matters were observed in this regard.

(a) The opportunity to get competitive prices for the bid was lost by giving a short period of 04 days for inviting bids.

(b) Due to non-execution of normal orders related to the years 2021 and 2022 and decision to award the bid to the only bidder who submitted bids, an increase of 338 per cent was observed compared to the price of the last normal order because it had to award the bid at US$ 1.6438 higher than the previous supply.

(c) Even though a bid of Rs.670 had been submitted for the above bid, the bid had been awarded to the same bidder due to the agreement to reduce the price to Rs.636.50, the actual cost of Rs.668.59 per unit had to be incurred because it had to pay in dollar terms. Accordingly, it was observed that it was not possible to save the amount expected to be saved by awarding the bids.

30. Epirubicin HCL Ing 10mg vial (SR No. 01201201)

(a) Activities had been commenced to purchase a number of 250 units in relation to this pharmaceutical under the normal order of 2022 and despite the procurement was stopped as per the letter dated 23 September 2021 from the Director of the Medical Supplies Division, the Medical Supplies Division had made a request through the system to the State Pharmaceuticals Corporation on 25 March 2022 to purchase under the Indian Credit Line. Accordingly, it was stated that it was necessary to obtain the stock of pharmaceuticals on 01 October 2022, and according to the procurement notice on 26 March 2022, the calling quotation was completed on 31 March 2022. When the bids were opened on that day, only one supplier had submitted the quotation and the certificate of National Medicines Regulatory Authority had not been obtained. The Technical Evaluation Committee report of the procurement was submitted on 26 April 2022 and the Procurement Committee met on the same day. In this procurement, only 4 days were given to submit the quotations and almost a month was spent to evaluate the bids. Therefore, it was observed that it was not possible to get competitive suppliers. The Minor Procurement Committee had decided to reduce the bid price of Rs.6,700 per unit submitted by the supplier and accordingly, decided to reduce the price to Rs.6,365 per unit. The estimated price of this pharmaceutical was Rs. 667.09 and it was observed that this supply price is an increase of 854 per cent of that price. According to the Technical Evaluation Committee and the Procurement Committee, the nearest purchase price of the pharmaceutical was Rs.608. The Procurement Committee had decided to purchase 250 vials at Rs.6,365 on 15

June 2022, fifty days after the original procurement. It was observed that the Procurement Committee had worked in a slow manner regarding the procurement of this pharmaceutical and the tender offer letter to the relevant supplier was made on 25 July 2022 that is more than a month after the procurement and the relevant supplier accepted the offer on 26 July 2022. It was observed that the Procurement Committee had forwarded the Indent to the relevant manufacturer on 07 September 2022 and it was after the expiry of nearly 03 months after the procurement. Even though the selected bidder for this pharmaceutical had obtained the Waiver of Registration of the National Medicines Regulatory Authority, due to the Authority which had issued this certificate had transferred the responsibility regarding the quality, safety and efficacy of this pharmaceutical to the Technical Evaluation Committee and the Procurement Committee, the institution had ruled out from its responsibility.

(b) It had been requested through the system on 16 November 2022 to obtain 500 vials of the above pharmaceutical for the normal requirement of the year 2023 and the request was made in writing on 22 November 2022. When the Medical Supplies Division submitting this request, it had informed that 300 vials need to be obtained by 12 January 2023 and 200 vials by 12 April 2023. A quotation was called on 13 February 2023 for obtaining these pharmaceuticals and although 11 days were given for it, about 10 weeks were spent for the procurement decision. The Procurement Committee had decided on 09 May 2023 to purchase 500 vials of injection at a cost of Rs.1,687 per vial at a total cost of Rs.843,500. It was a price increase of 150 per cent compared to the estimated price of Rs.676. It is stated that there was no any stock in the Medical Supplies Division or nationally by the time this Procurement Committee met on 09 May 2023 and the supplier should also have obtained the Waiver of Registration (WOR) from the National Medicines Regulatory Authority. This procurement had been offered on 02 June 2023 and by that time, 03 weeks had elapsed since the decision of the Procurement Committee was received. An Indent had not been issued for this even by 15 November 2023.

Subsequently, according to the order dated 02 February 2023 the Medical Supplies Division had stated that 175 injections of this pharmaceutical need to be purchased by 15 February 2023. Accordingly, the bidding process was commenced on 15 February 2023 and closed on 17 February 2023 to procure this pharmaceutical as an emergency purchase. Although only 03 days were given for the quotation, the procurement decision was given on 21 March 2023, more than a month was spent for the procurement. The following matters were further observed in this regard.

(i) Even though the supplier who had submitted the second lowest price was approved to purchase 175 vials of injection for Rs.3,040 per each totaling to Rs.532,000 based on a Waiver of Registration of the National Medicines Regulatory Authority, it was observed that this procurement price was a Rs.349 per cent price increase more than its estimated price of Rs.676.

(ii) According to the Indent dated 21 April 2023, although these pharmaceuticals had to be received on 28 May 2023, it was observed that they were received on 04 August 2023. It was informed that the supply of pharmaceuticals could be done within 02 weeks in accordance with the bid documents given by the selected bidder in relation to this emergency procurement and although the procurement was offered taking this into consideration while selecting the supplier, the supply was delayed for more than 02 months from the date on which the stock was to be supplied.

(iii) In case of failure of the performance of the contract in accordance with the Guideline 5.4.10(b) of the Government Procurement Guidelines, although a performance security is to be furnished and a performance security is required to be obtained as per clause 6 of Part Two of the bid invitation in order to protect the integrity of the procurement in the event of failure of contract performance, due to the fact that 10 per cent of the value to be paid to the supplier has been asked to be retained for up to 30 days after the completion of the supply instead of getting a performance security as per the recommendation of letter No. SH/PSRP/01/SPC/2021 dated 10 January 2023 of the Secretary, Ministry of Health, actions had not been taken to obtain a performance security.

(iv) Even though the Waiver of Registration No. NMRA/EA/WOR/MED/SPC/03/025/23 dated 09 June 2023 had been received, it was observed in audit that the by transferring the responsibility for the quality, safety and efficacy of the procurement of this pharmaceutical to the related Technical Evaluation Committee and the Procurement Committee by the National Medicines Regulatory Authority, which issued this certificate had ruled out from its responsibility.

(c) A request had been made on 30 January 2023 for the emergency purchase of 250 vials of the above pharmaceutical by the Medical Supplies Division. For this, the Health Emergency Procurement Committee had been appointed on 22 March 2023 and bids were invited on 27 March 2023 and only 03 days were given to submit bids. The Technical Evaluation Committee had

evaluated the bids on 24 April 2023, almost 03 weeks after that. The National Medicines Regulatory Authority certificate had not been obtained for all the 06 suppliers who appeared for this procurement and 02 institutions had submitted the National Medicines Regulatory Authority Certificate (NMRA Manufacturing Site Approval) and out of them 20 days from the date of evaluation of bid that is on 12 May 2023, the Ministry of Health Emergency Procurement Committee had given the decision to purchase 250 units at Rs.2,948 per unit to the institution that submitted the lowest price. This procurement price had increased by 336 per cent as compared to its estimated price of Rs.676. In the Procurement Committee dated 12 May 2023, even though it had been mentioned that there is no stock of this item and as a result the procurement should be done without delay, as per the above procurement decision, an Indent had been issued on 16 June 2023 that is more than a month after the procurement. Even though the Waiver of Registration related to this order had been requested on 04 September 2023, there was no information in the file that it had been received. However, according to the Indent, although the pharmaceuticals should have been received by 30 July 2023, the stock of injections had not been received until the audited date of 06 October 2023. According to the Swastha System, these stocks had not been received even by 11 March 2024 .

(d) The Medical Supplies Division had placed an order for 1,500 units of the pharmaceutical on 25 May 2023, and the Health Division Emergency Procurement Committee had appointed on 15 June 2023 in anticipation of purchasing under Indian Credit Line. The acceptance of bids was completed on 16 June 2023 and Technical Evaluation Committees had been held on 27 June, 2023. The Procurement Committee had met on 28 June 2023 and the Emergency Procurement Committee had decided to award the procurement to the organization that submitted the second lowest price out of the 06 suppliers who had the certificate of the National Medicines Regulatory Authority. Accordingly, it was decided to purchase 1,500 injections at Rs.1,500 per injection. It was observed that it was a 122 per cent higher price increase as compared to the estimated price of Rs.676. Although this was an emergency procurement, the Indent thereon was issued on 07 September 2023, after a delay of 2 months the procurement decision was received. According to the Indent, although these pharmaceuticals were to be delivered on 11 December 2023, the stock was received on 19 February 2024 after a delay of 02 months . According to the above facts, a slow form was observed in the process of purchasing these pharmaceuticals , even though it was seen as an urgent need.

31. Natamycin Ophthalmic Suspension 5% in 15 ml Dropper Bottle (SR No.00904901)

(a) A normal order related to the year 2022 was not executed and according to the order dated 25 March 2022 it had been expected to procure 19,000 vials of pharmaceutical at a total cost of Rs.6,659,120 on 30 April 2022 and 9,500 units each on 30 June 2022 under the Indian Credit Line. In this regard, the bids were called on 26 March 2022 and opened on 31 March 2022. Only one supplier had submitted bids and as there was a huge difference between the estimated price and the previous delivery price of bid price per unit as per the decision of the Technical Evaluation Committee dated 26 April 2022 and the decision of the Departmental Minor Procurement Committee dated 27 April 2022, actions had been taken to negotiate with the supplier.

(i) The calling for quotation was implemented as an emergency procurement and it was observed that due to providing a short period such as 04 days for the calling of bids, this procurement was not directed towards proper competition. The supplier had agreed to reduce the price per unit from Rs.970 to Rs.893 and the Procurement Committee dated 15 June 2022 had decided to purchase 19,000 vials at US$ 2.99 per unit for a total cost of US$ 56,810 at that price. As a result, it had to pay 248 per cent more per unit than the last nearest purchase price and 154 per cent higher than the estimated unit price.

(ii) Despite the bids were invited as an urgent purchase and the bidder was informed that they could supply within 14 days of submitting the bid, as it was informed that 9,500 units should be supplied on 30 November and 30 December 2022 as per the Indent dated 31 October 2022 the audit did not observe this procurement as emergence. However, it was observed that the stock of pharmaceuticals had not supplied on the above dates and, the stock of pharmaceuticals was supplied simultaneously on 04 April 2023 after a delay of about 04 months.

(iii) Even though the bid related to the above procurement was presented in rupees, it was observed that due to having to pay in US dollars, it had to pay Rs.990.82 per unit. Due to this, it was not possible to get the expected savings and it had to pay Rs.97.82 more than the deducted bid price, that is the total value of Rs.1,858,580 .

(b) According to the order dated 15 November 2022 regarding the purchase of 10,000 units of this pharmaceutical under the normal order of 2023, it was expected to procure 10,000 units of pharmaceutical as 5000 units each at a total estimated cost of Rs.3,504,800 on 10 January 2023 and 03 April 2023. Bids were invited in this regard on 21 December 2022 and the bidding had been closed on 05 January 2022. Accordingly, two bidders had submitted the

prices and the Departmental Procurement Committee dated 23 January 2023 had decided to award to the lowest bidder who submitted Rs.750 vials of pharmaceutical with a shelf life of 18 months at a total cost of Rs. 7,500,000. The unit price of the bidder was observed to be 113 per cent higher than the estimated unit price. However, the bid awarding letter dated 20 February 2023 had been sent by fax and accordingly it was stated that 5,000 units should be supplied immediately and the remaining 5,000 units after 02 months. According to the letter dated 01 March 2023 sent by the institution, it was informed that 5,000 units will be supplied in May 2023 and the remaining units will be supplied within 60 days after payment for the first stock. It was observed during the audit that due to the delay in settling the bills of Rs. 437.7 million for the pharmaceuticals purchased from 2018, the above supplier had delayed the supply of pharmaceuticals. At this time, it was observed that the pharmaceuticals in the Medical supplies Division were in zero condition and it was observed that this stock shortage situation continued until the 19,000 units of pharmaceuticals given in relation to an order in 2022 receive on 04 April 2023. According to the Swastha Computing System, an Indent had not been issued in relation to the above order even by 12 March 2024.

32. Chlorambucil Tabs BP/usp 2mg (SR - 01200201)

(a) An order dated 25 March 2022 had been submitted to the State Pharmaceuticals Corporation for the purchase of 30,000 tablets of this pharmaceutical under the Indian Credit Line with an estimated value of Rs.10,309,500 as the annual requirement of the year 2022. A number of 10,000 tablets each were to be supplied on 01 April 2022, 31 August 2022 and 30 November 2022. Bids were invited on 26 March 2022 for this procurement. Two bidders had appeared for the procurement and the Technical Evaluation Committee had evaluated the bids on 31 March 2022. The Departmental Minor Procurement Committee dated 27 April 2022 had selected the lowest bidder who did not have a valid registration with the National Medicines Regulatory Authority and informed to obtain approval for supply of pharmaceuticals under the Indian Credit Line.

(i) Even though the selected bidder for this pharmaceutical had obtained the Waiver of Registration from the National Medicines Regulatory Authority, it was the observed in audit that the Authority, which issued this certificate, had ruled out from its responsibility by transferring the responsibility regarding the Quality, Safety and Efficacy of this pharmaceutical to the Procurement Committee and the Technical Evaluation Committee.

(ii) The State Pharmaceuticals Corporation had sent an email on 02 June 2022 asking for the agreement to supply pharmaceuticals under the Indian Credit Line and a period of 36 days had been spent for that from the procurement decision. The Procurement Committee dated 15 June 2022 had approved the purchase of a tablet for Rs. 551 equivalent to US$ 1.84 after the supplier had agreed to reduce the price by 5 per cent. The order awarding letter was issued on 25 July 2022 and a period of 40 days had elapsed since the procurement approval.

(iii) Even though 30,000 tablets had to be supplied by 30 November 2022 as per the Indent, the stock of pharmaceuticals had been supplied to the Medical Supplies Division on 19 May 2023. Nevertheless, the Swastha Computer System had not been updated regarding the stock receipts even by 12 March 2024,. Due to non-delivery of the stock of pharmaceutical related to this order on the proper date, it had to arrange an emergency purchase for that year.

(b) The emergency order of 2,500 units of this pharmaceutical with an estimated value of Rs.859,125 issued by the Medical Supplies Division had been submitted to the Corporation on 28 June 2022 due to not receiving the pharmaceuticals ordered under the Indian Credit Line within the given time frame. By now, according to the MSMIS Computer System, the stocks of the Medical supplies Division were at zero. It had been decided to re-bid due to lack of a registration certificate and non-submission of samples by both the suppliers who appeared for the procurement.The following observations are made in this regard.

(i) As this pharmaceutical is given to cancer patients as well and also the hospitals currently do not have stock and also it was stated in the bid document that the previous supplier can supply the pharmaceutical within 15 days, the bid price of Rs.3,100 per tablet was reduced to Rs.2,000 in negotiation with that supplier and the approval was given by the Health Sector Emergency Procurement Committee dated 16 August 2022. It was observed that the unit cost of this supplier's emergency procurement was 262 per cent higher than the previous procurement unit cost and 482 per cent higher than the estimated unit cost.

(ii) Although it was an emergence purchase, the Indent was issued to the supplier on 30 August 2022 after a delay of 15 days from the procurement decision. Accordingly, although it was stated that 2,500 tablets of the pharmaceutical should be supplied on 05 October 2022, this pharmaceutical was received by the Medical Supplies Division on 15 November 2022, after a period of one month.

(iii) Even though the Technical Evaluation Committee had rejected both the suppliers, and also the Procurement Committee had considered only the ability to supply the pharmaceutical in 15 days while selecting the bidder, it had taken 89 days from the date of the procurement decision for the supplier to supply the pharmaceutical to the Medical Supplies Division.

(iv) It was observed that the manufacturer of both the bidders was the same Indian company and due to the fact that the lowest bidder who was not selected had informed that he could supply the pharmaceutical within a period of 45 days from the date of opening of the Letter of Credit though he was rejected, it was observed that the selected supplier had not supplied within 15 days and the State Pharmaceuticals Corporation had given a period of 35 days while issuing the Indent. Accordingly, a sum of Rs.5,000,000 had to be spent for 2,500 tablets and the additional cost that the government had to spend by not selecting the lowest bidder was Rs.3,618,025 .

(v) Although an emergency procurement was resorted due to not receiving the annual requirement order within the planned time, it was observed that the same order had been awarded to the supplier who had awarded the annual order, and it was observed that the main order was deliberately delayed and resorted to an emergency procurement.

(vi) Even though the bidder was selected by the decision of the Procurement Committee dated 16 August 2022 subject to checking the quality of the pharmaceutical, since this pharmaceutical could not be checked in the laboratory belonging to the State Pharmaceuticals Corporation, a request was made in writing to check it in the National Medicines Quality Assurance Laboratory and, an amount of Rs.427,348 had been paid to the State Pharmaceuticals Corporation by the supplier for that on 20 March 2023. However, the aforesaid laboratory had informed that this pharmaceutical cannot be tested because it is a cytotoxic pharmaceutical to living cells. Accordingly, the State Pharmaceuticals Corporation had submitted a proposal to the Procurement Committee on 26 June 2023 to remove these conditions. The Emergency Procurement Committee of Health Sector had decided to cancel the condition of testing a sample due to the fact that the stocks of pharmaceuticals had been received by the Medical Supplies Division in November 2022 and were currently being used in hospitals. Even though the selected bidder had obtained the Waiver of Registration of the National Medicines Regulatory Authority, the Authority, which issued this certificate has transferred the

responsibility on the quality, safety and efficacy of this pharmaceutical to the Procurement Committee and Technical Evaluations Committee, the audit observed that the institution has ruled out from its responsibility and it was further observed that this pharmaceutical was used without any quality check and due to this, the damage or effect caused by the use of this pharmaceutical which was given to cancer patients could not be checked during the audit.

(c) Due to the fact that the annual order for 2023 had not been received by January 2023, the Medical Supplies Division had forwarded an order to the State Pharmaceuticals Corporation on 30 January 2023 to purchase 7,500 tablets of the above pharmaceutical with an estimated value of Rs.2,577,375 as an emergency order. Accordingly, 7,500 tablets should have been supplied on 01 February 2023. The quotations were called for this procurement on 27 March 2023 and about 04 days were given for it. It was observed that a period of 55 days had been spent for calling the quotations from the date of submission of this order. Four bidders had submitted quotations for the procurement. However, the relevant Technical Evaluation Committee was appointed by the Ministry of Health on 20 April 2023. The following observations are made in this regard.

(i) The Health Sector Emergency Procurement Committee dated 12 May 2023 had selected the third lowest bidder who did not have a valid National Medicines Regulatory Authority Certificate However, bearing approved Manufacturing Site Approval of the National Medicines Regulatory Authority and the bid for the annual order 2023 had also been awarded to the Indian manufacturer of that local agent. However, the file did not include the information on a certificate of Waiver of Registration of the National Medicines Regulatory Authority was received even by the date of audit, 26 September 2023.

(ii) The Indent dated 22 June 2023 had been issued 39 days after the decision of the Procurement Committee and accordingly, although 7,500 tablets of this pharmaceutical should have been supplied on 24 July 2023, the stock of this pharmaceutical had not been received to the Medical Supplies Division according to the Swastha System even by 11 March 2024, the date of audit.

(d) The order for the purchase of 5,000 tablets at an estimated cost of Rs.1,718,250 using the money given by Foreign Employment Bureau to Ministry of Health to purchase cancer items for cancer patients in government hospitals, had been issued to the State Pharmaceuticals Corporation on 02 February 2023. Accordingly, the quantity of 5,000 tablets should have been supplied by 15 February 2023. Bids were invited for this procurement on 15

February 2023 and 3 bidders submitted their prices. The Technical Evaluation Committee had evaluated the bids on 24 February 2023, and the Health Sector Emergency Procurement Committee dated 09 March 2023 had rejected the bidder who had submitted the lowest price due to submitting of 2 bids and the bidder who submitted the second lowest price had been selected as the successful bidder. The Indent related to this was issued on 21 April 2023 and accordingly, 4,980 tablets should have been supplied on 26 May 2023. However, according to the Swastha System, the stock of pharmaceuticals had not been received even by 11 March 2024, the date of audit.

33. Epirubicin Hydrochoride Injection 50 mg (SR No. 01201202)

(a) A normal order of 2022 had not been executed and the Medical Supplies Division had ordered through the System on 25 March 2022 to the State Pharmaceuticals Corporation to procure 1,000 units of this injection by 01 December 2022. The procurement process had been commenced on 26 March 2022 to purchase under the Indian Credit Line and only 04 days had been given for inviting bids. Bid opening and evaluation was done on 31 March 2022. For this, three suppliers had submitted the quotations and the Departmental Procurement Committee dated 26 April 2022 had decided to award the bid to the supplier with NMRA certificate for the respective pharmaceutical for a total value of US$ 18,000 that is Rs.6,498,000 for injections at US$ 18 each. The previous nearest price was Rs.1,460 for an injection. The bid price of a pharmaceutical unit was Rs.6,498 and the estimated price of a unit of pharmaceutical was Rs.1,325, it was observed that the procurement was given at a price 390 per cent higher than the estimated price. An Indent dated 31 August 2022 had been issued and according to that, although the stock of pharmaceuticals should have been supplied on 30 November 2022, it had been received on 07 March 2023. Although the bid related to the above procurement was submitted in rupees, it was observed that, though the bid price was Rs.6,498 per unit, it had to pay Rs.6,637.86 per unit due to having to pay in US$ term.

(b) The Medical Supplies Division had informed the State Pharmaceuticals Corporation through the system on 16 November 2022 about the normal order required for the 2023 requirement of the above pharmaceutical. The related written request was made on 22 November 2022 and according to the order, 2,000 vials of injection were expected to be procured by 12 January 2023 and 12 April 2023. The Departmental Procurement Committee of the State Pharmaceuticals Corporation had called for limited quotations from registered suppliers on 22 February 2023. The decision of the Departmental Procurement Committee had been given on 15 June 2023 and it was decided to purchase 4,000 vials of injections at a total cost of US$ 30,000 at US$ 7.50 per each injection. Accordingly, the bid price of a vial of injection was Rs.2,529.65 and

thus the estimated price was Rs.1,446.76, the bid was awarded at a price 74 per cent higher than the estimated price in this procurement. According to the Swastha Computer System, the Indent had not been issued even by 11 March 2024. According to the Swastha Computer System, the Indent pertaining to this procurement had not been issued even by 11 March 2024 .

(c) Due to non-availability of pharmaceuticals for the normal procurement executed in 2023 for the purchase of these injections, the Medical Supplies Division had submitted an Indent as an emergency procurement on 30 January 2023 for the purchase of 2,000 units of this injection. The procurement activities had been started on 27 March 2023 and the bids were opened on 30 March 2023. Six suppliers had submitted their quotations. After a period of 03 weeks from that date, the quotations were submitted to the Evaluation Committee. It was decided to buy 2,000 injections for Rs.8,840,000 from the supplier who offered the third lowest price at Rs.4,420 per injection. The bid had been awarded at a price 205 per cent higher than the estimated price thus the estimated price of a vial of injection was Rs.1446.76. According to the Indent, although these injections should have been received by 26 July 2023, a Waiver of Registration of the Pharmaceuticals Regulatory Authority was requested on 13 July 2023 and there was no evidence that they were received until the date of audit . The respective stock of pharmaceuticals had not been received even by 11 March 2024 .

(d) A request had been made through the System on 02 February 2023 to obtain 1,350 vials of injections as an emergency purchase in the event that pharmaceuticals for 02 orders of 2023 were not received and, the procurement activities were commenced on 15 February 2023 and bids had been opened on 17 February 2023. On the same day, the recommendation was given to the Price Evaluation Committee. Only three suppliers had submitted bids and none of them had submitted the NMRA certificate. Only the company that submitted the second lowest price had submitted Manufacturing Site Approval and the Emergency Procurement Committee which met on 05 March 2023 agreed to purchase 1,350 vials at Rs.5,098 for Rs.6,883,218 and the bid had been awarded on the conditions of a price revision and submission of Waiver of Registration from the National Medicines Regulatory Authority subsequently. The Indent had been issued on 21 April 2023 after elapsing of 06 weeks. It was observed that the bid had been awarded at a price of 252 per cent higher than the estimated price thus the estimated price of a unit of this pharmaceutical was Rs.1446 .

(i) It had been informed in accordance with the bid documents given by the selected bidder in relation to this emergency procurement that, the supply of pharmaceuticals could be done within 02 weeks and it was observed that this had been taken into consideration while selecting the

supplier. According to the Indent, 1,350 vials for Rs.5,098 each should have been supplied by 28 May 2023 at a cost of Rs.6,883,218. However, since the pharmaceuticals were received on 14 August 2023, the supply had delayed by about 10 weeks from the date the stock was supposed to be supplied.

(ii) Although a performance security should be furnished and a performance security should be obtained as per Section 6 of Part Two of the Bid Invitation Document in order to protect the procurement entity in the event of failure of contract performance, in term of Guideline 5.4.10 (b) of the Government Procurement Guidelines, due to the fact that 10 per cent of the value to be paid to the supplier has been informed to be retained for up to 30 days after the completion of the supply instead of obtaining a performance security on the recommendation of the Secretary, Ministry of Health letter No. SH/PSRP/01/SPC/2021 dated 10 January 2023, actions had not been taken to obtain a performance security.

(e) A quotation was called on 14 June 2023 as an emergency purchase that had been applied for through the System on 25 May 2023 for the purchase of 6,300 units of this pharmaceutical and the Technical Evaluation Committee had given recommendations on 22 June 2023. According to the recommendation of the Technical Evaluation Committee, the Emergency Procurement Committee had decided to award the bid at Rs.5,100 per vial to the bidder who is the only bidder holding a valid NMRA certificate as per the procurement decision dated 28 June 2023. Even though it was implemented as an emergency purchase under the Indian Credit Line and also the stock of pharmaceuticals should have been received on 11 December 2023 according to the Indent issued on 08 September 2023 that is after 09 weeks of the procurement decision, the stock was received after 02 months according to the Swastha Computer System.

34. Tropicamide 0.8% with phenyl Phrine hyarochooloride 5% eye drops 5ml dropper bottle (SR No. 00901501)

Due to non-receipt of part of the 2023 annual order of this pharmaceutical by January, an emergency order dated 28 February 2023 for 10,500 units of pharmaceuticals with an estimated value of Rs. 2,261,175 issued by the Medical Supplies Division was received on 01 March 2023 to the State Pharmaceuticals Corporation. This order was supposed to be delivered on 10 March 2023. For this purpose, bids were invited on 15 March, 2023 and the bidding was completed on 17 March 2023. However, the related technical evaluation committee was appointed on 27 March 2023. The Health Sector Emergency Procurement Committee held on 12 April 2023 selected the third lowest bidder as the successful bidder as the two lowest

bidders did not have valid registration certificates out of three bidders. The following matters were observed in this regard.

(a) It was informed that the pharmaceutical could be supplied within a week in accordance with the bid documents provided by the selected bidder in relation to this emergency procurement, and it was observed that this was taken into consideration while selecting the supplier. The Indent was issued on 12 May 2023 regarding the aforesaid procurement and the stock was to be delivered on 18 May 2023.However, the consignment was received by the Medical Supplies Division on 20 September 2023. Accordingly, the stock was supplied with a delay of 125 days from the date it was supposed to be supplied.

(b) Although a performance security should be furnished and a performance security should be obtained as per Section 6 of Part Two of the Bid Invitation Document in order to protect the procurement entity in the event of failure of contract performance in term of Guideline 5.4.10 (b) of the Government Procurement Guidelines, due to the fact that 10 per cent of the value to be paid to the supplier has been informed to be retained for up to 30 days after the completion of the supply instead of obtaining a performance security on the recommendation of the Secretary, Ministry of Health letter No. SH/PSRP/01/SPC/2021 dated 10 January 2023, actions had not been taken to obtain a performance security.

(c) Even though it had been stated in the supplier's valid registration certificate issued on 21 September 2022 that the maximum retail price at which this vial should be sold was Rs.650, a vial was supplied at Rs.900, in this supply. The estimated price of a vial was Rs.215.35 and the previous supply price was Rs.299.42, and since the price of a vial was Rs.900 during the emergency purchase, the emergency purchase price was 318 per cent higher than the estimated price and 200 per cent higher than the previous supply price.

35. Brinzolamide Eye drops 1per cent in 5 ml dropper bottle (SR No. 00903001)

The order with an estimated value of Rs.34,260,000 was received as the annual requirement for the year 2022 to the State Pharmaceuticals Corporation on 25 March 2022. According to this order, 40,000 vials were to be supplied on 30 April 2022 and 30 June 2022 each. Bids were invited on 26 March 2022 and closed on 31 March 2022 for purchase under Indian Credit Line for this procurement. Only one supplier had submitted bids for the procurement. The Technical Evaluation Committee had evaluated the bids on 22 April 2022, and the Committee had noted that the bid price was higher than the maximum retail price mentioned in the registration certificate of the National Medicines Regulatory Authority. After 22 days from the date of opening of bids, the bids were evaluated and the Departmental Procurement Committee dated 28 April 2022 had informed to receive the consent to reduce the price with the lowest

bidder and offer the prices to be given in US Dollars. After 21 days of the decision of the Procurement Committee that is 19 May 2022, the Additional Secretary (Procurement) had given the approval and the letter was sent to the bidder inquiring about the agreement on 27 May 2022 after a delay of 30 days. From the letter forwarded by the bidder on 07 June, 2023, it was agreed to exempt the bid price and reduce other local charges (Clearing and Local Component Charges) by 5 per cent and submit the price in US dollars. The aforesaid bidder had been selected as the bidder by the Departmental Procurement Committee dated 13 June 2022. Indent No. DHS/ICL/AMS/226/2022 had been issued on 17 August 2022 in relation to that order. Accordingly, 40,000 units should have been supplied by 31 October 2022 and 31 December 2022 each. Accordingly, the first stock of pharmaceutical 40,000 units had been supplied to the Medical Supplies Division on 30 May 2023 after a delay of 07 months. Although the remaining stock of 40,000 units should have been supplied by 31 December 2022, it was supplied on 23 January 2024 .

36. Bentomethasone sodium phosphate for eye, ear or nosal drop 0.1per cent in 5ml vial (SR No. 01000601)

The order dated 15 November 2022 for the purchase of a number of 35,000 vials of this pharmaceutical with an estimated value of Rs.2,431,800 as the annual requirement for the year 2023 had been received by the State Pharmaceuticals Corporation on 17 November 2022. This order should have been supplied 17,500 vials on 10 January 2023 and 03 April each. Bids were invited for this procurement on 19 January 2023 and 3 bidders had appeared. The Technical Evaluation Committee conducted the evaluation on 14 February 2023 and the Departmental Procurement Committee dated 23 February 2023 had selected the lowest bidder with registration certificate . The following matters were observed in this regard.

(a) The Bidder had accepted the order on 16 March 2023 by the order awarding letter dated 09 March 2023. The Indent Number LP/DHS/NV/3665/2023 pertaining to this order had been issued on 23 March 2023. Accordingly, 17,500 vials should have been supplied on 25 May 2023 and 05 August 2023 each. However, a number of 16,927 vials as the first stock on 27 June 2023 and 18,070 vials as the second stock on 27 September 2023 had been supplied to the Medical Supplies Division. There was no written information in the file that delay charges were made for this.

(b) In checking the Swastha System on 06 October 2023, it was observed that the above order was included under both the order receivable and order received sections and although a remaining receivable stock of 35,003 vials was shown, it was observed that there is no such a receivable stock.

(c) The price per vial of this order had increased by 202 per cent higher than the estimated price and it had been increased by 287 per cent higher than the price per vial of the order 2022 .

37. Pralidoxime Chloride Injection 19/20 ml (SR No. 01601001)

This order dated 15 November 2022, with an estimated value of Rs.2,791,800 as the annual requirement of this pharmaceutical in the year 2023, was received by the Corporation on 24 November 2022. According to this order, a number of 12,000 vials were to be supplied on 10 January 2023. The quotations had been called from the registered and previous suppliers for this procurement on 16 February 2023 and the bidding was completed on 23 February 2023. Only one bidder had appeared for the procurement and the bids were evaluated by the Technical Evaluation Committee on 15 March 2023. Fifty four days after the decision of the Technical Evaluation Committee that was 09 May 2023, the Departmental Minor Procurement Committee had informed to call for bids from the registered and previous suppliers again by fax and e-mail as the price of the bidder was extremely higher than the previous price and estimated price. After 105 days of the procurement decision, the re-bidding process had been commenced by the State Pharmaceuticals Corporation. Accordingly, the bid invitation letters had been sent by fax and email on 27 September 2023 and the bid invitation was completed on 10 October 2023. The Medical Supplies Division had not been able to complete the annual requirement for the year 2023 until October 2023. It was observed that such a situation had arisen due to non-submission of orders within a proper time frame.

38. Morphine Sulphate Injection 15mg/ml Ampoule (SR - 00000807)

In the audit conducted regarding the determination, ordering, purchasing and utilization of the above pharmaceutical, the total estimate for the period from 2019 to 2023 was 3,339,831 units and the No. of units ordered related to that period was 3,083,344. However, it was revealed from the MSMIS Data System that the amount received in relation to the years 2019, 2020 and 2021 was 1,999,988 units. The following observations are made in this regard.

(a) Although the estimated volume in the year 2021 was 757,050 units, the annual order volume was 880,000 units. Accordingly, 122,950 units had been ordered exceeding the estimate.

(b) The estimated amount was 698,499 units in the year 2023, and the annual order amount was stated as 1,020,000 units and the annual order amount was 46 per cent more than the estimated amount, that is 321,501 units. However, these orders had not been supplied even by the date of audit.

(c) Bids were invited for the purchase of 460,000 units for the year 2023 and although it was mentioned according to the Indent dated 11 April 2023, a number of 250,000 units and 210,000 units should be supplied on 30 June and 31 October 2023 respectively, actions had not been taken accordingly.

(d) Even though a normal order for 100,000 units and an emergency order for 50,000 units of this pharmaceutical for the year 2022 had been placed with the State Pharmaceuticals Corporation according to the data provided by the computerized system of Medical Supplies Division, these orders had not been received even by the date of audit.

(e) The annual estimated amount was 651,971 units in the year 2022, and the volume of orders made on two occasions had been 150,000 units. It was also observed that this is a weak situation of preparing estimates to order at a minimum percentage of 23 per cent of the estimated quantity.

(f) Arrangements had been made to order 100,000 units by the Order No. 2022/SPC/N/R/P/00066 for the year 2022 and in this regard, although this order was shown in the computer system of the Medical Supplies Division it was also informed to the audit in writing that the State Pharmaceuticals Corporation (Import Division) had not received during the Covid-19 pandemic. Accordingly, it was observed in audit that the reliability of the information obtained by the Medical Supplies Division Computer System (MSMIS) could not be ascertained.

(g) In checking the stock data in the computer system (MSMIS) owned by the Medical Supplies Division, the Medical Supplies Division did not have any stock related to this pharmaceutical in the year 2022 and attention had not been drawn to maintain a lowest stock level. It was observed during the audit that this was an opportunity to resort to emergency orders.

(h) The purchase of pharmaceutical was carried out under normal purchase in the year 2021 and according to the order, it had been decided to purchase 880,000 units. It had been decided to get this order on 4 occasions and the following observations are made in this regard.

(i) The price per unit was Rs.50.20 for the purchases made on 01 May 2021 and the price of a unit had increased ranging from Rs.92.44 to 93.23 for the purchases made from 17August 2022 to 09 December 2022 related to that order and it was about a price increase of 86 per cent.

(ii) When comparing the dates of goods to be supplied related to this Indent with the dates of goods receipts, delays ranging from 3 months to 17 months were observed.

(iii) The agreement to be signed with the supplier as mentioned in the Public Contracts Act No. 03 of 1987 had not been registered with the Registrar of Companies.

(i) A number of 50,000 units of this pharmaceutical had been purchased under emergency purchases due to the need for continuous supply in the year 2022. In connection with this, the Order No. 2023/SPC/E/R/P/00442 had been issued and the Health Sector Emergency Procurement Committee had awarded bids for purchase of pharmaceuticals from Yaden International (Pvt.) Ltd. The following matters are observed in this regard.

(i) Although the Technical Evaluation Committee had decided to purchase 50,000 units for Rs.24,500,000 under the emergency purchase, even though it had been informed that a valid certificate or a Waiver of Registration should be submitted due to the expiry of the registration certificate of the National Medicines Regulatory Authority, evidence of submission of these certificates was not submitted for audit.

(ii) The Certificate of Good Manufacturing Practices issued by the Government of India for M/S Kwality Pharmaceuticals Limited had revoked on 17 December 2020 and the Certificate of a Pharmaceutical Product had revoked on 11 March 2020 and there may be complications in purchasing pharmaceuticals from such a legally invalid institution and it was observed during the audit that the attention of the parties responsible for the purchase should be drawn.

(iii) The order was placed under emergency purchase despite there was enough stock for 2 ½ months, and again it was cancelled. Accordingly, it is observed in the audit that acting without properly recognizing the needs is a weakness of the management.

(iv) Although the cost for 50,000 units was Rs.2,792,500 according to the order book in the computer system of the Medical Supplies Division , the order had been placed for Rs. 24,500,000 as per the recommendation of the Technical Evaluation Committee. Accordingly, the estimated value had exceeded by Rs.21,707,500 that is 777.3 per cent.

(j) Arrangements had been made to purchase 460,000 units of this pharmaceutical under normal purchase in relation to order No. 2023/SPC/N/R/P/00038 and the following points are observed in that regard.

(i) Although the order cost as per the computer system was Rs. 25,691,000, thus the price at which the order was offered by the State Pharmaceuticals Corporation was Rs. 34,832,593, a price variation of Rs. 9,141,594 was observed in the cost of order . It was observed that this is an increase of 35.58 per cent over the cost of order. Accordingly, it is observed that the preparation of estimates is not being done properly.

(ii) In awarding the order, informing that to supply 300,000 units fresh, the supplier had mentioned through a nominal invoice that he could supply 65,000 units promptly and out of which the expiry date of 49,000 units was June 2024 . As per general conditions No. 05 of the Indent, although it was stated that the remaining shelf life of the stock should be at least 85 per cent at the time of shipment, it is observed during the audit that the shelf life of these stocks may further decrease on the receipt of the stock.

(iii) It is observed that the expected period of supply of this total stock may be exceeded and the performance bond will be cancelled before the stock is received.

39. Doxycycline Cap 100 mg (SR – 00102301)

The estimated quantity for the period from the year 2019 to the year 2023 was 46,609,657 units and even though 34,097,600 units had been ordered in the remaining years except 2021, the Medical Supply Division had received 22,978,600 units related to the years 2019 and 2020. The following points are observed in this regard.

(a) Comparing the amount of annual orders with the amount of annual estimates, there were variances of 61, 171, 53 and 77 per cents in the years 2019, 2020, 2022 and 2023, respectively. Accordingly, it was observed that the preparation of estimates had not been done rationally .

(b) The estimated quantity for the year 2020 was 9,991,070 units and the annual order quantity was 17,097,800 units. Five orders had been made by the Medical Supplies Division. Accordingly, 7,106,730 units had been ordered exceeding the total estimate. A number of 15,353,600 units were received by the Medical Supplies Division and 6,639,500 units were issued and there was a balance of 8,714,100 units.

(c) A number of 33,822 units and 29,187 units were removed due to expiry and failure of quality respectively in the year 2021 .

(d) The pharmaceutical remained in shortage from 26 September 2022 to 03 September 2023 and the it was not revealed in audit that how the number of 5,869,550 units of annual requirement 2022 and the number of 10,338,322 units annual requirement 2023 were met in the health system in the event of failure of carrying out a normal order or regional purchases.

(e) Even though 06 months had elapsed since the selection of qualified bidders for the Order No. 2021/SPC/N/R/P/00061 for the year 2021, an Indent had not been issued to the supplier.

(f) The Order of the Project Director No. HSEP/AF/PMU/PPC/G.3036/215/2023 dated 21 April 2023 of Health Systems Improvement Project had been issued to purchase a quantity of 5,000,000 units at Rs.8,649 each under Order No. 2023/ADB/X/R/P/00013. However, as compared to the quotations of the State Pharmaceuticals Corporation, because of the value offered was very high, agreement had not been entered into with the bidder to minimize it. Also, as per the order, although the goods should be supplied within 60 days from the date of signing the agreement on 08 May 2023, the goods were received on 08 September 2023 that is after 120 days. Although a sum of Rs.1,729,800 should be charged for 08 weeks as 0.5 per cent of the contracted amount as late penalty for every week as per the purchase order, it was observed that a total amount of Rs.43,245,000 was paid to the supplier without making such deduction.

(g) According to the Public Contracts Act No. 03 of 1987, the agreement to be signed with the supplier had not been registered at the Registrar of Companies.

(h) The Order No. 2022 /SPC /X /R / P / 00267 had been issued on 14 October 2022 for the purchase of 4,000,000 units as 2,000,000 units each by the Indian Credit Line. According to the Indent, it had been mentioned that 2 million units should be supplied each in November and December 2022. However, the order was not received even on 18 September 2023 the date of audit and it was also observed in the audit that although 11 months had passed since the Indent was issued, the pharmaceutical have not been received and the Indent had not been canceled or extended.

(i) This pharmaceutical was not available in the Medical Supplies Division for a period of one year and it is observed that the above factors have directly affected this shortage.

40. Co-amoxiclav Tab.625 mg (SR No - 00100902)

Actions had been taken to order 13,999,000 tablets and 37,100,000 tablets of the above pharmaceutical in 06 occasions during the years 2022 and 2023 respectively. The following matters were observed during the inspection of requirement, supply and regulation in relation to this,

(a) The orders related to the years 2022 and 2023 consisted of a normal order, three donations and 03 orders obtained from suppliers under Buy Back Agreement in the Medical Supplies Division and the normal order No. 2022/SPC/N/R/P/00058 dated 18 March 2021 had been cancelled.

(b) In comparing Annual order quantity with annual estimated quantities thus it was 62,95,122 and 36 per cent in 2019, 2020, 2021 and 2022 respectively it was also observed during the audit that the preparation of estimates was not done rationally.

(c) Even though order number 2021/SPC/N/R/P/00038 dated 01 April 2021 had been given 04 time range for supply of 46 million tablets, a period of 04 months had been taken from the approval of the Ministry Procurement Committee dated 03 December 2020 for issuing the Indent. After issuing the indent dated 01 April 2021, it had taken more than two years to supply the pharmaceuticals. It is observed that it had to overpay Rs. 121,631,833 due to not making arrangements to receive the pharmaceuticals on the scheduled date as planned.

(d) The pharmaceuticals belonging to a category of this medicine purchased under the re-purchase agreement were given to a patient from Kurunegala Teaching Hospital and it was observed that the quality of the pharmaceutical was uncertain and not suitable for use. Based on this situation, although the responsible officials were notified in writing on two occasions to inspect this pharmaceutical and submit a report to the audit, the inspection was not carried out and reported to the audit until the date of this report.

(e) Despite there were normal order of 14,000,000 tablets for the year 2023 through counter-purchases by the State Pharmaceuticals Corporation and making arrangements to re-order 23,000,000 tablets of this pharmaceutical by Supplementary Order No. 2023/MSD/A/R/P/00064 in case of less demand for this pharmaceutical was problematic in audit.

41. Sodium Nitroprusside Inj. 50mg(SR No – 00202001)

It was revealed that the total estimate from the year 2019 to the year 2023 was 3,668 units and 1,789 units had been ordered for that period and only 200 units had been received by the Medical Supplies Division in the year 2022 according to the MSMIS data system. The following matters are observed in this regard.

(a) It was observed during the audit that the annual requirement of 2022 of the actual pharmaceutical was 517 vials and in ordering a number of 200 vials as grants and 500 vials under Indian Credit Line, it was observed in audit that 183 vials were ordered in excess .

(b) According to the information of the computer data systems regarding this pharmaceutical, which is an essential pharmaceutical according to the circular number 01-14/2023 of the Director General of Health Services dated 04 April 2023, out of the 1,789 vials ordered in 06 cases from the year 2019 to the year 2022, a number of 1,089 vials of pharmaceutical ordered in 04 cases had not been received by the Medical Supplies Division. The orders could not be received as scheduled due to the lack of proper recognition of the objectives of the procurement, uncertainties in the decisions taken by the officers of the procurement division and unnecessary delays.

(c) Due to failure of ordering properly, 209 vials of pharmaceutical cost at Rs. 258,070 had been purchased on 32 cases at regional level from the year 2020 to the year 2022 .

(d) The State Pharmaceuticals Corporation had invited bids for the purchase of 500 vials of pharmaceutical under Indian Credit Line through Order No. 2022/SPC/X/R/P/00264 and on the issues such as Waiver of Registration (WOR) certificate issued by the National Medicines Regulatory Authority and provision of a laboratory report by an independent party, the Departmental Procurement Committee had decided on 19 April 2022 to award the order to the lowest bidder. The following matters are observed in this regard.

(i) According to the Technical Evaluation Committee Report, it is observed during the audit that the aforesaid bidder has been selected without taking into consideration the elements such as the Pharmacopoeia Standard and the storage condition of the pharmaceutical.

(ii) It is observed in the audit that the WOR certificate given on 19 September 2022 for the aforesaid pharmaceutical had expired on 29 June 2023 due to the failure of the supplier to supply a number of 250

vials of pharmaceutical each as contracted in November and December 2022 and its validity period had to be extended up to 19 December 2023 .

(iii) Although the awarding of bids was made on 20 May 2022, the supplier had rejected the request made to reduce the value of the performance bond on 10 June 2022. Accordingly, it is observed in the audit that the supplier had spent 03 months for this procurement and accepted on 16 August 2022 .

(iv) In submitting the order, although it was stated that 250 vials of pharmaceutical should be supplied immediately, 125 vials of pharmaceutical within 02 months after receipt of first stock and remaining 125 vials of pharmaceutical within 01 month after receipt of second stock should be supplied, according to Indent No. DHS/ICL/IG/307/22 dated 27 September 2022, due to indicating conflicting time limits for supply of medicines in specifying that 250 vials of medicine should be supplied on 30 November 2022 and 250 vials of medicine on 31 December 2022, it was observed during the audit that maintaining the stock level as expected is causing controversy.

(v) Since there has been a long delay of 281 days for the supply of the first 250 vials of pharmaceutical and 250 days for the supply of the second pharmaceutical stock, instead of supplying the pharmaceuticals within the agreed period of procurement, it is observed in the audit that the State Pharmaceuticals Corporation should have an adequate and normal arrangement for taking stock after awarding the order.

(vi) As this pharmaceutical is an essential pharmaceutical used for patients suffering from high blood pressure as well as for patients suffering from intense heart disease, it is observed that the problems of stocks of pharmaceutical had arisen due to the uncertainties and unnecessary delays in the decisions taken by the officers deployed in the procurement sections.

(e) The Departmental Procurement Committee of State Pharmaceuticals Corporations had decided on 04 November 2020 to procure 350 vials of pharmaceuticals from the lowest bidder with a WOR certificate as per normal order No. 2021/SPC/N/R/P/00048. The following matters were observed in this regard.

(i) Since all the institutions that submitted bids are not registered with the National Medicines Regulatory Authority it was observed that keeping credibility on entities that had not fulfilled an essential factor in procurement is a controversial matter in audit.

(ii) Although the substantial bidder has applied for a Waiver of Registration, the National Medicines Regulatory Authority had refused to issue a WOR certificate on the grounds that the bid for the pharmaceutical was high. Accordingly, it was not observed in audit that whether the Procurement Committee made a proper evaluation on the competitive prices in the market.

(f) Bids were invited from eight previous suppliers according to the letter of the Procurement Officer (Pharmaceuticals) of State Pharmaceuticals Corporation dated 15 February 2023 addressing the Manager (Control) based on Order No. 2023/BPC/N/R/P/00120 and only two bids had received . One of the bidders is not a previous supplier, and the other bidder is a bidder who did not have the certificate of the National Medicines Regulatory Authority. Although it was decided to award the order subject to price reduction of the bid, it was observed that the bidder had not agreed to any price reduction as per the Departmental Procurement Committee report dated 27 September 2023 .

42. Pethidine Hydrochloride Injection 75mg (00001102)

The estimated number of units for the period from 2019 to 2023 was 1,056,630 and 703,120 units had been ordered from the year 2019 to 2022. Only 379,999 units had been received in 2019 and 2020 and the following matters are observed in this regard.

(a) Although the estimate for the year 2020 was 231,719 units, as the order was 326,120 units, it is observed that 94,401 units have been ordered beyond the estimate. Further, as the estimated amount were 264,138 and 210,864 units in the years 2021 and 2022 respectively, and due to the ordering of 32,000 units and 145,000 units, equal to 87 per cent and 31 per cent in less respectively in those years, it was observed that the preparation of estimates was done without following proper methodology.

(b) It is observed that 177,000 units of pharmaceuticals ordered in 03 occasions from the year 2021 to 2022 were not received even by the date of audit in October 2023 .

(c) It was mentioned in the computer data system that 32,000 units have been ordered by normal order No.2022/SPC/N/R/P/00066 on 22 March 2021 and since the Deputy General Manager has informed on 16 November 2023 to the audit in writing that such an order had not been received by the State

Pharmaceuticals Corporation, it was observed during the audit that the reliability of the information in the computer system could not be confirmed.

(d) Bids were invited from the local agents of the registered manufacturers of the National Medicines Regulatory Authority by Order No. 2021/SPC/L/R/P/00387 for obtaining 38,620 units of the said pharmaceutical and for this ,the quotations were received from only 02 institutions and the lowest bidder of Leader Pharma Agency (Pvt.) Ltd had been selected. The following matters are observed in this regard.

(i) The registration certificate of National Medicines Regulatory Authority of Leader Pharma Agency (Pvt) Ltd., which is the local agent of Verve Human care laboratories in India, had revoked on 07 July 2020, which was the date of the invoice and had elapsed one month and information regarding its extension was not submitted to the audit.

(ii) The agreement signed with the supplier had been not registered with the Registrar of Companies in terms of the Public Contracts Act No. 03 of 1987.

(e) Indian Verve Human Care Laboratories, a past supplier, had been selected to supply 230,000 units of pharmaceutical based on the order No. 2021/SPC/N/R/P/00060, and the bid value was US$ 805,000. The following matters are observed in this regard.

(i) According to the Indent No. DHS/AR/277/21 dated 04 March 2021, a number of 150,000 units of this pharmaceutical should have been supplied on 30 April 2021 and 80,000 units on 31 August 2021. The Medical Supplies Division and government hospitals were also out of stock as at 20 June 2022. However, it is observed in the audit that although 14 months had elapsed since the receipt of this first stock from the date of supplying of stock, arrangements had not been made for obtain the first stock.

(ii) As it was mentioned in the first page as Pethidine Injection BP 75 mg/1.5ml glass ampoule (VERPAT – 75) and on the second page as Codeine Phosphate BP 226,000g (226 Packs of 1000g) of Narcotic License No. NMRE/EA/LA/040/21 issued by the Director General of Health Services on 28 April 2021, offering the Indent to the bidder had further been delayed and it is observed that the Narcotic License was issued after about a month on 30 May 2021 .

(iii) Although nominal invoices had been approved by the Medical Supplies Division and the Ministry of Finance for procuring 150,000 units of this pharmaceutical, the Narcotic License had to be re-acquired due to delay in procuring the stock. Although it was mentioned as Pethidine Injection BP 75 mg/1.5mg (VERPAT – 75) , it should have been mentioned as Pethidine Injection BP 75 mg/ 1.5ml (VERPAT – 75) in the Narcotic License number NMRA/MA/IP/057/22 issued by the Director General of Health Services on 02 July 2022. Accordingly, it is observed that due to the carelessness of the officers, Narcotic License had been issued with mistakes in 2 instances.

(f) The order No. 2024/SPC/N/R/P/00023 dated 24 February 2023 in relation to the year 2024, had stated that 180,000 units of Ampoules were required and 100,000 units are expected to be received on 15 January 2024 and 80,000 units on 15 May 2024. As this pharmaceutical is not mentioned in the priority list according to the Circular No. 01 – 14 / 2023 of the Director General of Health Services and the circular dated 04 April 2023, even though 07 months had elapsed since the submission of the order by the date of the audit, it was observed that clear decision was not taken regarding the legally cancellation or suspension.

43. Alteplase 20mg Vial (SR No – 00205701)

The estimated quantity for the period from 2019 to 2023 was 5,861 units and during that period 3,865 units had been ordered. Out of that, 2,590 units had been received. The following matters are observed in this regard.

(a) Although the estimated quantity for the year 2021 was 1,204 units, in excess of that quantity, 1,400 units had been ordered. The estimated quantity were 1,164 and 1,303 units in the years 2022 and 2023 respectively, and the ordered quantity were 625 units and 450 units respectively. It is also observed that the preparation of estimates has been done without a proper method as compared to the estimated amount due to making the annual orders 46 per cent and 65 per cent less than the estimated amount in those years.

(b) The orders of 225 units and 450 units placed in two occasions in the year 2022 had not been received even by the date of audit.

(c) Even though 225 units were ordered for Rs.24,571,631 as emergency purchases in the year 2023, under order number 2023/SPC/E/C/P/00163 also, this order had not been entered in the MSMIS computer system.

(d) The Chairman of the State Pharmaceuticals Corporation had been informed by the Deputy Director General (Medical Supplies) by letter No. DDG/MSD/E/02/2023 dated 28 February 2023 to make an emergency purchase for a requirement of 03 months as decided by the Medical Supplies Review Committee (Pharmaceuticals). Even though the Emergency Procurement Committee had decided to call for bids for the purchase of 225 units, because of the quotations were not received, it had been informed that re-procurement should be carried out. Even though the time period spent for this had exceeded 08 months by the date of audit that is October and since no re-procurement has been carried out, it was observed in the audit that, the reason for emergency requirement is a matter of controversy.

(e) The Departmental Procurement Committee had approved inviting bids for order No. 2022/SPC/N/C/P/00017 for 400 Vials during the year 2022 under normal purchase. One bidder had appeared for this and the following matters were observed regarding the selection of that bidder.

(i) According to the conditions of supply and terms in the Indent received from the Medical Supplies Division regarding this pharmaceutical, although it is stated that "it should be supplied with a lowest shelf life of 24 months from the date of manufacture", it was observed that the required remaining shelf life of this pharmaceutical was 18 months and less than 75 per cent had been supplied. .

(ii) Although a debit note bearing No. D/N – DNS/P/022/2023 valued at Rs.2,544,574 (US$ 7,006.17) was issued by the State Pharmaceuticals Corporation to the supplier for charging additional fee due to shelf life was less than 75 per cent, no written relevant confirmation was submitted to the audit to check whether this amount was charged or not.

(iii) The agreement to be signed with the selected supplier had not been registered with the Registrar of Companies in terms of the Public Contracts Act No. 03 of 1987.

(iv) The period of validity of the registration certificate of the National Medicines Regulatory Authority had expired and it had been extended up to 30 June 2021 by the Director General of the said institution's letter No. NMRA/SP /CEO / 02N /2020 and dated 17 November 2020. However, even though 17 months had elapsed after expiring of the registration by 30 November 2022 which was the date of clearance of the respective pharmaceutical, actions had not been taken to extend it.

(f) Purchase of this pharmaceutical was made under normal purchase in the year 2023, and according to the procurement notice related to the order No. 2023/SPC/N/C/P/00124, the Departmental Procurement Committee had decided to purchase 450 units from the bidder who had submitted the only bid at Rs.49,143,262. The following observations are made in this regard.

(i) According to the computerized order list of the Medical Supplies Division 250 units and 200 units had been planned to be procured by orders dated 15 January and 16 April 2023 respectively. The Technical Evaluation Committees had selected this supplier as it was a previous supplier and was the only supplier who had submitted the bid. Even though 09 months had elapsed from the planned date to audited date, the Indent has not been issued to the supplier and arrangements had not been made to get the pharmaceuticals.

(ii) The Technical Evaluation Committee report stated that the registration certificate of the National Medicines Regulatory Authority had been expired on 14 December 2022. However, the evidence relating to the extension of the validity of the registration certificate was not submitted to the audit.

44. Haloperidol inj' 5 mg/1ml (SR - 00300803)

The total estimate was 448,349 injections and the amount issued was 228,873 injections from the year 2019 to the year 2023. The quantity used by the patients was 228,686 injections and the following matters are observed in this regard.

(a) It was observed that the estimation has not been done based on formal criteria in comparison with the estimation, issuance and consumption from the year 2019 to the year 2023.

(b) A number of 10,390 units had expired by 31 December 2022 and 70,000 units were to be expired on 31 October 2023.

(c) The Order No. 2023/SPC/N/R/P/00069 for 30,000 units had been sent by Medical Supplies Division on 24 November 2022. The order was to be completed by 30 May 2024 as per Indent No. DHS/MM/069/2023 for this purpose. Accordingly, although the average time taken to receive the pharmaceuticals related to the order submitted by the Medical Supplies Division was 11 months, it was observed that 07 months have been spent beyond that time.

45. Heparin Injection 25,000 I.U/ 5 ml (SR No – 00204601)

The total estimate from the year 2019 to the year 2023 was 1,876,233 units according to the MSMIS computer system and the order quantity related to that period was 2,106,660 units. The MSMIS computer system had revealed that 1,373,107 units have been received by 16 October 2023. The following observations are made in this regard.

(a) The annual requirement for the above pharmaceutical in the year 2022 was 396,317 vials of pharmaceutical. However, a total of 730,350 vials of pharmaceutical as 155,350, 100,000, 200,000 and 275,000 were ordered in 12 cases respectively under grants, emergency purchases, World Bank assistance and Indian Credit Line. It was observed in the audit that this is an order of more than 84 per cent of exceeding the annual estimate, and that, there was no formal system followed in formulating the orders.

(b) It was observed during the audit that this pharmaceutical is an essential pharmaceutical according to the priority list pharmaceuticals to save lives of patients. Nevertheless, it was observed during the audit that lack of proper understanding of procurement objectives, uncertainties and unnecessary delays in the decisions taken by the officers in various sections involved in procurement have led to shortage of pharmaceuticals.

(c) According to information obtained by MSFMS (Promto) computer system, 7,131 units of vial of the aforesaid pharmaceutical had been purchased locally in the year 2022 on 29 occasions from different suppliers at different prices. A total of Rs.15,179,957 had been spent for this purpose. A vial of these pharmaceuticals had been purchased at a wide range of price from Rs.1,500 to Rs.4,000 and it was observed in audit that the normal price of a vial of pharmaceutical was Rs.717.97. It was further observed during the audit that a large sum of money had to be incurred due to the failure of carrying out procurement of pharmaceuticals within the prescribed period.

(d) Out of the pharmaceuticals ordered in 2020 and 2021, number of 42,017 and 36,444 vials of pharmaceutical had been received in the year 2022, in relation to normal orders No. 2020/SPC/N/R/P/00055 and No. 2021/SPC/N/R/P/00066 respectively. It was observed during the audit that due to the inability to supply the ordered pharmaceuticals as per formal schedule it had been resorted to emergency purchases outside the normal purchase and other sources like credit facilities, other than normal purchases as mentioned in (e) below.

(e) The State Pharmaceuticals Corporation had been informed on 04 November 2022 to supply 75,000 vials of pharmaceutical under Order No. 2022/SPC/E/R/P/00738 on emergence basis. Accordingly, a supplier had been selected based on the certificate of the National Medicines Regulatory Authority and the agreement of supplying the pharmaceuticals within two weeks. The following matters were observed in this regard.

(i) Written evidence regarding the appointment of the Technical Evaluation Committee for this purchase and the decisions taken by the said Committee was not submitted to the audit.

(ii) It had been mentioned in the bidding documents that the quotation for the said pharmaceutical should be supplied in the form of vials. However, it was revealed in the examination of the related file that the company which was awarded the order had supplied it as "Ampoule". Accordingly, if vials of Heparin Injection or Ampoule had been defined in the bid documents, it could not be ruled out in audit that other parties could have participated in the order. Accordingly, it was a controversial matter in the audit that whether it was focused on providing fair, equal and maximum opportunities to the eligible interested parties to participate in the procurement.

(iii) It had been stated that the supplier should have a valid registration certificate from the National Medicines Regulatory Authority or have obtained the Waiver of Registration certificate on submission of lower prices as per the conditions of bidding. However, the registration of the supplier with the National Medicines Regulatory Authority had expired on 12 February 2022. Accordingly, although the State Pharmaceuticals Corporation had informed the National Medicines Regulatory Authority on 30 January 2023 to renew the registration supplier or issue a WOR certificate, neither the renewal registration nor the WOR was issued.

(iv) There was an acute shortage of this pharmaceutical in the Medical Supplies Division as on 02 November 2022 when the said order was submitted and according to the Indent No. LP/DHS/EP/HD/3595/2022 dated 01 February 2023 issued by the State Pharmaceuticals Corporation, the date for the supply of pharmaceuticals was mentioned as 15 January 2023. Accordingly, the fact that procurement documents were prepared differently from each other was a controversial matter in the audit.

(v) The Health System Emergency Procurement Committee had decided to grant the order according to the memorandum submitted by the Minister of Health bearing Cabinet Paper No. 22/1523/610/018 entitled "Maintaining a Continuous Medical Supply Service in Sri Lanka" and selecting a supplier from the bids submitted on the basis of the current shortage of stock. However, this supplier had failed to supply the pharmaceutical within the stipulated period.

(f) The State Pharmaceuticals Corporation had been informed by the Data System of the Medical Supplies Division for the purchase of 275,000 vials of pharmaceutical on emergency basis and under aforesaid Indian Credit Line by Order No. 2022/SPC/X/R/P/00284. The Ministry Procurement Committee had decided to purchase 275,000 vials to US$. 728,750 as a vial of pharmaceutical per US$ 2.65 each. The following matters are observed in this regard.

(i) Written evidence of the Technical Evaluation Committee appointed for this procurement or the decision taken by the said Committee was not submitted for audit.

(ii) This supplier had previously supplied these pharmaceuticals and the Chairman of the Medical Supplies Division had informed the National Medicines Regulatory Authority by letter No. MSD/SCU(I)/GMP/38/2015 dated 25 August 2015 stating that the cardiologists were not satisfied with the quality of the vials of pharmaceutical. In spite of this, the order had been awarded to the aforesaid company..

(iii) This supplier had submitted a registration certificate extended by the National Medicines Regulatory Authority and it was observed during the audit that the certificate had also been cancelled on 10 February 2022 .

(iv) The validity period of the import license given to the local agency to import these pharmaceuticals had expired on 10 February 2020 and there was no any evidence revealed in audit regarding the renewal of its registration.

(g) The State Pharmaceuticals Corporation had been informed to supply 25,000 vials of pharmaceutical under normal order No. 2022/SPC/E/R/P/00478. Accordingly, the Technical Evaluation Committee had decided on 28 July 2022 to award the bid to the organization that submitted the lowest bid and also bearing a valid registration certificate from the National Medicines Regulatory Authority. The following matters are observed in this regard.

(i) It was revealed in audit that the said order had been cancelled on 02 August 2022 by the Emergency Procurement Committee of the Health Sector due to the non-submission of samples by the institutions which were called for bids for this order, huge difference between the prices, asking for more time than the stipulated time for supply of pharmaceutical, due to receive stock of pharmaceuticals under Indian Credit Line. Nevertheless, it was observed during the audit that the vials of pharmaceutical for order No. 2022/SPC/X/R/P/00284 on Indian Credit Line stipulated to be received on April and July 2022 were supplied on 01 June 2023. Accordingly, it was problematic in audit that, whether it was practical to make decisions based on the supply of pharmaceuticals that would take a long time of about 10 months.

(ii) It was observed during the audit that by the date of submission of the said order, the Medical Supplies Division had 3,875 vials of pharmaceutical and 24,203 vials of pharmaceutical at the national level which was only sufficient for 0.7 months of consumption. The need for a formal schedule for the timely availability of such a pharmaceutical mentioned in the priority list is observed in audit.

(h) The order had been submitted on 17 November 2022 to the State Pharmaceuticals Corporation under Order No. 2023/SPC/N/R/P/00098, for the purchase of 150,000 vials of pharmaceutical under the normal order and the Departmental Procurement Committee had arranged to select a supplier. The following observations are made in this regard.

(i) According to the Technical Evaluation Report, although it was mandatory to obtain an independent laboratory report on this pharmaceutical because the supplier who submitted the said order had not supplied this pharmaceutical before, it was observed that the said report was not given to the procurement entity .

(ii) Although the performance bond was to be submitted within two weeks of the submission of the purchase order as per the procurement timetable, it had not been submitted even by 15 October 2023 the date of audit.

(iii) According to the Indent No. DHS/HD/131/2023 issued on 15 September 2023, although it had been mentioned that the date for supply of pharmaceuticals was 31 December 2024, it had been mentioned 75,000 vials of pharmaceuticals immediately and the rest of the vials as two months after the first stock was given as per the letter issued by the State Pharmaceuticals Corporation to the supplier.

Accordingly, it could not be ruled out in the audit that changing the times when pharmaceuticals to be supplied at different times had made adverse effects on the procurement process.

(i) The Order No. 2021/SPC/N/R/P/00066 had been submitted to State Pharmaceuticals Corporation on 26 February 2020 for the purchase of 350,000 vials of pharmaceutical under normal method. According to the audited documents, it was revealed that the vials of pharmaceutical had been purchased from two institutions under three Indents. The following points are observed in this regard.

(i) Although according to the procurement time frame, the bids should be invited within 04 weeks after the approval to invite the bids, the newspaper advertisement for the relevant procurement was published on 10 May 2020, as revealed in the audited file. Accordingly, it is observed in the audit that nearly 03 months had spent since receiving the written confirmation to submit the order.

(ii) The Departmental Procurement Committees had decided to purchase 300,000 vials of pharmaceutical and the remaining 50,000 vials of pharmaceutical on demand. Accordingly, as per the Indent issued for the purchase of 120,000 vials of pharmaceutical, although the date to supply the vials of pharmaceutical was stated as 30 January 2021, it was observed in the audit that the goods were supplied after a delay of 40 days.

(iii) The evidence on the appointment of Technical Evaluation Committee members had not been included in the file and it was revealed that one Cardiologist had recommended the decision of the Technical Evaluation Committee as per the audited file .

(iv) The Indent No. DHS/HD/472/2021 had been issued for the purchase of 125,000 vials of pharmaceutical, and the pharmaceutical had to be supplied on 31 October 2022. However, the remaining stock of the aforesaid order, which is 193,609 vials of pharmaceutical, had not been supplied by the date of audit 30 September 2023. Accordingly, it was observed in audit that the stock level cannot be maintained as expected due to the constant revision of the period the pharmaceutical stock to be supplied.

(j) An order had been submitted to the State Pharmaceuticals Corporation for the purchase of 250,000 vials of pharmaceutical under order number 2020/SPC/N/R/P/00055. The Procurement Committee had decided to give the aforesaid order to three institutions through three Indents and the following observations are made in this regard.

(i) The Medical Supplies Division had issued an order to the State Pharmaceuticals Corporation on 14 March 2019 for the supply of 250,000 vials of pharmaceuticals. Subsequently, this order quantity had been increased by 50 per cent. However, the State Pharmaceuticals Corporation had called the quotations on 03 June 2020. Accordingly, a long period of 14 months had spent for pre-procurement works.

(ii) Even though the Cardiologists had complained that abnormal and excessive bleeding was observed in heart patients after using this pharmaceutical purchased earlier and used for heart patients for surgery, without paying attention to it a quantity of 196,875 vials of pharmaceutical had been purchased from the pre-rejected supplier according to the order No.2020/SPC/N/R/P/00055. Accordingly, it is observed that the use of this pharmaceutical is a controversial matter in the audit .

(iii) Even though it had been mentioned that the stocks should be supplied immediately by Indent No. DMS/M/HD/681/2020 , it had been supplied with a delay of 21 days. Delay charges had not been levied for this period.

(iv) One of the suppliers had voluntarily submitted the quotation during the calling of bids for aforesaid orders and the Technical Evaluation Committee had not drawn much attention on it. However, the Ministry Procurement Committee “B”(MPC “B”) had decided to evaluate these prices as there was NMRA valid registration certificate. Accordingly, it is a matter of controversy in the audit that such a decision was taken only when there was a valid registration certificate from the National Medicines Regulatory Authority and the Procurement Committee of the Ministry had given approval for the purchase of this pharmaceutical from this institution.

(v) The bid had been awarded by Indent No. DMS/M/HD/682/2020 to a supplier for supplying of 84,375 units of vials on 17 January 2021 and 42,188 units of vials had been supplied to the Medical Supplies Division on 15 April 2021. Although the remaining quantity of 42,187 vials of pharmaceutical from the stock was stated to be supplied on 31

August 2022, the stock had been supplied to the Medical Supplies Division on 14 December 2022. Accordingly, the delay period had exceeded three months.

(vi) Although the said institution had indicated that it had a valid registration certificate from the National Medicines Regulatory Authority, its validity period had expired on 12 February 2022. Accordingly, it was observed in the audit that at the time of submitting the Indent No. DMS/M/H/717/20 on 29 June 2022, attention has not been paid to the registration certificate of the National Medicines Regulatory Authority.

46. Zoledronic Acid (SR-00703701)

(a) Although it had been mentioned that the price was Rs. 359.82 as per order No. 2022/SPC/N/R/P/00039, mentioning of the maximum retail price by the Regulatory Authority as Rs. 6,900 in the registration certificate was observed as a point of controversy during the audit.

(b) Even though it had been mentioned that, non-availability of stock or zero in stock as at 21 April the order No. 2023/SPC/T/R/P/00148 valued at Rs.4,426,800 for 3,400 injections at Rs.1,302 per pharmaceutical unit which should be obtained immediately was issued subject to obtaining Waiver of Registration (WOR) for reasons such as urgent need and non-availability of stock, the stock in Swastha System had not indicated as zero.

(c) As the Order No. 144121 and Indent No. LP/DHS/EP/PUN/3675/23 is an urgent order even though the supplier had been informed that the pharmaceutical should be supplied within 14 days, there was a delay of 53 days in supplying the pharmaceuticals.

47. Yellow Fever Vaccine 0.5ml (SR - 00600601)

(a) The variation between the estimated amount of 43,778 units submitted by the Medical Supplies Division and the actual amount of 15,150 units received was very high during the period from 2019 to 2023, and it had ranged from 15 per cent to 100 per cent. Accordingly, it was observed that in audit that the estimates are not prepared based on accurate data.

(b) Even though 04 orders were submitted, to get 10,000 units of pharmaceutical only 1500 units from one order was received and the remaining total requirement had been met through 2050 units of donations.

(c) The National Medicines stock requirement had become zero from time to time in the year 2022 and in the year 2023 due to insufficient stock levels being maintained by the Medical Supplies Division.

(d) According to the terms and conditions of the supply and bid documents of the Medical Supplies Division, although it was stated that the supply should be made with a lowest shelf life of 24 months, apart from that, the bid was awarded to the only bidder with a shelf life of 18 months. The copies of agreements related Indent No. DHS/AMS/460/2022 had not been set in the file.

(e) Although the bids under No. 2022/SPC/X/C/P/00283 had been canceled due to the fact that it was mentioned as an order receivable in the odata system, the data system had not been updated.

(f) The bids relating to order No. 2023/SPC/N/C/P/00088 had not been submitted and 03 months and 14 days had elapsed to decide to invite re-bids.

(g) The data system had not been updated due to the fact that the pharmaceuticals received as donations under No. 2023/WHO/A/C/P/00006 were shown as a receivable order in the data system.

48. Omeprazole Sodium InJ. 40mg (SR-00800803)

(a) The estimated quantity submitted by the Medical Supplies Division during the period 2019 to 2023 was 7,916,993 units supplied and the actual quantity received was 4,920,994 units. Accordingly, the variance was very high and had ranged from 11 per cent to 83 per cent. Accordingly, it was observed during the audit that estimates are not prepared based on accurate data.

(b) Even though a number of 540,000 units of the requirement of 800,000 units of pharmaceutical had been received from the orders No. 2022/SPC/N/R/P/00013, the delay period had exceeded by 05 months.

(c) The remaining stock of the above order No. 2022/SPC/Z/R/P/00770 had not been received as per the Swastha System even by the date audit 23 November 2023 .

(d) It had taken more than 02 years and 09 months to complete the procurement for this order.

(e) In inviting bids for 300,000 units valued at Rs.8,088,000 considering as an emergency order under No. 2022/SPC/E/R/P/00732, the bids had been submitted by bidders who did not have the registration certificate of the National Medicines Regulatory Authority and the bid had been awarded to one of the bidders.

(f) As per Order No. 2022/SPC/E/R/P/00732 , although the shelf life of the pharmaceutical should be 24 months in terms of clause 08 of the bid regulations, and conditions, the shelf life of the selected bid had been 20 months.

(g) As per the Order No. 2022/SPC/E/R/P/00732, the delay in supply of pharmaceuticals was 02 years 09 months and 12 days. The 5 per cent penalty for delayed delivery had not been collected and the procurement period for the order had exceeded 06 months.

(h) Even though Bids had been awarded for the supply of 600,000 units of pharmaceutical on 17 November 2023 valued at Rs.36,751,570 under No. 2023/SPC/N/R/P/00029 considering as an emergency requirement, due to being reported as a receivable order in the data system as at 14 December 2023, it was observed that the stock was not given to the Medical Supplies Division within the stipulated time.

49. Thyroxine tablets 25 micrograms (SR – 00701103)

(a) The estimated quantity submitted by the Medical Supplies Division was 45,138,510 and the actual quantity received was 12,524,580 units during the period 2019 to 2023 . Accordingly, the variance between the estimated quantity and the actual order quantity had ranged from 39 per cent to 100 per cent. Therefore, it was observed during the audit that estimates are not prepared based on accurate data.

(c) The estimated units were over-calculated because the Medical Supplies Division took the over-estimates sent by the hospitals into their estimates without any verification.

(c) Due to failure of accurately estimating the annual requirement, in the submission of the order for 13,000,000 tablets to the bidder as per order No. 2020/SPC/A/R/P/00278, it had been procured only 5,000,000 tablets due to the availability of sufficient stocks.

(d) Due to not paying attention to zero stock levels in the Medical Supplies Division, the Medical Supplies Division was not able to maintain adequate stock levels as a result of procurement activities were not being carried out in a fixed time frame, and being canceled and being suspended of orders.

(e) Although the stocks pertaining to Order No. 2020/SPC/A/R/P/00278 should be received by 31 January 2021, due to the receipt of stocks to Medical Supplies Division on 16.06.2021 and 29.06.2021, the delay period had exceeded 05 months.

(f) It had taken more than a year to notify by the Medical Supplies Division for the failure of 4,941,500 units of pharmaceuticals received under batch number L-68005 as per above order and the entire amount had been issued to 55 hospitals. The remaining units in 19 hospitals were 45,300 and all 4,896,000 units had been issued to patients.

(g) Due to non-availability of pharmaceuticals in Medical Supplies Division and hospitals and although the bid was awarded to supply one million from the stock on hand and the rest in a month to purchase 3,282,600 units of Thyroxine pharmaceuticals with a total value of Rs.13,130,400 by order No. 2020/MSD/C/R/P/00046, the delay in supply of pharmaceuticals was between 02 months to 05 months.

(h) After the Departmental Procurement Committee observed that there was zero need for medical supplies and National medicine stocks, although the bid was awarded to get the pharmaceuticals immediately for the purchase of 1,200,000 units by order No.2023/SPC/C/N/R/P/000084, it had been stated in the Data System that the stocks had not been received even by December 2023.

50. Hydrocortisone Tab. 10 mg (SR-00701502)

(a) The estimated quantity submitted by the Medical Supplies Division was 8,734,735 units during the period from 2019 to 2023 and the actual quantity received was 5,940,320 units. Accordingly, the variance was a high figure and it had ranged from minus (12) to 47 per cent. Accordingly, it was observed during the audit that estimates are not prepared based on accurate data..

(b) Bids had been opened to procure 850,000 units at Rs. 6,791,500 by Order No. 2022/SPC/N/R/P/00039. A number of 295 days had been spent for procurement from the date of bid opening. The bid award related to the submission of bids was temporarily stopped and the bid was re-awarded to the bidder and the bidder had spent a delay of 06 months in providing the pharmaceuticals.

(c) Indent No. DHS/ICL/SA/381/22 had been issued to a supplier who had not have a NMRA registration certificate and supply of pharmaceuticals had been done with 08 months delay as per the scheduled date.

(d) Order No. 2022/SPC/V/R/P/00640 had been re-implemented under Medical Supplies Division order No. 2022/MSD/V/R/P/00076 without revoking by the State Pharmaceuticals Corporation. However, it was observed that the system has not been updated due to both these orders being indicated as receivables in the Swastha system.

(e) A number of 1,455,000 units pertaining to Order Nos. 2022/MSD/V/R/P/00076, 2022/SPC/E/R/P/00569 and 2023/SPC/N/R/P/00084 had not received by the Medical Supplies Division even by December 2023.

51. Anti-Rabies Human lg 300 I.U (SR-00602501)

(a) The estimated amount submitted during the period from 2019 to 2023 by the Medical Supplies Division was 27,112 units and the actual amount received was 10,550 units. Accordingly, the variance was very high and it had ranged from minus (07) per cent to 77 per cent. Accordingly, it was not observed during the audit that the estimates are prepared based on accurate data.

(b) It had decided to cancel the Indent bearing DHS/TN/482/2022 on 09 August 2023 and there was no information in the relevant file that the supplier was notified that the order was cancelled. In the data system , this attachment was indicated as receivable.

(c) A number of 400 vials of pharmaceutical had been purchased under the indent number LP/DHS/EP/TN/3532/2022, on an emergency basis, and although the stock of pharmaceutical should be supplied on 30 September 2022, it had been decided not to levy fines for the delay of 84 days which had occurred due to the supply on 22 December 2022.

52. Salbutamol Respiratory 501 0.5per cent 15ml vial (SR-00500109)

(a) According to the estimated 2,177,591 units submitted during the period from 2019 to 2023 by the Medical Supplies Division and the actual units received was 713,000, the variance was very high and it had ranged from 52 per cent to 102 per cent. Accordingly, it was not observed during the audit that the data was estimated correctly.

(b) As per purchase order No. ICL/EOI/PI/124/2022 to purchase 60,000 units of pharmaceutical according to the Order No. 2022/MSD/V/R/P/000103 although the pharmaceuticals should have received by February 2023 the Supplies Division had not received the pharmaceutical stock even by December 2023 .

(c) According to the order No. 2023/SPC/N/R/P/00098 a number of 120,000 units of pharmaceuticals should have supplied as the annual requirement of 2023 as 60,000 units each in January and April 2023 respectively. However, a confirmation whether these pharmaceuticals were received or not had not been submitted to audit.

53. Mesna Injection 200 mg in 2 ml (SR - 01210101)

(a) The normal order 2022 related to the purchase of 23,000 units of this pharmaceutical was issued on 27 February 2021 through the data system and was received on 18 March 2021. Only one company had submitted bids according to the international competitive bidding process. According to the bid documents, although the National Medicines Regulatory Authority registration was valid until 21 June 2025, the registration certificate submitted had remained valid only up to 30 June 2021. The Technical Evaluation Report had been signed without mentioning the names and positions of the relevant members. It was observed that the Medical Supplies Division had taken 07 months to temporarily suspend the order dated 27 February 2021 due to non-ordering of pharmaceuticals based on normal and accurate data and it has taken more than 07 months to re-activate it and from that date another 03 months have been spent to award the order to the supplier for offering, and another 03 and 06 months have been spent for receiving the pharmaceutical and accordingly, it was observed that this process had taken 23 months. Similarly, the agreement had been signed on 18 October 2023 after receiving the stock of these pharmaceuticals.

(b) The normal order for the year 2023 for the purchase of 15,000 units was placed on 16 November 2022 after a delay of 10 months. According to this order, 7,500 units of injection were to be supplied on 12 January 2023 and 12 April 2023 each. After issuing the order, 03 months had been spent for inviting bids. Almost a month had been spent for the bids to be opened and evaluated and the bid evaluation report dated 18 April 2023 had been signed without mentioning the names and positions of the relevant members. Three months after the submission of this Technical Evaluation Committee Report, since the organization that submitted the lowest price was not a registered organization of the National Medicines Regulatory Authority, it had been recommended to award this order to the organization that submitted the second lowest price with the same registration at the rate of Rs.600 per unit.

(c) This order was awarded to the said company on 14 August 2023 and it was stipulated that 7,500 units should be supplied within 90 days from the order and the remaining 7,500 units should be supplied 03 months after the first stockh. Although the temperature point given by the supplier was less than 25 degrees Celsius as per the Medical Supplies Division, the required temperature was 30 degrees Celsius, a confirmation was requested for the same. According

to the email dated 20 August, 2023, if the item is registered under the above storage condition of the National Medicines Regulatory Authority and awarded by the Technical Evaluation Committee and the Procurement Committee, it had been mentioned that it was fair as per the Medical Supplies Division. It was specified that the storage condition should be below 25 degrees Celsius and the shelf life should be 24 months. Again an Indent was issued on 12 October 2023 and it was stated that the storage condition should be below 30 degrees Celsius and the shelf life should be 21 months. A number of , 7,500 units were received on 10 October 2023 and it was observed that the stock was undertaken out of specification.

(d) Order No. 2023/SPC/X/C/P/00192 for the purchase of 25,000 units with an estimated value of Rs.13,020,750 was issued on 25 May 2023. According to this order, 13,000 units and 12,000 units of injections were to be supplied respectively. Three organizations had submitted bids. These bid documents had been evaluated by the Technical Evaluation Committee and it was decided to award the order to the only registered supplier who offered the highest price through price negotiation and the Procurement Committee recommended to award this procurement to the above supplier at the price of Rs.550 per unit. Evidence was not submitted to the audit that the cover approval of the Cabinet of Ministers was obtained for this procurement decision or that the Chief Internal Auditor certified that this procurement was done as scheduled. It took nearly 68 days to award the order after the procurement evaluation activities. According to the terms of supply regarding this pharmaceutical, although it was stated that the shelf life of the pharmaceutical is 24 months, the fact that the lowest shelf life of the Indent was stated as 12 months (with assurance) was problematic during the audit.

(e) Even though Maharagama Apeksha Hospital had requested 27,600 units of this pharmaceutical from the Medical Supplies Division on 15 occasions in the year 2022 and October 2023, only 23,106 units had been received.

(f) Due to excess stock of 13,129 units for the year 2024 as per order control form prepared by Medical Supplies Division for the year 2024, an order had not been prepared for the year 2024. However, as there is a problematic situation regarding the accuracy of the data used to prepare this order control form, it was observed in the audit that there is a risk of resorting to emergency purchases in the year 2024 as well.

54. Epoetin injection 10,000 IU (SR N0. 00404004)

(a) Although the annual requirement for the year 2021 was 45,987 units, this pharmaceutical had not been ordered for the year 2021 due to orders receivable of 50,000 units and stock- in -hand of 39,558 units is sufficient.

However, only 12,500 units were received out of the units of the order received. Accordingly, annual orders were estimated based on uncertain data without considering to the availability of stock or the progress of those orders.

(b) Although the 2022 annual estimate of this pharmaceutical was 60,311 units, orders for 85,000 units were issued during the year. Of this, 36,000 units were ordered under normal orders, 24,000 units under "emergency requirements" and another 25,000 units under Indian credit facilities. As only 3,600 units were received from the normal order of 2022, the Medical Supplies Division had arranged to purchase under emergency purchases and other credit facilities.

(c) The Medical Supplies Division had not prepared an order control form for the year 2023 and only the annual requirement of the hospitals had been obtained. However, a normal order of 24,000 units had been issued on 24 November 2022, and the information based on that was not submitted to the audit.

(d) The Order No. 2022/SPC/V/C/P/00633 had been issued on 24 September 2022 for the purchase of 12,000 units and the , the Order No. 2022/MSD/V/C/P/00091 was issued on 01 November 2022 instead. However, both these orders remained as orders issued in the Swastha System at the time of audit.

(e) Only 19,200 units had been received for the year 2022 for the normal order of 36,000 units given in the year 2021, and the remaining amount of 16,800 units had not been received by the Medical Supplies Division by the audit date of 2023.

(f) Due to failure to place the orders and insufficient stock in hand, orders had been issued for a total of 49,000 units on 07 September , 01 November and 02 November 2022 respectively. Out of this, only 22,000 units had been received by the Medical Supplies Division by 31 March 2023, and 27,000 units including 25,000 units ordered under the Indian Credit Line had not been received by the Medical Supplies Division even as at the audited date of October 2023.

(g) Accordingly, It is observed in audit that the orders have been issued for these emergency purchases on the basis of informal and unspecified data in the date of supply of stock in the normal order has been changed from time to time, delay in issuance of WOR by the National Medicines Regulatory Authority and failure of the Medical Supply Division to provide accurate information about the existing stock levels to the State Pharmaceuticals Corporation etc. and hence, the respective responsible officers are accountable in this regard.

(h) Although the annual normal order should be placed at least 11 months in advance the orders for 24,000 units for the year 2023 had been placed on 24 November 2022. These pharmaceuticals were expected to be available at least by April 2023. According to the procurement time frame, although bids should be invited within 03 weeks of receipt of the order, the Procurement Committee had decided to invite quotations from registered and previous suppliers on 13 March 2023, four months after receipt of the order. However, the relevant invitation to bid had not been opened and no action had been taken to cancel this order even by the date of audit.

(i) The normal order 2022 of 36,000 units had been placed on 27 February 2021. After 53 days of receiving the order, the Procurement Committee had recommended to invite bids under the international competitive bidding system. After 24 days of this approval, the newspaper advertisements related to the invitation of bids were published. Accordingly, two Indents were issued on 21 September and 23 September 2021 respectively. A re-order was issued on 11 October 2021 to the bidder supplying 70 per cent of the order that is 25,200 units, stating a wrong address in the earlier order. Although the accurate address was mentioned in the bid documents, inquiries had not been carried out from the respective officers regarding the issuance of the purchase order to a wrong address.

(j) Even though only the supplier who supplies 70 per cent of the actual order had to supply 16,800 units, the performance bond offered by the supplier had expired on 28 February 2023. The responsible officers had not extended or taken over this performance bond amounting to Rs.2,948,400 before the expiry of its term.

(k) Even though the selected bidder for supply of 25,200 units had not supplied the stock of pharmaceuticals on the date mentioned in the Indent in relation to normal order No. 2022/SPC/N/C/P/00021, a price revision had been requested due to the depreciation of the rupee. Accordingly, a unit at Rs.1,170 instead, on two occasions, a price increase of Rs.2,142 and Rs.2,154 per unit was requested respectively. The Procurement Committee had based this 81 per cent price variation on the value of the U.S. Dollar prevailing on the date of submission of bids and the value of the U.S. Dollar prevailing on the date of requesting the price revision. Since the supplier had not yet supplied the stock of pharmaceuticals, the actual cost incurred by the supplier was not confirmed, and although the price increase should be given by obtaining written evidence confirming the actual cost incurred by the supplier it was not done accordingly. After 93 days the price revision was approved and 8,400 units had been supplied at Rs.2,000 per unit.

(l) The Order No. 2022/SPC/X/C/P/00575 of 25,000 units had been issued to be procured on emergency basis. The Procurement Committee had recommended immediate supply of 25,000 units at US$ 5.75 per unit to the lowest bidder based on the recommendations and price evaluation of Technical Evaluation Committee. Although it was decided to invite bids on an emergency basis and the bids were invited stating that they should be supplied immediately, the fact that the "emergency" basis was limited to inviting bids from bidders was problematic as the stock of pharmaceuticals had not been supplied by 26 October 2023. Although it was decided to cancel this order as it does not belong to the priority category, the State Pharmaceuticals Corporation informed that it cannot be canceled as it is an order approved under the Indian Credit Line and is currently in operation. Even though more than a year had elapsed since the order was issued, due to the non-implementation of the order in an updated manner it was observed during the audit that the stock related to this order is not available and there is a tendency for the order to be cancelled.

(m) Purchase order No. 2022/MSD/V/C/P/0633 of 12,000 units was issued on 04 November 2022. As per the purchase order, on 26 December 2022 and within 50 days of the selected bidder was to supply the stock as published in the bid, the supply was terminated after 94 days on 30 March 2023. A number of 2,000 units had not been provided by 09 October 2023. There was no clause in the bid documents regarding availability of performance bond and as per the letter dated 28 October 2022 from the Secretary to the Ministry of Health to the Deputy Director General (Medical Supplies Division) that the duration and amount of the performance bond shall be determined as per the delivery schedule and as per the exigencies. Although informed, it did not state that the guarantee should not be taken. However, subsequently, the Secretary of the Ministry had overstepped his authority and exempted him from obtaining performance bonds and entering into contracts with the contractor.

55. Imatinib Mesilate Tab/Cap 100 mg (SR - 01204401)

(a) The annual estimate of hospitals for the year 2021 was 835,000 units, and the number of units issued during the year was 1,613,875. That amount was a 93 per cent increase compared to the estimate. Out of the orders issued, the stock of pharmaceuticals related to the normal order of 1,562,500 units had not been received by the Medical Supplies Division by 15 November 2023.

(b) The annual estimate of hospitals for the year 2022 was 582,080 units and the number of units issued during the year was 1,325,000 units. That amount was a 128 per cent increase over the estimate. Out of the orders issued, only 30,000 units received as grants were received by the Medical Supplies Division during the year.

(c) Although the orders of 140,000 units, 137,500 units , 137,500 units were shown as issued orders by order No. 2022/SPC/E/R/P/00610, No. 2022/SPC/V/R/P/00690 and No. 2023/SPC/E/R/P/00143 respectively within Swastha System, these stocks of pharmaceutical were not shown in the Swastha system as receivables.

(d) It had been decided not to release the normal order 2022 based on the order control form prepared. However, 1,325,000 units including 30,000 units received as donations had been issued during the year as Indian loan assistance and emergency purchases.

Even though a normal order, pertaining to the order of 1,562,500 units issued on 08 January 2020 for the year 2021 had not been issued for 2022 considering pharmaceutical stocks on receivables basis, the said stock of pharmaceuticals that was due to be received had not been received by the Medical Supplies Division by the audited date of 15 November 2023 .

(e) The Order No. 2022/SPC/X/R/P/00306 of 600,000 units for the year 2022 had been issued on emergency basis. Seven bidders had submitted bids and it was decided to award the procurement to the bidder who submitted the lowest price out of the two qualified bidders according to the recommendations of the Technical Evaluation Committee and the recommendation of the Procurement Committee given on 06 October 2022, that is 167 days after that recommendation. Although the performance bond was supposed to be submitted within 14 days of issuing the purchase order, it was submitted 96 days later. The order was placed on 07 April 2023, that is 97 days after the date of delivery of the pharmaceuticals mentioned in the purchase order, and the remaining shelf life of the pharmaceuticals was in between 18 and 19 months. The supply of pharmaceuticals had been delayed for more than a year after the order on 26 March 2022 was issued on an emergency basis, and accordingly, it was problematic in the audit whether the emergency basis is only valid for "giving a period about 05 days to submit bids".

(f) The Order No. 2022/MSD/V/R/P/00074 for 137,500 units, a supplier with the registration certificate of the National Medicines Regulatory Authority had been selected to supply 137,500 units at US$ 0.0044 per unit. According to the purchase order, although it was mentioned that 6,000 units and 131,500 units should be supplied, and the selected bidder in his bid documents said that he would supply 6,000 units immediately and the rest within 30 days, the stock of pharmaceuticals related to the Medical Supplies Division had not been supplied even by October 2023, which was the date of audit..

(g) The Ministry of Finance issued the order on 16 June 2022 for the purchase of 140,000 units No. 2022/SPC/E/R/P/00730 as per the guidelines for the Health Sector Emergency Procurement Process (HSEPP). Although the recommendation had been made by the Emergency Procurement Committee of the Health Sector to award the procurement to the lowest responsive bidder of Rs 59.66 per unit under a Waiver of Registration (WOR) on the basis of the prevailing emergency, the related Covering Approval letter of the Cabinet of Ministers was not in the file. A number of 139,980 units were specified to be supplied and it was stated in the bid documents that the stock of pharmaceuticals would be supplied "immediately" and the bid documents of the selected bidder stated that the stock of pharmaceuticals would be supplied after the issuance of the WOR. Furthermore, even at the time when the purchase order was issued, the Medical Supplies Division did not have any stock of pharmaceuticals and the fact that the order was not issued to supply the stock stating, "immediately" was also problematic in the audit. The request for WOR Certificate was forwarded by the State Pharmaceuticals Corporation to the National Medicines Regulatory Authority on 23 January 2023 and after 24 days on 16 February 2023 this approval was given. Accordingly, due to the delay in issuing the WOR Certificate, the supply of pharmaceuticals was not done on 28 February 2023 as mentioned in the purchase order, and the order was given to the Medical Supplies Division 16 days after the WOR Certificate was issued.

(h) The Procurement Committee had given recommendation to invite bids from registered suppliers at limited prices after 07 days of issuing of order No. 2022/SPC/E/R/P/00744 for 140,000 units. The Technical Evaluation Committee had recommended awarding the bid to the lowest responsive bidder. At the time the purchase order was issued, the medical supplies division had no stock and the national stock condition was limited to 0.01 months as per the system. Accordingly, as per the bid documents, the purchase order had been issued stating that the stock of pharmaceuticals would be supplied on 31 March 2023, instead of being supplied "immediately".

(i) Although the Medical Supplies Division had decided not to issue the normal order for the year 2023 for this pharmaceutical as per the order control form prepared, two orders were issued about 10 months later as a normal order of 275,000 units and an emergency purchase order of 137,500 units. Accordingly, the accuracy of the information based on when the orders were issued was problematic in the audit.

(j) Although the normal order should be issued at least 11 months in advance, the normal order of 275,000 units for the year 2023 had been issued on 16 November 2022. If a normal order is placed on the scheduled date, although it is possible to carry out the procurement under an open bid method in the

current emergency situation, although the Procurement Committee had recommended calling for bids at limited prices within 07 days, the bids were called without giving a reasonable time to the bidders to respond after 75 days of this approval. The purchase order was issued on 17 July 2023, a delay of 131 days after the award of bids, stating that the stock on hand is sufficient for 09 months by 07 July 2023, stating that the pharmaceutical stock should be supplied on 15 May 2024. According to the order control form prepared in January 2022, despite it had decided that there is no need to issue an order for the year 2023, issuing an order without preparing a reorder control form was problematic in the audit. The supplier had not given the performance bond as of the audited date of 06 November 2023, and had also not entered into a contract agreement with the supplier. Further, an assurance from this supplier had not been obtained that the stock of Pharmaceutical would be supplied on the date mentioned in the purchase order.

(k) According to the Guidelines No. PFD/PMD/Health/ HSEPP/01/2022 dated 16 June 2022 had been issued by the Ministry of Finance for the Health Sector Emergency Procurement Process (HSEPP), the order No. 2023/SPC/E/R/P/00143 for 137,500 units had been issued. Although it had been decided that there is no need to issue an order for the year 2023 in January 2022, issuing of this emergency order in January 2023 itself was problematic in the audit. Although there was no enough time was given to submit the bids, the Technical Evaluation Committee had submitted its recommendations on 24 April 2023, about 25 days after the invitation for bids. Accordingly, it was problematic in the audit whether the basis of procurement of pharmaceuticals was "immediate" only for bidders to submit bids. According to the recommendation of the Technical Evaluation Committee, the Medical Supplies Division had stated that the stock of this pharmaceutical is sufficient for 12 months, and the Procurement Committee had decided to cancel the order 18 days after issuing the recommendation. Accordingly, it was a controversial matter during the audit that the Medical Supplies Division had issued orders on emergency basis stating that they did not have sufficient stock and canceled the order stating that they had sufficient stock. Accordingly, the time, effort and cost spent on this order had been useless.

(l) An order control form for determining the normal order quantity for the year 2024 had not been prepared by 15 November 2023. Accordingly, a decision had not been taken in respect of issuance of the order for the year 2024 .

(m) The Medical Supplies Division did not have the stock of pharmaceuticals during the period from 02 September 2022 to 13 March 2023 and accordingly, 02 hospitals purchased 724 units were purchased for Rs.260,480 as 400 units at Rs.500 each and 270 units at Rs.224 each during this period .

56. Oxaliplatin injection 50 mg in 10ml vial (SR-01203801)

(a) According to Swastha Computer Data System, all the quantities of this pharmaceutical had been totally out of stock as at 12 October 2023 .

(b) A number of 15,000 units, 2,550 units and 2,750 units were ordered for the years 2021, 2022 and 2023 respectively, and when these orders were placed, it was observed that there was no sufficient stock. It was observed in the audit that the cancellation of the orders issued after 2020 was the reason for this.

(c) A normal order of 12,000 units of this pharmaceutical for the year 2021 was placed on 06 January, 2020, and bids were called on 02 February 2020 according to the international competitive bidding system and the bids were opened on 24 April 2020. It had been decided to award the procurement to the lowest bidder 7 months after the opening of bids. The decision was communicated to the selected supplier 02 months later. In issuing the Indent on 31 March 2021, the Indent was issued with a delay of more than one year from the delivery dates mentioned at the time of placing the orders.

(d) The National Medicines Regulatory Authority (NMRA) certificate which was submitted by the selected bidder was a certificate obtained for another SR number named Oxaliplatin for injection USP 50mg in 30ml vial and its acceptability was problematic during the audit. It was also observed that this certificate has been canceled on 14 June 2023.

(e) The Medical Supplies Division had terminated this order and the previous order of 12,000 units on 23 September 2021 as the demand for this pharmaceutical had decreased due to the ongoing Covid epidemic in the country. However, even though the Director of the Medical Supplies Division informed on 21 July 2022 to recall 3,000 units from this order, the pharmaceuticals had not been received by the Medical Supplies Division by the date of audit 12 October 2023 .

(f) Orders for purchase of 1,800 units had been placed under Order No. 2022/SPC/X/R/P/00306 despite two earlier issued orders had been suspended. The Departmental Procurement Committee had decided to award the bid to the organization that submitted the lowest price. Again after three months, it was observed that the Procurement Committee had decided to invite the supplier to get an explanation regarding the supply of the awarded item, and failure of submission of the required performance guarantee and not signing the contract were mentioned as reasons for that. At that time, the supplier had sent a letter to the State Pharmaceuticals Corporation and requested an increase in the price offered at US$ 3.50 to US$ 6.875 due to the increase in prices of

raw material. It was observed that the Procurement Committee had canceled the relevant procurement on the basis of price increase of the supplier. It was observed that the NMRA certificate submitted during the bid evaluation of this pharmaceutical was related to another SR number.

(g) The order No. 2020/SPC/E/R/P/00744 for the emergency purchase of 750 units had been forwarded by the Medical Supplies Division. Despite this order was mentioned as an urgent order, 15 days had been spent for inviting bids. However, only 06 days were given for submission of bids and it was observed that by giving six days for submission of quotations considering it as an emergency purchase, and giving long time intervals like 1 ½ months for evaluations, the competition had been limited on the grounds of emergency and no emergency has been shown in other matters. The NMRA certificate for the other dose of this pharmaceutical submitted in relation to this order had been expired by 21 April 2020 and it was extended again and presents as a valid certificate by the time of the Indent was issued . Although the certificate is a pharmaceutical related to another SR number, it was not taken into consideration during the evaluation of bids. This stock of pharmaceutical was received by the Medical Supplies Division on 10 March 2023 and it was observed that it was included in the stock under a different order number and SR number.

(h) Order No. 2023/SPC/N/R/P/00081 of 1500 units related to the year 2023 had been forwarded on 16 November 2022. According to the order control sheet, there was an excess stock of pharmaceuticals of 23,501 units related to the forecast period and an order of 1,500 units had been issued as a normal order. Although the normal order of the year 2023 should be submitted 11 months in advance, based on the pending orders, the above normal order was submitted about a month before the commencement of the year 2023. It was observed during the audit that the responsible officers were negligent in taking decisions by the Departmental Procurement Committee for this pharmaceutical which was not included in the priority list.

(i) When the procurement activities related to the normal order 2023 were being carried out, the order had been issued on two occasions for the purchase of 750 units and 500 units and due to it was not included in the priority list, the Health Sector Emergency Procurement Committee had decided to cancel these procurements.

(j) It was observed in audit test checks carried out that 18 units of this pharmaceutical had been purchased for Rs.162,000 as one unit of for Rs.9,000 by Badulla General Hospital because of delays of all the orders due to various reasons.

57. Ergometrine maleate inj.500mcg/1ml amp (SR - 01300102)

(a) The order No. 2022/SPC/N/R/P/00007 for 15,000 units of injection had been submitted to the State Pharmaceuticals Corporation for the year 2022 on 27 February 2021 through the Information Management System and the order had been sent in writing 18 days later. According to the international competitive bidding system, although 02 bids had been submitted, this order was temporarily suspended at the request of the Medical Supplies Division . As per 5.3.10 of the Procurement Guidelines, although the bid should be awarded and completed within the bid validity period, this bid had been awarded on 05 October 2022 without extending the validity period. The validity period of the NMRA registration certificate related to the pharmaceutical had also expired on 20 May 2022 by that time. However, the Indent was issued on 17 October 2022. The pharmaceuticals related to this order had not been supplied as at October 2023.

(b) The procurement had been awarded to the lowest bidder from 2 firms that submitted quotations in respect of order No. 2022/SPC/X/R/P/00284 for 35,000 units of injections. The Indent had been issued on 04 July 2022, stating that the entire stock should be received by 31 March 2023. The total number of injections of this pharmaceutical was provided on 12 April 2023. The performance security applicable to this procurement was given with a delay of 41 days. At the time of awarding this contract to the supplier, although the NMRA registration certificate of the pharmaceutical had expired and the supplier has applied for re-registration, the National Medicines Regulatory Authority had not taken steps to renew the registration or reject it accordingly. A shipment clearance letter had been issued. Estimated cost related to this order was calculated as Rs. 17,035,200 and the actual cost was Rs.8,845,561. Accordingly, there was a variation of 92 per cent between the estimated cost and the actual cost. Due to delay in bank guarantee related to this order although an additional cost of Rs. 75,600 had been incurred as cold room charges the amount had not been recovered from the supplier.

(c) Although the normal order related to the year 2023 should be issued by January 2022, the normal orders 2023 of 17,500 units had been issued on 17 November 2022. According to the decision of the Departmental Procurement Committee, The bid was awarded to a company that was the only bidder for the purchase at a cost of US$ 2.80 per unit. However, since the normal order units are to be received in the years 2021 and 2022, the date to receive this order had been postponed to March 2025 and the procurement process had been terminated.

(d) Although there was sufficient stock of this pharmaceutical , 53 units in 4 cases had been purchased locally for Rs.21,925.

(e) It was observed that this pharmaceutical had expired in the hospitals due to the fact that the estimates of the pharmaceutical were not prepared properly, the quantities to be ordered were not properly predicted, the hospitals maintained unnecessary excess stock, and information about the excess stock quantities was not submitted and purchase cost of expired stock had been only Rs. 5,238,344 .

58. Pazopanib tablet 200 mg (SR-01208101)

(a) Quotations were invited from registered previous suppliers by fax on 25 August 2021 under order No. 2021/SPC/O/C/P/00528 dated 20 July 2021 for obtaining 18,505 units of pharmaceutical and only one company had submitted the quotations. The Indent was given to the same supplier on 25 October 2021 and the order had to be delivered by 18 April 2022. This stock of pharmaceuticals had not been delivered even on the audit date of 02 November 2023, and was shown as a receivable stock in the Swastha System. The performance bond related to this order was valid until 30 July 2022 and the registration with the National Medicines Regulatory Authority was also valid only until 03 June 2022 .

(b) Even though it had been stated in the Swastha System about an order for obtaining 30,000 units (Tabs) of pharmaceutical under order number 2021/SPC/E/C/P/00653 dated 08 September 2021, information regarding such order was not made available during the audit as per MSMIS system and as per data system of State Pharmaceuticals Corporation.

(c) According to the Order No. 2021/SPC/E/C/P/00680 dated 16 September 2021 , the approval of the Departmental Procurement Committee had been given on 25 October, 2021 to invite quotations by fax from registered previous suppliers for procuring 25,000 units of pharmaceuticals. The procurement had been awarded on 26 January 2022. The order had been cancelled by the Departmental Procurement Committee on 18 August 12022 as the supplier requested a period of 45 weeks. As there were no other responsive bids, it was decided to re-invite quotations and quotations had been invited from registered and previous suppliers. Accordingly, the procurement was awarded subject to obtaining WOR certificate on 20 October 2022 and independent laboratory report for samples prior to shipment. However, as per WOR Committee decision dated 16 February 2023, WOR certificate had not been awarded. Accordingly, since the order could not be awarded even after 02 years and this stock of pharmaceutical was shown as a receivable stock in the Swastha Data System even by 03 November 2023, it was observed during the audit that no special attention has been paid to prioritize the purchasing of cancer pharmaceuticals to cancer treatment centers in Sri Lanka.

(d) It was observed according to the information obtained from the MSMIS computer system that due to the non-receipt of orders related to this pharmaceutical , there were no stock in the Medical Supplies Division for 94 days during the period from 20 July to 29 November 2021 .

(e) The order No. 2022/SPC/N/C/P/00081 for 50,000 units was forwarded to the State Pharmaceuticals Corporation by the data system on 17 September 2021 and the respective order was given in writing to the Corporation after a delay of 12 days. There was zero stock in hand as at 08 September 2021. Although the members of the Technical Evaluation Committee had signed the Evaluation Report, their names and positions were not mentioned. In submitting its bid, the supplier had indicated that it would be able to supply the pharmaceutical in 45 weeks after receiving the Indent and Letter of Credit. Based on these facts, the relevant supplier was selected on 02 February 2022. Although the supplier had accepted this order on 09 February 2022 subject to the above conditions, the Procurement Committee Meeting held on 18 August 2022 had decided to cancel this order and re-bid. Accordingly, it was observed that almost a year had elapsed to cancel the order regarding the conditions notified by the supplier on 15 February 2022 and although the order was cancelled due to the fault of the supplier, the action taken against him was not observed according to the file.

(f) The quotations were called again on 08 September 2022 under the Departmental Procurement Committee to procure these 50,000 units. The Procurement Committee which met on 15 November 2022 had recommended to get a unit of pharmaceutical at an unusually low price of Rs.330 subject to obtaining a Waiver of Registration (WOR) without considering on the bid of Rs. 1,370 for a unit supplied by a supplier with a registered certificate from the National Medicines Regulatory Authority and subject to obtaining an independent laboratory report for pre-shipment samples . The stock level of this pharmaceutical was zero as at 08 November 2022. As per WOR Committee decision, this certificate was not allowed because of both the pharmaceuticals manufacturer and the local agent were not registered. According to the Swastha Data System, it is shown that 50,000 units of pharmaceutical are to be received from this order number and it was further observed during the audit that continuous supply of pharmaceuticals cannot be given to cancer patients by indicating such stocks as items to be received in the data system for an order that has not been issued even an Indent.

(g) The written order documents containing the supply conditions related to this order No. 2022/SPC/X/C/P/00331 which was placed on 26 March 2022 for the purchase of 54,000 units of this pharmaceutical under the Indian Credit Line, had not been included in the file submitted for audit. The Departmental Procurement Committee had recommended on 21 April 2022, to award the procurement to the Indian supplier who submitted the lowest unit price of US$ 3.05 per unit. After 12 days of taking that decision, the order had been awarded to the respective

agency. The order was placed subject to an independent laboratory report to be provided at the supplier's cost and a WOR certificate to be submitted prior to shipment of the pharmaceuticals. Although the supplier should obtain the WOR certificate before issuing the Indent, the Indent had been issued on 04 July 2022 and the WOR certificate was had been on 06 September 2022. It was informed that DHS mark could not be embossed on this pharmaceutical on 10 August 2022 and the Medical Supplies Division had approved this proposal on 17 August 2022 . The first 27,000 units of this stock had been delivered to the Medical Supplies Division with a delay of about 04 months and the third stock of 10,000 units with a delay of about 1 ½ months. Even one unit of this pharmaceutical for 23 days from 08 July to 01 September 2022 and for 104 days from 01 September to 14 December 2022, was not available in the Medical Supplies Division.

(h) The approval was given on 15 November 2022 to invite quotations from registered and previous suppliers within 07 days for procurement as per Emergency Purchase Order No. 2022/SPC/E/C/P/00748 dated 09 November 2022 for 22,500 units. Accordingly, quotations were requested from 04 institutions on 25 November 2022 by fax. Bids had been opened on 02 December 2022. The representatives of 08 institutions had participated as representatives of bidders. However, according to the Bid Opening Minutes dated 02 December 2022, the number of companies that sent quotations was two. According to the Evaluation Committee Report dated 02 December 2022, although two organizations had been evaluated, it was stated in the minutes of the Procurement Committee Meetings dated 28 December 2022 and 04 January 2023 that three organizations had submitted bids for this procurement. As the entity which submitted the lowest bid of Rs.1,256.63 per unit was not registered with NMRA and the other supplier was registered with NMRA, it was recommended to award the procurement subject to price negotiation. This company had agreed to supply Rs.1,467 per unit with a price reduction of Rs.10 per unit. However, the relevant stock of pharmaceuticals had been given with a delay of 64 days. Accordingly, this procurement, which was expected to be done on 09 November 2022 as an emergency purchase, had taken more than 5 months.

(i) An order No. 2022/SPC/E/C/P/00497 had been issued on 29 June 2022 to meet the one month requirement of 9,000 units. According to this order, the pharmaceuticals were to be supplied on 15 July 2023. Accordingly, as per the quotations called for bids by 22 July 2023, out of 03 bids submitted by the Technical Evaluation Committee, which met on 05 August 2022 had recommended to buy at a unit for Rs. 1,987.15 from the supplier who offered the lowest price. However, the Procurement Committee which met on 30 August 2022 had decided to give to the same company that had awarded the main pharmaceutical order at a price such as Rs.1,609.30 for the purpose of

expediting the procurement. The file did not include details of the newspaper advertisement inviting bids or letters sent to registered suppliers. Also, even on the audit date of 23 October 2023, this stock of pharmaceuticals had not been received.

(j) The approval had been given to the Medical Supplies Division on 04 October 2022 to enable private sector importer agent to import medical supplies and to purchase sufficient stock of medical supplies by order No. 2023/SPC/X/C/P/00195 for 60,000 units for three months under the approval of the National Medicines Regulatory Authority as emergency procurement using the remaining funds under the Indian Credit Line. On 15 June 2023 and 15 September 2023, a number of 30,000 units of pharmaceutical had to be supplied each. According to the calling for bids made on 14 June 2023 by the Health Sector Emergency Procurement Committee from suppliers registered under the National Medicines Regulatory Authority, bids were to be submitted by 16 June 2023. Thus, it was observed that 04 organizations had submitted bids and no sufficient time had been given to submit bids.

(k) Although all the 4 bidders did not have NMRA certificate and other conditions are the same out of two institutions with NMRA-Manufactured site approval, the Technical Evaluation Committee met on 27 June 2023 had recommended the institution which submitted a unit at a price of Rs. 1,905 considering the supply schedule as well . As the institution had agreed to provide this supply at a unit price of Rs.1,835.17, the Procurement Committee meeting on 28 June 2023 had recommended that this supply to be given to the institution and evidence that the cover approval of the Cabinet of Ministers was obtained for this procurement decision was not submitted to the audit. The Indent was issued on 07 September 2023 and the supplier had to supply 60,000 units of pharmaceutical by 07 November 2023. The performance bond and agreement related to this order were not included in the file submitted for audit. This supplier had agreed to supply the pharmaceuticals within 30 days from the date of WOR certificate and was able to get the pharmaceutical stock at Rs. 34,552,200 less than the price of the selected supplier. However, this supplier had not provided the stock of pharmaceuticals even by 17 November 2023 .

(l) The Emergency Purchase Order No. 2023/SPC/E/C/P/00145 of 22,500 units had been issued on 27 January 2023. Accordingly, this emergency procurement was done by the Emergency Procurement Committee of the Ministry of Health. The evidences were not submitted to the audit that approval of the Cabinet of Ministers was obtained for the procurement decision. The performance security related to this order was not included in the file.

(m) According to the MSMIS system, although the historical data of the pharmaceuticals given to the named patients and the historical data of the pharmaceuticals given as substitutes had been included, it was observed that during the audit that the facilities for entering that information in the Swastha Data System had not yet been created and due to this it was also observed pharmacists were not able to obtain information about the history of pharmaceuticals given to patients when necessary.

(n) Although the quantities of pharmaceuticals ordered are shown as the quantities of pharmaceuticals to be received in the MSMIS system and the Swastha Data System, due to failure to properly cancel those orders and remove them from the data system if the stocks are not actually received after investigating the possibility of further receipt of these pharmaceuticals, the reason for non-receipt, the progress related to the relevant order and the possibility of receiving the pharmaceuticals in the future, the forecasts made in ordering pharmaceuticals had become inaccurate. By making forecasts based on inaccurate data and preparing order quantities and supply schedules, pharmaceutical shortages occur due to non-availability of stocks of pharmaceutical predicted as relevant orders and to make local purchases and emergency purchases as a remedy to the pharmaceutical shortage and having to purchase pharmaceuticals at high prices under emergency purchases were also observed during the audit.

(o) Due to the failure of the Medical Supplies Division to maintain adequate stock levels in the years 2020, 2021 and 2022, and the failure of the State Pharmaceuticals Corporation to supply this pharmaceutical according to the supply schedules, this pharmaceutical was unavailable in the hospital system on 06 occasions for a period of 319 days. Likewise, nearly 50 per cent of this pharmaceutical is given to the Maharagama Apeksha Hospital and only 24,700 units had been supplied from the 36,000 units requested in 04 occasions in 2022 and 2023 from that hospital.

59. Capecitabine Tab 500 mg (SR - 01201601)

(a) A number of 200 units ordered for the year 2020 and 64 per cent of the units ordered for the year 2021 had not been received even by 30 September 2023.

(b) Four months had been spent to evaluate bids after issuing the normal order of 230,000 units for 2022. After the technical evaluation, the Procurement Committee had spent more than 02 months for the meeting and nearly 55 days had been spent for awarding the order. According to the Indent, although 250,000 units had to be received by 31 October 2023, the stock had not been received even by 28 November 2023 according to the data system.

(c) It had been decided to invite bids from registered suppliers for an emergency order of 83,000 units by order No. 2022/SPC/E/R/P/00457. As the consent was given to supply as the unit price was Rs.290 to the entity which submitted the lowest unit price of Rs.310, this order had been recommended to be awarded subject to obtaining the WOR certificate. Due to issuing emergency orders in this way, the quantity of pharmaceutical related to the year 2022 was ordered according to a fixed plan and without arranging to get the stock on the specified days, the price of the unit Rs.35.98 related to the normal order of the year 2022 had increased to Rs. 290. Accordingly, the additional cost to be incurred was Rs. 21.083 million. This was a about a 706 per cent price variation .

(d) The order of 160,000 units of this pharmaceutical had been issued under No. 2022/SPC/E/R/P/00603. Even though it had been decided to award to the lowest bidder at Rs. 68.59 each in the Technical Evaluation Committees subject to obtaining NMRA certificate or WOR, there was no evidence on file that further action was taken or canceled in respect of this order. Likewise, the evidence that the cover approval of the Cabinet of Ministers was obtained for the above decisions given by the Health Sector Emergency Procurement Committee was not submitted to the audit.

(e) The company has agreed to reduce the price by 0.5 per cent from the lowest unit price for order No. 2022/ SPC/E/R/P/00702 of 83,000 units and has agreed to supply the pharmaceutical within 3 weeks, it had been recommended to grant the order. The performance bond and contract agreement were not included in the file. After awarding the order, one month was spent requesting the WOR certificate and more than 06 months had been spent to provide it. Since the WOR certificate is only valid for 06 months from the date of issue, although this stock of pharmaceuticals should be received by 01 December, it was observed that since the pharmaceuticals had not been received even on 30 November 2023, a WOR certificate had to be obtained again.

(f) It had been decided to invite bids from registered suppliers for the order of 250,000 units by No. 2022/SPC/E/R/P/00730. Bids had been submitted by 05 institutions and as the Procurement Committee met and could not agree on the time taken for supply of pharmaceuticals by the institution which submitted unit price of Rs.250 with National Medicines Regulatory Authority registration out of these orders, it had been recommended to place the order subject to taking WOR certificate to the company that submitted the bid at the unit price of Rs.102.27. According to the information provided to the audit by the National Medicines Regulatory Authority, a WOR certificate had not been issued to this institution by 20 November 2023. For this order, which was awarded as an emergency order, the pharmaceuticals had not been received even by 30 November 2023 .

(g) Despite the emergency orders of 83,000 units and 250,000 units had been issued, an emergency order bearing No. 2022/SPC/E/R/P/00744 of 250,000 units had been issued by the Medical Supplies Division. The Procurement Committee had decided to invite bids from registered and previous suppliers within the purview of the Departmental Procurement Committee. A formal and specific recommendation had not been given by the Evaluation Report and the Committee Members had signed the relevant report without mentioning their names and positions. The Procurement Committee met and decided to reduce the price from the National Medicines Regulatory Authority registered entity, which submitted the lowest unit price of Rs.99 out of these bids. The Indent was issued on 12 January 2023, and 249,990 units had to be supplied on 13 March 2023, and 247,440 units, that is 2,550 units less, were received on 04 April 2023. A debit note of Rs.2,449,656 was sent to the supplier due to receipt 22 days late. The supplier had submitted a letter of excuse on 01 June 2023 and again submitted a letter on 04 August 2023 indicating that the remaining stock of 2,550 could not be supplied. However, the information to confirm these payments was not included in the file.

(h) Although the normal order for the year 2023 should have been issued in January 2022, the order of 500,000 units had been issued on 16 November 2022 with a delay of about 10 months. The Procurement Committee had decided to invite bids from suppliers registered under the National Medicines Regulatory Authority and according to the evaluation report, no formal and specific recommendation had been made. After the order was issued, a period of 04 months had been spent to evaluate the bids. It took more than 02 months to meet the Procurement Committee after the recommendation of the Technical Evaluation Committee and almost 55 days to award the order after the procurement evaluation. According to the Indent, although 250,000 units had to be received by 31 October 2023, this stock of pharmaceuticals had not been received even by 28 November 2023 according to the Data System.

(i) Bids were opened for order number 2023/SPC/X/R/P/00191 for 600,000 units and 08 entities had submitted bids. The supplier had agreed to reduce the unit price from Rs.95.89 to Rs.95.79. A performance bond was not given as per the file and the inventory was listed as a receivable as per the system. Only 02 days period was given for submission of bids. Although the cover approval of the Cabinet of Ministers should be obtained, the evidence that the approval was obtained had not been submitted to the audit. It took almost 70 days to award the order after procurement evaluation. Even though it was mentioned that the shelf life of the pharmaceutical is 24 months, it was problematic in the audit because it was stated as 12 months in the Indent.

(j) Bids were invited for the order No. 2023/SPC/E/R/P/00204 of for 300,000 units and bids were opened on 14 September 2023 and 07 organizations had submitted bids. As the bidder who had submitted the lowest price was not a registered supplier and the second lowest institution who was the previous registered supplier had been recommended at a price of Rs.108.31. According to the minutes of the Procurement Committee Meeting, it was stated that this pharmaceutical is sufficient for another month only and it was stated that the company that offered the lowest price should reduce the prices and verify the registration of the National Medicines Regulatory Authority and the file was closed after this note. Only 03 days period was given for submission of bids. Even though 40 days had elapsed since the opening of bids, the order had not been awarded because a supplier could not be selected even by the audited date of 04 December 2023 .

(k) According to the Swastha system, it was shown that 1,919,416 units of this pharmaceutical to be received on 07 December 2023. However, the information on how the number of units was set, had not been included in this system.

(l) Although the normal order relating to the year 2024 should be issued in January 2023 the order had not been issued by the end of November 2023. Due to the fact that the normal orders related to the last two years of this pharmaceutical were not issued as scheduled based on formal forecasts and emergency orders were issued in several cases, the opportunity to purchase the pharmaceutical at a lower price through better competition was lost and due to the normal order related to the year 2024 not being issued on the scheduled date in the year 2024 it is also observed that this may be bought under emergency purchases at a higher than an average cost.

60. Cytarabine Inj 100mg/5ml (SR 01201701)

Seven orders had been issued to the State Pharmaceuticals Corporation for the purchase of 29,500 units of injection by the Medical Supplies Division from this pharmaceutical which injects in combination with other approved anti-cancer pharmaceutical to treat leukemia from 2020 to 2023. Even though the procurement process for the 07 orders had been commenced, even one of the order of pharmaceutical had not been able to receive. Accordingly, a zero stock situation was observed from the year 2020 until 19 October 2023. It was observed during the audit, that the following factors which had been done during the procurement process caused this zero stock situation.

(a) No one has responded regarding the 11 faxes sent directly to 12 foreign companies out of invitations to bid sent to suppliers selected under Order No. 2020/SPC/A/R/P/00168 and Procurement No. DHS/RP/408/2020 and the faxes

sent directly to 11 foreign companies out of the invitations to bids sent to suppliers under Order No. 2023/SPC/ N/R/P/00081 .

(b) Although the samples should be submitted by the bidders under the order No. 2021/SPC/N/R/P/ 00020 and procurement No. DHS/RP/51/2021, the samples had not been submitted by the selected supplier even by the time of bid opening.

(c) Although the supplier selected under No. 2021/SPC/N/R/P/00020 had paid for the renewal of registration on 16 November 2021 and also it took a period of 220 days to renew the registration, the National Medicines Regulatory Authority was unable to issue the registration renewal certificate even by 19 October 2023**.**

(d) Although the Order No. 2022/SPC/E/R/P/00744 to purchase 750 vials of injection was awarded to the supplier M/S Tabrane, who had submitted Rs.1,700 per each vial of injection with the Waiver of Registration of the National Medicines Regulatory Authority, the procurement had been withdrawn on 16 January 2023 due to shortage of raw materials by the supplier. Accordingly, although it had been decided on the recommendation of the Technical Evaluation Committee to award to the supplier M/S Tabrane itself who had submitted as the lowest second bid price for this vial of injection with a Waiver of Registration of National Medicines Regulatory Authority based on experience prior to recall bid. Despite the said supplier has withdrawn the procurement as above, the Procurement Committee irresponsibly approved on 02 March 2023 to award the procurement to the same supplier without ascertaining whether the supplier is capable of procuring the pharmaceutical during the re-bid process. The supplier has applied for Cytarabine Inj 100mg /ml and the Corporation has applied for Cytarabine Inj 100mg /5ml and on 01 June 2023 and it had been applied for Waiver of Registration on 26 September 2023 for purchase of Cytarabine Inj 100mg /ml dosage spending a period of 89 days as at 03 September 2023 to enter a proper decision in that regard from the date of informing the Medical Supplies Division on 06 June 2023 regarding the issue related to the problem arising on the notification of the supplier on 01 June 2023 .

(e) Even though the Departmental Minor Procurement Committee had given its approval on 23 May 2023 to the lowest second bidder who was the supplier submitted a vial of injection at Rs. 1,310 to the bid invitation of purchasing of 1,500 vials of injection under order number 2023/ SPC/N/R/P/00081 subject to receipt of Waiver of Registration (WOR). The supplier has informed on 20 June 2023 that the supplier had applied for procurement Cytarabine Inj 100mg/ml. In a background where it is not possible to provide pharmaceutical due to non-availability of raw materials to the awarded supplier and non-availability of that dose of the pharmaceutical ordered by the Corporation for both orders awarded in

the year 2022, taking the decision of the Procurement Committee to award this order to the said supplier is problematic in audit.

(f) The Emergency Procurement Committee of the Ministry of Health has given approval on 28 June 2023 on the recommendation of the Technical Evaluation Committee to award the procurement to the lowest second bidder who had submitted value of vials for (after price agreement) Rs. 1025.00 each for the invitation to bid for purchase of 1,500 vials of injection under Order No. 2023/SPC/X/R/P/00191 with registration certificate from National Medicines Regulatory Authority. Even though the National Medicines Regulatory Authority registration certificate of the Bidder who had submitted the lowest bid per unit as Rs.950 had expired on 20 May 2022 and the renewal certificate had been issued, without considering that, the lowest bidder had been rejected.

61. Methylene Blue injection W/V 10 ml Ampoule 500 mg (SR - 01601201)

(a) Order No. 2022/SPC/V/R/P/ 00715 was issued on 28 October 2022 for the purchase of 750 units of this pharmaceutical and it had not been implemented. Even though the order No. 2022/MSD/E/R/P/00041 had been issued on 25 August 2022 , a file related to this order had not been submitted to audit and it was observed that even on the date of audit on 17 November 2023, both of the aforesaid orders were showing as issued orders in the System.

(b) The normal order 2022 of 4,000 units had been issued on 02 February 2021. It was observed that 4,000 units under this order had indicated as stock receivable as per the system as at the date of audit 17 November 2023. Due to the decision of the Procurement Committee without considering the recommendation of Technical Evaluation Committee to purchase from the registered supplier of the National Medicines Regulatory Authority, the prices had to be re-quote in the year 2023 for the order made to purchase the pharmaceuticals for the year 2022 .

(c) The Order No. 2022 /SPC/E/R/P/00500 for 250 units had been issued on 30 June 2022. According to the decision of the Health Sector Emergency Procurement Committee, the last date for submission of bids was 22 July 2022 as per the invitation of bids made through newspapers on 15 July 2022. The Procurement Committee had met on 16 August 2022, and it had recommended that the entity that submitted the lowest price of Rs. 6,100 per a unit to be awarded of this order. The Indent had been issued on 02 September 2022 with an excessive delay of 02 months. The evidence that the cover approval of the Cabinet of Ministers was obtained for this Procurement Committee decision was not available in the file. Kandy National Hospital had purchased 25 units of this pharmaceutical for Rs.56,000 due to the lack of pharmaceuticals during this period. The estimated unit price of this pharmaceutical was Rs. 17,000 and the accepted price per unit in the normal order was Rs.6,500 and the unit price purchased under emergency

purchase was Rs. 6,100 and the unit costs of Rs.1,600 and Rs. 2,400 in local purchases were also problematic in the audit.

(d) The order control form related to the normal order to be issued by January 2022 was prepared in June 2022 and after it was decided that orders of pharmaceutical should not be issued, the normal order 2023 of 750 units had been issued on 15 November 2022, about 11 months after the scheduled date. After awarding the order, it took almost 03 months to invite bids. Bids were opened and evaluated on 07 and 08 March 2023 and nearly 03 weeks were spent for that. The procurement committee that met on 23 March 2023 had given instructions that since the organization that offered the lowest price of Rs. 4,408.18 for a unit is a registered organization of the National Medicines Regulatory Authority, a representative of that organization should be called and negotiate a price negotiation. The Procurement Committee had met again on 01 June, 2023 and since the company that submitted the lowest price did not agree to a price reduction, it was decided to ask the company that submitted the second lowest price of Rs 6,659.32 per unit about reducing the price and the file was closed after this decision. Although this order had been issued on 15 November 2022, these orders had been shown as an order issued on 23 June 2022 according to the Swastha system. Despite a unit of this pharmaceutical was purchased at a price of Rs. 6,100 as an emergency purchase in the year 2022, although efforts were made to further reduce the price of Rs.4,408.18 per unit offered for the normal order 2023, due to supplier not agreeing to it, trying to keep prices down by considering the bidder who submitted the second lowest price of Rs.6,659.32 was an attempt to award the bid to that bidder could not rule out in audit.

(e) The national level stock related to this pharmaceutical as at 21 November 2023 was 254 units and although the normal order related to the year 2024 should be given in January 2023, the order had not been issued even by 21 November 2023. As it is observed in the audit that there is no certainty of receiving the quantity of pharmaceuticals of 25,020 units indicated to be received on the date of the audit, it was observed that in this situation, emergency purchases may have to be resorted to in the year 2024.

62. Exemestane Tab. 25mg (SR 01207901)

(a) As per the information submitted to the audit by the Ministry regarding the estimated quantities of this pharmaceutical, quantities ordered, quantities received by the Medical Supplies Division and quantities utilized from 2020 to 31 May 2023, the total units of 248,500 in relation to the 06 orders issued during the period from 2019 to 2023 had been shown as orders receivable. However, only 02 orders totaling 65,500 units for the years 2021 and 2022 had been shown as receivable in the Swastha system as at 17 November 2023 .

(b) Although an order of 15,500 units bearing number 2022/SPC/V/R/P/ 00690 was shown as an issued order in the Swastha System, the quantity of pharmaceuticals related to that order had not been shown as a pending order in the Swastha System.

(c) The normal order 2022 had not been issued on the basis of receipt of 122,500 units of stock of pharmaceuticals in relation to the normal order issued for the year 2021 and the stock had not received to the Medical Supplies Division by the audited date of 15 November 2023. Although normal order was not issued for the year 2022, two orders totalling 20,500 units had been issued on emergency basis.

(d) An order of 5,000 units bearing No. 2022/SPC/E/R/P/00469 had been issued for the year 2022 by the Ministry of Finance on 28 June 2022 as per the Guidelines for the Health Sector Emergency Procurement Process (HSEPP). Two bidders had submitted bids, and the members of the Emergency Procurement Committee of the Health Sector had given the decision to award the bids on 29 August 2022. However, the letter for the approval of the Cabinet of Ministers related to this decision had not been included in the file.

(e) The Order No. 2022/MSD/V/R/P/00110 for 15,500 units had been issued on 01 November 2022. Purchase order had been issued on 30 November 2022. According to the purchase order, although it was stated that the pharmaceuticals should be supplied on 30 December 2022, the stock of pharmaceuticals related to the Medical Supplies Division had not been supplied even by the date of audit 16 November 2023. There was no clause regarding obtaining performance bond in the bid documents and, the Secretary of the Ministry of Health overstepped his authority on 02 November 2022 and approved that the performance bond should not be obtained and no contract was required. Accordingly, the Ministry had no cover whatsoever for not providing this stock.

(f) Despite of taking actions for emergency purchases in the year 2022 without issuing the normal order related to the year 2022 on the basis that the stock of pharmaceuticals related to the normal order of the year 2021 to be received, it was further assumed that the pharmaceuticals related to the year 2021 should be received and it was decided not to issue a normal order for the year 2023 also and , a normal order had been placed on 23 November 2022 to supply 30,000 units, about 11 months after the normal order for 2023 to be issued.

(g) If a normal order was placed on the scheduled date, although there is a possibility to carry out the procurement under an open calling of quotation, the Procurement Committee had given approval 30 days after issuing the order to call for bids from registered and previous suppliers at limited prices within 07 days in the

existing emergency situation. After 56 days of this approval, the registered and previous suppliers were made aware by fax on 16 February 2023 and the bidders had not been given reasonable time to respond.

(h) As per the Guidelines issued by the Ministry of Finance for the Health Sector Emergency Procurement Process (HSEPP), Order No. 2023/SPC/X/R/P/00191 of 50,000 units had been issued on 25 May 2023 under the Indian Credit Line. Bids were invited 20 days after the order, and only 02 days bid period had been given. Two bidders did not have a valid registration certificate from the National Medicines Regulatory Authority. Accordingly, although the remaining bidder had submitted the highest bid value, 11 days after the opening of the bids, on 27 June 2023, on the recommendations of the Technical Evaluation Committee and although that bidder was selected on the basis of the recommendations of the Emergency Procurement Committee members of the Health Sector on 28 June 2023, evidence on the coverage approval of the Cabinet of Ministers had not been included in the file.

(i) After 71 days for the awarding of the bid, the purchase order had been issued on 07 September 2023 for the purchase of Rs. 1,286.17 per unit, and it had been mentioned to supply 50,000 units by 30 November 2023. However, the order was given by the System to supply 25,000 units of pharmaceutical on 15 June and 15 August 2023, and according to the bid documents, it had also been stated that 50,000 units should be supplied within one month. It was also problematic in the audit that the order was not issued to supply the pharmaceutical stock "immediately" at the time when the order was issued and the Medical Supplies Division did not have the stock of pharmaceuticals. The supplier had not provided the performance bond and it had had not been entered into a contract agreement with the supplier even by the audited date of 17 November 2023 .

(j) An order control form to determine the normal order quantity for the year 2024 had not been prepared even by 17 November 2023. Accordingly, a decision was not reached on whether to issue the order for the year 2024 or not. In this situation, it was observed that emergency purchases may have to be resorted to in the year 2024 as well.

63. Thalidomide Capsule 100mg (SR - 01206401)

(a) According to the information submitted to the audit, a total of 447,463 units in relation to 07 orders issued during the period from 2019 to 2023 were stated as receivable orders. However, only 02 orders totaling 156,500 units for the years 2021 and 2022 had been shown as receivable in the Swastha system as at 17 November 2023. The description of the availability stock in the Swastha system shows 563,500 units as balance due, and specific information about which orders the stock is to be received had not been included in the system.

(b) The Medical supplies Division had not received the stocks of Pharmaceutical related to two orders of 134,463 units issued for the year 2020 by 21 November 2023 and since no orders related to the year 2022 or the previous years had been received, the quantity of issuances related to that year was only 13 per cent as compared to the orders.

(c) The annual estimate of hospitals for the year 2023 was 175,250 units, and the quantity of units ordered as at 31 May 2023 was 241,500 units. That amount was a 38 per cent increase compared to the estimate as at that day.

(d) Although order number 2022/SPC/V/R/P/00690 was shown as an issued order in the Swastha System, the quantity of pharmaceuticals related to that order had not been shown as a receivable order in the Swastha System.

(e) Although 23,024 units were to be ordered as per the prepared attachment control sheet, the Medical Supplies Division had decided not to issue the normal order for the year 2022 for this pharmaceutical. Although the total issuance for the years 2018, 2020 and 2021 was based on the stock to be received in relation to the orders of 412,500 units, the Medical Supplies Division had not received the stock of 163,463 units out of that even as at the date of audit.

(f) The Order No. 2022/SPC/X/R/P/00306 of 100,000 units had been sent through the system to the State Pharmaceuticals Corporation on the basis of emergency. The Procurement Committee had given the recommendation to the lowest bidder. The approval of the Credit Coordination Unit for the supply of stock of pharmaceuticals under the Indian Credit Line was received on 05 December 2022, and due to the delay in receiving the approval, the order was placed on 30 January 2023, after 122 days delay of the date of supply of the stock of pharmaceuticals mentioned in the purchase order. By that time, the remaining shelf life of the stock of pharmaceuticals was about 21 months. The order on 26 March 2022 was issued on an emergency basis and the supply of pharmaceuticals was delayed for about 310 days and the need of emergency was limited to "giving a time of about 05 days to submit bids".

(g) The Procurement Committee had recommended inviting bids by fax for order No. 2022/SPC/E/R/P/00744 for emergency requirement of 40,000 units. It had been decided to award the order of a unit of Rs.347 to the fifth lowest bidder whose National Medicines Regulatory Authority registration certificate expired on 15 March 2022 subject to price negotiation . The purchase order a unit of Rs. 297 each, was issued 13 days after the bid approval. The supplier had supplied the stock of pharmaceutical before the date mentioned in the order, 30 January 2023, and although the lowest shelf life of this pharmaceutical was stated as 24 months according to the bid conditions, it was stated in the bid documents that the supplier would supply stock of pharmaceutical with a shelf life of 36 months.

Furthermore, although it was mentioned in the contract agreement that the remaining shelf life of the pharmaceutical will be provided with a lowest shelf life of 12 months on the date of supply of pharmaceutical stock to Sri Lanka, the Medical Supplies Division had been provided a stock –in- hand of the supplier with a shelf life of about 06 months.

(h) Accordingly, the stock of pharmaceutical was taken over without in compliance with the terms of the bid and the terms of the agreement and the terms of the bid had also been subjected to change in accordance with the agreement. The supplier did not have a National Medicines Regulatory Authority registration certificate nor a Waiver of Registration (WOR) for this pharmaceutical. Despite the situation, the pharmaceutical was taken over in violation of the bid conditions. It had been decided on 04 May 2023 to increase the number of units related to this order by 100 per cent. Accordingly, the Emergency Procurement Committee of the Health Sector had decided on 13 June 2023 to procure 40,000 units at Rs.297 per unit from the supplier, and the evidence were not included in the file whether the covering approval of the relevant Cabinet of Ministers were taken . Only the supply in relation to this stock of pharmaceutical had been done based on the certificate issued on 24 June 2023 by the National Medicines Regulatory Authority.

(i) The registration of the sole supplier registered with the National Medicines Regulatory Authority for this pharmaceutical had expired on 15 March 2022 and had requested to renew its registration on 20 May 2023. In the absence of a registered supplier for the pharmaceutical, although this request should be considered immediately, the National Medicines Regulatory Authority had not given a decision for it by the time of the audit on 01 December 2023, though seven months had elapsed.

(j) Despite of working for emergency purchases in the year 2022, without issuing the normal order for the year 2022 pharmaceutical stock of 412,500 units on receivables basis pertaining to orders issued for the years 2018, 2020 and 2021, although an order of 79,534 units should be issued assuming that 167,523 units are due out of these orders furthermore, it is observed in the audit that the decision not to issue a normal order for the year 2023 is irresponsible on the part of the responsible officials. .

(k) The normal order 2023 of 30,000 units was issued on 16 November 2022 and accordingly 45,000 units and 40,000 units had to be supplied on 12 January and 12 April 2023 respectively. The Procurement Committee had recommended inviting bids after 27 days of issuing the order. Bids were invited by fax on 16 February 2023, after 65 days of the procurement decision, and the details of the invitations to bids through web page and newspaper advertisements were not available in the file. The Bidders had submitted bids during the bidding period of

07 days, and all the bidders did not have a valid registration certificate from the National Medicines Regulatory Authority.

(l) An Oncologist had recommended a second lowest bidder who had submitted a unit for Rs. 90.62. According to the recommendation of Technical Evaluation Committee held on 24 March 2023, the bidder who had submitted a unit for Rs. 74.50, had been given the Procurement Committee recommendation on 19 April 2023, twenty five days after the submission of the Technical Evaluation Committee recommendation on the basis of obtaining a Waiver of Registration from the National Medicines Regulatory Authority and 26 days after the award of the bid, the awarding of bid was communicated to the bidder on 16 May 2023, and after 6 days on 26 May 2023, the supplier confirmed the bid. However, the supplier was informed through e-mail from time to time to submit the relevant documents for obtaining the WOR certificate, it had not acted accordingly. The file submitted to the audit had not been included information on whether this procurement was formally cancelled, whether there was a related procurement decision, whether a performance bond was obtained, or whether there was an agreement.

(m) As per the instructions issued by the Ministry of Finance for the Health Sector Emergency Procurement Process (HSEPP) , the Order No. 2023/ SPC/T/R/P/00146 had been issued for the purchase of 28,500 units using the funds provided by the Foreign Employment Bureau. A bidder who had submitted the lowest bid out of the bidders for Rs. 79.80 was not selected due to insufficient stock- in-hand, and accordingly, on the basis of obtaining a Waiver of Registration from the National Medicines Regulatory Authority the decision to award the bid to the second lowest bidder to supply at a unit price of Rs.150 was made by the members of the Emergency Procurement Committee of the Health Sector on the recommendations of the Technical Evaluation Committee. However, the letter of the approval of the Cabinet of Ministers related to this decision had not been included in the file. The purchase order was issued on 08 May 2023, after 48 days for the approval of the bid. A Waiver of Registration (WOR) from the National Medicines Regulatory Authority was issued on 19 May 2023, and the supplier delivered the stock of pharmaceuticals to the Medical Supplies Division on 05 October 2023, after 114 days of the date mentioned in the purchase order.

(n) According to the instructions given by the Ministry of Finance for the emergency procurement process in the health sector, the order of 128,000 units bearing No. 2023/SPC/X/R/P/00191 had been issued on 25 May 2023 using the funds provided by the Indian Credit Line. The bids of the four bidders who had submitted bids as a unit Rs.76, Rs.164.05, Rs. 171.5 and Rs.220, had not been selected on the basis of inconsistency with valid registration certificate of the

National Medicines Regulatory Authority, stock- in -hand and delivery time and with the bid conditions.

(o) Accordingly, the Emergency Procurement Committee Members of the Health Sector had given the decision to award bids to supply Rs. 657 per unit to the highest bidder who had submitted Rs. 657 per unit on the recommendations of the Price Evaluation Committee on 27 June 2023 11 days after the date of opening of bids. However, the covering approval of the letter of the Cabinet of Ministers related to this decision was not included in the file. In case of all the bidders do not have a valid registration certificate from the National Medicines Regulatory Authority, it was problematic in the audit that the awarding of the bid to the bidder who submitted the highest price and the cost per unit of order issued on 02 February 2023 near to this order had been Rs.150. Further, the price increase was 786 per cent compared to the lowest bidder. The purchase order was issued on 08 September 2023, after 72 days of bid approval. However, the Medical Supplies Division had not been supplied with stock of pharmaceuticals even by the date of audit.

(p) An order control form to determine the normal order quantity for the year 2024 had not been prepared even by 23 November 2023. Accordingly, no decision was reached on whether to issue the order for the year 2024 or not. In this situation, it is observed in audit that emergency purchases may have to be resorted to in the year 2024 as well.

64. Allopurinol Tab 100mg (SR - 01401001)

(a) A percentage of 127 pharmaceuticals had been ordered beyond the estimated quantity in the year 2020, and from the year 2021 to the audited date of the year 2023, sufficient stocks had not been ordered for the estimated quantities and the ordered quantities had not been received as scheduled.

(b) It was observed that orders have been made from hospitals exceeding the estimate in the years 2020 and 2022. However, when comparing the amount issued with the estimated values, it had been of 68 per cent and 51 per cent .

(c) Likewise, it was observed that sufficient stock of pharmaceuticals was not issued to the hospitals as per the order and it had ranged from 16 per cent to 62 per cent when taken as a percentage. It was observed that hospitals had not been provided 277,650 units of pharmaceutical requested in 37 cases from January 2023 to 31 May 2023.

(d) Although the Order No. 2022/MSD/V/R/P/00072 had been issued instead of Order No. 2022/SPC/V/R/P/00659, the order No. 2022/SPC/V/R/P/00659 was shown as an issued order in the Swastha System even on the date of audit.

(e) The normal order of 4,200,000 units for the year 2022 had been sent to the State Pharmaceuticals Corporation. It took 28 days to inform the bidder about the procurement decision. The remaining stock of 2,200,000 units of pharmaceutical had not been received up to October 2023.

(f) Order No. 2022/SPC/E/R/P/00627 had been issued on 16 September 2022. The documents related to the 89 pharmaceuticals mentioned by the Managing Director of the State Pharmaceuticals Corporation had been submitted to the Additional Secretary (Procurement) of the Ministry of Health for purchase under the Asian Development Bank (ADB) and the Emergency Procurement Committee of the Ministry of Health had given approval to call bids from the registered suppliers of the National Medicines Regulatory Authority (NMRA). Although the Technical Evaluation Committee had decided to procure from the lowest bidder subject to obtaining NMRA certificate or WOR , there was no evidence in the file that any further action was taken or canceled with respect to this order. Similarly, the evidence whether the covering approval of the Cabinet of Ministers was obtained for the above decisions given by the Health Sector Emergency Procurement Committee was not submitted to the audit.

(g) The normal purchase order No. 2024/SPC/N/R/P/00044 for the purchase of 1,800,000 units was forwarded to the State Pharmaceuticals Corporation and according to the order control sheet, although the quantity of units to be ordered for the year 2024 was 4,871,610 units, a number of 3,071,610 units had been ordered in less.

65. Bicalutamide Tab. 50mg (SR - 01207001)

(a) It was observed that the orders exceeded the estimated quantities in the year 2021 and it was an increase of 5 per cent of the estimated value in the year 2021 and it was an increase of 56 per cent of the estimated value of the year 2022.

(b) The annual estimate of hospitals for the year 2023 was 415,300 units, and the amount of units of pharmaceuticals issued by November 2023 was 177,526 units. The amount as at that date was 43 per cent of the estimated amount and the stock of pharmaceutical was not received even by October 2023.

(c) Even though Order No. 2022/MSD/V/R/P/00074 had been issued instead of Order No. 2022/SPC/V/R/P/00690, the order No. 2022/SPC/V/R/P/00690 of the Swastha System had further been recorded as an issued order.

(d) It was shown in the Swastha System that 930,416 units of this pharmaceutical will be received on 21 November 2023. However, the information on the number of units how to set had not been included in this system.

(e) Although the purchase order had been issued to the selected bidder to supply 2,000 units and 80,500 units respectively relating to Order No. 2022/MSD/V/R/P/00074 for 82,500 units, the stock of pharmaceutical had not been received even on 31 October 2023. The Secretary of Health had overstepped his authority and approved the issuance of Indents without signing an agreement and obtaining a performance bond.

(f) Although the annual normal order 2022 should have been placed at least 11 months in advance, the order for 165,000 units had been issued on 16 November 2022 . Even though it was possible to execute the procurement under an open bids if the normal order is placed on the scheduled date, the Procurement Committee had recommended to call for bids from registered and past suppliers at limited prices within 07 days in the current emergency situation.

(g) Bids were invited after 60 days of approval to invite bids. The Technical Evaluation Committee had given its recommendation on 22 March 2023 to award the bid to the lowest bidder at Rs. 27.38 (US$ 0.0757) per unit out of the bid documents submitted by 05 bidders and for that, the Procurement Committee had given the recommendation on 19 April 2023. The purchase order had been issued on 12 July 2023, after 83 days of the awarding of bids. The pharmaceuticals related to this order had not been handed over even by 29 November 2023 .

(h) The order No. 2023/SPC/X/R/P/00191 of 190,000 units had been issued in 25 May 2023 to purchase according to the guidelines issued for the Health Sector Emergency Procurement Process (HSEPP) by the Ministry of Finance. Twenty days after the order, bidders with National Medicines Regulatory Authority registration certificate were invited to submit bids on 14 June, 2023, and it was informed by it that the bids will be closed on 16 June 2023 at 10 a.m. after a 02 days bidding period.

(i) Only 05 bidders had submitted bids and two bidders did not have a valid registration certificate of the National Medicines Regulatory Authority and two had applied for the registration certificate of the National Medicines Regulatory Authority. Accordingly, the lowest bidder's price was Rs.22.75 per unit and as his NMRA certificate had expired on 22 December 2022, and the bid had been awarded to the institution who hold a valid NMRA certificate offered a value of Rs.46.77 per unit and, although he was selected on 27 June 2023 on the recommendations of the Technical Evaluation Committee and on the recommendations of the Emergency Procurement Committee Members of the Health Sector on 28 June 11 days after the bid opening date, the evidence had not been available in the file whether the cover approval of the Cabinet of Ministers for the procurement decision was obtained.

(j) The purchase order was issued for the purchase of Rs.43.77 per unit on 11 September 2023, after 75 days of the awarding of the bid and it had been informed to supply 189,990 units by 08 November 2023. However, the order had been given by the system to supply 190,000 units by 15 August 2023, and according to the bid documents, it was stated that 190,000 units should be supplied within one month. The supplier had not given the performance bond as at the audited date of 27 November 2023 and a contract agreement with the supplier had also not been entered into.

(k) Even though the order control form related to determining the pharmaceuticals requirement related to the year 2024 had been prepared on 23 January 2023, the order had not been foewarded. Although an order should be submitted approximately 11 months before the commencement of the year to supply the normal annual requirement of the year 2024, it was observed that the normal order related to the year 2024 had not been submitted even by 29 November 2023, the date of audit.

66. Vincristine SuIphate Inj.1mg/mL Vial (SR - 01202401)

(a) A number of 13,250 units pertaining to order No. 2021/SPC/N/R/P/00095 and 11,000 units pertaining to order No. 2022/SPC/N/R/P/00032 had not been supplied even by the date of audit November 2023 and the 55,344 injection units related to 06 orders issued had not been fully procured.

(b) The normal order 2022 of 22,000 units had been issued on 27 February 2021. The bids had been awarded on 03 August 2023 and the first batch of 11,000 units had been procured on 27 September 2022. After the evaluation of the bids, evaluation report had not been submitted with a specific recommendation and only signatures were used without the names and positions of the Members. The validity of the performance security obtained in relation to this order had expired on 16 November 2022 and only half of the order had been procured.

(c) The Order No. 2022/MSD/V/R/P/00074 for 5,750 units had been issued on 26 September 2022. According to the memorandum of Cabinet of Ministers dated 26 September 2022 submitted by the Minister of Health under Cabinet Paper No. 22/1523/610/018 entitled “Maintaining a Continuous Medical Supply Service in Sri Lanka”, the Medical Supplies Division had invited bids from interested parties (Expression of interest EOI) on 27 September 2022 through the Promise.lk website to import and supply essential pharmaceuticals to Sri Lanka.

(d) It had been decided to procure this pharmaceutical on the basis of obtaining WOR from the National Medicines Regulatory Authority. A price evaluation report and a procurement committee report were not included in the relevant file, although it had been noted that it would be evaluated by the price evaluation

committee of the Emergency Procurement Committee of the Ministry of Health and approved by the Procurement Committee. According to the purchase order, even though it had been stated that the pharmaceuticals should be supplied by 05 January 2023, the stock of pharmaceuticals related to the Medical supplies Division had not been supplied even by 15 November 2023, which was the date of the audit. The Secretary of the Ministry had released him on 02 November 2022 from obtaining performance bonds and agreement with the contractor by overstepping his authority. In this situation, no cover whatsoever was received to the Ministry for not supplying this stock.

(e) The 12,000 units of normal order 2023 had been placed on 16 November 2022. Even though the bids had been evaluated on 20 March 2023 an evaluation report was not submitted and the second lowest bidder was decided to be awarded at a unit of Rs. 595 each by the Departmental Procurement Committee held on 09 May 2023 subject to renewal of product registration pertaining to the pharmaceutical. According to the order control form that was prepared for the year 2023, although the number of injection units to be ordered for the year 2023 was 8,000 units, a number of 12,000 injection units in line with the requirement of 06 months had been ordered by the above order and the basis for doing so was not revealed during the audit. According to the procurement schedule, although the tenders should have been awarded within 14 days of taking the procurement decision, it had been done with a delay of 52 days. An unconditional performance bond of 10 per cent of the total cost had not been obtained within 14 days of the awarding bid. The pharmaceuticals related to this order had not been received even by the date of audit November 2023.

(f) An order bearing No. 2023/SPC/E/R/P/00143 for 5,750 units had been issued on 30 January 2023. The Technical Evaluation Committee held on 24 April 2023 had recommended the second lowest bidder subject to price reduction and the basis of obtaining WOR because of no bidder had obtained registration with the National Medicines Regulatory Authority and had obtained the pharmaceutical sample import license and applied for registration with the National Medicines Regulatory Authority. It had been decided to award bids for 5,750 units at Rs. 1,665 each to the above supplier and the relevant Indent was issued on 15 June 2023 .

(g) The bidding related to the said procurement had been recommended by the Emergency Procurement Committee of the Ministry of Health held on 12 May 2023 and the document did not include evidence that the decision was submitted to the Cabinet of Ministers and the cover approval was obtained and the Chief Internal Auditor did not confirm that the procurement was done properly. The difference between the estimated price and the bid awarded price was 411 per cent.

(h) Although an unconditional performance security of 10 per cent of the total cost should be obtained within 03 days of the bid, such performance security had not been obtained. Also, although the tenderer should sign a contract agreement with the supplier immediately, the procuring entity had not done so. Although it was decided to procure this pharmaceutical under the urgent need and a limited time of 03 days was given to submit the prices, the related Indent had been issued on 15 June 2023 and 75 days had elapsed since the opening of bids. The pharmaceuticals related to this order had not been received even by the audit date of November 2023.

(i) The Order No. 2023/SPC/X/R/P/00191 for 18,000 units had been issued on 25 May 2023. The Emergency Procurement Committee of the Ministry of Health held on 28 June 2023 had decided to award bids for 18,000 units at 362 each the supplier based on the of re-registration with the National Medicines Regulatory Authority or obtaining a WOR as per Technical Evaluation Committee held on 27 June 2023 . Although the related procurement decision should be submitted to the Cabinet of Ministers and cover approval should be obtained, evidence that this was done was not available in the file and the Chief Internal Auditor did not confirm that this procurement was done as scheduled. Although it had been decided to buy the pharmaceuticals related to the calling of quotation which was made on 28 June 2023 by giving less time such as 03 days to submit the quotations, the related Indent had been issued on 06 September 2023 and more than 02 months had been spent for that. The pharmaceuticals related to this order had not been received even by the date of audit November 2023 .

(j) Although the normal order for this pharmaceutical for the year 2024 had to be issued in January 2023, it had not been issued by the Medical Supplies Division at the time of the audit on 15 November 2023. In this situation, it is observed in the audit that this pharmaceutical may have to be purchased under emergency purchases in the year 2024.

(k) According to the Swastha Information System, the stocks to be received related to this pharmaceutical had been stated as 76,750 units of injections in one place (Balance Due) and 23,750 units of injections in another place (Pending Orders). Therefore, the reliability of the information provided by the System was problematic during the audit as the information given to the users in different places of the same information system is contradictory.

67. Procarbazine capsule 50mg (SR 01203901)

(a) The normal order 2022 of 3,000 units had been placed on 27 February 2021. Bids were invited on 5 occasions and although in one of them, the bids were awarded later it had been cancelled. As the procurement activities were in the

initial stage, it is observed during the audit that emergency procurement may have to be resorted to in the year 2024.

(b) The Emergency Order No. 2022/SPC/E/R/P/00744 of 600 units had been issued on 09 November 2022. Although the Procurement Committee held on 16 February 2023 had decided to cancel this procurement and call for bids again on two occasions due to the high unit price, actions had not been taken in respect of that even as at 31 October 2023, the date of audit.

(c) The normal order 2023 of 1,200 units had been placed on 16 November 2022. Due to high unit prices, although the procurement related to the normal order 2023 had been canceled on two occasions, re-bids had also not been called even as at the audited date of 15 November 2023.

(d) The Order No. 2023/SPC/T/R/P/00146 dated 02 February 2023 for the purchase of 400 units had been issued using the funds provided by the Foreign Employment Bureau. The Emergency Procurement Committee held on 09 and 21 March 2023 had decided to award the bid on the basis of receipt of WOR to the supplier with manufacturing plant approval of National Medicines Regulatory Authority. There was no evidence in the file that the covering approval of the Cabinet of Ministers was obtained for that decision or that a certificate from the Chief Internal Auditor was obtained that the procurement was done properly.

(e) Although a limited time such as 03 days was given to submit the quotations , a period of 33 days had been spent for issuing the relevant Indent. Subsequently, even though this procurement process had stopped, due to the fact that a contract agreement had not been signed and a valid performance security had not been obtained it was observed during the audit that the procurement entity was not able to take any action against the supplier.

(f) The Order No. 2023/SPC/X/R/P/00191 for 2,000 units had been issued on 25 May 2023. The Emergency Procurement Committee of the Ministry of Health held on 28 June 2023 had decided to award bids subject to obtaining a WOR of Rs.3,000 per unit to the approved supplier for the pharmaceutical. Although this procurement decision should have been submitted to the Cabinet of Ministers and covering approval should have been obtained, the evidence that this had been done was not available in the file. Likewise, the Chief Internal Auditor had not confirmed that this procurement was done as scheduled. Although less than 03 days were given to submit the quotations, more than 02 months had been spent to issue the Indent.

(g) Although the normal order for this pharmaceutical for the year 2024 should have been issued by January 2023, it had not been issued even at the date of audit 15 November 2023.

68. Paclitaxel Inj. 30mg/5mlVial (SR - 01204901)

(a) This order had been given by the Director of Medical Supplies to the Additional Secretary (Procurement), Ministry of Health on 16 September 2022 for procurement of 25,000 units bearing No. 2022/SPC/E/R/P/00600. Even though it was decided to procure 25,000 units subject to price reduction and immediately available in the Technical Evaluation Committee held on 26 October 2022 there was no evidence in the file that further work was done or canceled regarding this order. Also, evidence that the covering approval of the Cabinet of was obtained for these decisions taken by the Health Sector Emergency Procurement Committee was not submitted to the audit.

(b) The normal order 2023 of 50,000 units had been placed on 16 November 2022. Due to the late delivery of the normal order related to the year 2023 by about ten months, the opportunity to competitively purchase pharmaceuticals through an open bids was lost. Although an unconditional performance guarantee of 10 per cent of the total cost was to be obtained , it was obtained on 17 July 2023 with a delay of 108 days. According to the Indent issued on 23 June 2023, although the stock should have been delivered on 15 August, 2023, these pharmaceuticals had not been received by 10 November 2023.

(c) An order for procurement of 25,000 units bearing number 2023/SPC/E/R/P/00143 under emergency procurement was placed on 30 January 2023, without placing the annual normal order 2023 on the due date. The Technical Evaluation Committee had decided to award bids for the purchase of 25,000 units at a cost of Rs 59,250,000 to the lowest bidder at Rs 2,370 per unit subject to price reduction and it had been recommended by the Emergency Procurement Committee of the Ministry of Health held on 12 May 2023. The evidence that the decision was submitted to the Cabinet of Ministers and the covering approval was obtained had not been available in the file.

(d) It was decided to procure this pharmaceutical under the emergency requirement and although a limited time of 03 days was given to submit the quotations, the relevant Indent was issued 80 days after the opening of bids. A new Indent had been issued on 24 August, 2023 due to the fact that the actual Indent was not shown in the Swastha System to take further steps to procure this pharmaceutical, and the stock receipt period was stated as 31 August 2023. However, even then these pharmaceuticals were not available and performance security had not been obtained.

(e) The Order No. 2023/SPC/T/R/P/00146 dated 02 February 2023 had been issued by the Medical Supplies Division for purchase using the funds provided by the Foreign Employment Bureau. This procurement was carried out by the Emergency Procurement Committee of the Ministry of Health and after the price

committee held on 24 February 2023, it was decided to awarding the bid to the lowest bidder on the basis of obtaining the WOR and the evidence that the covering approval of the Cabinet of Ministers was obtained for that decision was not available in the file. It had been decided to cancel this order due to non-compliance with specifications. Therefore, it was observed that during the bid evaluation, the opportunity to reject the bids that did not conform to the specifications was missed.

(f) Although the order had to be canceled due to the fault of the supplier, it was observed that the opportunity to recover the costs incurred for the relevant procurement from the supplier was deprived due to failure to obtain the performance security. Similarly, although a contract agreement should be signed with the supplier just after awarding the bid, the procuring entity had not done so. The manufacturer of this pharmaceutical had not taken steps to obtain documents confirming that the local representative has been duly appointed.

(g) The Order No. 2023/SPC/X/R/P/00191 had been issued on 25 May 2023 for the purchase of 75,000 units under Indian Credit Line. The Emergency Procurement Committee of the Ministry of Health held on 28 June 2023 had recommended to award bids for the supply of this pharmaceutical at a cost of Rs. 129,705,750 for 75,000 units of Rs.1,729.41 per unit to the sole bidder with NMRA registration and the evidences for the covering approval of the Cabinet of Ministers for that decision were not available in the file.

(h) The Medical Supplies Division had spent more than 02 months to issue the Indent for the purchase of pharmaceuticals related to the calling of quotations , which was given a time less than 02 days for submitting the quotations. Although an unconditional performance bond of 10 per cent of the total cost had to be obtained within 03 days of bidding for the procurement of this pharmaceutical, such performance bond had not been obtained.

(i) Kurunegala Teaching Hospital had purchased 500 units locally at a high cost of Rs. 4,960 per unit due to failure of maintaining sufficient stock of this pharmaceutical.

(j) Although the normal order for this pharmaceutical for the year 2024 should have been issued by January 2023, it had not been issued by the Medical Supplies Division, at the time of audit on 15 November 2023. Four receivable orders based on the preparation of the order control form had been cancelled as at the date of audit. As a result, it is observed during the audit that, it may be necessary to resort to emergency procurement in the year 2024 due to not preparing an normal order for the year 2024.

69. Tamoxifen Tab. 20mg (SR අංක 01206802)

(a) Although the Order No. 2022/MSD/V/R/P/00074 had been issued instead of Order No. 2022/SPC/V/R/P/00690, the first order in the Swastha System was shown as a further issued order.

(b) It was shown in the Swastha system that 4,953,285 units of this pharmaceutical had to be received on 21 November 2023. However, the information on how the number of units were set had not been included in this system.

(c) An order bearing No. 2022/MSD/V/R/P/00074 for 450,000 units had been issued and although the purchase order had been submitted to the selected bidder to supply 150,000 units on 05 December 2022, and 300,000 units on 06 February 2023, the stock of pharmaceuticals had not been received even by 21 November 2023. The Secretary of Health gave an approval on 02 November 2022 that it was not necessary to obtain a performance bond and agreement with the contractor by overstepping his authority. Accordingly, the Ministry had no any cover whatsoever for not providing this remaining stock. It is observed during the audit that if the government has to bear any loss in this regard, the officers who approved and recommended this decision will be personally responsible.

(d) The Order No. 2023/SPC/E/R/P/00143 of 450,000 units had been issued on 30 January 2023 and the Technical Evaluation Committee held on 24 April 2023 had recommended to award the bid to the lowest bidder who had obtained registration from the National Medicines Regulatory Authority. The related Indent had been issued on 12 July 2023 and although the Emergency Procurement Committee of the Ministry of Health had recommended that bids be offered for the above procurement, the evidence that the decision was submitted to the Cabinet of Ministers for covering approval had not been available in the file.

(e) Estimated price per unit was Rs. 4.73 and the lowest bidder had submitted and the price was Rs.10.48. Accordingly, the difference between the estimated price and the bid price was 121 per cent. A performance bond was not obtained for the procurement of this pharmaceutical and a contract agreement had not been signed with the supplier. Although it was decided to procure this pharmaceutical under the emergency need and given a limited time of 03 days to submit the prices, the relevant Indent had been issued after a period of 103 days from the date of opening of bids.

(f) The normal order 2023 of 900,000 units had been issued on 16 November 2022 with a delay of about 10 months and no order control form had been prepared on the date of issue of the order. After evaluating the bid documents on 19 April 2023, two organizations had submitted valid NMRA certificates and had signed

without specifying the names and positions of the respective members, stating only that they had fulfilled the other criteria. With a delay of two months from the Technical Evaluation Committee. The Procurement Committee had invited a price negotiation with a delay of two months after the evaluation of the Technical Committee. The decision of the Procurement Committee was received by the Technical Division of the State Pharmaceuticals Regulatory Corporation on 25 September 2023 and the file had not been updated after that date.

(g) According to the Guidelines introduced by the Ministry of Finance for the Health Sector Emergency Procurement Process (HSEPP), the Order No. 2023/SPC/T/R/P/00146 for 300,000 units had been issued on 02 February 2023 for the purchase using funds provided by the Foreign Employment Bureau. Only 02 days were given to invite bids. The NMRA certificate of the fifth lowest bidder had expired in the year 2020.

(h) The decision to award the bids was given after 07 days from the date of opening of bids and 47 days after the recommendation of the Bid Evaluation Committee on the basis of obtaining a Waiver of Registration from the National Medicines Regulatory Authority. The approval letter Cabinet of Ministers related to this decision had not been included in the file. The purchase order of Rs.222.19 per unit was issued on 02 May 2023 that is 20 days after bid approval. By the time the Bid evaluation committee was giving its recommendation, the stock level of the Medical Supplies Division had been sufficient for about 06 months. Here, the estimated price per unit was Rs. 4.73 and the quoted price of the qualified bidder was Rs.222.19. Accordingly, the difference between the estimated price and the bid awarding price was 4597.46 per cent.

(i) The order number 2023/SPC/X/R/P/00191 of 1,300,000 units had been issued on 25 May 2023, and the decision to award the bid was given by the Members of the Health Sector Emergency Procurement Committee. However, letter of receiving the covering approval of the Cabinet of Ministers related to this decision had not been available in the file.

(j) The bid value of the lowest bidder was Rs.11.22 and after a price negotiation, the purchase order of Rs.11 per unit was issued on 13 September 2023, after 77 days of the bid approval. Accordingly, the purchase order was issued stating that it would be supplied on 13 November 2023. However, the Medical Supplies Division had not been supplied with stock of pharmaceuticals even by the audit date of 24 November 2023 .

(k) Although the order control form related to determining the pharmaceuticals requirement related to the year 2024 was prepared on 23 January 2023, an order for the predicted quantity of 2,600,000 units was not submitted. Although an order should be submitted approximately 11 months before the commencement

of the year to supply the normal annual requirement of the year 2024, it was observed that no normal order related to the year 2024 has been submitted even by 30 November 2023, which was the date of audit. In this situation, it is observed that emergency purchases may have to be resorted to in the year 2024 as well.

70. Anastrozole Tab 1 mg (SR - 01206701)

(a) The normal order 2022 of 1,000,000 units had been issued on 27 February 2021 and this order was received by the Corporation on 17 March 2021. After the technical evaluation, more than 02 months were spent for the first meeting of the Procurement Committee and another 02 months for the meeting of the second Procurement Committee and almost 02 months had been spent for awarding the order. After issuing the order, it took 05 months to issue the Indent. As a result of above delays the exchange rate had increased to a value of 54 per cent. As a whole, almost a year had passed since the order was issued to receive the goods. Also, the evidence whether the actual cost incurred by the supplier in calculating the price variation were ascertained by the payment information for relevant letters of credit, customs documents were not submitted to audit.

(b) The Order No. 2022/SPC/X/R/P/00306 for 2,000,000 units had been issued on 25 March 2022. The Departmental Procurement Committee had decided on 27 April, 2022 to award the bid to the firm that submitted a price of US$ 0.0234 the lowest price per unit. The Indent was issued after 02 months by receiving the procurement decision and the stock of pharmaceuticals was received on 21 April 2023. As the supplier has violated the terms and conditions of this transaction, the relevant bank was requested to recover the relevant (US$ 46.50) from the performance bond. Accordingly, written evidence on whether late fees were collected to the government and how other payments were made, had not been available in the file.

(c) The Order No. 2023/SPC/X/R/P/00191 for 1,200,000 units had been issued on 25 May 2023. The Procurement Committee had decided to call quotations from suppliers registered under the National Medicines Regulatory Authority within the limit of Health Sector Emergency Procurement Committee. A performance bond had not been submitted as per the file and, the stock had been shown as a receivable stock as at 22 November 2023 as per Swastha system.

(d) It had been given less than 02 days for submission of bids. Although the covering approval of the Cabinet of Ministers should be obtained, the evidence that the approval was obtained had not been submitted to the audit. It took nearly 70 days to award the order after procurement evaluation. Although it had been stated that the shelf life of the pharmaceutical was 24 months, stating that

the minimum shelf life of the Indent was 12 months was problematic during the audit.

(e) The normal order of 1,000,000 units for the year 2023 had been issued on 16 November 2022 with a delay of about 10 months. The bid documents had been evaluated on 22 March 2023 and according to the evaluation report that had mentioned the evaluation facts, a formal and specific recommendation had not been made and the relevant members had signed the evaluation report without mentioning their names and positions.

(f) Although the order control forms prepared for the year 2023 were requested by the audit they were not provided even by the audit date of 08 December 2023. A period of 03 months till 27 February 2023 had been spent for the order dated 16 November 2022, and one month had been spent for technical evaluation. It took another month to meet the Procurement Committee and another month to award the order. According to the second Indent, although the entire stock had to be received by 31 October 2023, the stock of pharmaceuticals had not been received according to the data system even by 04 December 2023.

(g) The normal order relating to the year 2024 had not been issued by the end of November 2023. Due to the fact that the normal orders related to the last two years of this pharmaceutical were not issued as scheduled based on formal forecasts and emergency orders were issued in several cases, the opportunity to buy the pharmaceutical at a lower price through better competition was lost and, it is observed that this pharmaceutical may have to be bought under emergency procurement this year 2024 also due to the normal order related to the year 2024 not being issued on the scheduled date.

(h) According to the Swastha System, it was shown that 1,919,418 units of this pharmaceutical will be received on 21 November 2023. However, the information on how the number of units to set was not included in this system.

71. Hydroxyurea (Hydroxycarbamide) Capsule 500mg (SR - 01203501)

(a) According to the information submitted to the audit, the pharmaceuticals totalling 2,557,139 units related to 09 orders issued from 2019, 2020 to 2023, had not been received even by the audit date of 07 December 2023. However, only 792,000 units were receivable in the Swastha System as at that date. Similarly, according to the Swastha information system, 2,285,000 units were shown as receivable stocks in the description of the existing stocks related to this pharmaceutical. Therefore, Because the information provided to users in different locations of the same system regarding orders issued and receivables is

conflicting, the reliability of the information provided by the system was problematic during the audit.

(b) A number of 1,500,000 units had been ordered by Order No. 2021/SPC/N/R/P/00020 and of which, only units totaling 750,000 as 118,600 units on 02 February 2021 and 631,400 units on 25 February 2021 had been received. Out of that, number of 144,914 units with a total cost of Rs.15,071,056 related to Batch No. JD 20051 had failed in quality. Accordingly, although Rs. 93,750,000 should be recovered from the supplier, the amount had not been recovered even by 14 December 2023 .

(c) The order of 200,000 units bearing No. 2022/SPC/N/R/P/00047 issued on 27 February 2021 was suspended and the order of 300,000 units bearing No. 2022/SPC/X/R/P/00306 on 25 March 2022 had been issued. Indian suppliers/manufacturers and local agents intending to supply Indian origin pharmaceuticals were invited to submit bids on the website of the State Pharmaceuticals Corporation and through the newspaper advertisement on 26 March 2022, and only 05 days bidding period was given. Even though the bids had been evaluated, an evaluation report relevant to that had not been submitted. One of these three bidders had not signed the bid documents.

(d) It was decided to procure this pharmaceutical under the emergency need and although a limited time of 05 days was given to submit the quotations , 197 days had been spent to issue the relevant Indent. This stock of pharmaceuticals had not been received by the Medical Supplies Division even by 07 December 2023 .

(e) The normal order 2023 of 400,000 units had been issued on 16 November 2022. Even though bid evaluations had been done on 25, 26 and 27 April 2023, evaluation report had not been submitted. According to the order control form prepared for the year 2023, it was observed that there is no need to order pharmaceuticals for the year 2023. When the order related to this pharmaceutical was issued, the estimated price per unit was Rs.104 and the price of the selected supplier was Rs.34.60. Accordingly, the difference between the selected price and the estimated price was 67 per cent. According to the procurement timetable related to this order, although the Indent related to the purchase of pharmaceuticals should be issued by 18 June 2023, it had not been issued even by 30 November 2023.

(f) The Order No. 2023/SPC/E/R/P/00143 for 200,000 units had been issued on 30 January 2023. The Technical Evaluation Committee held on 24 April 2023 had recommended awarding the bid to the second lowest bidder since the lowest bidder had not a registered supplier of the National Medicines Regulatory Authority. The bidding related to the procurement was recommended by the

Emergency Procurement Committee of the Ministry of Health held o**n** 12 May 2023 and evidence that the decision of the Cabinet of Ministers and the covering approval for that had received was not available in the file, and the Chief Internal Auditor did not confirm that the procurement was done properly.

(g) When the order for this pharmaceutical is issued, the estimated price per unit was stated as Rs.104 and the price of the selected supplier was Rs. 43.20. Accordingly, the difference between the selected price and the estimated price was 58 per cent. A performance security had not been obtained and a contractual agreement had not been signed with the supplier. It was decided to procure this pharmaceutical under the emergency need and although a limited time of 03 days was given to submit the quotations , a period of 74 days was spent from the date of opening of bids to issue the relevant Indent.

(h) The Order No. 2023/SPC/T/R/P/00146 dated 02 February 2023 was issued for the purchase by using the funds provided by the Foreign Employment Bureau. After the price evaluation committee held on 24 February 2023, it had been decided to offer the bid for 135,000 units at Rs. 76 per unit to the third lowest bidder who has the approval of the National Medicines Regulatory Authority's manufacturing plant on the basis of obtaining WOR, the evidence that the cover approval of the Cabinet of Ministers was obtained for that decision or a certificate from the Chief Internal Auditor that the procurement was done properly were not available in the file. The condition relating to performance security had been removed from the terms of the agreement. Although a limited time of 03 days had been given to submit the quotations , a period of 220 days had been spent from the date of opening of bids to issue the second Indent.

(i) The Order No. 2023/SPC/X/R/P/00191 for 657,000 units had been issued on 25 May 2023. The Technical Evaluation Committee had recommended awarding the bid to the lowest bidder. Although the procurement decision related to the aforesaid procurement should be submitted to the Cabinet of Ministers and covering approval should be obtained, the evidences whether it was done so was not available in the file and the Chief Internal Auditor had also not confirmed that this procurement was done as scheduled.

(j) Even though it had decided to purchase the pharmaceuticals related to the calling of quotations, which was given a period less than 02 days for submitting the quotations , the related Indent had been issued on 15 September 2023, and more than 02 months had been spent for that .

(k) Although there was sufficient stock of this pharmaceutical , it was observed that 06 hospitals have procured 3,428 units at a cost of Rs. 469,970 at regional level. In a Ministry procurement, although it was agreed to supply with unit price of Rs.36.80 each by Order No. 2023/SPC/X/R/P/00191 dated 28 June 2023, it was

observed that purchases had been made at higher prices from 63 per cent to 647 per cent when buying locally and comparing with that price.

(l) Although the normal order for this pharmaceutical for the year 2024 should be issued by January 2023, it was not issued by the Medical Supplies Division even by 15 November 2023. Within this situation, it is observed in the audit that, this pharmaceutical may have to be purchased under emergency purchases in the year 2024 .

72. Propofol Inj.50 ml Amp/Vial (SR - 01500302)

(a) According to the information submitted to the audit, a total of 249,800 units in relation to 08 orders issued for the years 2019, 2020, 2022 and 2023 were stated as orders to be received. However, only one order of 25,000 units for the year 2022 had been shown as receivable in the Swastha system as at 27 November 2023. Although 783,420 units were shown as receivables as at 21 November 2023, in the description of the existing stocks in the Swastha system , the information on how that amount was set, had not been indicated within the system.

(b) Even though the normal order for the year 2022 had not been issued on the basis that a total of 290,737 units were receivable in relation to the 03 orders issued for the years 2020 and 2021, a total of 157,737 units related to those years had not been received by the Medical Supplies Division even by 01 December 2023.

(c) An order for 50,000 units bearing No. 2022/SPC/X/R/P/00330 had been issued on 26 March, 2022 to obtain on the basis of emergency need and under Indian Credit Line. The recommendation of the Procurement Committee had been given to the lowest bidder on the basis of obtaining an waiver of registration from the National Medicines Regulatory Authority. The Procurement Committee had recommended that the next supplier should be awarded as this supplier had not confirmed the supply even though 117 days had elapsed after giving recommendations. Although 132 days had elapsed as this supplier has also not confirmed the supply and the terms of the supplier cannot be accepted, it had been decided to cancel the bid and call for bids from registered and past suppliers. However, the Procurement Committee had not taken actions to recover the bid bond valued at Rs.245,000 from the bidder who violated the conditions and to blacklist the bidder.

(d) Order No. 2022 /SPC/E/R /P/00768 dated 30 November 2022 had been issued to obtain 25,000 units for the year 2022. Thirty two days after the date of opening of bids to award bids to the third lowest responsive bidder, although the Emergency Procurement Committee members on the same day had recommended on the decision of the Technical Evaluation Committee of the

Health Sector Emergency Procurement Committee, the related approval letter of the Cabinet of Ministers was not in the file. The following matters were observed in this regard.

(i) It was problematic during the audit regarding the determination of the bids based on the "samples" provided in the background where all the five bidders who submitted the bids did not have valid registration certificates (Certificate of NMRA) from the National Medicines Regulatory Authority and it was also problematic that the unavailability of media (letters/ by e-mail etc.) that informed the bidders for the submission of samples and information about the bidders who submitted the samples in the file .

(ii) The purchase order had been issued a unit at Rs. 1,290 each to supply 25,000 units 06 days after bid approval on 26 January 2023 and although the performance bond was to be submitted within 14 days of issuing the purchase order, after 68 days the supplier had submitted the performance bond on 04 April 2023 . Before the supplier submitted the bond, the request to made consider to grant the WOR license was communicated by the Managing Director of the State Pharmaceuticals Corporation to the Chief Executive Officer of the National Medicines Regulatory Authority on 02 February 2023. Accordingly, the WOR Committee of the National Medicines Regulatory Authority had given this approval on 16 February 2023, after a short period of about 14 days.

(iii) A number of 23,158 units of pharmaceuticals manufactured in March 2023 and expiring in February 2025 under 04 Batches (23CPF01, 23CPF02, 23CPF03, 23CPF04) were received by the Medical Supplies Division on 07 April 2023, and 22 days later, due to serious adverse reactions, the Chief Executive Officer of the National Medicines Regulatory Authority had informed the Director of the Medical Supplies Division in a letter dated 29 April 2023, that the Batch No. 23CPF03 to be withheld. Accordingly, the Director of the Medical Supplies Division had removed this pharmaceutical from use. By the time this circular was issued, a number of 6,755 units belonging to this Batch had been issued to all hospitals / Regional Health Directorates.

(iv) Then, after 08 days, due to the National Medicines Regulatory Authority had informed the Medical Supplies Division via e-mail on 10 May 2023 that it is necessary to suspend the stock of two more batches of pharmaceuticals, the Director of the Medical Supplies Division had ordered to suspend the stocks pertaining to first 02 Batches related to 23CPF01 and 23CPF02. After 05 days of these circulars, once again the Director of Medical Supplies had ordered on 15 May 2023 to suspend

the entire pharmaceutical. At the time of issuing this circular, 16,403 units belonging to these Batches had been issued to all hospitals / Regional Health Directorates and since the hospitals had issued pharmaceuticals to the patients, the amount of suspended stock had been only 1,660 units.

(v) The Director of the National Drug Quality Assurance Laboratory had informed the Director of the National Medicines Regulatory Authority in a letter dated 29 May 2023 that the batch number 23CPF03 of this pharmaceutical, which was tested based on a complaint filed by the government, was defective, and a day after that, it had been informed that the report was sent to the Director of the Medical Supplies Division on 30 May. The letter emphasized that the aforesaid Batch of pharmaceuticals should be withdrawn from use immediately and that it should be confirmed that this Batch is not in use in the health sector. Accordingly, the Director of the Medical Supplies Division had ordered by circular No. MSD/Q/P/2023/31 dated 31 May 2023 to withdraw the Batch of this pharmaceutical. However, by the time this circular was issued, only 4,230 units had been removed out of the 6,755 units that had been issued.

(vi) The National Medicines Regulatory Authority has decided to suspend Batch Nos. 23CPF03, 23CPF01 and 23CPF02 due to serious adverse reactions and accordingly, the State Pharmaceuticals Corporation had informed the supplier by an email on 12 May 2023 to provide relevant explanations within 28 days. Accordingly, the supplier informed the Director of the National Medicines Regulatory Authority in a letter on 30 May 2023 that he would discuss with the manufacturer and provide relevant explanations. However, the Director of the National Medicines Regulatory Authority had informed the Director of the Medical Supply Division by the letter No. NMAR/P41/VR06/2023 dated 24 June 2023, to voluntarily withdraw the stock of the respective pharmaceutical (Batch 04) .

(vii) The Medical Supplies Division had informed the situation to the State Pharmaceuticals Corporation and thereby to the supplier through e-mail, and the supplier had informed to the Director of the National Medicines Regulatory Authority on 16 June 2023 that the aforesaid stock of pharmaceuticals would be voluntarily withdrawn after 23 days of the order of the Director of the National Medicines Regulatory Authority. After 111 days of this, the supplier was informed to pay the amount of Rs. 37,342,275 for which the total cost of 23,158 units and 25 per cent overhead administrative expenses on 05 October 2023 for the supply of

pharmaceuticals that have failed in quality and the written documents about the related payments were not submitted to the audit.

(e) A stock order control form related to the issuance of the normal order in the year 2023 had not been prepared. However, the normal Order No. 2023/SPC/N/R/P/00112 had been issued for the supply of 50,000 units about 11 months after the date of the normal order for the year 2023 to be issued. If a normal order was placed on the scheduled date, although it was possible to carry out the procurement under an open bids, in the current emergency situation, it was decided 21 days after the issue of the order to call for bids from registered and past suppliers and from other sources or at limited prices within 07 days.

(f) About 44 days had been spent for inviting bids. The Technical Evaluation Committee had submitted its recommendations on 09 March 2023 only in respect of one bidder with registration certificate who submitted the third lowest bid. Accordingly, although the Procurement Committee had recommended on 09 March 2023 to award the bid after price negotiation with the bidder who submitted the bid at US$ 4 (Rs. 1,448.56) per unit, the Additional Secretary (Development) had not approved the said recommendations.

(g) However, it had been notified on 15 March 2023 through e-mail that the price cannot be reduced further, and accordingly Even though the Procurement Committee had submitted its recommendations on 15 March 2023, seven days after the Technical Evaluation Committee had submitted its recommendations, the said bidder bid at US$ 4 (Rs. 1,448.56) per unit subject to pre-shipment related sample inspection, the Additional Secretary (Procurement) had also not approved this recommendation as he had not approved the initial procurement decision. Accordingly, 54 days after the recommendations of the Procurement Committee, the Chairman of the State Pharmaceuticals Corporation sent a letter to the then Secretary of the Ministry of Health, and the Secretary of the Ministry of Health had approved the recommendations of the Procurement Committee on 12 May.

(h) Twenty six days after the approval of the Secretary of the Ministry of Health, the bid award was sent to the supplier on 07 June 2023, and 12 days after that, the bid award had been accepted on 07 June, 2023 informing the supplier could not carry out pre-shipment sample testing and to issue the purchase order to be the shelf life of the stocks of pharmaceuticals 20 months. Accordingly, the recommendations had been given on 17 July 2023 to remove the condition of sample testing related to pre-shipment, changing the Procurement Committee recommendations once again to make the payment after a satisfactory performance report from the Director of Medical Supplies Division and approved by the Additional Secretary (Procurement) on 18 July.

(i) Three days after the re-approval, the purchase order of 50,000 units was issued on 21 July 2023 at US$ 4 per unit, and the related Letter of Credit had been issued on 10 August, 2023. The Medical Supplies Division received the stock of pharmaceutical on 01 December 2023, after 113 days the issuance of the Letter of Credit. Accordingly, this normal order had taken more than a year to be implemented in case the Medical Supplies Division does not have stock.

(j) Even though the Order No. 2023/MSD/E/R/P/00047 for 25,000 units had been issued on 25 January 2023, this order had not been executed. However, actions had not been taken to remove this order from the Swastha System.

(k) The Order No. 2023/SPC/E/R/P/00142 dated 25 January 2023 for 25,000 units had been issued. All the bidders did not have a valid registration certificate from the National Medicines Regulatory Authority. Accordingly, due to the lack of registration certificate, the evaluators had decided to check the samples of the stock of pharmaceuticals and made aware the bidders about it. Only two bidders, the lowest bidder and the fourth lowest bidder, had submitted samples to the Technical Evaluation Committee.

(l) The bidder had agreed to supply pharmaceutical stock for Rs.2,900 as per the price negotiation carried out with the highest bidder that was Rs. 3,910 and the fourth lowest bidder. Accordingly, the Technical Evaluation Committee had recommended both these bidders on 24 February 2023, after 24 days the closing date of bids. However, the decision to award the bid was given by the Members of the Emergency Procurement Committee of the Health Sector on 21 March 2023 to the fourth lowest price that is Rs. 2,900, twenty five days after the recommendation of the Technical Evaluation Committee subject to WOR Certificate depending on the time of delivery of the stock on the basis of the prevailing emergency. However, the cover approval letter of the Cabinet of Ministers related to this decision had not been included in the file.

(m) It was problematic during the audit regarding the determination of the bids based on the "samples" given in the background where all the four bidders who submitted the bids did not have valid registration certificates from the National Medicines Regulatory Authority and, unavailability of the media (letters/e-mail etc.) for which made aware the bidders for the submission of samples and the information about the bidders who submitted the samples in the file was also problematic. The prices offered by the remaining three bidders in this bid were Rs.983 (US$ 2.65), Rs. 1,465 (US$ 3.95) , and Rs. 1,470 and bidding at a price increase of 195 per cent from the lowest bid was also problematic. The purchase order for purchase of 25,000 units for Rs.2,900 units each had been issued on 21 April 2023, that is 31 days after bid approval.

(n) National Medicines Regulatory Authority had issued a Waiver of Registration on 07 May 2023, and 133 days after the date mentioned in the purchase order, the supplier had given 17,000 units of pharmaceuticals with a shelf life of 24 months to the Medical Supplies Department on 02 October 2023. By the time the file was handed over to the audit on 02 October 2023, the supplier had not given the performance bond and had not entered into a contract with the supplier. Accordingly, the Ministry did not have any coverage regarding the remaining 8,000 units of stocks of pharmaceutical to be supplied by the supplier.

(o) The Order No. 2023/SPC/E/R/P/00149 of 16,000 units for the year 2023 had been issued on 06 February 2023. Only two bidders had a valid registration certificate from the National Medicines Regulatory Authority. After 14 days the date of closing of bids on 24 April 2023 the Technical Evaluation Committee had recommended that out of the two bidders with registration certificate, one of the bidders who offered the lowest price as a unit of Rs. 2,153, was not suitable due to non-compliance with the requirement of the time required to supply the stock and that it was suitable to be awarded the bid after price negotiation with the bidder who offered a price of Rs.2,200 per unit.

(p) Accordingly, according to the price negotiation with the bidder, the bidder had agreed to supply stocks of pharmaceutical for Rs. 2,100 and 18 days after the recommendation of the Technical Evaluation Committee on 12 May, 2023, the emergency Procurement Committee of the Health Sector had given the decision to award the bid. However, the covering approval of Cabinet of Ministers r related to this decision had not been available in the file.

(q) The 2024 normal order of 50,000 units was placed on 27 March 2023. After 86 days of issuing the order, it was decided to invite bids under international bidding on 22 June 2022 and all the bidders had registration certificates of National Medicines Regulatory Authority. The Technical Evaluation Committee had met on 20 October 2023 and when the file was submitted to the audit on 16 November 2023, no further action had been taken.

(r) Thirty four hospitals had purchased 11,185 units at different prices for Rs,14,194,606 for the years 2022 and 2023 due to non-availability of stock of pharmaceutical to the Medical Supplies Division in the year 2022.

73. Dexamethasone Injection 8mg / 2ml (SR. 00701602)

The following matters were observed regarding this pharmaceutical which is an essential pharmaceutical.

(a) Because of the remaining stock in the warehouse and hospitals and the stock to be received from previous orders has been identified as 2,909,913 (Amp) as per Order Control Form - 2022, the normal order for the year 2022 had not been submitted. Nevertheless, the 650,000 units of pharmaceutical related to the order 2021/SPC/N/R/P/00093 included in the stock to be received from previous orders had not been received by the Medical Supplies Division by the audit date of 15 November 2023 had directly affected to have zero stock of these pharmaceuticals.

(b) As the waiting period for obtaining pharmaceuticals is usually about 11 months, although the normal order for the year 2023 (2023/SPC/N/R/P/00084) should be submitted to the State Pharmaceuticals Corporation by February 2022, the Medical Supply Division had submitted the normal order for the year 2023 to the State Pharmaceuticals Corporation on 22 November 2022 with a delay of 09 months.

(c) The State Pharmaceuticals Corporation of Sri Lanka had spent about 07 months for the procurement process of the normal order for the year 2023, which was submitted with a delay, and related to the order, 300,000 pharmaceuticals (Amp) were delivered on 15 October 2023 and the remaining 300,000 (Amp) should also be supplied on 15 December 2023. Even the first stock had not been received by the date of audit, 15 November 2023.

(d) The Medical Supplies Division had submitted the normal order for the year 2021 (2021/SPC/N/R/P/00093) for the procurement of 1,100,000 units (Amp) of the pharmaceutical on 20 February 2020 and the Director of Medical Supplies had revised the order to 1,750,000 units on 23 April 2020. However, despite the ability to carry out procurement activities at the same time, without doing so, due to the State Pharmaceuticals Corporation of Sri Lanka had carried out the procurement on two occasions, a more than 2 years had delayed and due to the increase in the price of the pharmaceuticals and the increase in the exchange rate, it had to incur expenses by Rs. 6,939,453 (14470560 – (650×0.062×186.8761)) in excess.

(e) Even though the order was submitted on 04 November 2022 to a supplier selected under EOI (Expressions Of Interest) basis for procuring 250,000 units of pharmaceutical for 3 months using Indian Credit Line by order No. 2022/MSD/V/R/P/00076 dated 01 November 2022, due to failure of that supplier to supply the stock of pharmaceutical, it was decided to give the order of pharmaceuticals to another supplier in the Health Sector Emergency Procurement Committee (HSEPC) held on 28 June 2023. Accordingly, a number of 40,800 (Amp) pharmaceuticals were received on 03 August 2023, and a number of 209,200 (Amp) pharmaceuticals had been received by the

Medical Supply Division on 14 September 2023 . The following matters were observed during the examination regarding that.

(i) The supply of pharmaceuticals was delayed for more than 06 months due to the failure of the first selected supplier to supply this stock of pharmaceuticals by 28 June 2023. Nevertheless, it was not possible to take legal actions against the supplier as he is not liable for the failure of obtaining performance bonds in the purchase of pharmaceuticals from the suppliers selected on the basis of EOI and not entering into a written agreement with the supplier.

(ii) The order of 250,000 pharmaceutical units (Amp) had been placed with the second selected supplier on 25 July 2023 and the due date of the stock of pharmaceutical was 26 July 2022. Nevertheless, the stock of pharmaceutical was received as 40,800 (Amp) on 03 August 2023 and 209,200 on 14 September 2023. Although the late fee to be charged as per the terms of the purchase order was Rs.758,737, the late fees had not been charged due to being notified to take action to eliminate penalty charges imposed on suppliers for delay in delivery of EOI order by letter No. SH/misc/03/2022 dated 01 March 2023 of the Secretary of Health addressed to the Deputy Director General of Medical Supplies.

(iii) Even though the first supplier had failed to deliver on 04 November 2022, the order had not been cancelled even as at 24 November 2023 which was the date of audit and the order had been entered as an active order in the Swastha Computer System.

(f) The Order No. 2023/SPC/E/R/P/00156 was submitted to the State Pharmaceuticals Corporation on 28 February 2023 for the purchase of 300,000 units (Amp) of pharmaceutical under the emergency procurement process to meet the three-month requirement of the pharmaceutical and the due date for the stock was 10 March 2023. Even though the quotations were called on 15 March 2023 and the bids were opened on 17 March 2023, it had taken up to 25 April 2023 to inform the decision taken by the Health Sector Emergency Procurement Committee on 12 April 2023 to the State Pharmaceuticals Corporation. Accordingly, the State Pharmaceuticals Corporation had submitted the Purchase Order dated 08 May 2023 to the selected supplier. The following matters were observed in this regard.

(i) According to the computer systems (Pronto and Swastha), it was observed that this pharmaceutical remained zero in the Medical Supplies Division for almost 04 months from 11 April 2023 to 04 August 2023.

(ii) Although the date to deliver the stock is 10 March 2023, the Health Sector Emergency Procurement Committee had spent 52 days from 15 March 2023 to 08 May 2023 for the procurement process for this order.

(iii) According to the purchase orders, although the delivery date of the pharmaceuticals was 28 May 2023, the Medical Supplies Division received the stock on 17August 2023 with a delay of 80 days. Accordingly, it was observed in the audit that this delay has directly affected the pharmaceuticals to be zero for almost 04 months.

(iv) According to the supply conditions of the purchase order, although a maximum penalty of 10 per cent of the total value should be charged for the stock received after 3 weeks from the due date, the late fee had been waived off as per the letter No. SH/MISC/03/2022 of Secretary of Health dated 23 November 2022 .

(g) Due to one of the two bidders had not submitted the Power of Attorney for the order No. 2023/ADB/N/R/P/00008, for which commenced calling for quotations on 10 March 2023, although the Sri Lanka Resident Operations Office of the Asian Development Bank on 22 August 2023 had cancelled due to disagreement with the decision of the Project Procurement Committee regarding the negotiation of the contract price with the other bidder who submitted higher prices, it was observed that the order of 750,000 units of pharmaceutical was further shown as an approved order in the Swastha Computer System as at 24 November 2023, the date of audit.

(h) A number of 12640 units (Amp) of this pharmaceutical had been received on 27 July 2023, as donations and the donation stock had not been included in the 'Swastha' Computer System.

(i) Although 7-10 months had passed since the audit date of 26 November 2023, when two batches of pharmaceuticals belonging to two orders of the pharmaceuticals were temporarily withdrawn from consumption, there was no confirmation from the National Drug Quality Assurance Laboratory regarding the quality of the pharmaceutical through a sample test. Due to this delay, it was observed in the audit that there will be a possibility to expire the stocks of pharmaceutical belonging to the above two batches which were to be expired in May and June 2024.

Annex 1

Summary of Pharmaceuticals as at 13/05/2022

Out of Stock"0" Vital and Essential Items	No of Items	
VEN	MSD	Institutions
Vital(N-14)	2	1
Essential(N- 646)	188	50
Total	**191**	**51**

Non Essential(N - 486)	121	49

311

Stock Level Less than 03 months

VEN	Out of Stock"0"	Below one month	Between 01-02 Months	Between 02-03 months
Vital(N-14)	2	6	1	1
Essential(N-646)	188	104	52	51
Non essential(N-486)	121	45	27	15

Stock Level more than 03 months

VEN	Above 03 months
Vital(N-14)	3
Essential(N-646)	176
Non essential(N-486)	88

Current Stock Level of Surgical Items.

Out of Stock"0" Vital and Essential Items	No of Items	
VEN	MSD	Institutions
Vital	3	3
Essential	2721	2153
Total	2724	2156

Non Essential	2330	1459

Stock Level Less than 03 months

VEN	Out of Stock"0"	Below one month	Between 01-02 Months	Between 02-03 months	Total
Vital	3	0	0	0	3
Essential	2721	540	18	22	3301
Non essential	2724	562	35	31	3352

2330

Current Situation with regard to Laboratory Items.

	OUT of Stock MSD and Institutions	Below 3 months(MSD and Other Institutions)
Regular items - 800	250	85
Complementary Items- 3100	600	300
Total – 3900 items	850	385

Current Situation with Regard to the X-Ray Items

	Out of Stock	Below I month	Below 3 months
Regular items(44)	18	4	2

ඇමුණුම 02

දුරකථන) 0112669192 , 0112675011
தொலைபேசி) 0112698507 , 0112694033
Telephone) 0112675449 , 0112675280

ෆැක්ස්) 011-2082162
பெக்ஸ்)
Fax)

විද්‍යුත් තැපෑල)
மின்னஞ்சல் முகவரி)
e-mail) info.psrp@health.gov.lk

වෙබ් අඩවිය)
இணையத்தளம்)
website) www.health.gov.lk

ඔසු පියස
ஒசு பியச
OSU PIYASA

මගේ අංකය)
எனது இல)
My No.) SM/PSRP/01/Treasury/2022

ඔබේ අංකය)
உமது இல)
Your No.)

දිනය)
திகதி) 22. 04. 2022
Date)

ඖෂධ නිෂ්පාදනය, සැපයීම් හා නියාමන රාජ්‍ය අමාත්‍යාංශය
ஔடத உற்பத்திகள்இ வழங்குகைகள் மற்றும் ஒழுங்குறுத்துகை இராஜாங்க அமைச்சு
State Ministry of Production, Supply and Regulation of Pharmaceuticals

Mr. K M Mahinda Siriwardana
Secretary to the Treasury,
Ministry of Finance,
Sri Lanka.

Through
Dr S. H. Munasinghe
Secretary
Ministry of Health

Financial Requirements to purchase Medical Supplies

The State Ministry of Production, Supply and Regulation of Pharmaceuticals and its institutions are completely responsible for procuring, distribution, and regulation of pharmaceuticals, consumables, and all kinds of medical supplies for all healthcare institutions in Sri Lanka.

02. Government of Sri Lanka has allocated nearly 65 billion Rupees for the year 2022 for this task. Due to recent exchange rate (USD to LKR) fluctuations and other conditions beyond our control, the price of the pharmaceuticals, laboratory and radiology consumables and all kinds of medical supplies has increased by 29-35 %. Considering these facts, the State Ministry had to allow to increase the minimum controlled price of the medical supplies by 29-35 % to avoid shortages of most essential medical supplies.

03. Under the pertaining forex issues, SPC, SPMC and Private sector healthcare institutes have been facing considerable challenges to open L/Cs for essential medical supplies and raw materials imports. Meanwhile, Ministry of Health and State Ministry of PSRP has been taken many attempts to maintain the supplier chain up to now.

04. Therefore, we anticipate an increase in medical supplies expenditure due to the continuous hiking of the exchange rate is a greater challenge to the Ministry of Health. Accordingly, we would be informed you about Monthly estimated foreign currency requirements for all the pharmaceutical imports for your kind consideration.

Dr. R. M. S. K. Ratnayake
Secretary
State Ministry of Production, Supply & Regulation of Pharmaceuticals

Dr. R.M.S.K. Ratnayake
Secretary,
State Ministry of Production, Supply and Regulation of Pharmaceuticals

Fund Requirement of Foreign Currency - SMPSRP

Immediate Fund Requirement for Pharmaceutical Imports

Status of LCs	Value in Million USD		
	DHS	SPC	Total
LC applications pending at Bank	3.0	3.0	6.0
LC applications ready to send to Bank	7.0	0.2	7.2
Total	10.0	3.2	13.2

Estimated Monthly Fund Requirement for Pharmaceuticals

Description	Value in Million USD for a Month
DHS Supplies by SPC	15 - 20
DHS Supplies through SPC by Private Suppliers	10 - 12
Supplies for SPC "Osusala" Outlets	3 - 4
Total	28 - 36

Estimated Monthly Fund Requirement for Pharmaceutical Raw Material for a Month

Description	Value in Million USD for a Month
Raw materials for SPMC	2.0
Raw materials for Local Manufactures	10.0
Total	12.0

Estimated Monthly Fund Requirement for Private Sector Healthcare Institutions & Pharmacies for a Month

Description	Value in Million USD for a Month
Pharmaceuticals & Surgical Consumables	30.0
Total	30.0

Attention Mr. Nonis (SA)

LC's to be Established as at 20.04.2022 (Peoples Bank)

	Indent No.	Supplier	Item	LC Value in Foreign Currency		Date of Sent to Bank	Age from LC open date
1	LP/DHS/L/WW/47/17SM/2022	M/s. Hemsons International Pte. Ltd - Colombo 01	Laboratory Consumables	LKR	6,004,635.84	3/3/2022	49
2	LP/DHS/M/S/WW/3/152CP/2021	M/s. A.J. Medichem International Pvt. Ltd - Colombo 09	Dural Graft Matrix Absorbable Various Types	LKR	167,871,060.00	3/3/2022	49
3	LP/DHS/RSS/RO/96/489NB/2021	M/s. CIC Holding PLC - Colombo 02	Mini Caps	LKR	12,325,000.00	3/4/2022	48
4	LP/DHS/MM/3204/2021	M/s. George Steuart Health Pvt. Ltd - Mount Lavinia	Nifedipine Extended Release Tablets USP 20mg	LKR	16,275,339.00	3/4/2022	48
5	LP/DHS/SUS/WW/46/371DR/2021	M/s. SS Dento Pharma - Colombo 7	Dental Items	LKR	16,062,500.00	3/10/2022	42
6	LP/DHS/IN/3455/2022	M/s. Softcare International Pvt. Ltd - Colombo 05	Quetiapine Tablets USP 100mg	LKR	2,975,000.00	3/10/2022	42
7	LP/DHS/RSS/RO/45/535KM/2020	M/s. Lifeserv Pvt. Ltd - Colombo 03	Drug Eluting Coronary Stent	LKR	9,166,500.00	3/11/2022	41
8	LP/DHS/SA/3070/2021	M/s. Chamee Chemist - Veyangoda	Hydrocortisone Tablets USP 10mg	LKR	19,575,000.00	3/16/2022	36
9	LP/DHS/IG/3452/2021	M/s. Hemas Pharmaceuticals Pvt. Ltd - Colombo 03	Botulinum Toxin Type A Purified Neurotoxin Complex 50Au	LKR	6,998,500.00	3/21/2022	31
10	LP/N9/DHS/B/SA/358/2021	M/s. Pettah Pharmacy Pvt. Ltd - Colombo 10	Golimumab Solution for Injection in Prefilled Pen 50mg/0.5ml	LKR	8,718,171.00	3/21/2022	31
11	LP/DHS/SUS/WW/205/451DR/2021	M/s. SS Dento Pharma - Colombo 7	Preformed Arch Wires in Various Sizes	LKR	10,009,000.00	3/24/2022	28
12	LP/DHS/SUS/WW/246/13SKM/2021	M/s. CIC Holding PLC - Colombo 02	Surgical Non Consumables	LKR	93,550,084.15	3/24/2022	28
13	LP/DHS/L/WW/SS/116WAC/2021	M/s. Millers Limited - Kelaniya	X'Ray Dental Occlusal Size 5cm x 7cm	LKR	9,800,000.00	3/24/2022	28
14	LP/DHS/M/SS/WW/9/431NB/2021	M/s. Lucky Industries - Colombo 12	Particulate Filtering Face Mask	LKR	34,686,000.00	3/24/2022	28
15	LP/DHS/L/WW/74/18NK/2022	M/s. Hemsons International Pte. Ltd - Colombo 01	Membrane Lactose Glucuronide Agar & Buffered Peptone Water	LKR	1,108,127.52	3/24/2022	28

	Indent No.	Supplier	Item	LC Value in Foreign Currency		Date of Sent to Bank	Age from LC open date
16	LP/DHS/WD/3358/2021	M/s. Klintas Pvt. Ltd - Ragama	Metareminol Injection BP 10mg/ml	LKR	23,200,000.00	3/24/2022	28
17	LP/DHS/C/PH/3354/2021	M/s. New Arumed Pvt. Ltd - Peliyagoda	Anit Rabies Vaccine BP 0.5ml	LKR	138,960,000.00	3/25/2022	27
18	LP/DHS/RSS/RQ/158/S19MPN/2021	M/s. TMI Solutions Pvt. Ltd - Colombo 06	Personal Protective Equipment	LKR	245,000,000.00	4/1/2022	20
19	LP/DHS/L/WW/35/20WAC/2022	M/s. S.J. Enterprises Pvt. Ltd - Dehiwala	Laboratory Consumables	LKR	24,799,360.00	4/6/2022	15
20	LP/NP/DHS/O/SA/495/2021	M/s. Emerchemie NB Ceylon Ltd - Colombo	Palbociclib Capsules 125mg	LKR	25,410,000.00	4/6/2022	15
21	LP/DHS/RSS/RQ/14/179NSL/2021	M/s. Fresenius Medical Care Lanka Pvt. Ltd	Hollow Fibre Dialyzer	LKR	28,440,000.00	4/6/2022	15
22	LP/DHS/RL/92/155SR/2021	M/s. Surgicare Pvt. Ltd - Colombo 06	Laboratory Consumables	LKR	17,015,500.00	4/6/2022	15
Total Value LKR					917,949,777.51		

249,141,646.80

Total 1,165,091,424.31

260

LC's to be Established as at 20.04.2022 (Bank of Ceylon)

	Indent No.	Supplier	Item	LC Value in Foreign Currency		Date of Sent to Bank	Age from LC open date
1	LP/DHS/M/SA/3466/2022	M/s. Ciniqon Biotech Pvt. Ltd - Maharagama	Trastuzumab Powder for Concentrate for Solution for IV Infusion 440mg	LKR	101,080,000.00	3/3/2022	49
2	LP/DHS/NV/3454/2021	M/s. Pharma Associates - Colombo 14	Verapamil Injection BP 5mg/2ml	LKR	31,000,000.00	3/15/2022	37
3	LP/NP/DHS/B/SA/397/2021 LP/NP/DHS/B/SA/398/2021 LP/NP/DHS/B/SA/399/2021	M/s. Sunshine Healthcare Lanka Ltd - Colombo 01	Adalimumab Injection 40mg/0.8ml	LKR	16,116,000.00	3/16/2022	36
4	LP/DHS/MMN/3445/2021	M/s. A. Baur & Co. Pvt. Ltd - Colombo 14	Tocilizumab Injection 200mg/10ml for IV Infusion	LKR	92,307,810.00	3/21/2022	31
5	LP/NP/DHS/B/SA/424/2021 LP/NP/DHS/B/SA/425/2021 LP/NP/DHS/B/SA/426/2021 LP/NP/DHS/B/SA/427/2021	M/s. Ciniqon Biotech Pvt. Ltd - Maharagama	Adalimumab Injection 40mg/0.8ml	LKR	19,170,000.00	3/24/2022	28
6	LP/DHS/DR/3460/2021	M/s. A. Baur & Co. Pvt. Ltd - Colombo 14	Nilotinib Hard Gelatin Capsules 200mg	LKR	28,267,836.80	4/5/2022	15
Total Value LKR					**247,141,646.80**		

Local Funds - requirement

(23)

(2) - 1

Total payment (LC) as at 19.06.2022 based on Supplier

	Debit Note No	Supplier	Indent No	Item	Invoice No	LC No	Delivery Date	Payment Due Date	Bank	Currency of Credit	Invoice Amount	Amount Paid in LKR (90% OR 25%)	
02.03.2022	0000030181	094ABAUR A.BAUR & COMPANY (PVT) LTD	LP/DHS/SUS/MW/85/2021	Micro Drill Electric	400415904	M113738	9-Jun-21	6-Aug-21	BOC	LKR	12,319,000.00	11,087,100.00	
09.03.2022	0000028155	094ABAUR-A.BAUR & COMPANY (PVT) LTD	LP/CPU-DHS/307/2019	Paracamb Tablets 10mg	400307815	M105345	2-Jan-21	25-Feb-21	BOC	LKR	39,286,334.04	39,286,334.04	
03.03.2022	0000031068	094ABAUR A.BAUR & COMPANY (PVT) LTD	LP/DHS/MW/33336/2021	Tocilizumab Injection 20mg/ml	400415210	M114859	29-Nov-21	28-Feb-22	BOC	LKR	8,451,174.25	8,506,300.05	58,879,734.09
	0000028015	094ABLPH-ABL PHARMA SERVICES (PVT) LTD	LP/DHS/S/MW/1340/19BOC/20	Surgical Consumables Items	4201	0042001300003658	21-May-21	1-May-21	PB	LKR	2,815,400.00	2,227,500.00	
	0000028017	094ABLPH-ABL PHARMA SERVICES (PVT) LTD	LP/DHS/S/MW/1340/19BOC/20	Surgical Consumables Items	3735	0042001300003625	21-May-21	6-Jul-21	PB	LKR	1,075,000.00	967,500.00	
	0000030469	094ABLPH-ABL PHARMA SERVICES (PVT) LTD	LP/DHS/MW/1340/19BOC/20	Surgical Consumables Items	3600	0042001300003659	21-May-21	6-Jul-21	PB	LKR	1,168,200.00	1,051,380.00	
	0000029019	094ABLPH-ABL PHARMA SERVICES (PVT) LTD	LP/DHS/S/MW/1340/19BOC/20	Surgical Consumables Items	4236	0042001300003629	30-May-21	6-Jul-21	PB	LKR	2,475,000.00	2,227,500.00	
				Surgical Consumables Items	3798	0042001300003628	20-May-21	6-Jul-21	PB	LKR	4,820,000.00	4,338,000.00	10,811,880.00
07.03.2022	0000031357	094ANAIN ANALYTICAL INSTRUMENTS	LP/DHS/DA/322/PP/21										
22.02.2022	0000029406	094ANAIN ANALYTICAL INSTRUMENTS	LP/DHS/L/MW/57/584PHP/19	Inactivated Rabies Vaccine 10	AAPSH-051830	M113770	6-Sep-21	6-Oct-21	BOC	LKR	55,000,000.00	50,396,380.00	
				Malathion Grade Spray	AI-PSI-080042	0042001300003121	5-May-21	30-Jun-21	PB	LKR	16,891,247.00	15,122,122.80	
	0000032744	094ANSM Instruments	LP/DHS/L/55/2458/2021	Thermo Fisher Scientific Taqpath COVID-19CE-IVD RT-PCR Kit	21-PSI-080017	0042001210000169	12-Jan-22	28-Feb-22	PB	LKR	48,378,600.00	43,540,740.00	209,178,913.40
07.01.2022	0000032550	A I Medichem International											
01.02.2022	0000032755	AJ Medichem International	LP/DHS/S/MW/334/2390C/2021	Surgical Consumables	SPC/MSD450	M115317	15-Dec-21	28-Feb-22	BOC	LKR	1,800,000.00	1,620,000.00	
10.02.2022	0000031756	A I Medichem International		Radiology Consumables Items	SPC/MSD456	M115256	21-Dec-21	28-Feb-22	BOC	LKR	8,757,936.00	7,882,132.40	
				Disinfectant Soft Contactable Tertiary Care	SPC/MSD456	M117449	22-Jan-22	13-Mar-22	BOC	LKR	5,617,715.00	5,617,715.00	15,119,847.40
09.02.2022	0000031743	AMBALANGODA (PVT) Ltd	LP/DHS/AD/83/21	Peroxymonosulphate High Level Disinfectant for Manual Reprocessing Endoscopes (Activated Powder 100 g Sachet)	2883021724	0042001210000417	16-Dec-21	28-Jan-22	PB	LKR	51,984,066.00	47,185,559.40	47,185,559.40
10.02.2022	0000031744	AMBALANGODA (PVT) Ltd			2334	M115801	8-Dec-21	28-Feb-22	BOC	LKR	37,415,342.40	37,415,342.40	37,415,342.40
09.02.2022	0000031497	BIOMEDICO (CEYLON) ASSOCIATES	LP/DHS/S/MW/1340/19BOC/21	Surgical Consumables	20123	0042001210001675	15-Feb-21	27-Dec-21	PB	LKR	202,500.00	358,576.53	
17.02.2022	0000031493	BIOMEDICO (CEYLON) ASSOCIATES		Biopsy Needles Set Various Sizes	6067	M115126	15-Dec-21	28-Feb-22	BOC	LKR	12,841,215.33	43,096,476.85	
				Biopsy Needles Set Various Sizes	15130	M115259	10-Jan-22	8-Feb-22	BOC	LKR	35,747.93	35,747.93	43,390,820.33
02.03.2022	0000032184	094CEOZO-CEYLON OXYGEN LIMITED	LP/DHS/S/MW/1340/19BOC/2021	Bone Cement System for Cavities	374655335	M113859	8-Dec-21	28-Feb-22	BOC	LKR	9,691,775.25	8,304,330.88	
19.01.2022	0000031607	094CEOZO-CEYLON OXYGEN LIMITED.	LP/DHS/MW/1340/19BOC/2021	Endoscopic Oxygen Therapy Kit	374440197	M112661	10-Nov-21	28-Dec-21	BOC	LKR	14,617,200.00	11,139,200.00	
19.01.2022	0000031726	094CEOZO-CEYLON OXYGEN LIMITED.	LP/DHS/MW/1340/19BOC/2021	Endoscopic Oxygen Therapy Kit	374400212	M112661	8-Oct-21	28-Nov-21	BOC	LKR	24,654,240.00	19,726,400.00	83,964,170.88
22.02.2022	0000031615	CHEMIMAK-CEYLIKA (PVT) LIMITED.	LP/DHS/M/PS/3330/2021	Cefoz - 1G Real Time Kit Kits	10249501	0042001210000261	11-Mar-21	28-Dec-21	PB	LKR	37,199,987.78	29,919,999.80	
22.02.2022	0000032647	CHINAWAK-CEYOKA (PVT) LIMITED.	LP/DHS/M/PS/3330/2021	Liposomal Amphotericin B Injection 50mg/20ml	1100/1424	M113870	4-Jan-22	28-Feb-22	BOC	LKR	60,697,400.00	47,773,050.00	
07.01.2022	0000031523	Ceylika	LP/DHS/MW/1340/19BOC/2021	Liposomal Amphotericin B Injection 50mg/20ml	TE00145	M114020	24-Dec-21	14-Feb-22	BOC	LKR	60,697,400.00	47,773,050.00	
07.01.2022	0000031615	Ceylika	LP/DHS/MW/1340/19BOC/2021	Recombinant Human Erythropoietin alpha injection	TE00143	M116887	8-Dec-21	17-Feb-22	BOC	LKR	30,456,420.00	27,342,315.00	
29.03.2022	0000033110	Ceylika	LP/DHS/S/MW/1340/19BOC/2021	Recombinant Human Erythropoietin alpha injection	TE00143 A	M116887	8-Dec-21	15-Feb-22	BOC	LKR	36,571,080.00	27,428,310.00	
				Salbutamol Pressurized Inhaler BP 200mcg/dose	TE00149	0042001210003851	4-Mar-22	18-Apr-22	PB	LKR	92,610,000.00	83,349,000.00	307,591,723.00
03.03.2022	0000032593	094CIC-CIC HOLDINGS PLC	LP/DHS/SUR/MW/1340/19BOC/20	Dry Gel Foil Consumables	91136650	0042001210002273	16-Jan-22	23-Mar-22	PB	LKR	12,510,091.01	12,159,622.16	
14.02.2022	0000032396	094CIC-CIC HOLDINGS PLC	LP/DHS/PM/1340/21	Dydrogesterone Tablets 10mg	91135984	0042001210003021	4-Jan-22	3-Jan-22	PB	LKR	6,334,780.00	4,835,302.00	
22.02.2022	0000032856	094CIC-CIC HOLDINGS PLC	LP/DHS/MW/S/MW/1340/19BOC/2021	Mini Caps	91138004	0042001210002624	27-Dec-21	27-Jan-22	PB	LKR	36,250,000.00	32,625,000.00	
23.02.2022	0000031734	094CIC-CIC HOLDINGS PLC	LP/DHS/SUS/MW/100/7384PH/19	Surgical Non Consumables	91127551	M110057	19-Jul-21	2-Sep-21	BOC	LKR	79,249,910.64	63,442,538.50	
25.02.2022	0000029837	094CIC-CIC HOLDINGS PLC	LP/DHS/SUS/WW/134/5358/20	Surgical Consumables Various	91124756	M112472	17-May-21	2-Jul-21	BOC	LKR	37,500,000.00	35,750,000.00	
01.03.2022	0000030581	094CIC-CIC HOLDINGS PLC	LP/DHS/M/LB/DO/1/8195/2020	FCI Reagents	91124766	0042001200002050	19-Jul-21	3-Sep-21	PB	LKR	25,444,887.41	25,083,661.81	
03.03.2022	0000028931	094CIC-CIC HOLDINGS PLC	LP/DHS/PH/3697/2020	Sodium Chloride Injection USP 0.9% w/v	91138824	0042001200002988	26-Jan-21	26-Feb-21	PB	LKR	9,987,500.00	8,638,187.50	
11.03.2022	0000029926	094CIC-CIC HOLDINGS PLC	LP/DHS/SUS/WW/36/525PL/19	Neurology Items	91124816, 91124265	M110316	18-May-21	16-Aug-21	BOC	LKR	84,366,017.35	75,929,415.62	
21.03.2022	0000030709	094CIC-CIC HOLDINGS PLC	LP/DHS/SUS/WW/20/4070R/2020	Hydrocellularpolyurethane Dressing in Various Sizes	91141196	M111659	25-Feb-22	11-Apr-22	BOC	LKR	2,660,000.00	2,357,548.75	224,842,276.35

262

	Debit Note No	Supplier	Indent No	Item	Invoice No	LC No	Delivery Date	Payment Due Date	Pay Mode	Currency Code	Invoice Amount	Amount Paid in LKR (50% OR 75%)	
10.03.2022	0000032737	094CLOUD-CLOUD HEALTHCARE PVT LTD	LP/DHS/RSS/RQ/128/483MPN/21	Personal Protective Equipment	T10032	0042001220000201	7-Jan-22	7-Feb-22	PB	LKR	55,690,000.00	52,907,000.00	
10.03.2022	0000032870	094CLOUD-CLOUD HEALTHCARE PVT LTD	LP/DHS/RSS/RQ/128/483MPN/21	Personal Protective Equipment	T10035	0042001220000201	27-Jan-22	27-Feb-22	PB	LKR	5,099,000.00	4,264,000.00	
10.03.2022	0000032869	094CLOUD-CLOUD HEALTHCARE PVT LTD	LP/DHS/RSS/RQ/128/483MPN/21	Personal Protective Equipment	T10034	0042001220000201	27-Jan-22	27-Feb-22	PB	LKR	5,030,000.00	4,561,000.00	
10.03.2022	0000032738	094CLOUD-CLOUD HEALTHCARE PVT LTD	LP/DHS/RSS/RQ/128/483MPN/21	Personal Protective Equipment	T10033	0042001220000201	7-Jan-22	7-Feb-22	PB	LKR	55,690,000.00	52,907,000.00	
29.03.2022	0000032971	094CLOUD-CLOUD HEALTHCARE PVT LTD	LP/DHS/RSS/RQ/128/483MPN/21	Personal Protective Equipment	T10036	0042001220000201	11-Feb-22	11-Mar-22	PB	LKR	4,682,800.00	4,234,520.00	
29.03.2022	0000032973	094CLOUD-CLOUD HEALTHCARE PVT LTD	LP/DHS/RSS/RQ/128/483MPN/21	Personal Protective Equipment	T10037	0042001220000201	11-Feb-22	11-Mar-22	PB	LKR	5,760,800.00	5,190,720.00	82,641,240.00
07.03.2022	0000032455	094DELMG-DELMEGE FORSYTH & COMP	LP/DHS/S/WW/167/321IP/21	Intra Ocular Lens Various Sizes	20211201SPL-RA	M116603	7-Dec-21	7-Mar-22	BOC	LKR	3,324,000.00	3,260,998.42	
22.03.2022	0000032827	094DELMG-DELMEGE FORSYTH & COMP	LP/DHS/RSS/RQ/128/483MPN/20	Intra Ocular Lens Various Sizes	20220111RA-SPC	0042001210007424	11-Jan-22	11-Apr-22	PB	LKR	15,150,600.00	13,635,540.00	
22.03.2022	0000032570	094DELMG-DELMEGE FORSYTH & COMP	LP/DHS/RSS/RQ/71/1046HP/20	Intra Ocular Lens Various Sizes	20211209SPC-RA	M116603	7-Jan-22	7-Apr-22	BOC	LKR	68,377,000.00	50,649,300.00	
24.03.2022	0000032783	094DELMG-DELMEGE FORSYTH & COMP	LP/DHS/RSS/RQ/75/1062HP/20	Intra Ocular Lens Various Sizes	20220110RA-SPC	0042001210000433	13-Jan-22	13-Apr-22	PB	LKR	39,950,000.00	17,955,000.00	85,460,298.42
11.02.2022	0000032304	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/94/310IT/21	Surgical Hair Cap	13015	M114343	25-Nov-21	10-Jan-22	BOC	LKR	790,125.00	711,112.50	
11.02.2022	0000032135	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/94/310IT/21	Surgical Hair Cap	13013	M114343	23-Nov-21	7-Jan-22	BOL	LKR	1,470,000.00	1,323,000.00	
25.02.2022	0000031976	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/141T/21	Surgical Face Mask	60046	M112363	5-Nov-21	5-Dec-21	BOC	LKR	1,598,400.00	1,438,560.00	
25.02.2022	0000031975	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/141T/21	Surgical Face Mask	60049	M112363	5-Nov-21	30-Dec-21	BOC	LKR	1,598,400.00	1,438,560.00	
25.02.2022	0000032073	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/141T/21	Surgical Face Mask	60047	M112363	5-Nov-21	30-Dec-21	BOC	LKR	1,598,400.00	1,438,560.00	
25.02.2022	0000032074	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/141T/21	Surgical Face Mask	60048	M112363	5-Nov-21	30-Dec-21	BOC	LKR	1,598,400.00	1,438,560.00	
25.02.2022	0000032189	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/141T/21	Surgical Face Mask	60050	M112363	8-Nov-21	23-Dec-21	BOC	LKR	1,598,400.00	1,438,560.00	
25.02.2022	0000032188	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/141T/21	Surgical Face Mask	60053	M112363	15-Nov-21	30-Dec-21	BOL	LKR	1,598,400.00	1,438,560.00	
25.02.2022	0000032402	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/141T/21	Surgical Face Mask	60053	M112363	19-Nov-21	3-Jan-22	BOC	LKR	1,598,400.00	1,438,560.00	
25.02.2022	0000032401	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/141T/21	Surgical Face Mask	60054	M112363	22-Nov-21	6-Jan-22	BOC	LKR	1,598,400.00	1,438,560.00	
25.02.2022	0000032303	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/141T/21	Surgical Face Mask	60055	M112363	26-Nov-21	10-Jan-22	BOC	LKR	1,598,400.00	1,438,560.00	
25.02.2022	0000032371	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/141T/21	Surgical Face Mask	60056	M112363	29-Nov-21	13-Jan-22	BOC	LKR	1,598,400.00	1,438,560.00	
25.02.2022	0000032190	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/141T/21	Surgical Face Mask	60057	M112363	30-Nov-21	13-Jan-22	BOC	LKR	1,598,400.00	1,438,560.00	
29.03.2022	0000033052	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/286IT/21	Surgical Face Mask	60031	M112363	11-Nov-21	27-Dec-21	BOL	LKR	1,598,400.00	1,438,560.00	
29.03.2022	0000033053	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/286IT/21	Surgical Face Mask	1400	M112363	23-Jan-22	23-Feb-22	BOC	LKR	3,374,400.00	3,036,960.00	
29.03.2022	0000033068	094DISWE-DISPOWEAR (PVT) LTD	LP/DHS/S/WW/60/286IT/21	Surgical Face Mask	1405	M112363	25-Feb-22	12-Apr-22	BOC	LKR	3,374,400.00	2,956,840.00	
29.03.2022	0000033138	Disposwear	LP/DHS/S/WW/60/139UT/21	Surgical Face Mask	1404	M112363	7-Mar-22	21-Apr-22	BOC	LKR	3,374,400.00	3,036,960.00	
				Surgical Face Mask	1400	M112363	9-Mar-22	24-Apr-22	BOC	LKR	3,486,400.00	2,737,760.00	10,475,812.50
1.2022	0000032581	094DIVAS-Divaka Pharma Ltd	LP/DHS/MI/PIL/04/128/PW/2021	SARS CoV-2 Rapid Ag Assay	INV2830-M	0042001210003336	24-Nov-21	24-Jan-22	PB	LKR	281,100,000.00	199,823,000.00	
03.2022	0000032602	094DIVAS-Divaka Pharma Ltd	LP/DHS/MI/PIL/04/128/PW/2021	SARS CoV-2 Rapid Ag Assay	INV2831-M	0042001220000121	7-Jan-22	7-Mar-22	PB	LKR	70,275,000.00	52,706,250.00	
22.03.2022	0000032735	094DIVAS-Divaka Pharma Ltd	LP/DHS/MI/PIL/04/128/PW/2021	SARS CoV-2 Rapid Ag Assay	INV2838-M	0042001220000121	7-Jan-22	8-Mar-22	PB	LKR	70,275,000.00	52,706,250.00	256,237,500.00
04.01.2022	0000032125	094ELSHADI-ELSHADDAI ENTERPRISES PVT	LP/DHS/LB/DO/128/PW/2021	7500 RAT Extraction Kits	DIACO028	0042001210000406	8-Nov-21	7-Jan-22	PB	LKR	178,234,400.00	133,660,800.00	133,660,800.00
04.01.2022	0000031669	094EMAR-EMAR PHARMA (PVT) LIMITED	LP/DHS/LB/DO/128/PW/2021	Laboratory Consumables	CP 65369	0042001210000440	26-Sep-21	26-Dec-21	PB	LKR	3,611,930.42	2,708,947.82	
18.01.2022	0000031670	094EMAR-EMAR PHARMA (PVT) LIMITED	LP/DHS/LB/DO/128/PW/2021	Laboratory Consumables	CP 65369	0042001220000221	10-Jan-22	10-Feb-22	PB	LKR	961,565.22	811,408.70	
18.01.2022	0000031684	094EMAR-EMAR PHARMA (PVT) LIMITED	LP/DHS/LB/DO/128/PW/2021	Laboratory Consumables	CP 65369	0042001220000221	10-Jan-22	10-Feb-22	PB	LKR	961,565.22	811,408.70	
25.02.2022	0000032583	094EMAR-EMAR PHARMA (PVT) LIMITED	LP/DHS/SUS/WW/50/01NB/2022	Theraputic Plasma Exchange Kit for Haemonetics MCS + Apheresis System	CP 66782	0042001210003316	27-Jan-22	14-Mar-22	PB	LKR	4,350,000.00	3,915,000.00	
	0000032601	094EMAR-EMAR PHARMA (PVT) LIMITED	LP/DHS/SUS/WW/50/01NB/2022	Theraputic Plasma Exchange Kit for Haemonetics MCS + Apheresis System	CP 66872	0042001210003316	27-Jan-22	14-Mar-22	PB	LKR	25,650,000.00	23,085,000.00	
10.03.2022	0000032840	094EMAR-EMAR PHARMA (PVT) LIMITED	LP/DHS/C/WW/99/004/PW/2021	ELISA Test Kit for the Detection of Antigen & Antibodies to HCV	CP 67184	0042001210002736	27-Jan-22	27-Feb-22	PB	LKR	23,367,362.90	21,030,626.61	
14.03.2022	0000032096	094EMAR-EMAR PHARMA (PVT) LIMITED	LP/DHS/C/LB/DO/1/1210A/20	Laboratory Consumables	CP 65593	0042001220000186	6-Jan-22	6-Feb-22	PB	LKR	8,602,429.39	8,040,493.89	
22.03.2022	0000032862	094EMAR-EMAR PHARMA (PVT) LIMITED	LP/DHS/C/WW/100/05CPW/2021	ELISA Test Kit for the Detection of Antigen & Antibodies to HCV	CP 66757	0042001210000736	27-Jan-22	28-Feb-22	PB	LKR	16,163,195.73	14,546,876.16	
	0000032840	Emar pharma	LP/DHS/SUS/WW/50/01NB/2022	Theraputic Plasma Exchange Kit for Haemonetics MCS + Apheresis System	CP 67461	0042001210003316	27-Jan-22	14-Mar-22	PB	LKR	15,000,000.00	13,500,000.00	56,639,761.87
22.02.2022	0000029198	094EMCHE-EMERCHEMIE NB (CEYLON)	LP/DHS/NV/2597/2019	Tiotropium Bromide Monohydrate BP Dry Powder Inhalation Capsules 18mcg	00141919	0042001210000480	12-Mar-21	12-Apr-21	PB	LKR	5,250,000.00	4,725,000.00	4,725,000.00

263

	Debit Note No	Supplier	Indent No	Item	Invoice No	LC No	Delivery Date	Payment Due Date	Bank	Currency Code	Invoice Amount	Amount Paid in LKR (90% OR 75%)	
18.04.2022	0000033163	094MEDIROC-ENDOCARE MEDIAL (PVT) LTD	LP/DHS/S/WW/162/586CP/2021	Pancreatic Pseudocyst Drainage (NAGI Self Expandable Stent Various Sizes	ENDO/2122-297	M118571	15-Mar-22	29-Apr-22	BOC	LKR	5,650,000.00	5,085,000.00	5,085,000.00
18.01.2022	0000032175	094EUROC-EURO CHEM PRODUCTS ,	LP/DHS/L/WW/17/002CPW/2022	Topical Chlorite of Lime BP	21-002-A-1/ECPPSL	0042001210003003	5-Nov-21	6-Jan-22	PB	LKR	22,500,000.00	20,250,000.00	
22.03.2022	0000032227	094EUROC-EURO CHEM PRODUCTS ,	LP/DHS/L/WW/12/002CPW/2022	Topical Chlorite of Lime BP	21-002-A-1/ECPPSL	0042001210003003	5-Nov-21	6-Jan-22	PB	LKR	23,850,000.00	21,465,000.00	
24.03.2022	0000032340	094EUROC-EURO CHEM PRODUCTS ,	LP/DHS/L/WW/12/002CPW/2022	Topical Chlorite of Lime BP	21-005-A-1/ECPPSL	0042001210003003	23-Nov-21	23-Jan-22	PB	LKR	69,750,000.00	62,775,000.00	184,490,000.00
26.01.2022	0000033526	094GEORG-GEORGE STEUART HEALTH	LP/DHS/L/WW/127/75NK/2021	Rapid Alcohol Test Kit & Multi Panel Drugs Test Kits	190007	0042001210003004	24-Nov-21	8-Jan-22	PB	LKR	26,036,504.88	23,434,654.39	
08.02.2022	0000032482	094GEORG-GEORGE STEUART HEALTH	LP/DHS/L/WW/127/75NK/2021	Rapid Alcohol Test Kit & Multi Panel Drugs Test Kits	193545	0042001210003004	5-Dec-21	17-Jan-22	PB	LKR	3,199,980.17	2,879,982.15	
25.02.2022	3000032289	094GEORG-GEORGE STEUART HEALTH	LP/DHS/AMS/3284/20	L-Asparaginase for Injection 10,000Ku Vial	M-0711	M116886	29-Nov-21	28-Feb-22	BOC	LKR	3,400,000.00	3,060,000.00	
01.02.2022	3000032173	094GESTU-GEORGE STEUART HEALTH (P	LP/DHS/MS/WW/01/048R/19	Sodium Fluoride Varnish	M-0709	0042001210002745	17-Nov-21	1-Jan-22	PB	LKR	11,843,350.00	8,882,512.50	
11.02.2022	0000032673	094GESTU-GEORGE STEUART HEALTH (P	LP/DHS/MS/WW/01/048R/19	Sodium Fluoride Varnish	M-0711	0042001210002745	30-Dec-21	28-Feb-22	PB	LKR	137,000.00	95,900.00	
18.04.2022	0000033018	094GESTU-GEORGE STEUART HEALTH (P	LP/DHS/S/WW/153/	Urine Strips & Pregnancy Test Strip	M-0724	0042001210003037	23-Feb-22	8-Apr-22	PB	LKR	15,212,750.00	11,697,280.00	59,253,425.05
10.01.2022	0000032196	094GLAXO-GLAXOSMITHKLINE PHARMA	LP/DHS/SP/3220/2021	Hepatitis B Vaccine 20mcg/ml	4025397579	M116869	8-Nov-21	7-Jan-22	BOC	LKR	35,001,500.00	35,371,350.00	35,371,350.00
27.01.2022	0000032203	094GLOBMD-GLOBALMED (PVT) LTD	LP/DHS/RS/RQ/121/1008HS/19	Detachable Embolization Coil Various Size	GM/SPF/21/158	0042001210002132	10-Dec-21	24-Jan-22	PB	LKR	34,335,000.00	31,901,500.00	
24.03.2022	0000032315	094GLOBMD-GLOBALMED (PVT) LTD	LP/DHS/RS/RQ/121/1008HS/19	Detachable Embolization Coil Various Size	GM/SPF/21/158	0042001210002132	10-Dec-21	24-Jan-22	PB	LKR	34,335,000.00	31,901,500.00	
24.05.2022	0000033016	094GLOBMD-GLOBALMED (PVT) LTD	LP/DHS/RS/RQ/84/2162HS/20	Surgical Consumables items	GM/SPF/21/186	0042001210003183	24-Feb-22	11-Apr-22	PB	LKR	7,865,000.00	7,079,500.00	
18.04.2022	0000033145	094GLOBMD-GLOBALMED (PVT) LTD	LP/DHS/S/WW/80/1244C/2020	ERCP Multi Diameter & Biliary Dilatation Balloon Various Sizes	GM/SPF/21/200	M117020	14-Mar-22	28-Apr-22	BOC	LKR	9,709,300.00	8,738,190.00	
31.05.2022	0000033487	Unpublished	LP/DHS/S/WW/156/1300C/2021	Detachable Embolization Coil Various Sizes	GM/SPF/21/200	0042001210003030	14-Mar-22	28-Apr-22	PB	LKR	10,369,500.00	9,332,550.00	66,127,318.00
5.01.2022	0000032261	094HEMAS-HEMAS PHARMACEUTICALS	LP/DHS/RJ/5287/21	Botulinum Toxin Type A Purified Neurotoxin Complex 100Unit	300570662	0042001210003193	17-Nov-21	17-Dec-21	PB	LKR	47,726,000.00	42,953,400.00	
10.03.2022	0000032981	094HEMAS-HEMAS PHARMACEUTICALS	LP/DHS/M/RS/RQ/101/R/SROC/20	Intra Ocular Lens Various Sizes	300570662	0042001210003193	17-Nov-21	17-Dec-21	PB	LKR	47,726,000.00	42,953,400.00	
29.01.2022	0000032342	094HEMAS-HEMAS PHARMACEUTICALS	LP/DHS/M/RS/RQ/101/R/SROC/20	Intra Ocular Lens Various Sizes	300570662	0042001210003193	17-Nov-21	17-Dec-21	PB	LKR	40,000,000.00	36,000,000.00	
30.01.2022	0000032109	094HOSUR-HEMAS SURGICAL & DIAG RO	LP/DHS/RSS/RQ/21/415UR/20	Therapeutic Plasma Exchange Kits	330096614	M116824	3-Nov-21	1-Feb-22	BOC	LKR	16,720,000.00	15,048,000.00	238,303,400.00
24.03.2022	0000032337	Isotec Biotech	LP/DHS/PM/2412/2021	Disodium Hydrogen Orthophosphate Anhydrous	IBBA LBC 22.01.01	0042001210000560	8-Mar-22	22-Apr-22	PB	LKR	11,250,000.00	10,125,000.00	10,125,000.00
01.03.2022	0000033134	094KISH-KISH INTERNATIONAL (PVT) LIM	LP/DHS/RS/RQ/93/964AK/20	Micro Guidewire with Hydrophilic Coating	KI5159	0042001310002870	13-Jan-22	28-Feb-22	PB	LKR	6,435,000.00	5,791,500.00	
07.03.2022	0000033308	094KISH-KISH INTERNATIONAL (PVT) LIM	LP/DHS/RS/RQ/93/1046AK/19	Inferior Vena Cava Filter	KI5315	M118701	26-Jan-22	26-Mar-22	BOC	LKR	10,380,000.00	9,342,000.00	
24.03.2022	0000033068	094KISH-KISH INTERNATIONAL (PVT) LIM	LP/DHS/RS/RQ/73/566DC/21	Micro Catheter Various Sizes	KI5496	M118891	25-Feb-22	11-Apr-22	BOC	LKR	60,000,000.00	54,000,000.00	
09.03.2022	0000032756	094KISHL- Kish Laboratories (Pvt) Ltd	LP/DHS/L/WW/37/27SR/20	Urine Strips	KL03635	0042(K)1210003318	11-Jan-22	25-Feb-22	PB	LKR	8,432,500.00	7,074,375.00	
04.04.2022	0000033660	094KISHL- Kish Laboratories (Pvt) Ltd	LP/DHS/CFPC/RL/81/1405R/21	SARS-CoV-2 Rapid Ag Assay	KI5784A	0042001210000826	24-Feb-22	11-Apr-22	PB	LKR	79,000,000.00	71,100,000.00	
27.01.2022	0000033263	Kish International	LP/DHS/S/WW/107/88ACP/2020	Intracranial Stent	KI5310	M118416	25-Jan-22	25-Apr-22	BOC	LKR	9,968,000.00	8,971,200.00	166,379,075.00
18.01.2022	0000033506	094KLIN-KLINTAS (PVT) LTD	LP/DHS/HMS/3324/21	Desmopressin Nasal Spray Gr	A 16694	M117016	18-Dec-21	8-Jan-22	BOC	LKR	7,000,000.00	6,300,000.00	6,300,000.00
04.01.2022	0000031782	094LIFED-LIFESERV ' (PRIVATE) LIMITED.	LP/DHS/SS/PCI/008/191DP/2021	Balloon Dilatation Catheter	106553	M114821	8-Oct-21	10-Jan-22	BOC	LKR	11,375,000.00	10,237,500.00	
21.01.2022	0000031975	094LIFED-LIFESERV ' (PRIVATE) LIMITED.	LP/DHS/SS/PCI/002/201PL/2020	Drug Eluting Coronary Stent	103110	M115690	19-Nov-21	17-Feb-22	BOC	LKR	17,275,000.00	15,547,500.00	
22.03.2022	0000033879	094LIFES-LIFESERV ' (PRIVATE) LIMITED.	LP/DHS/SUS/WW/138/033DP/2021	Drug Eluting Coronary Stent 2.75mm Diameter	102092	0042001210003807	2-Feb-22	4-May-22	PB	LKR	10,026,000.00	9,023,400.00	
24.03.2022	0000031277	094LIFED-LIFESERV ' (PRIVATE) LIMITED.	LP/DHS/RSS/RQ/94/583RD/20	Drug Eluting Coronary Stent Various Sizes	107174	M115547	19-Nov-21	17-Feb-22	BOC	LKR	7,100,000.00	6,390,000.00	
24.03.2022	0000031263	094LIFED-LIFESERV ' (PRIVATE) LIMITED.	LP/DHS/RSS/RQ/94/583RD/20	Drug Eluting Coronary Stent Various Sizes	107175	M115547	19-Nov-21	17-Feb-22	BOC	LKR	14,200,000.00	12,780,000.00	53,978,400.00
04.01.2022	0000031312	094LSCIE-LIFE SCIENTIFIC PRIVATE LTD	LP/DHS/S/WW/120/368KC/2021	Esophageal Band Ligation Set	946	0042001210001700	23-Nov-21	7-Jan-22	PB	LKR	12,672,500.00	11,405,250.00	
01.02.2022	0000032675	094LSCIE-LIFE SCIENTIFIC PRIVATE LTD	LP/DHS/RS/RQ/7/388DC/21	Disposable Metal Bone Marrow Biopsy Needles	996	M115356	4-Jan-22	18-Feb-22	BOC	LKR	4,165,000.00	3,740,131.56	

	Debit Note No	Supplier	Indent No	Item	Invoice No	LC No	Delivery Date	Payment Due Date	Bank	Currency Code	Invoice Amount	Amount Paid in LKR (90% OR 75%)	
01.02.2022	0000031600	094LSCIE-LIFE SCIENTIFIC PRIVATE LTD	LP/DHS/RS/RQ/7/368DC/21	Disposable Metal Bone Marrow Biopsy Needles	1003	M119356	5-Jan-22	21-Feb-22	BOC	LKR	3,272,500.00	2,945,250.00	
17.2.2022	0000032217	094LSCIE-LIFE SCIENTIFIC PRIVATE LTD	LP/DHS/S/WW/126/940/T/20	Urological Surgery Instruments	914	M114090	15-Nov-21	30-Dec-21	BOC	LKR	2,735,000.00	2,032,400.00	
31.03.2022	0000031813	094LSCIE-LIFE SCIENTIFIC PRIVATE LTD	LP/DHS/S/WW/126/940/T/20	Urological Surgery Instruments	1004	M114090	11-Oct-21	25-Nov-21	BOC	LKR	1,483,000.00	1,328,189.22	23,451,319.68
14.02.2022	0000032252	094LUKIN-LUCKY INDUSTRIES	LP/DHS/M/SS/WW/9/831NB/2021	Particulate Filtering Face Mask	LU028/MSD/2021	0042002210003343	15-Nov-21	15-Jan-22	PB	LKR	4,700,000.00	3,525,000.00	
14.02.2022	0000032317	094LUKIN-LUCKY INDUSTRIES	LP/DHS/M/SS/WW/9/831NB/2021	Particulate Filtering Face Mask	LU029/MSD/2021	0042001210003343	19-Nov-21	19-Jan-22	PB	LKR	2,350,000.00	1,762,500.00	
14.02.2022	0000032502	094LUKIN-LUCKY INDUSTRIES	LP/DHS/M/SS/WW/9/831NB/2021	Particulate Filtering Face Mask	LU031/MSD/2021	0042001210003343	7-Dec-21	7-Feb-22	PB	LKR	2,350,000.00	1,762,500.00	
14.02.2022	0000032634	094LUKIN-LUCKY INDUSTRIES	LP/DHS/M/SS/WW/9/831NB/2021	Particulate Filtering Face Mask	LU030/MSD/2021	0042001210003343	26-Nov-21	26-Jan-22	PB	LKR	4,700,000.00	3,525,000.00	
14.02.2022	0000032649	094LUKIN-LUCKY INDUSTRIES	LP/DHS/M/SS/WW/9/831NB/2021	Particulate Filtering Face Mask	LU034/MSD/2021	0042001210003343	27-Dec-21	27-Feb-22	PB	LKR	4,230,000.00	3,172,500.00	
14.02.2022	0000032593	094LUKIN-LUCKY INDUSTRIES	LP/DHS/M/SS/WW/9/831NB/2021	Particulate Filtering Face Mask	LU033/MSD/2021	0042001210003343	15-Dec-21	14-Feb-22	PB	LKR	4,465,000.00	3,348,750.00	
14.02.2022	0000032674	094LUKIN-LUCKY INDUSTRIES	LP/DHS/M/SS/WW/9/831NB/2021	Particulate Filtering Face Mask	LU035/MSD/2021	0042001210003343	30-Dec-21	28-Feb-22	PB	LKR	4,606,000.00	3,454,500.00	
14.02.2022	0000032596	094LUKIN-LUCKY INDUSTRIES	LP/DHS/M/SS/WW/9/831NB/2021	Particulate Filtering Face Mask	LU036/MSD/2021	0042001210003343	6-Jan-22	7-Mar-22	PB	LKR	4,700,000.00	3,525,000.00	
14.02.2022	0000032536	094LUKIN-LUCKY INDUSTRIES	LP/DHS/M/SS/WW/9/831NB/2021	Particulate Filtering Face Mask	LU032/MSD/2021	0042001210003343	9-Dec-21	9-Feb-22	PB	LKR	4,935,000.00	3,701,250.00	26,014,500.00
18.04.2022	0000032180	094MARKS-MARKS INC (PVT) LTD.	LP/DHS/M/HDT/444/2021	Paclitaxel Nanoparticle Injection with Concentrate of Diluent	10276	0042002210000659	17-Mar-21	10-May-21	PB	LKR	5,754,925.00	4,877,462.50	4,877,462.50
30.03.2022	0000031941	094MEDAP-Medapp Pvt Ltd	LP/DHS/S/WW/154/236DC/21	Cerebral Clot Retrieval Device/Catheter	00000332	0042001210002763	4-Mar-22	18-Apr-22	PB	LKR	21,000,000.00	18,000,000.00	18,500,000.00
14.01.2022	0000031120	094NEGAM-MEGA MEDITECH PVT LTD	LP/DHS/RH/378/2019	Organ Preservation & Protection Solution for Multi Organ Uptake	GCO19843	0042001210001400	1-Dec-21	31-Dec-21	PB	LKR	3,814,000.00	2,721,660.00	2,721,660.00
10.01.2022	0000032228	094MERVY- MERVYNSONS (PVT) LTD	LP/DHS/RH/540/2020/2021	Surgical Non Consumables	MV11645	0042001210001755	12-Nov-21	10-Feb-22	PB	LKR	15,682,450.00	14,114,204.00	
18.03.2022	0000032110	094MERVY- MERVYNSONS (PVT) LTD	LP/DHS/S/WW/47/233DC/21	Oesophagoscope Negus Type or Similar Various Sizes	MV11735	MV11735	30-Nov-21	19-Jan-22	BOC	LKR	18,204,879.00	16,384,391.10	30,498,595.10
10.03.2022	0000031356	094MILER-MILLERS LIMITED	LP/MHS/S/WW/57/132WP/21	Laser Film Blue Base for: SR, DR, CT & MRI	MLSPC/X-11/2021	0042001210001154	30-Nov-21	15-Jan-22	PB	LKR	23,874,995.00	19,687,495.50	19,687,495.50
10.03.2022	0000032988	094MITEC- MICRO TECH BIOLOGICAL (PV	LP/DHS/L/WW/319/1485S/19	Antibodies with an Indication for HIV Antibodies	13570	M116510	15-Feb-22	4-Apr-22	BOC	LKR	8,833,600.00	7,941,240.00	7,941,240.00
09.01.2022	0000031504	094NEWAR-NEW ARUMED PRIVATE LIM	LP/DHS/S/PH/3534/2021	Anti Rabies Vaccine BP 0.5ml Vials	1686	0042001210001835	15-Dec-21	18-Jan-22	PB	LKR	118,960,000.00	106,200,000.00	
24.02.2022	0000031939	094NEWAR-NEW ARUMED PRIVATE LIM	LP/DHS/RS/RQ/96/582DC/21	Hypodermic Syringe Luer Slip 50ml without Needle	1746	0042001210003934	1-Mar-22	30-Mar-22	PB	LKR	10,050,000.00	9,045,000.00	
04.04.2022	0000032078	094NEWAR-NEW ARUMED PRIVATE LIM	LP/DHS/RS/RQ/96/582DC/21	Hypodermic Syringe Luer Slip 50ml	1748	0042001210003934	7-Mar-22	6-Apr-22	PB	LKR	14,020,000.00	12,618,000.00	132,828,000.00
28.02.2022	0000032230	094OSVIK-OSVIK INTERNATIONAL PVT LT	LP/DHS/RS/RQ/58/1030A/21	Complet Vaccine Set	1451/1000/22	0042001210001822	20-Jan-22	21-Feb-22	PB	LKR	36,260,000.00	32,634,000.00	32,634,000.00
10.01.2022	0000031501	Ogami & Company	LP/DHS/RS/RQ/54/410AM/2021	Polishing & Finishing Discs for Composites Assorted Pack	6800	0042001210002805	13-Dec-21	27-Jan-22	PB	LKR	16,672,500.00	15,005,250.00	15,005,250.00
10.12.2021	0000032746	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/128/429KM/2021	Personal Protective Equipment	PG-000014	0042001220000017	9-Nov-21	10-Dec-21	PB	LKR	50,900,000.00	45,810,000.00	
07.03.2022	0000032857	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300025	0042002220000194	25-Jan-22	25-Feb-22	PB	LKR	5,180,000.00	4,662,000.00	
07.03.2022	0000032872	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300026	0042002220000194	27-Jan-22	4-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
09.03.2022	0000032741	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300028	0042002220000194	27-Jan-22	4-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
09.03.2022	0000032935	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300021	0042002220000194	7-Jan-22	7-Feb-22	PB	LKR	31,080,000.00	27,972,000.00	
09.03.2022	0000032967	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300027	0042002220000194	1-Feb-22	4-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
09.03.2022	0000032951	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300030	0042002220000194	3-Feb-22	7-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
09.03.2022	0000032932	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300031	0042002220000194	7-Feb-22	10-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
22.03.2022	0000032996	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300032	0042002220000194	7-Feb-22	10-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
22.03.2022	0000032967	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300036	0042002220000194	11-Feb-22	11-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
22.03.2022	0000032965	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300037	0042002220000194	11-Feb-22	11-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
24.03.2022	0000032958	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300038	0042002220000194	11-Feb-22	11-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
06.04.2022	0000032997	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300035	0042002220000194	11-Feb-22	11-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
06.04.2022	0000032996	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300039	0042002220000194	25-Feb-22	28-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
06.04.2022	0000032998	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300040	0042001220000194	7-Mar-22	6-Apr-22	PB	LKR	5,180,000.00	4,662,000.00	
06.04.2022	0000033011	094PHARMIC-PHARMICON GLOBAL (PV	LP/DHS/RSS/RQ/158/481MPN/21	Personal Protective Equipment	PG300041	0042001220000194	10-Mar-22	11-Apr-22	PB	LKR	5,180,000.00	4,662,000.00	
25.02.2022	0000032240	Pharmicon Global	LP/DHS/RSS/RQ/158/481MPN/2021	Personal Protective Equipment	PG300042	0042001220000194	14-Mar-22	18-Apr-22	PB	LKR	5,180,000.00	4,662,000.00	
				Personal Protective Equipment	PG300027	0042001220000194	4-Jan-22	4-Feb-22	PB	LKR	31,080,000.00	27,972,000.00	

Debit Note No	Supplier	Indent No	Item	Invoice No	LC No	Delivery Date	Payment Due Date	Bank	Currency Cy Code	Invoice Amount	Amount Paid in LKR (50% OR 75%)	
25.02.2022	0000032913	Harmicon Global	LP/DHS/RSS/RQ158/481MPH/2021	Personal Protective Equipment	PG300034	00420012200001594	27-Jan-22	28-Feb-22	PB	LKR	5,180,000.00	4,662,000.00	
25.02.2022	0000032914	Harmicon Global	LP/DHS/RSS/RQ158/481MPH/2021	Personal Protective Equipment	PG300035	00420012200001594	1-Feb-22	7-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	
25.02.2022	0000032916	Harmicon Global	LP/DHS/RSS/RQ158/481MPH/2021	Personal Protective Equipment	PG300036	00420012200001594	1-Feb-22	7-Mar-22	PB	LKR	5,180,000.00	4,662,000.00	181,986,000.00
31.01.2022	0000031765	094 PREMI-PREMIUM INTERNATIONAL (I	LP/DHS/LB/DQ/36/123CPW/2019	Laboratory Consumables	PI/17772-E	00420012000001694	8-Dec-21	24-Jan-22	PB	LKR	336,571.20	302,914.08	
	0000031766	094 PREMI-PREMIUM INTERNATIONAL (I	LP/DHS/LB/DQ/36/123CPW/2019	Laboratory Consumables	PI/17772-F	00420012000001694	8-Dec-21	24-Jan-22	PB	LKR	336,571.20	302,914.08	
	0000030611	094 PREMI-PREMIUM INTERNATIONAL (I	LP/DHS/LB/DQ/36/123CPW/2019	Laboratory Consumables	PI/17772-C	00420012000001694	8-Dec-21	24-Jan-22	PB	LKR	14,771,518.00	13,294,424.40	
	0000030622	094 PREMI-PREMIUM INTERNATIONAL (I	LP/DHS/LB/DQ/36/123CPW/2019	Laboratory Consumables	PI/17772-B	00420012000001694	8-Dec-21	24-Jan-22	PB	LKR	336,571.20	302,914.08	
	0000030623	094 PREMI-PREMIUM INTERNATIONAL (I	LP/DHS/LB/DQ/36/123CPW/2019	Laboratory Consumables	PI/17772-D	00420012000001694	8-Dec-21	24-Jan-22	PB	LKR	336,571.20	302,914.08	
	0000031232	094 PREMI-PREMIUM INTERNATIONAL (I	LP/DHS/LB/DQ/36/123CPW/2019	Laboratory Consumables	PI/17772-G	00420012000001694	8-Dec-21	24-Jan-22	PB	LKR	336,571.20	302,914.08	
	0000031508	094 PREMI-PREMIUM INTERNATIONAL (I	LP/DHS/LB/DQ/36/123CPW/2019	Laboratory Consumables	PI/17772-H	00420012000001694	8-Dec-21	24-Jan-22	PB	LKR	336,571.20	302,914.08	
06.04.2022	0000033840	094 PREMI-PREMIUM INTERNATIONAL (I	LP/DHS/LB/DQ/36/123CPW/2019	Laboratory Consumables	PI/17797	00420012000001694	22-Feb-22	5-Apr-22	PB	LKR	15,201,864.00	13,681,677.60	28,793,886.48
04.04.2022	0000033155	Softmedi	LP/DHS/LB/DQ/36/123CPW/2021	EDTA Blood Collecting Tube	SM/22/002	00420012200003619	16-Mar-22	6-May-22	PB	LKR	36,120,000.00	32,508,000.00	32,508,000.00
28.02.2022	0000032771	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0277	M117757	16-Nov-21	16-Dec-21	BOC	LKR	7,592,000.00	7,592,000.00	
18.02.2022	0000032260	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0258	M117757	17-Nov-21	17-Dec-21	BOC	LKR	3,888,000.00	3,499,200.00	
16.02.2022	0000032038	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0262	M117757	23-Nov-21	23-Dec-21	BOC	LKR	3,240,000.00	2,916,000.00	
16.02.2022	0000032039	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0263	M117757	24-Nov-21	24-Dec-21	BOC	LKR	3,240,000.00	2,916,000.00	
30.08.2022	0000032759	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0302	M117757	6-Jan-22	6-Feb-22	BOC	LKR	5,400,000.00	4,860,000.00	
10.03.2022	0000032927	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0319	M117757	17-Jan-22	17-Feb-22	BOC	LKR	5,400,000.00	4,860,000.00	
10.03.2022	0000032810	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0322	M117757	22-Jan-22	22-Feb-22	BOC	LKR	5,400,000.00	4,860,000.00	
22.03.2022	0000032927	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0323	M117757	2-Feb-22	2-Mar-22	BOC	LKR	5,400,000.00	4,860,000.00	
22.03.2022	0000032838	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0270	M117757	1-Dec-21	1-Jan-22	BOC	LKR	3,240,000.00	2,916,000.00	
22.03.2022	0000032430	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0271	M117757	2-Dec-21	2-Jan-22	BOC	LKR	3,240,000.00	2,916,000.00	
22.03.2022	0000032108	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0272	M117757	7-Dec-21	7-Jan-22	BOC	LKR	3,240,000.00	2,916,000.00	
22.03.2022	0000032515	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0279	M117757	10-Dec-21	10-Jan-22	BOC	LKR	3,240,000.00	2,916,000.00	
22.03.2022	0000032530	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0288	M117757	15-Dec-21	15-Jan-22	BOC	LKR	3,240,000.00	2,916,000.00	
22.03.2022	0000032567	094SISIL-SISILI PROJECTS CONSORTIUM	LP/DHS/RS/RQ/57/462/I/21	Surgical Face Mask	2021/0287	M117757	14-Dec-21	14-Jan-22	BOC	LKR	3,240,000.00	2,916,000.00	
17.02.2022	0000031727	CHEMICOL-CHEMICAL INDUSTRIES (PVT)	LP/DHS/S/WW/21/DHS/2021	Immobilization Cast (Light Weight)	2021/02	00420012200001590	7-Jan-22	8-Feb-22	PB	LKR	31,264,000.00	46,137,600.00	98,625,600.00
07.01.2022	0000031000	Zeta Pharmaceuticals	LP/DHS/C/DA/3327/2021	Enoxaparin Sodium Injection 40mg/0.4ml	7912	M116589	17-Dec-21	18-Jan-22	BOC	LKR	181,500,000.00	145,200,000.00	145,125,600.00
21.01.2022	0000031221	CENTAUR-TARRANE PHARMACEUTICA	LP/DHS/RS/2020/2020	Gastro Resistant Naproxen Tablets BP 250mg	1X Vials	00420012100003269	21-Dec-21	20-Jan-22	PB	USD	8,500,000.00	6,204,913.50	6,204,913.50
07.01.2022	0000031369	DENTAL TAS MEDICAL SUPPLIERS & CO	LP/DHS/NS/S/WW/21/DENT/2021	Vacuum Cotton	2021/DENTAL/0001	M115722	9-Dec-21	9-Jan-22	BOC	LKR	6,150,000.00	6,112,500.00	6,112,500.00
14.03.2022	0000030675	DSMTECHN-TECHNOMEDICS INTERNATIO	LP/DHS/S/WW/21/826IT/20	Mucus Extractor X Passive Infusor with Bag	TMINS21-15109	M112266	13-Jul-22	27-Aug-21	BOC	LKR	7,683,000.00	5,600,665.00	
18.04.2022	0000033038	DSMTECHN-TECHNOMEDICS INTERNATIO	LP/DHS/SUS/WW/80/321IMPN/21	Inflation Devices for PTCA	TMINS21-14282	00420021210003543	24-Feb-22	26-Mar-22	PB	LKR	34,560,000.00	31,104,000.00	36,904,665.00
10.01.2022	0000032892	Vision 2000 Techno	LP/DHS/S/WW/21/846HP/2021	Paracentesis Knife	2021123	00420012100002191	6-Dec-21	20-Jan-22	PB	LKR	9,540,000.00	8,946,000.00	8,946,000.00
										Total Amount (LKR)			3,143,733,700.65

STATE [illegible] CORPORATION
[illegible]
21/4/22

M. H. ALWIS
Deputy General Manager - Pharmaceuticals
(Procurement & Imports)
State Pharmaceuticals Corporation of Sri Lanka
27th Floor, "Mehewara Piyasa"
No: 41, Kinula Road, Colombo 06
Tel: (00) 94-11-2686227 - Fax: (00) 94-11-2682496

Local currency requirement -LKR - Present position -25.05.2022

LKR MN.

	BOC	PB	Total
Local Lcs to be established	251	733	984
Pending local LC payments on DHS operations	1,191	2,283	3,474
Pending Cheque payments on DHS operations	2,127	-	2,127
Usance Bills already paid to suppliers by banks & pending for payments to the banks / Balance payments to be made to Suppliers (10% ,20% , 25% & etc.) -Estimated	300		300
Monthly requirement for clearing & imports control payments - Approxi	250		250
Total requirement to meet the above	**4,119**	**3,016**	**7,135**
Overdraft already Utilized	**7,992**	**7,996**	**15,988**
Total Fund Requirement	**12,111**	**11,012**	**23,123**

ශ්‍රී ලංකා
ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ
පාර්ලිමේන්තුව

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

[සහතිකය සටහන් කළේ 2015 මාර්තු මස 19 වැනි දින]

ආණ්ඩුවේ නියමය පරිදි මුද්‍රණය කරන ලදී.

2015 මාර්තු මස 20 වැනි දින ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රයේ II වන කොටසේ අතිවිශේෂයක් වශයෙන් පළ කරන ලදී.

ශ්‍රී ලංකා රජයේ මුද්‍රණ දෙපාර්තමේන්තුවේ මුද්‍රණය කරන ලදී.

කොළඹ 5, රජයේ ප්‍රකාශන කාර්යාංශයෙන් මිළදී ලබාගත හැක.

මිල : රු. 100.00 සි. තැපැල් ගාස්තුව : රු. 70.00 සි.

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

[සභාතිකය සටහන් කළේ 2015 මාර්තු මස 19 වැනි දින]

එල්.ඩී.ඕ. 21/2012

ජාතික ඖෂධ ප්‍රතිපත්තියට අනුකූල වන ආකාරයට ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදන ලියාපදිංචි කිරීම, බලපත්‍ර ලබාදීම, නිෂ්පාදනය කිරීම, ආනයනය කිරීම සහ එකී ඖෂධ, වෛද්‍ය උපකරණ හා සීමාස්ථ නිෂ්පාදනවලට අදාළ වෙනත් සියලු කරුණු සහ ඖෂධීය පරීක්ෂණ පවත්වන ආකාරය නියාමනය කිරීම සහ පාලනය කිරීම සම්බන්ධයෙන් වගකිව යුතු ජාතික ඖෂධ නියාමන අධිකාරිය යනුවෙන් හඳුන්වනු ලබන නියාමන අධිකාරියක් පිහිටුවීම සඳහා ද; ඖෂධ නියාමන අංශය, වෛද්‍ය උපකරණ නියාමන අංශය, සීමාස්ථ නිෂ්පාදන නියාමන අංශය සහ ඖෂධීය පරීක්ෂණ නියාමන අංශය ඇතුළු ජාතික ඖෂධ නියාමන අධිකාරියේ අංශ පිහිටුවීම සඳහා විධිවිධාන සැලැස්වීම සඳහා ද; ජාතික උපදේශක කමිටුවක් පිහිටුවීම සඳහා ද; 1980 අංක 27 දරන විලවුන්, උපකරණ සහ ඖෂධ පනත ඉවත් කිරීම සඳහා ද; ඊට සම්බන්ධ හෝ ආනුෂංගික කරුණු සඳහා ද, විධිවිධාන සැලැස්වීම පිණිස වූ පනතකි.

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ පාර්ලිමේන්තුව විසින් මෙසේ පනවනු ලැබේ :-

මේ පනත 2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත යනුවෙන් හඳුන්වනු ලබන අතර එය අමාත්‍යවරයා විසින් ගැසට් පත්‍රයේ පළ කරනු ලබන නියමයක් මගින් නියම කරනු ලබන (මෙහි මින්මතු "නියමිත දිනය" යනුවෙන් සඳහන් කරනු ලබන) දිනයක සිට ක්‍රියාත්මක විය යුතු ය. — ලුහුඬු නාමය සහ ක්‍රියාත්මකවීමේ දිනය.

I වන පරිච්ඡේදය

ජාතික ඖෂධ නියාමන අධිකාරිය

I වන කොටස

අධිකාරිය පිහිටුවීම

2. (1) (මෙහි මින්මතු "අධිකාරිය" යනුවෙන් සඳහන් කරනු ලබන) ජාතික ඖෂධ නියාමන අධිකාරිය නම් වූ අධිකාරියක් පිහිටුවනු ලැබිය යුතු ය. — ජාතික ඖෂධ නියාමන අධිකාරිය පිහිටුවීම.

2—PL 008816—2,850 (2015/02)

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

අංක 1920/28 - 2015 ජුනි මස 25 වැනි බ්‍රහස්පතින්දා - 2015.06.25

(රජයේ බලයපිට ප්‍රසිද්ධ කරන ලදී)

I වැනි කොටස: (I) වැනි ඡෙදය - සාමාන්‍ය

රජයේ නිවේදන

ජාතික ඖෂධ නියාමන අධිකාරිය පනත

වෛද්‍ය රාජිත සේනාරත්න, සෞඛ්‍ය හා දේශීය වෛද්‍ය අමාත්‍ය වන මම, 2015 අංක 05 දරන ජාතික ඖෂධ අධිකාරිය පනතේ, පළවන වගන්තිය අනුව මා වෙත පවරා ඇති බලතල අනුව, එකී පනත ක්‍රියාත්මක වන දිනය ලෙස 2015 ජුලි මස 01 වන දිනය නියම කරමි.

වෛද්‍ය රාජිත සේනාරත්න,
සෞඛ්‍ය හා දේශීය වෛද්‍ය අමාත්‍ය.

2015 ජුනි මස 18 වැනි දින,
කොළඹ දී ය.

07 - 518

1A - G 21760 — 506 (2015/06) ශ්‍රී ලංකා රජයේ මුද්‍රණ දෙපාර්තමේන්තුවේ මුද්‍රණය කරන ලදී.

මෙම අති විශෙෂ ගැසට් පත්‍රය www.documents.gov.lk වෙබ් අඩවියෙන් බාගත කළ හැක.

(2) මේ වගන්තිය මගින් පවරන ලද නාමයෙන් අධිකාරිය සංස්ථාවක් විය යුතු අතර ඊට අවිච්ඡින්න පැවැත්මක් සහ පොදු මුද්‍රාවක් තිබිය යුතු අතර, එකී නාමයෙන් එය විසින් ද එයට එරෙහිව ද නඩු පවරනු ලැබිය හැකිය.

අධිකාරියේ අරමුණු.

3. අධිකාරියේ අරමුණු :-

(අ) ප්‍රත්‍යක්ෂ, ආරක්ෂාකාරී සහ නිවැරදි තත්වයෙන් යුතු ඖෂධ, ප්‍රත්‍යක්ෂ, ආරක්ෂාකාරී සහ නිවැරදි තත්වයෙන් යුතු වෛද්‍ය උපකරණ සහ ප්‍රත්‍යක්ෂ, ආරක්ෂාකාරී සහ නිවැරදි තත්වයෙන් යුතු සීමාස්ථ නිෂ්පාදන සාධාරණ මිලකට මහජනතාවට ලබා දෙන බවට තහවුරු කිරීම;

(ආ) ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදන ලියාපදිංචි කිරීම, බලපත්‍ර ලබා දීම, ලියාපදිංචිය හෝ බලපත්‍ර අවලංගු කිරීම, නිෂ්පාදනය කිරීම, මිල නියම කිරීම, ආනයනය කිරීම, ගබඩා කිරීම, ප්‍රවාහනය කිරීම, බෙදා හැරීම, විකිණීම, ප්‍රචාරණය කිරීම සහ බැහැර කිරීම හා සම්බන්ධ සියලු කාරණා සඳහා මධ්‍යම නියාමක ලෙස කටයුතු කිරීම;

(ඇ) ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන සහ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන ලියාපදිංචි කිරීම, බලපත්‍ර ලබා දීම සහ ආනයනය කිරීමට අදාළ සියලු කටයුතු විනිවිදභාවයකින් යුතුව, නිරසාර ලෙස සහ සාධාරණ ආකාරයට සිදුකරන බවට තහවුරු කිරීම;

(ඈ) අත්‍යවශ්‍ය ඖෂධ සාධාරණ මිලකට පැවතීම සහතික කිරීමේ අරමුණින් ශ්‍රී ලංකාව තුළ නිවැරදි තත්වයෙන් යුතු ඖෂධ නිෂ්පාදනය දිරිමත් කිරීම;

(ඉ) සෞඛ්‍ය සත්කාර වෘත්තිකයන් හා පාරිභෝගිකයන් විසින් ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදන ආරක්ෂාකාරී ලෙස සහ විචාරශීලී ලෙස භාවිතය ප්‍රවර්ධනය කිරීම;

(ඊ) ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදනවලට සම්බන්ධිත අදාළ නීති සඳහා උචිත සංශෝධන නිර්දේශ කිරීම;

ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදන පිළිබඳ මහජනතාව, සෞඛ්‍ය සත්කාර වෘත්තිකයන් සහ ඒ පිළිබඳව සැලකිල්ලක් දක්වන සියලු දෙනා දැනුවත් කිරීම;

(උ) ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදන ප්‍රවර්ධනය සහ අළෙවිකරණය නියාමනය කිරීම;

රට තුළ ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදන පැවතීම නියාමනය කිරීම;

(ඒ) ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදනවල තත්ත්වය, ආරක්ෂාකාරී බව සහ අහිතකර ප්‍රතික්‍රියාවන් පිළිබඳව පශ්චාත් අළෙවිකරණ සමීක්ෂණ පැවැත්වීම; සහ

(ඔ) ශ්‍රී ලංකාවේ සායනික පරීක්ෂණ පැවැත්වීමට අදාළ සියලු කටයුතු නියාමනය කිරීම,

ආදිය වේ.

අධිකාරියේ සංයුතිය.

4. අධිකාරිය පහත දැක්වෙන තැනැත්තන්ගෙන් සමන්විත විය යුතු ය:-

(අ) නිලබලයෙන් පත්වන සාමාජිකයන්, එනම් -

(i) සෞඛ්‍ය සේවා අධ්‍යක්ෂ ජනරාල්;

(ii) භාණ්ඩාගාර ලේකම් හෝ ඔහුගේ නාමිකයකු; සහ

(iii) අධිකාරියේ ලේකම් වශයෙන් කටයුතු කළ යුතු 15 වන වගන්තිය යටතේ පත් කරනු ලබන අධිකාරියේ ප්‍රධාන විධායක නිලධරයා;

(ආ) (මෙහි මින්මතු "පත්කළ සාමාජිකයන්" යනුවෙන් සඳහන් කරනු ලබන) අමාත්‍යවරයා විසින් පත්කරනු ලබන පහත සඳහන් තැනැත්තන් එනම් -

(i) පහත දැක්වෙන සායන විෂය නියෝජනය කරන්නා වූ ද, පිළිවෙලින් වූ ස්වකීය වෘත්තීමය ආයතන විසින් නම් කරනු ලබන්නා වූ ද සෞඛ්‍ය අමාත්‍යාංශයට අනුයුක්ත විශේෂඥ වෛද්‍යවරුන් සිව්දෙනෙකු-

අධිකරණයක් විසින් වරදකරු කරනු ලැබීමේදී රුපියල් දස ලක්ෂයකට නොවැඩි දඩයකට හෝ අවුරුදු තුනකට නොවැඩි කාලයක් සඳහා දෙයාකාරයෙන් එක් ආකාරයක බන්ධනාගාරගත කිරීමකට හෝ එම දඩය හා බන්ධනාගාරගත කිරීම යන දෙකටම හෝ ඔහු යටත් විය යුතු ය.

හදිසි අවස්ථා සහ වෙනත් විශේෂ අවස්ථානුගත කරුණු.

109. (1) ජීවිතයක් බේරාගැනීම සඳහා හෝ බෝවන රෝගයක් හෝ වසංගත රෝගයක් පැතිරීම වැළැක්වීම සඳහා වැනි විශේෂ අවස්ථානුගත කරුණුවලදී හෝ වෙනත් යම් ජාතික හදිසි අවශ්‍යතාවක් සඳහා හෝ ජාතික ආරක්ෂාව සඳහා යම් විශේෂිත ඖෂධ, වෛද්‍ය උපකරණ හෝ සීමාස්ථ නිෂ්පාදන නිශ්චිත ප්‍රමාණවලින් ආනයනය කිරීමට සහ සැපයීමට අධිකාරිය විසින් අවසරය ලබාදිය හැකි ය.

(2) (අ) සෞඛ්‍ය අමාත්‍යාංශය විසින් කරනු ලබන ඉල්ලීමක් මත; හෝ

(ආ) යම් පුද්ගලයකු හෝ සංවිධානයක් විසින් කරනු ලබන ඉල්ලීමකට අනුව සෞඛ්‍ය අමාත්‍යාංශය විසින් කරන ලද නිර්දේශයක් මත,එවැනි අවසරයක් ප්‍රදානය කරනු ලැබිය හැකිය.

(3) මේ වගන්තිය යටතේ ආනයනය කරනු ලබන ඖෂධ, වෛද්‍ය උපකරණ හෝ සීමාස්ථ නිෂ්පාදන කළමනාකරණය සහ වගවීම සඳහා ආනයනකරු බැඳී සිටිය යුතු ය.

(4) මේ වගන්තිය යටතේ ආනයනය කරන ලද යම් ඖෂධයක්, වෛද්‍ය උපකරණයක් හෝ සීමාස්ථ නිෂ්පාදන පිළිබඳව ආනයනකරු විසින් අධිකාරිය වෙත නියමිත ආකාරයට පටිපාටිගතව වාර්තා ඉදිරිපත් කරනු ලැබිය යුතු ය.

ඖෂධ ආදියේ සාම්පල් විකිණීම හෝ බෙදාහැරීම තහනම් බව.

110. (1) (අ) කිසිම තැනැත්තකු විසින් වෛද්‍යවරයාගේ සාම්පලයක් වශයෙන් ලකුණු කරන ලද යම් ඖෂධයක්, වෛද්‍ය උපකරණයක් හෝ සීමාස්ථ නිෂ්පාදනයක් පොදු මහජනතාව වෙත බෙදා හැරීම නොකළ යුතු ය.

(ආ) වෛද්‍යවරයාගේ සාම්පල වශයෙන් ලකුණු කරන ලද යම් ඖෂධයක්, වෛද්‍ය වෘත්තිකයකු, දන්ත වෛද්‍යවරයකු හෝ පශු වෛද්‍යවරයකු විසින් එම වෛද්‍යවරයාගේ, දන්ත වෛද්‍යවරයාගේ හෝ පශු වෛද්‍යවරයාගේ රෝගියකුට බෙදා දීම සම්බන්ධයෙන් (අ) ඡේදයේ සඳහන් විධිවිධාන අදාළ නොවිය යුතු ය.

ශ්‍රී ලංකා ජනාධිපති
இலங்கை சனாதிபதி
President of Sri Lanka

අමාත්‍ය මණ්ඩල සටහන

කෝවිඩ් 19 වෛරසය සමඟ මහජන සෞඛ්‍යාරක්ෂාව කළමනාකරණය සහ ජනතාවට අත්‍යවශ්‍ය ද්‍රව්‍ය සම්පාදනය

ජාතික අවශ්‍යතාවය මහජන සෞඛ්‍ය සහ ආහාර සුරක්ශිතතාවය පිළිබඳ අවධානය යොමු කරමින් කෝවිඩ් 19 වයිරසය නිසා ගෝලීය ආර්ථිකයට සිදු වූ බලපෑම හේතුවෙන් ඇතිවූ අභියෝග සහ ආර්ථිකය කළමනාකරණය කිරීම මෙයෙන් 2020 මාර්තු මස 18 දින මා විසින් ඉදිරිපත් කරන ලද අමාත්‍ය මණ්ඩල සංදේශයට අදාළව ගනු ලැබූ තීරණ සම්බන්ධයෙන් වාර්තා කරන ලද 2020 මාර්තු මස 25 දිනැති අමාත්‍ය මණ්ඩල සටහනට වැඩිමනත් වශයෙනි. (ලෝක සෞඛ්‍ය සංවිධානයේ නවතම වාර්තාව ඇමුණුම 1).

1. 2020.03.25 දිනැති අමාත්‍ය මණ්ඩල සටහන යටතේ ඉදිරිපත් කරන ලද සහන පැකේජය දැනට දිස්ත්‍රික් ලේකම් සහ ප්‍රාදේශීය ලේකම් යටතේ පවතින යාන්ත්‍රණයන් හරහා වඩා වැඩි ප්‍රතිලාභීන් පිරිසක් ඈපුවූ ආවරණය කිරීමට හැකි වන පරිදි තවදුරටත් පුළුල් කර ඇත. මාගේ උපදෙස් මත මාගේ ලේකම් විසින් නිකුත් කරන ලද චක්‍රලේඛය මේ සමඟ ඉදිරිපත් කර ඇත (ඇමුණුම II). එසේම සෑම ගෘහ ඒකකයකටම මූලික අවශ්‍යතා සඳහා ප්‍රවේශය සහතික කිරීමට ගෘහ ඒකක වෙත සියලුම සැපයීම් බෙදාහැරීම් සංවිධානය කරන ලෙසට මා විසින් ජනාධිපති කාර්ය සාධක බලකාය වෙතින් ඉල්ලා ඇත.

2. ජනාධිපති කාර්ය සාධක බලකාය විසින් දිස්ත්‍රික් ලේකම් කාර්යාල 25 ද, ප්‍රාදේශීය ලේකම් කාර්යාල 314 ද, ග්‍රාම නිලධාරීන් 14,022 ද සෞඛ්‍ය, ආපදා කළමනාකරණ, කෘෂිකර්ම අංශවලට අයත් අනෙකුත් ක්ෂේත්‍ර නිළධාරීන්, පොලිස් සහ ආරක්ෂක සේවාවන් සහ ප්‍රාදේශීය ලේකම් බලප්‍රදේශය තුල ජීවත්වන උපාධිධාරී අභ්‍යාසලාභීන් ද, සේවා සම්පාදනය, සෞඛ්‍යාරක්ෂණය සහ සමාජ ආරක්ෂණය සහතික කිරීමට පෙළගස්වා ඇත. සෞඛ්‍ය සේවා සහ සහ සමාජ ආරක්ෂණය සහතික කිරීමට පූර්ණ රාජ්‍ය සේවය ක්ෂේත්‍ර මට්ටමින් ක්‍රියාත්මක කරවන ප්‍රථම අවස්ථාව මෙය වේ.

3. ගෝලීය වශයෙන් හුදකලාවීම තුල, සාර්ව ආර්ථික තත්ත්වයන් සම්බන්ධයෙන් සාකච්ඡා කිරීම සඳහා මා මහ බැංකු අධිපතිතුමා සහ ඔහුගේ ජ්‍යෙෂ්ඨ කාර්ය මණ්ඩලය සමඟ හමු විය. සංචාරක ක්ෂේත්‍රයෙන් අරමුදල් ප්‍රවාහයන් සහ ඉපැයීම් අඩු වී ඇති අතර අපනයන සීමා වී ඇති බවට ඔවුන් කරුණු ඉදිරිපත් කරන ලදී. අත්‍යවශ්‍ය නොවන ද්‍රව්‍ය සඳහා ආනයන සීමා පැනවීමට මා විසින් ලබාදෙන ලද උපදෙස් මත ආනයන සීමා කර ඇත. කෙසේ වෙතත්, ණය සේවාකරණ අවශ්‍යතා සපුරාලීම සඳහා සංවර්ධනය වෙමින් පවතින ආර්ථිකයන්හි සිට ඇමරිකාව, ජපානය වැනි සුරක්ෂිත ගෝලීය ආර්ථිකයන් වෙත ණය සහ කොටස් වෙළෙඳපල හරහා විශාල ප්‍රාග්ධනයක් ගලායෑම අවධානයට ලක් විය යුතු කාරණා බව ඔවුන් පැහැදිලි කරන ලදී. වේ.

1

4. මෑතකදී ශ්‍රී ලංකා මහ බැංකුව විසින් නිවේදනය කරන ලද රුපියල් බිලියන 50ක පහසුකම සහිත නව ණය වැඩසටහන, වෙළෙඳපළෙහි ද්‍රවශීලතාවය ඉහළ නැංවීම සඳහා ප්‍රයෝජනවත් වන බව මහ බැංකුවේ අධිපතිතුමා සහ එහි ජ්‍යෙෂ්ඨ කාර්ය මණ්ඩලය විසින් පැහැදිලි කරන ලදී (ඇමුණුම III). මහ බැංකුව විසින් රුපියල් බිලියන 125 ක් මුදා හැර ඇති අතර එමගින් මහජනයා අතැති මුදල් ප්‍රමාණය වර්ධනය වී ඇත. කෙසේවෙතත්, ජනගහනයෙන් සියයට 30 - 40 ප්‍රමාණයකට පමණක් විධිමත් බැංකු පද්ධතිය මගින් බැංකු ද්‍රවශීලතාවය සලසන බවත්, සියයට 60 - 70 කට පමණ ක්ෂුද්‍ර මූල්‍ය සහ සමෘද්ධි බැංකු, සමූපකාර බැංකු සහ කෘෂිකාර්මික බැංකු ආදී කුඩා මූල්‍ය ආයතන විසින් ද්‍රවශීලතාවය සම්පාදනය කරනු ලබන බවත් මහ බැංකුව විසින් පෙන්වා දෙන ලදී. එම ක්ෂුද්‍ර සහ කුඩා මූල්‍ය ආයතනවල තැන්පතු බැංකු පද්ධතිය තුල සිරවීමේ ප්‍රථිඵලයක් වශයෙන් ඔවුන්ට ප්‍රමාණවත් ද්‍රවශීලතාවක් පවත්වා ගැනීමට නොහැකි වී ඇත. මහ බැංකු නියෝජිතයින් විසින් ඍජුවම සමෘද්ධි වැඩසටහන සඳහා ද්‍රවශීලතා සහාය ලබාදීමට එකඟතාවය පළකිරීම නිසා ඔවුන්ට එම වැඩසටහන හරහා සමෘද්ධි අඩු ආදායම් පවුල් වැඩිදියුණු කිරීමට හැකියාව ලැබේ.

5. බැංකු නීතිය යටතේ මහ බැංකුවට මූල්‍ය සහ කල්බදු සමාගම් වැනි විශේෂිත මූල්‍ය ආයතන සඳහා ද්‍රවශීලතා පහසුකම් ලබාදීමට නොහැකි බැවින්, ලංකා බැංකුව සහ මහජන බැංකුව හරහා එම ආයතන වෙත මූල්‍ය පහසුකම් සැපයීමට මහ බැංකුව විසින් එකඟතාවය පළකරන ලදී.

6. එසේම, ස්වෛරී ණය වෙළෙඳපල තුළ ශ්‍රී ලංකාවේ විශ්වසනීයත්වය පවත්වා ගෙනයාම සඳහා විනිමය අනුපාතිකය ස්ථාවරව පවත්වාගෙන යාමට තවදුරටත් ගතයුතු ක්‍රියාමාර්ග සම්බන්ධයෙන් මා විසින් මහ බැංකු නියෝජිතයින් සමග සාකච්ඡා කරන ලදී. බැංකුව මෙම ගැටළු සම්බන්ධයෙන් ක්‍රියාකිරීමට අපේක්ෂිත අතර, ඒ සම්බන්ධයෙන් එළඹෙන සතියේදී අමාත්‍ය මණ්ඩලය දැනුවත් කිරීමට මට හැකිවනු ඇත.

7. ශ්‍රී ලංකා විසින් මහ බැංකුව විසින් සියලුම බැංකු, බැංකු ශාඛා සහ ජංගම සේවා පවත්වාගෙන යාමට නියෝග ලබා දී ඇත.

8. අපේ මැදිහත්වීම මත ලෝක බැංකුව, ආසියානු සංවර්ධන බැංකුව, ලෝක සෞඛ්‍ය සංවිධානය සහ අනෙකුත් ද්විපාර්ශ්වික ණය දෙන ආයතන විසින් හදිසි අවශ්‍යතා සඳහා අරමුදල් සම්පාදනය කිරීම ආරම්භ කොට ඇත. ලෝක බැංකුව විසින් රජයේ උත්සාහයට සහාය පළකිරීමක් වශයෙන් ඔවුන්ගේ ඇතැම් ව්‍යාපෘති බැඳීම් රජය විසින් ප්‍රකාශයට පත් කර ඇති වැඩසටහන් බවට පරිවර්තනය කිරීමට එකඟතාවය පළකරන ලදී. ලෝක බැංකුව විසින් අ (2020.03.31) දින පැවැත්වෙන අධ්‍යක්ෂ මණ්ඩල රැස්වීමේදී මෙම කරුණු සාකච්ඡාවට ගැනීමට නියමිත අතර, මෙම පහසුකම 2020 මාර්තු 04 වන සිකුරාදා දින සිට බලාත්මක වන පරිදි ක්‍රියාත්මක කරන ලෙස ඉල්ලා ඇත. ඒ අනුව, භාණ්ඩාගාර ලේකම් විසින් ඉදිරි කටයුතු කිරීම සඳහා බලය ප්‍රදානය කරනු ඇත.

9. එසේම ප්‍රංශ සංවර්ධන අධිකාරිය French Development Agency (KFD) විසින් ද, රටේ හදිසි අවශ්‍යතා සඳහා යොදාගැනීමට ඇමරිකා එක්සත් ජනපද ඩොලර් මිලියන 100ක අයවැය සහනයක් ලබාදීමට කැමැත්ත පළකර ඇත.

10. ලෝක බැංකුව සහ ජාත්‍යන්තර මූල්‍ය අරමුදල වැනි අන්තර්ජාතික මූල්‍ය ආයතනවල සහාය ලබාදීම සඳහාත්, චීනය සහ ජපානය වැනි විශාල සංවර්ධන පාර්ශ්වකරුවන් වෙතින් ශ්‍රී ලංකාව වැනි අවදානමට ලක්විය හැකි සංවර්ධනය වෙමින් පවතින රටවලට ණය සහය පැනවීම සඳහාත්, මැදිහත්වන ලෙස මා විසින් ලෝක සෞඛ්‍ය සංවිධානයේ අධ්‍යක්ෂ ජනරාල් වෙතින් නිල වශයෙන් ඉල්ලා සිටින ලදී. ණය තහනමක් පැනවීම හෝ ණය විලම්භනය කිරීමේ පහසුකම ලබාදීම මගින් මූල්‍ය සහන ලබාදෙන ලෙසට ජපානය සහ මහජන චීන

සමූහාණ්ඩුව (ශ්‍රී ලංකාවේ විශාලතම ද්විපාර්ශ්වික ණය ලබාදෙන්නන්) වෙතින් මා විසින් පෞද්ගලිකව ලිඛිතව ඉල්ලා සිටින ලදී.

11. තවද, මා විසින් හදිසි සෞඛ්‍යාරක්ෂණ අවශ්‍යතාවන් වෙනුවෙන් යොදාගැනීම සඳහා පරිත්‍යාගශීලීන්ගේ අරමුදල්වලින් ජනාධිපති අරමුදල යටතේ සෞඛ්‍ය සහ සමාජ සංරක්ෂණ අරමුදලක් ස්ථාපිත කරන ලදී. වෘත්තීය කළමනාකරණ කණ්ඩායමක් විසින් මෙම අරමුදල කළමනාකරණය කරනු ලබන අතර එය, අරමුණු කිහිපයක් අත්පත් කරගැනීම ඉලක්ක කර ඇත (ඇමුණුම IV). කෙසේවෙතත්, මෙම අරමුදල සඳහා රාජ්‍ය අංශයේ ආයතන සහ පුද්ගලයින්ට පරිබාහිරව අරමුදල් සපයා ගැනීමට ඉලක්ක කළයුතු බැවින්, කිසිදු රාජ්‍ය ආයතනයක් මෙම අරමුදලට දායකත්වය ලබාදීමට දරන උත්සාහයන් දුර්වල කරන ලෙස සියලු අමාත්‍යවරුන්ට සහ ලේකම්වරුන්ට උපදෙස් දීමට මම කැමැත්තෙමි.

12. එසේම, ශ්‍රී ලාංකිකයන් සතුව විදේශයන්හි පවතින මුදල් මෙරටට ගෙන ඒම සඳහා සියලුම සීමාවන් ලිහිල් කිරීමට ශ්‍රී ලංකා මහ බැංකුවේ අධිපතිතුමා සහ ජ්‍යෙෂ්ඨ කාර්ය මණ්ඩලයට මා විසින් යෝජනා කරන ලදී. මෙම ලිහිල් කිරීම තුළින් විදේශගත සියලු ශ්‍රී ලාංකිකයන්ට ශ්‍රී ලංකාවේ කෝවිඩ් 19 මහජන සේවා සෞඛ්‍යාරක්ෂණ සහ අනෙකුත් සමාජ ආරක්ෂණ ක්‍රමවේදයන් සඳහා දායකත්වය ලබාදීමට පහසුකම් සලසනු ඇත.

13. ශ්‍රී ලංකාවේ කොරොනා නිරෝධායන වැඩපිළිවෙල ආරම්භ කරන ලද 2020 මාර්තු 11 එනම් ලෝක සෞඛ්‍ය සංවිධානය විසින් නිවේදනය කරන ලද සහ දෙවන කෝවිඩ් 19 රෝගියා හඳුනාගනු ලැබූ දින සිට 2020 මැයි 30 දක්වා කාල පරිච්ඡේදය තුළ රාජ්‍ය නිළධාරීන්, රාජ්‍ය ආයතන, විදේශයෙන් ලංකා සනොස, රාජ්‍ය ඖෂධ සංස්ථාව, අදාළ රෝහල්වල රෝහල් අධ්‍යක්ෂවරුන් දිස්ත්‍රික් ලේකම්වරුන් සහ ප්‍රාදේශීය ලේකම්වරුන් විසින් සිදු කරනු ලබන කොරොනා ආශ්‍රිත භාණ්ඩ සහ සේවා ප්‍රසම්පාදනය ලිහිල්කරණයක් කළ යුතුව ඇත. ප්‍රසම්පාදන අත්පොත සඳහා එකතු කළ 35 ලිහිල්කරණය කළ යුතු අතර වගවීමට යටත්ව, විශේෂිත ආයතනවල ප්‍රසම්පාදන අවශ්‍යතා දෙයාට සපයා ගැනීමට අවස්ථාව ලබා දිය යුතුයි.

14. විගණන සහ වාර්තාකරණ අවශ්‍යතාවයන් අත්හැරීම සම්බන්ධයෙන් අමාත්‍ය මණ්ඩලය විසින් ප්‍රතිපත්තිමය තීරණයක් ලබා ගත යුතුව ඇති අතර, එවිට පොදු ප්‍රසම්පාදන ක්‍රියාවලියේ දී වගවීම සහතික කරමින් අදාළ ලිහිල්කරණයන් අනුගමනය කිරීමට විගණකාධිපතිවරයාට හැකිවේ.

15. විගණන සහ වාර්තාකරණ අවශ්‍යතාවයන් අත්හැරීම සම්බන්ධයෙන් අමාත්‍ය මණ්ඩලය විසින් ප්‍රතිපත්තිමය තීරණයක් ලබා ගත යුතුව ඇති අතර, එවිට පොදු ප්‍රසම්පාදන ක්‍රියාවලියේ දී වගවීම සහතික කරමින් අදාළ ලිහිල්කරණයන් අනුගමනය කිරීමට විගණකාධිපතිවරයාට හැකිවේ. ඒ අතර, රාජ්‍ය ඖෂධ සංස්ථාව සඳහා ඖෂධ ප්‍රසම්පාදනය කඩිනම් කිරීමට පෙයකර ගෙවීම් සඳහා බිලියන 1ක් සහ එහි බැංකු අයිරාව පිසවීමට බිලියන 12ක් වශයෙන් රුපියල් බිලියන 30ක භාණ්ඩාගාර ඇපකරයක් අවශ්‍ය වේ. එසේම, රාජ්‍ය ඖෂධ නිෂ්පාදන සංස්ථාව සඳහා ද අත්‍යවශ්‍ය ඖෂධ දේශීය වශයෙන් නිෂ්පාදනය පුළුල් කිරීමට රුපියල් බිලියන 5ක භාණ්ඩාගාර ඇපකරයක් අවශ්‍ය වේ. ආසියානු සංවර්ධන බැංකුවෙන් අරමුදල් ලද පසු, එවා ඉහත වියදම් ප්‍රතිපූර්ණය කිරීමට යෙදවීමට හැකිවනු ඇත.

16. ඒ අනුව, පහත යෝජනා ක්‍රියාත්මක කිරීමට අමාත්‍ය මණ්ඩලයේ අනුමැතිය පතමි.

i.කොරොනා ආශ්‍රිත හදිසි ප්‍රසම්පාදන, විශේෂයෙන් 25.03.2020 ප්‍රසම්පාදන අත්පොතට අදාල පරිපූරක 35, ආවරණය කිරීමට සරල ප්‍රසම්පාදන මාර්ගෝපදේශයන් ප්‍රසම්පාදන කොමිෂන් සභාව සමග සාකච්ඡාවෙන් නිකුත් කරන ලෙසට රාජ්‍ය මුල්‍ය දෙපාර්තමේන්තුවේ අධ්‍යක්ෂ ජනරාල් වෙත නියෝග කිරීමට අමාත්‍ය මණ්ඩල ලේකම් වෙත බලය පැවැරීමට,

ii.මහ බැංකුවේ අධිපති විසින් නිවේදනය කර ඇති මහ බැංකු ප්‍රතිමුල්‍ය යෝජනා ක්‍රමය (ඇමුණුම V පරිදි) සඳහා අනුමැතිය ලබාදීමට,

iii.රාජ්‍ය ඖෂධ සංස්ථාවට සහ රාජ්‍ය ඖෂධ නිෂ්පාදන සංස්ථාවට විශේෂ භාණ්ඩාගාර ඇපකර නිකුත් කිරීමට ඉහත අංක 15 පරිදි භාණ්ඩාගාර ලේකම් වෙත බලය පැවැරීමට,

iv.පුළුල් ලෙස සමාජයට හඳුන්වා දී ඇති නව සහන රැසකට අදාලව සහ රජයේ නිළධාරීන්ට නිවසේ සිට සිට රාජකාරී කල හැකි ක්‍රමවේදයට අදාළ මාර්ගෝපදේශ වලට (ඇමුණුම V) අදාලව මාගේ අධීක්ෂණය යටතේ සහ ජනාධිපති කාර්යසාධන බලකායේ උපදේශණය සහිතව මාගේ ලේකම් විසින් නිකුත් කර ඇති චක්‍රලේඛ උපදෙස් සහ ලේකම්, රාජ්‍ය පරිපාලන, ස්වදේශ කටයුතු, පළාත් සභා හා පළාත් පාලන අමාත්‍යාංශය විසින් දිස්ත්‍රික් ලේකම්වරුන් සහ හා ප්‍රාදේශීය ලේකම්වරුන් වෙත නිකුත් කර ඇති චක්‍රලේඛ උපදෙස් (ඇමුණුම VI) අනුමත කිරීමට,

v.අත්‍යවශ්‍ය ආහාර ද්‍රව්‍ය, ඖෂධ, ඉන්ධන, පොහොර, බීජ සහ අත්‍යවශ්‍ය අමුද්‍රව්‍ය සඳහා ගෙවීම් කිරීමට පමණක් විදේශ විනිමය නිකුත් කිරීම සීමාකිරීමට සහ දේශීය සංචිතවල ස්ථායීතාවය කළමනාකරණය කිරීමටත්, විනිමය අනුපාතිකය ස්ථාවරව පවත්වා ගැනීමත් සඳහා විදේශ විනිමය අයවැය ක්‍රියාත්මක කිරීමට මහ බැංකුවට බලය පැවැරීමට,

vi.සුරැකුම්පත්හි ආයෝජනය කරනු ලබන ආයෝජකයින් හඳුනා ගැනීමටත්, එවැනි ආයෝජන මත ණය සේවාකරණය ප්‍රතිස්ථාපනය කිරීමට මහ බැංකුවේ අධිපති සහ එහි නම් කරන ලද නිළධාරීන් වෙත බලය පැවරීමට

vii.මෙරට සිටින සියලු ශ්‍රී ලාංකිකයන්ගේ විදේශ ඉතිරි කිරීම් ශ්‍රී ලංකාවේ බැංකු වෙත ප්‍රේශණය කිරීම සඳහා ඇති බාධා ලිහිල් කිරීමට අවසරය ලබා දීම. මෙය එතෙර සිටින ශ්‍රී ලාංකිකයන්ටද අදාළ වේ.

ගෝඨාභය රාජපක්ෂ
ජනාධිපති

2020 අප්‍රේල් 01

ඇමුණුම 10

රහසිගතයි

අමාත්‍ය මණ්ඩල කාර්යාලය
அமைச்சரவை அலுவலகம்
OFFICE OF THE CABINET OF MINISTERS

CABINET DECISION අමාත්‍ය මණ්ඩල තීරණය அமைச்சரவைத் தீர்மானம்

මගේ අංකය: අමප/20/0694/201/016 2020 අප්‍රේල් මස 09 දින.

පිටපත්:

නීතිපතිතුමා.
අග්‍රාමාත්‍ය ලේකම්.
සෞඛ්‍ය සහ දේශීය වෛද්‍ය සේවා අමාත්‍යාංශයේ ලේකම්.
රාජ්‍ය පරිපාලන, ස්වදේශ කටයුතු, පළාත් සභා හා පළාත් පාලන අමාත්‍යාංශයේ ලේකම්.

ක්‍රියා කළ යුතු:

ජනාධිපති ලේකම්.
අමාත්‍ය මණ්ඩලයේ ලේකම්.
මුදල්, ආර්ථික සහ ප්‍රතිපත්ති සංවර්ධන අමාත්‍යාංශයේ ලේකම්.
ශ්‍රී ලංකා මහ බැංකුවේ අධිපති.
සභාපති, ජාතික ප්‍රසම්පාදන කොමිෂන් සභාව.
විගණකාධිපති.
අධ්‍යක්ෂ ජනරාල්, රාජ්‍ය මුදල් දෙපාර්තමේන්තුව

කොවිඩ් - 19 වෛරසය සමඟ මහජන සෞඛ්‍යාරක්ෂාව කළමනාකරණය සහ ජනතාවට අත්‍යාවශ්‍ය සේවා සම්පාදනය

(අතිගරු ජනාධිපතිතුමා ඉදිරිපත් කළ 2020-04-01 දිනැති අමාත්‍ය මණ්ඩල සටහන)

2020 අප්‍රේල් මස 01 දින පැවැත්වුණු අමාත්‍ය මණ්ඩල රැස්වීමේදී ඵළඹී තීරණයක් අඩගැසීම කටයුතු සඳහා මෙම සමඟ එවා ඇත.

ඩබ්ලිව්.එම්.කේ.ප්‍රනාන්දු
ජ්‍යෙෂ්ඨ අතිරේක ලේකම්.

අ.කළේ/එස්.අමරසේකර
අමාත්‍ය මණ්ඩලයේ ලේකම්.

→2

(ආ) අමාත්‍ය මණ්ඩල පත්‍රිකා:

19. අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 20/0694/201/016 වූ, "**කොවිඩ් - 19 වෛරසය සමඟ මහජන සෞඛ්‍යාරක්ෂාව කළමනාකරණය සහ ජනතාවට අත්‍යවශ්‍ය ද්‍රව්‍ය සම්පාදනය**" යන මැයෙන් අතිගරු ජනාධිපතිතුමා ඉදිරිපත් කළ 2020-04-01 දිනැති අමාත්‍ය මණ්ඩල සටහන - ඉහත සඳහන් අමාත්‍ය මණ්ඩල සටහන අමාත්‍ය මණ්ඩලය විසින් සලකා බලන ලදී. මේ පිළිබඳව සාකච්ඡා කිරීමෙන් අනතුරුව, පහත සඳහන් පරිදි තීරණය කරන ලදී:

(i) ආයතනික මට්ටමින් පවතින විශේෂිත අවශ්‍යතාවන් හඳුනාගනිමින්, කොරෝනා වසංගතයට අදාළ හදිසි ප්‍රසම්පාදනයන් පහසුවෙන් සිදු කිරීමට හැකිවනු පිණිස, ජාතික ප්‍රසම්පාදන කොමිෂන් සභාව විමසමින් 2020-03-25 දිනැති ප්‍රසම්පාදන අත්පොතට අදාළ පරිපූරක 35හි විධිවිධාන තවදුරටත් ලිහිල් කොට, ඉතාමත් සරල ප්‍රසම්පාදන මාර්ගෝපදේශ නිකුත් කිරීම පිණිස කඩිනම් පියවර ගන්නා ලෙස රාජ්‍ය මූදල් දෙපාර්තමේන්තුවේ අධ්‍යක්ෂ ජනරාල්ට නියම කිරීම පිණිස අමාත්‍ය මණ්ඩලයේ ලේකම්වරයාට බලය පැවරීම;

(ii) ශ්‍රී ලංකා මහ බැංකුවේ අධිපති විසින් නිවේදනය කර ඇති මහ බැංකු ප්‍රතිමූල්‍ය යෝජනා ක්‍රමය සඳහා අමාත්‍ය මණ්ඩලයේ එකඟතාව ලබා දීම;

(iii) සටහනේ 15 ඡේදයෙහි සඳහන් වර්ධනාකම සඳහා රාජ්‍ය බැංකුවල ණයකරු සංස්ථාවට සහ රාජ්‍ය ආයතන නිෂ්පාදන සංස්ථාවට විශේෂ භාණ්ඩාගාර ඇපකර නිකුත් කිරීම පිණිස භාණ්ඩාගාර ලේකම්වරයාට බලය පැවරීම

(iv) සමාජයේ පුළුල් කොටසකට සහන සැලසීම සහ රජයේ නිලධාරීන්ට නිවසේ සිට සිය රාජකාරී කටයුතු ඉටු කිරීමේ වැඩපටිපාටිය පිළිබඳ මාර්ගෝපදේශ සම්බන්ධයෙන් ජනාධිපති ලේකම්වරයා විසින්, අතිගරු ජනාධිපතිතුමාගේ

නියමය පරිදි ජනාධිපති කාර්යසාධක බලකාය විමසමින් නිකුත් කරන ලද 2020-03-30 දිනැති චක්‍රලේඛ උපදෙස්වලට (සටහනේ V ඇමුණුම) සහ රාජ්‍ය පරිපාලන, ස්වදේශ කටයුතු, පළාත් සභා හා පළාත් පාලන අමාත්‍යාංශයේ ලේකම් විසින් නිකුත් කරන ලද 2020-03-29 දිනැති චක්‍රලේඛ උපදෙස් (සටහනේ VI ඇමුණුම) සඳහා අමාත්‍ය මණ්ඩලයේ එකඟතාව ලබා දීම;

(v) අත්‍යවශ්‍ය ආහාර ද්‍රව්‍ය, ඖෂධ, ඉන්ධන, පොහොර, බීජ සහ අත්‍යවශ්‍ය අමුද්‍රව්‍ය සඳහා පමණක් වන ගෙවීම් මූල්‍යයනය කිරීම පිණිස විදේශ විනිමය නිකුත් කිරීම සීමා කිරීමේ ප්‍රතිපත්තියක් අනුගමනය කිරීම සහ ශ්‍රී ලංකාවෙන් පිටතට සිදු කරනු ලබන සියලුම ගෙවීම් හැකිතාක් අඩු කිරීම මඟින් රටේ විදේශ සංචිතවල ස්ථායිතාව කළමනාකරණය කරගැනීම පිණිස මෙන්ම විනිමය අනුපාතය ස්ථාවරව පවත්වා ගැනීම පිණිස ශ්‍රී ලංකා මහ බැංකුව විසින් විදේශ විනිමය අයවැයක් පිළියෙල කිරීම;

(vi) විදේශ ආයෝජකයින් ආරක්ෂා කිරීම සම්බන්ධයෙන් වන ශ්‍රී ලංකාවේ කැපවීම සහතික කිරීම පිණිස ස්වෛරීත්ව බැඳුම්කරවල ආයෝජනය කරනු ලබන ආයෝජකයන් එවැනි ආයෝජන මත ණය සේවාකරණය ප්‍රතිස්ථාපනය කිරීම සඳහා දිරිගැන්වීම පිණිස ශ්‍රී ලංකා මහ බැංකුවේ අධිපතිට සහ ඔහු විසින් නම් කරනු ලබන නිලධාරීන්ට බලය පැවරීම; සහ

(vii) දැනට මෙරට වෙසෙන සියලුම ශ්‍රී ලාංකිකයන්ගේ විදේශ්‍රීය ඉතිරි කිරීම් ශ්‍රී ලංකා බැංකු වෙත ප්‍රේෂණය කිරීමට හැකිවනු පිණිස, පවතින සියලුම සීමා කිරීම් ලිහිල් කිරීම සහ එකී සහනය විදේශ රටවල වෙසෙන ශ්‍රී ලාංකිකයන් හට ද සැලසා දීම.

→4

තවද පහත සඳහන් පරිදි අමාත්‍ය මණ්ඩලයේ ලේකම්වරයාට බලය පැවරීමට තීරණය කරන ලදී:

(අ) ඉහත තීරණයේ අන්තර්ගත කරුණු නීතිපතිතුමාගේ අවධානය පිණිස යොමු කිරීම; සහ

(ආ) ඉහත සඳහන් සටහනේ 14 ඡේදයෙහි සඳහන් පරිදි, වගවීම තහවුරු කරමින් නම්‍යශීලීව කටයුතු කරන ලෙස විගණකාධිපතිවරයාගෙන් ඉල්ලා සිටීම.

තවද, මෙම තීරණය සම්මත කරනු ලැබූ සේ සැලකීමටත්, ඒ අනුව අවශ්‍ය කටයුතු සඳහා අදාළ බලධාරීන් වෙත මෙම තීරණය දන්වා යැවීම සඳහා අමාත්‍ය මණ්ඩලයේ ලේකම්ට බලය පැවරීමටත් තීරණය කරන ලදී.

ක්‍රියා කළ යුතු: **ජනාධිපති ලේකම්**
අමාත්‍ය මණ්ඩලයේ ලේකම්
මුදල්, ආර්ථික සහ ප්‍රතිපත්ති සංවර්ධන අමාත්‍යාංශය - සටහනේ පිටපතක් යා කොට ඇත.
ශ්‍රී ලංකා මහ බැංකුවේ අධිපති - සටහනේ පිටපතක් යා කොට ඇත.
සභාපති, ජාතික ප්‍රසම්පාදන කොමිෂන් සභාව - සටහනේ පිටපතක් යා කොට ඇත.
විගණකාධිපති - සටහනේ පිටපතක් යා කොට ඇත.
අධ්‍යක්ෂ ජනරාල්, රාජ්‍ය මුදල් දෙපාර්තමේන්තුව - සටහනේ පිටපතක් යා කොට ඇත.

පිටපත්: **නීතිපතිතුමා** - සටහනේ පිටපතක් යා කොට ඇත.
අග්‍රාමාත්‍ය ලේකම් - සටහනේ පිටපතක් යා කොට ඇත.
සෞඛ්‍ය සහ පදීය වෛද්‍ය සේවා අමාත්‍යාංශය - සටහනේ පිටපතක් යා කොට ඇත.
රාජ්‍ය පරිපාලන, ස්වදේශ කටයුතු, පළාත් සභා හා පළාත් පාලන අමාත්‍යාංශය - සටහනේ පිටපතක් යා කොට ඇත.

(B) Cabinet Papers :

19. Cabinet Paper No.20/0694/201/016, a Note to the Cabinet dated 2020-04-01 by H.E. the President on **"Managing with COVID-19 public healthcare and provision of essentials to the people"** - the above Note was considered by the Cabinet. After discussion, it was decided -

(i) to authorize the Secretary to the Cabinet of Ministers to direct the Director General of the Department of Public Finance to take expeditious action to issue simplest procurement guidelines, in consultation with the National Procurement Commission, to facilitate emergency Corona related procurements with further relaxation of the provisions in Supplement 35 to the Procurement Manual dated 2020-03-25, recognizing institutional specific circumstances;

(ii) to grant concurrence of the Cabinet to the Central Bank of Sri Lanka Re-finance Scheme announced by the Governor of the Central Bank of Sri Lanka;

(iii) to authorize the Secretary to the Treasury to provide special Treasury Guarantees to the State Pharmaceuticals Corporation and the State Pharmaceuticals Manufacturing Corporation to the values referred to in paragraph 15 of the Note;

(iv) to grant concurrence of the Cabinet to the Circular instructions dated 2020-03-30 issued by the Secretary to the President in consultation with the Presidential Task Force and under the direction of H.E. the President, regarding the concessions to a wider section of the society and guidelines to the Public Servants on the Home Stay Work Programme (Annex-V to the Note) and the Circular Instructions dated 2020-03-29 issued by the Secretary, Ministry of Public Administration, Home Affairs, Provincial Councils & Local Government (Annex-VI to the Note);

(v) to adopt a policy to limit foreign exchange payments to finance only the payments for essential foods, pharmaceuticals, fuel, fertilizer, seeds and essential raw materials and the Central Bank of Sri Lanka to work out a Foreign Exchange Budget to manage the stability of the country's reserves and also to stabilize the exchange rate by curtailing all outward payments;

Contd./2-

(vi) to authorize the Governor of the Central Bank of Sri Lanka and its designated officers to pursue investors in Sovereign Bonds to re-profile the debt servicing on such investments to ensure Sri Lanka's commitment to foreign investor protection; and

(vii) to relax all restrictions for all Sri Lankans presently living in the country to bring their foreign savings to Sri Lankan Banks and to extend the same concessions to the Sri Lankans living overseas as well.

It was also decided to authorize the Secretary to the Cabinet -

(a) to bring the contents in the above decision to the notice of the Attorney General; and

(b) to request the Auditor General to adopt relevant flexibility while ensuring accountability, as stated in paragraph 14 of the above Note.

It was further decided to treat this decision as confirmed and to authorize the Secretary to the Cabinet of Ministers to convey the same to the relevant authorities for necessary action accordingly.

Action by: **Secretary to the President**
Secretary to the Cabinet
My/Finance, Economy and Policy Development - copy of Note annexed.
Governor of the Central Bank of Sri Lanka - copy of Note annexed.
Chairman, National Procurement Commission - copy of Note annexed.
Auditor General - copy of Note annexed.
Director General, Department of Public Finance - copy of Note annexed.

Copied to: **Attorney General** - copy of Note annexed.
Secretary to the Prime Minister - copy of Note annexed.
My/Healthcare and Indigenous Medical Services - copy of Note annexed.
My/Public Administration, Home Affairs, Provincial Councils & Local Government - copy of Note annexed.

ඇමුණුම 11

මුදල්, ආර්ථික සහ ප්‍රතිපත්ති සංවර්ධන අමාත්‍යාංශය
நிதி, பொருளாதாரம் மற்றும் கொள்கை அபிவிருத்தி அமைச்சு
MINISTRY OF FINANCE, ECONOMY AND POLICY DEVELOPMENT

මහලේකම් කාර්යාලය, කොළඹ 01,
ශ්‍රී ලංකාව.

செயலகம், கொழும்பு 01,
இலங்கை.

The Secretariat, Colombo 01,
Sri Lanka.

කාර්යාලය / அலுவலகம் / Office: 011 2484500, 011 2484600, 011 2484700
ෆැක්ස් / தொலைநகல் / Fax: 011 24-19823
වෙබ් අඩවිය / இணைய தளம் / Website: www.treasury.gov.lk

මගේ අංකය / எனது இல / My No: PFD/PMD/149/000/2020-02

ඔබේ අංකය / உமது இல / Your No:

දිනය / திகதி / Date: 07.04.2020

Secretary,
Ministry of Healthcare and Indigenous Medical Services

Secretary,
Ministry of Defence,

Secretary,
Ministry of Public Administration, Home Affairs, Provincial Councils & Local Government

Secretary,
Ministry of Mahaweli, Agriculture, Irrigation and Rural Development

Secretary,
Ministry of Internal Trade, Food Security and Consumer Welfare

Secretary,
Ministry of Urban Development, Water Supply and Housing Facilities

Secretary,
Ministry of Higher Education, Technology and Innovation

Secretary,
Ministry of Industries and Supply Chain Management

Further relaxation of provisions under the Supplement 35 issued to the Procurement Manual – 2006 (Goods and Works) to facilitate expeditious handling of COVID-19 related Emergency Procurements

In terms of the directive issued by the Cabinet of Ministers, vide decision No 20/0694/201/016 dated 01.04.2020 to further relaxation of the provisions stipulated under the Supplement 35 to the Procurement Manual – 2006 (Goods and Works) facilitating expeditious handling of urgent procurements related to **COVID-19 emergency situation**, it has been decided to issue following Procurement Guidelines with the concurrence of the National Procurement Commission (NPC) exclusively to the entities which are carrying out **COVID-19 related procurements** under the purview of your Ministry.

02. Whilst these revised guidelines will be applicable for a temporary period, respective Procurement Committees and Procuring Entities must ensure that relaxation of any of the Procurement Guidelines to be undertaken in a transparent and responsible manner deriving maximum value for money to the procuring entity. Accordingly, if it deems necessary, relaxation of existing procurement guidelines should be considered only for the urgent procurements which are directly related to the COVID -19 emergency situation. The duration of applicability of said provisions will be determined by the General Treasury. The Ministries and Institutions that are implementing procurements under the provisions of this circular letter shall report all procurements conducted by them to the General Treasury (Department of Public Finance) and to the National Procurement Commission.

03. **Revised Procurement Guidelines directly related to the COVID -19 emergency situation**

Authority limits of Procurement Committees for Contract Award Recommendation/ Determination under Open Competitive Bidding Procedure (Guideline 3.1, 3.2 or 3.3), Shopping Procedure (Guideline 3.4), Direct Contracting (Guideline 3.5) or Repeat Orders (Guideline 3.6) for procurement of Works, Goods and Services other than Consultancy Services.

Table 1

PROCUREMENT GUIDELINE REFERENCE: 2.14.1		
AUTHORITY LIMITS OF PROCUREEMENT COMMITTEE FOR CONTRACT AWARD RECOMMEDNATION/DETERMINATION		
When Open Competitive Bidding Procedure (Guideline 3.1, 3.2 or 3.3), Direct Contracting Procedure (Guideline 3.5) or Repeat Order Procedure (Guideline 3.6) is followed for the procurement of goods, works and services other than consultancy services. 1. The total cost estimate of each procurement shall be considered in deciding the Procurement Authority limit; 2. In the case of rentals and leases, the contract value for the entire rental or lease period shall be considered in deciding the procurement authority limit 3. Authority Limits		
Authority	**GOSL Funded Projects**	**Foreign Funded Projects**
Standing Cabinet Appointed Procurement Committee (SCAPC)	More than Rs.500 Mn.	More than Rs.1,000 Mn.
Cabinet Appointed Procurement Committee (CAPC)		
Ministry Procurement Committee (MPC)	Up to Rs.500 Mn.	Up to Rs.1,000 Mn.
Department Procurement Committee (DPC)/Project Procurement Committee (PPC)	Up to Rs.200 Mn.	Up to Rs.500 Mn.
Regional Procurement Committee (RPC)	Up to Rs.25 Mn.	Up to Rs.50 Mn.

4. The Procuring Entity may use standard bidding documents. However, when the respective procurement falls under the provision of Guideline 3.8, "Emergency Procurement", relevant Procurement Committee (PC) in consultation with Procurement Entity (PE) may decide the use of the following guidelines appropriately with necessary changes, strictly subjected to the recording of justifications for such relaxation by the PC and PE. Also, PC and PE shall make every effort to implement Fair, Justifiable, Transparent, Competitive and Cost Effective Procurement process while servicing for urgent procurement requirements with the relaxation of the below mentioned guidelines in the **COVID -19** emergency situation.

I. Guidelines 3.6.1 - Repeat Orders - "Percentage limit of original contract value", "Period to be initiate repeat order from original date of awarded"

II. Guidelines 3.8.2 - "Value limit for Works"

III. Guidelines 3.8.2(d) - "period of bidding" Subjected to Providing Minimum 3 days

IV. Guidelines 5.3.4, 5.3.5 & 5.3.7 - "Eligibility of Bidders" **-whilst blacklisted bidders should not be considered, priority should be given to triforces, police, state owned construction entities and other state owned institutions as appropriate**

V. Guidelines 5.3.10 - "Bid Validity Period"

VI. Guidelines 5.3.11 & 5.3.13 - "Bid Security" from "0" % to percentages given in the Section

VII. Guidelines 5.4.4/ 5.4.5 "Advance Payment"

VIII. Guidelines 5.4.8. - "Performance Security" Works

IX. Guidelines 5.4.10. - "Performance Security" Goods

X. Guidelines 5.3.19 - "Evaluation Criteria"

XI. Guidelines 6.2 & 6.2.2 - "Biding Period" "Minimum period of bidding"

XII. Guidelines 6.3 - "Submission of Bid" "6.3.1 (a) (i), (ii), (i), (b), (c) may be change appropriately by PC in consultation with PE (e.g. Acceptance of Electronic bids to a Software System, fax message or as an email). **In the event of acceptance of electronically received bids, all the necessary precautionary measures must be in place to ensure the strict confidentiality of such bids, until formal opening of the same.**

XIII. Guidelines 6.3.2 & 6.3.3 – "Rejection of Late Bids" and "Public Bid Opening"

XIV. Guidelines 7.8.3 & 7.8.4 – Definition of "Minor and Major Deviations"

XV. Guidelines 7.9.7 – "Clarification from Bidders" 7.9.7 (a) PC may permit any substantive changes to the initial price quoted by any bidder. However, the PC shall handle such negotiations process entirely and shall extend equal opportunity for all the bidders participated in the respective bidding process.

XVI. Guidelines 4.2– "Master Procurement Plan" will be suspended temporally under these Guidelines for emergency procurements

XVII. Guidelines 8.3, 8.4 & 8.5 – "Procurement Appeal Process" will be suspended temporally under these Guidelines f for emergency procurements. **Temporary suspension of the Procurement Appeal Process neverthdess means denying the right of an aggrieved party seeking redress under the civil law. Therefore, the PC and the PE must exercise utmost due diligence in the evaluation process.**

3

Table 2

PROCUREMENT GUIDELINE REFERENCE: 2.14.1 (Cont.)

When Shopping Procedure (Guideline 3.4) is followed for the procurement of goods, works and services other than consultancy services

1. For supply & service contracts, quotations may be invited from:
   i. (a) Suppliers Identified from the locality/area,
   ii. (b) Suppliers listed in SLT rainbow pages etc., if sufficient number of reputed vendors are listed,
   iii. (c) Suppliers registered with the Procuring Entity: if applicable

2. For construction contracts, quotations may be invited from registered contractors including Community Based Organizations (CBO)

The Procuring Entity may use standard documents in line with the Government Procurement Guidelines, where applicable and bids may be closed at pre-disclosed deadline (Minimum duration given in the item number (iii) of section 4 of the Table 1 is not applicable).

Applicability of the authorities given under the section 4 of the Table 1 to the Procurement Committees and Procurement Entities should be decided by the relevant procurement Authorities.

Level of Authority	Minimum quotations to be invited	Limits of Authority	
		GOSL funded (Rs. Mn.)	Foreign Funded (Rs. Mn.)
MPC	**Works** By inviting at least three quotations	Up to 50	Up to 50
	Goods & Services other than Consultancy Services By inviting at least three quotations	Up to 50	Up to 50
DPC/ PPC	**Works** By inviting at least three quotations	Up to 35	Up to 35
	Goods & Services other than Consultancy Services By inviting at least three quotations	Up to 35	Up to 35
RPC	**Works** By inviting at least three quotations	Up to 20	Up to 20
	Goods & Services other than Consultancy Services By inviting at least three quotations	Up to 20	Up to 20

CAO	**Works** By inviting at least three quotations	Up to 10
	Goods & Services other than Consultancy Services By inviting at least three quotations	Up to 10
HD/ PD	**Works** By inviting at least three quotations	Up to 5
	Goods & Services other than Consultancy Services By inviting at least three quotations	Up to 5

Table 3

PROCUREMENT GUIDELINE REFERENCE: 2.14.1 (Cont.)		
Direct Purchase of smaller value repair works, goods and services (Guideline 3.5 and 3.6) (by GOSL funds or foreign funds)		
Level of Authority	**Requirements to be fulfilled**	**Authority Limit**
CAO/ HD/PD	**Works** • Satisfying the requirements given under Guideline 3.5 or 3.6	Up to Rs. 1,000,000
	Works • When it is uneconomical to follow competitive procedure. • CAO/HD/PD must ensure the economy of procurement. • This authority should be used under the personnel supervision of CAO/HD/PD & should not be delegated to any person.	Up to Rs. 500,000
	Goods & Services other than Consultancy Services • Satisfying the requirements given under Guideline 3.5 or 3.6	Up to Rs. 500,000
CAO/ HD/PD	**Goods & Services other than Consultancy Services directly from open market** • When it is uneconomical to follow competitive Procedure. • CAO/HD/PD must ensure the economy of procurement. • This authority should be used under the personnel supervision of CAO/HD/PD.	Up to Rs. 300,000

HD/ PD	**Repairs to motor vehicles and other equipment** • When it is uneconomical to follow competitive procedure. • HD/PD must ensure the economy of procurement. • This authority should be used under the personnel supervision of HD/PD • For repairs exceeding Rs.200,000/-CAO's approval should be obtained at the first available opportunity.	Up to Rs. 300,000
Regional Heads or Officers in charge of separate units who were delegated authority by HD	**Goods or Services including equipment of smaller value not exceeding Rs.100,000/- per event** • Total of such purchases during any calendar month should not exceed Rs.1,000,000/-.	Up to Rs. 100,000
	Repair motor vehicle to a value not exceeding Rs. 100,000/- per month	Up to Rs. 100,000

Table 4

PROCUREMENT GUIDELINE REFERENCE: 2.14.1 (Cont.)
AUTHORITY LIMITS FOR DEVIATING FROM PROCUREMENT PROCEDURE
When it becomes necessary to deviate from tender procedures in very urgent and exceptional circumstances about procurements under funds of the Government of Sri Lanka, the following competent authorities may authorize such deviations within the limits prescribed, provided that, the reasons are explicitly recorded in writing and a copy is forwarded to the Auditor General. Applicability of the authorities given under the section 4 of the Table 1 to the Procurement Committees and Procurement Entities should be decided by the relevant procurement Authority together with Procurement Entities.

6

Competent Authority	Authority limits for deviating from Procurement Procedure
Head of Department (HD)/ Project Director(PD) {His personal approval is required}	Up to Rs. 1 Mn.
Chief Accounting Officer (CAO) {His personal approval is required}	Up to Rs. 5 Mn.
Regional Procurement Committee (RPC)	Up to Rs.10 Mn.
Department Procurement Committee (DPC)	Up to Rs. 15 Mn
Ministry Procurement Committee (MPC)	Up to Rs. 25 Mn.
Cabinet of Ministers	Above Rs. 25 Mn. (The respective Standing Cabinet Appointed Procurement Committee (SCAPC) should handle these urgent procurements. However in the absence of such SCAPC, a suitable committee may be appointed with the respective Secretary as the Chairman and two other suitable Secretaries as members decided by the respective Secretary)

Table 5

APPROVING AUTHORITY	
Approval from the following authorities (subject to the delegation of authority provided under FR 135) should be obtained for the recommendation / determination by the PD/HD/CAO/PCs at the first available opportunity.	
PD/HD/CAO	Chief Accounting Officer
Regional Procurement Committee (RPC)	Head of the Department
Project Procurement Committee (PPC)	Chief Accounting Officer
Department Procurement Committee (DPC)	
Ministry Procurement Committee (MPC)	
Cabinet Appointed Procurement Committee (CAPC)	Cabinet of Ministers
The Chief Accounting Officer (CAO) may appoint a minor committee (s) to act on the smaller value procurements within the authority limits of the MPC/DPC/PPC. Accordingly, CAO may consider changing the composition given under the Procurement Manual 2.7.4, 2.7.5 and 2.7.6.	

S.R. Attygalle
Secretary to the Treasury

Copies :
1. Secretary to the President
2. Secretary to the Prime Minister
3. Secretary to the Cabinet of Ministers
4. Auditor General, National Audit Office
5. Chairman, National Procurement Commission

For information please

ඇමුණුම 12

442

මුදල් අමාත්‍යාංශය
நிதி அமைச்சு
MINISTRY OF FINANCE

ලේකම්ගේ කාර්යාලය, කොළඹ 01. ශ්‍රී ලංකාව	செயலகம், கொழும்பு 01. இலங்கை	The Secretariat, Colombo 01. Sri Lanka
කාර්යාල අලුවලකම් Office	(94)-11-2484600 (94)-11-2484700	ෆැක්ස් பெக்ஸ் Fax	(94)-11-2484700
වෙබ් අඩවිය වෙப் සைட் Website	www.treasury.gov.lk

මගේ අංකය எனது இல. My No.	PFD/PMD/149/000/2020-02	ඔබේ අංකය உமது இல. Your No.		දිනය திகதி Date	12.10.2020

SECRETARY
Ministry of Health & Indigenous Medicine
13 OCT 2020

Secretary
Ministry of Health

Further relaxation of provisions under the Supplement 35 issued to the Procurement Manual – 2006 (Goods and Works) to facilitate expeditious handling of COVID-19 related Emergency Procurements

This is further to my letter No. PFD/PMD/149/000/2020-02 dated 09.04.2020 on the above subject.

In terms of the directive issued by the Cabinet of Ministers, vide decision No 20/0694/201/016 dated 01.04.2020 to further relaxation of the provisions stipulated under the Supplement 35 to the Procurement Manual – 2006 (Goods and Works) facilitating expeditious handling of urgent procurements related to **COVID-19 emergency situation**, it has been decided to issue following Procurement Guidelines with the concurrence of the National Procurement Commission (NPC) exclusively to the entities which are carrying out **COVID-19 related procurements** under the purview of your Ministry.

02. Whilst these revised guidelines will be applicable for a temporary period, respective Procurement Committees and Procuring Entities must ensure that relaxation of any of the Procurement Guidelines to be undertaken in a transparent and responsible manner deriving maximum value for money to the procuring entity. Accordingly, relaxation of existing procurement guidelines should be considered only for the urgent procurements which are directly related to the COVID -19 emergency situation. The duration of applicability of said provisions will be determined by the General Treasury. The Ministries, Institutions and Independent Commissions that are implementing procurements under the provisions of this circular letter is required to report all procurements conducted by them to the General Treasury (Department of Public Finance) and to the National Procurement Commission.

03. Revised Procurement Guidelines directly related to the COVID -19 emergency situation

Authority limits of Procurement Committees for Contract Award Recommendation/ Determination under Open Competitive Bidding Procedure (Guideline 3.1, 3.2 or 3.3), Shopping Procedure (Guideline 3.4), Direct Contracting (Guideline 3.5) or Repeat Orders

(441)

IV.	Guidelines 5.3.4, 5.3.5 & 5.3.7 - "Eligibility of Bidders" -**whilst blacklisted bidders should not be considered, priority should be given to tri forces, police, state owned construction entities and other state owned institutions as appropriate**
V.	Guidelines 5.3.10 - "Bid Validity Period"
VI.	Guidelines 5.3.11 & 5.3.13 - "Bid Security" from "0" % to percentages given in the Section
VII.	Guidelines 5.4.4/ 5.4.5 "Advance Payment"
VIII	Guideline 5.4.8. - "Performance Security" Works
	Guideline 5.4.10. - "Performance Security" Goods
X.	Guideline 5.3.19 - "Evaluation Criteria"
XI.	Guidelines 6.2 & 6.2.2 - "Biding Period" "Minimum period of bidding"
XII.	Guideline 6.3 - "Submission of Bid" "6.3.1 (a) (i), (ii), (iii), (b), (c) may be changed appropriately by PC in consultation with PE (e.g. Acceptance of Electronic bids to a Software System, fax message or as an email). **In the event of acceptance of electronically received bids, all the necessary precautionary measures must be in place to ensure the strict confidentiality of such bids, until formal opening of the same.**
XIII.	Guidelines 6.3.2 & 6.3.3 – "Rejection of Late Bids" and "Public Bid Opening"
XIV.	Guidelines 7.8.3 & 7.8.4 – Definition of "Minor and Major Deviations"
XV.	Guideline 7.9.7 – "Clarification from Bidders" 7.9.7 (a) PC may permit any substantive changes to the initial price quoted by any bidder. However, the PC shall handle such negotiations process entirely and shall extend equal opportunity for all the bidders participated in the respective bidding process.
XVI.	Guideline 4.2– "Master Procurement Plan" will be suspended temporally under these Guidelines for emergency procurements
XVII.	Guidelines 8.3, 8.4 & 8.5 – "Procurement Appeal Process" will be suspended temporally under these Guidelines for emergency procurements. **Temporary suspension of the Procurement Appeal Process nevertheless means denying the right of an aggrieved party seeking redress under the civil law. Therefore, the PC and the PE must exercise utmost due diligence in the evaluation process.**

Table 2

PROCUREMENT GUIDELINE REFERENCE: 2.14.1 (Cont.)
When Shopping Procedure (Guideline 3.4) is followed for the procurement of goods, works and services other than consultancy services
1. For supply & service contracts, quotations may be invited from: i. (a) Suppliers Identified from the locality/area, ii. (b) Suppliers listed in SLT rainbow pages etc., if sufficient number of reputed vendors are listed, iii. (c) Suppliers registered with the Procuring Entity: if applicable

3

(440)

Table 3

PROCUREMENT GUIDELINE REFERENCE: 2.14.1 (Cont.)		
Direct Purchase of smaller value repair works, goods and services (Guideline 3.5 and 3.6) (for GOSL funds or foreign funds)		
Level of Authority	**Requirements to be fulfilled**	**Authority Limit**
CAO/ HD/PD	**Works** • Satisfying the requirements given under Guideline 3.5 or 3.6	Up to Rs. 1,000,000
	Works • When it is uneconomical to follow competitive procedure. • CAO/HD/PD must ensure the economy of procurement. • This authority should be used under the personnel supervision of CAO/HD/PD & should not be delegated to any person.	Up to Rs. 500,000
	Goods & Services other than Consultancy Services • Satisfying the requirements given under Guideline 3.5 or 3.6	Up to Rs. 500,000
CAO/ HD/PD	**Goods & Services other than Consultancy Services directly from open market** • When it is uneconomical to follow competitive Procedure. • CAO/HD/PD must ensure the economy of procurement. • This authority should be used under the personnel supervision of CAO/HD/PD.	Up to Rs. 300,000
HD/ PD	**Repairs to motor vehicles and other equipment** • When it is uneconomical to follow competitive procedure. • HD/PD must ensure the economy of procurement. • This authority should be used under the personnel supervision of HD/PD • For repairs exceeding Rs.200,000/-CAO's approval should be obtained at the first available opportunity.	Up to Rs. 300,000

439

Table 5

APPROVING AUTHORITY	
Approval from the following authorities (subject to the delegation of authority provided under FR 135) should be obtained for the recommendation / determination by the PD/HD/CAO/PCs at the first available opportunity.	
PD/HD/CAO	Chief Accounting Officer
Regional Procurement Committee (RPC)	Head of the Department
Project Procurement Committee (PPC)	Chief Accounting Officer
Department Procurement Committee (DPC)	
Ministry Procurement Committee (MPC)	
Cabinet Appointed Procurement Committee (CAPC)	Cabinet of Ministers
The Chief Accounting Officer (CAO) may appoint a minor committee(s) to act on the smaller value procurements within the authority limits of the MPC/DPC/PPC. Accordingly, CAO may consider changing the composition given under the Procurement Manual 2.7.4, 2.7.5 and 2.7.6.	

Further, please note that this letter will replace the letter No. PFD/PMD/149/000/2020-02 dated 09.04.2020 by Department of Public Finance addressed to Secretary, Ministry of Healthcare and Indigenous Medical Services on "Further relaxation of provisions under the Supplement 35 issued to the Procurement Manual – 2006 (Goods and Works) to facilitate expeditious handling of COVID-19 related Emergency Procurements".

S.R. Attygalle
Secretary to the Treasury

Copies :
1. Secretary to the President
2. Secretary to the Prime Minister
3. Secretary to the Cabinet of Ministers
4. Auditor General, National Audit Office
5. Chairman, National Procurement Commission

For information please

21/07/1/309/040

දුරකථන
தொலைபேசி
Telephone
0112 669192, 0112 675011
0112 698507, 0112 694033
0112 675449, 0112 675280

ෆැක්ස්
தொலைநகல்
Fax
0112 693866
0112 693869
0112 692913

විද්‍යුත් තැපෑල
மின்னஞ்சல்
e-mail
postmaster@health.gov.lk

වෙබ් අඩවිය
இணையத்தளம்
Website
www.health.gov.lk

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

මගේ අංකය
எனது இல.
My No.

ඔබේ අංකය
உமது இல.
Your No.

දිනය
திகதி
Date

ඇමුණුම 13

36

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
MINISTRY OF HEALTH

අමාත්‍ය මණ්ඩල සංදේශය

කොවිඩ් 19 වසංගතයේ නෙවන රැල්ල සමය තුළ PCR ධාරිතාව වැඩිකිරීම

01. පසුබිම :

1.1 කොවිඩ් 19 ව්‍යසනයේ පළමු සහ දෙවන රැල්ල සාර්ථකව මැඩ පවත්වමෙන් පසුව ශ්‍රී ලංකාව කොවිඩ් 19 ගෝලීය ව්‍යසනයේ තෙවන රැල්ලට මුහුණ දී ඇත. කොවිඩ් PCR පරීක්ෂණ ක්‍රමය කොවිඩ් 19 හඳුනාගැනීම සහ බෝවීමට අදාළ ස්වර්ණමය ප්‍රමිති පරීක්ෂණය (Gold Standard Test) ලෙස පිළිගෙන ඇත. ඉතා සීඝ්‍රයෙන් පැතිර යන සහ බෝවෙන මෙම කොවිඩ් ප්‍රභේදය පිළිබඳ අනාවරණයත් සමඟ ශ්‍රී ලංකාව තුළ කොවිඩ් 19 PCR පරීක්ෂණ ධාරිතාවය වැඩි කිරීම හදිසි අවශ්‍යතාවයක් බවට පත්වී ඇත.

02. විස්තරය සහ සාධාරණීයකරණය:

2.1 කොවිඩ් 19 වසංගතයේ දෙවන රැල්ල සාර්ථකව මර්දනය කිරීමෙන් පසු 2021 අප්‍රේල් මස මුල් කාලය වන විට නව කොවිඩ් ආසාධිතයින්ගේ සංඛ්‍යාව දිනකට 200 දක්වා පහළ බැස ඇති බව අනාවරණය වී තිබුණි. සෞඛ්‍ය අමාත්‍යාංශය නව PCR යන්ත්‍ර යොදාගනිමින් PCR පරීක්ෂණ ධාරිතාව ඉහළ දැමීම නිසා දිනකට PCR පරීක්ෂණ 15000 ක් දක්වා වර්ධනය කළ නමුදු පසුව ආසාධිතයින්ගේ සංඛ්‍යාව පහළ අගයක් ගැනීම නිසා දිනකට PCR පරීක්ෂණ 8000 දක්වා පහළ බසින ලදී.

2.2 කොවිඩ් PCR පරීක්ෂණ සිදුකිරීම සඳහා ප්‍රතිකාරක සහ පාරිභෝජ්‍ය කට්ටල (Reagents and Consumables) අවශ්‍ය කෙරේ. දැනට වෛද්‍ය සැපයීම් අංශයේ පවතින ප්‍රතිකාරක සහ පාරිභෝජ්‍ය කට්ටල තොගය 2021 අප්‍රේල් මය මුල් යතියේදී කරන ලද පුරෝකථනයන් මත පාදක වී ඇත.

2.3 කොවිඩ් නව ප්‍රභේදය අනාවරණය වීමත් සමඟ රජයේ රසායනාගාර තුළ කොවිඩ් PCR පරීක්ෂණ සඳහා වන ඉල්ලුම දිනකට පරීක්ෂණ 20,000 දක්වා හදිසියේම ඉහළ ගොස් ඇත. දිනකට PCR පරීක්ෂණ 20,000 ක් සඳහා ඉල්ලුම පැවතිය දී එහිමින් ප්‍රතිකාරක සහ පාරිභෝජ්‍ය කට්ටල තොගය ප්‍රමාණවත් වන්නේ දින 15ක් සඳහා පමණි.

2.4 කොවිඩ් 19 PCR පරීක්ෂණ සඳහා අවශ්‍ය ප්‍රතිකාරක සහ පාරිභෝජ්‍ය කට්ටල මිලදී ගැනීම සඳහා ප්‍රයෝගික කාර්යයන් දැනටමත් සිදු නෙරෙමින් පවතී. එහෙත් වුවද එම ක්‍රියාවලිය සම්පූර්ණ කිරීමට තෙමාසයක පමණ කාලයක් ගතවනු ඇත.

03. නිර්දේශ / අනුමැතිය

3.1 දිනකට PCR පරීක්ෂණ 20,000 බැගින් අඛණ්ඩව ඉදිරි මාස 03 තුළ දී සිදුකිරීමට අවශ්‍ය බැවින් ඒ සඳහා අවශ්‍ය PCR කට්ටල සහ අනෙකුත් පාරිභෝජ්‍ය ද්‍රව්‍ය මිලදී ගැනීම සඳහා ඒ සම්බන්ධයෙන් දැනටමත් පිරිනමා ඇති ප්‍රසම්පාදනය පදනම් කර ගනිමින් තවත් මාස 03ක් සඳහා ඇණවුම් කිරීමට අමාත්‍ය මණ්ඩලයේ අනුමැතිය අපේක්ෂා කරමි.

නීතීඥ පවිත්‍රා වන්නිආරච්චි, (මෙ.මි)
සෞඛ්‍ය අමාත්‍ය

2021-05-01

නීතීඥ පවිත්‍රා වන්නිආරච්චි (මෙ.මි)
සෞඛ්‍ය අමාත්‍ය

කාර්යාලය
அலுவலகம்
Office 2422438

වෙබ් අඩවිය
வெப் தளம்
Website www.cabinetoffice.gov.lk

ෆැක්ස් අංකය
தொலைநகல்
Fax No. 2323730, 2389150, 2389151

විද්‍යුත් තැපෑල
மின்னஞ்சல்
E-mail info@cabinetoffice.gov.lk

අමාත්‍ය මණ්ඩල කාර්යාලය
அமைச்சரவை அலுவலகம்
OFFICE OF THE CABINET OF MINISTERS

ජනරජ ගොඩනැගිල්ල, ශ්‍රීමත් බාරන් ජයතිලක මාවත, කොළඹ 01.
குடியரசுக் கட்டடம், சேர் பரோன் ஜயதிலக்க மாவத்தை, கொழும்பு 01.
Republic Building, Sir Baron Jayathilaka Mawatha, Colombo 01, Sri Lanka.

මගේ අංකය
எனது இல.
My No. 21/0791/309/040

ඔබේ අංකය
உமது இல.
Your No.

දිනය
திகதி
Date 2021-05-04

Urgent & Confidential

(Dr.) R.M. Saman Kusumsiri Ratnayake
Secretary
State Ministry of Production, Supply and Regulation of Pharmaceuticals
Fax : 2082162

CABINET DECISION

Given below is an extract of **Item No.(36)** of the Minutes of the Cabinet Meeting held on 2021-05-03.

Item No.(36)

Cabinet Paper No.21/0791/309/040, a Memorandum dated 2021-05-01 by the Minister of Health on **"Increasing the COVID-19 PCR testing capacity during the third wave of the COVID-19 Pandemic"** - the above Memorandum was considered by the Cabinet along with the further clarifications made by the Minister of Health at this meeting. After discussion, considering the special reasons adduced in the Memorandum, it was decided -

(i) to grant approval to enhance the quantities for the already awarded procurements to purchase COVID-19 PCR Kits and other consumables required for a further period of three (03) months; and

(ii) to direct the Secretary, Ministry of Health to take expeditious action to implement the decision at (i) above.

It was also decided to treat this decision as confirmed and to authorize the Secretary to the Cabinet of Ministers to convey the same to the relevant authorities for necessary action accordingly.

Action by: **My/Health**
State Ministry of Production, Supply and Regulation of Pharmaceuticals - copy of Memorandum annexed.

Copied to: **Secretary to the President** - copy of Memorandum annexed.
Secretary to the Prime Minister - copy of Memorandum annexed.
My/Finance - copy of Memorandum annexed.
State Ministry of Primary Health Care, Epidemics and Covid Disease Control - copy of Memorandum annexed.

W.M.D.J. Fernando
Secretary to the Cabinet of Ministers

ලේකම්
செயலாளர்
Secretary 2329620

අතිරේක ලේකම්
மேலதிகச் செயலாளர்
Additional Secretary 2431004

ජ්‍යෙෂ්ඨ සහකාර ලේකම්
சிரேட்ட உதவிச் செயலாளர்
Senior Assistant Secretary 3136199, 2325279, 2422276

ඇමුණුම 15

මුදල් අමාත්‍යාංශය
நிதி அமைச்சு
MINISTRY OF FINANCE

මහලේකම් කාර්යාලය, කොළඹ 01.
ශ්‍රී ලංකාව.

செயலகம், கொழும்பு 01.
இலங்கை

The Secretariat, Colombo 01.
Sri Lanka

කාර්යාලය / அலுவலகம் / Office: (94)-11-2484500, (94)-11-2484600, (94)-11-2484700
ෆැක්ස් / பெக்ஸ் / Fax: (94)-11-2449823
වෙබ් අඩවිය / வெப் சைட் / Website: www.treasury.gov.lk

මගේ අංකය / எனது இல. / My No. PFD/PMD/COVID19/Guide/21

ඔබේ අංකය / உமது இல. / Your No.

දිනය / திகதி / Date 13.05.2021

Secretary, Ministry of Defence

Secretary, Ministry of Health

Secretary, State Ministry of National Security and Disaster Management

Secretary, State Ministry of Home Affairs

Secretary, State Ministry of Indigenous Medicine Promotion, Rural and Ayurvedic Hospitals Development and Community Health

Secretary, State Ministry of Production, Supply and Regulation of Pharmaceuticals

Secretary, State Ministry of Primary Health Care, Epidemics and COVID Disease Control

Introducing guidelines for COVID-19 Emergency Procurement Process (CEPP)

Decision has been taken by the Cabinet of Ministers on 01.04.2020 for the Cabinet Memorandum No. 20/0694/201/016 under the heading "Managing with COVID-19 Public Healthcare & Provision of Essential to the people" where decisions were taken to ensure effective and efficient response to the Covid-19 Pandemic including to relax the procurement process with a view to expedite the COVID related activities. Further to this, the Cabinet of Ministers on 03.05.2021 decided, to relax the health related procurement based on the Cabinet paper No. 21/0791/309/040 submitted by the Minister of Health under the heading "Increasing the COVID-19 PCR Testing Capacity during the third wave of the COVID-19 pandemic.

02. The COVID-19 pandemic requires swift decisions and actions being taken to ensure that not only the health related issues are resolved expeditiously, but also the issues pertaining to livelihood related matters such as ensuring an uninterrupted availability of essential items.

03. Accordingly, new guidelines has been issued for "COVID-19 Emergency Procurement Process (CEPP)" to facilitate the emergency procurements for purchase of vaccines, other medical requirements and essential items, as attached in Annexure 01.

04. Any clarification with regard to this circular could be obtained from the Director General Public Finance on Tel. 011-2484614.

S.R. Attygalle

Secretary to the Treasury

Copies to:

1. Secretary to the President
2. Secretary to the Prime Minister
3. Secretary to the Cabinet of Ministers
4. Auditor General

Annexure -01

Guidelines for COVID - 19 Related EMERGENCY PROCUREMENTs PROCESS (CEPP)

The purpose of the implementation of the COVID -19 Emergency Procurement Process (CEPP) is to address the issues in the prevailing procurement process in the backdrop of the COVID - 19 pandemic, which is an unprecedented emergency situation. This has compelled the adoption of a practical and speedy Government procurement process, to safeguard public interest, public safety and public health. The introduction of the CEPP is expected to facilitate an effective response in the current context of the current disruptions in the supply chains, consequent scarcities and price fluctuations, in the backdrop of which general procedural compliance will become counterproductive and is likely to create situations where procurement opportunities that are available, will be missed which could then have an inimical impact on the COVID-19 response of the government.

2. Hence, confined to the period the COVID -19 pandemic persists, Procuring Entities (PEs) of Government are authorized to follow the process outlined herein, without having to comply with the standard competitive bidding process that is generally expected to be complied by such Procuring Entities in accordance to the Government Procurement Guidelines 2006.

2.1 Emergency Procurements

In relation to emergency procurements required during the time COVID-19 pandemic prevails, any product or service irrespective of the value and especially with regard to the procurement of Pharmaceuticals, Medical Equipment and Devices, other essential goods or food, a "COVID-19 Emergency Procurement Committee" (CEPC) shall be formed.. The CEPC will act in place of Standing Cabinet Appointed Procurement Committee (SCAPC), Cabinet Appointed Procurement Committee (CAPC) and Cabinet Appointed Negotiating Procurement Committee (CANPC) specified in the Government Procurement Guidelines 2006 and related Manuals/ Circulars. In relation to urgent and emergency procurements, the CEPC may obtain inputs/ advice from technical experts, if it is deemed necessary as Technical Evaluation Committees (TEC) will not be appointed, in line with the paragraph 5.2 of the Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007. The CEPC will operate, above the thresholds imposed under (i) 6.6.4 and (ii) 6.7.2 (a) of the Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007, as amended in the paragraph 3 of the this Guideline.

The decisions made by the CEPC, when all members of a CEPC have placed their signatures to the related procurement decision shall be considered final, whereby the relevant PE should make the required award of contracts as decided by the CEPC. All such procurements undertaken by the CEPC shall be informed to the relevant Minister/State Minister. The relevant Minister is required to submit a monthly statement of such procurement, for the covering approval of the Cabinet of Ministers. Such statement shall include the Item/s purchased, the supplier, the value and a brief justification of the requirement for such procurement.

2.2 Composition of the COVID-19 Emergency Procurement Committee (CEPC)

1) Secretary to the relevant Ministry/ Secretary to the relevant State Ministry - Chairperson
2) Director General or an officer at an equivalent position of a Treasury Department or the Ministry of Finance as nominated by the Secretary to the Treasury - Member
3) The Head of the related PE or his nominee. - Member

The Head of the PE should make a request to the Secretary to the Treasury requesting a nominee to the CEPC.

When the PE is the relevant Ministry, the Secretary may appoint a senior officer as deemed appropriate to be the third member of the CEPC

To ensure that the process undertaken in reasonably effective in the context of the emergency nature prevailing in the country, the CEPC could invite the Chief Internal Auditor /Internal Auditor (CIA/IA) of the PE to observe the procurement process undertaken. However, once the procurement process is completed the CIA/IA should be provided the relevant documentation to ensure that a reasonably effective procedure has been followed.

2.3 Selection of Procurement Method

Depending on the urgency, the CEPC may select to adopt one of the procurement methods noted hereunder since they are time efficient;

1) Direct Contracting (DC)
2) Single Source Selection (SSS)
3) Shopping (S) having obtained three quotations as applicable to facilitate repeat procurements with least time spent.

It is desirable that when procuring Pharmaceuticals, Medical Equipment and Devices, their availability with the World Health Organization (WHO), United Nations Agencies, Global Drug Facility Inter-Agency Procurement Services Office and the Green Light Committee, be checked. Checking availability with any local manufacturer is also encouraged to promote local manufacturers, provided the CEPC is satisfied that required standard/ quality is met. Every effort shall be made to procure such products initially from the list of prequalified suppliers/ producers/ manufactures. At the same time, every effort must be taken to purchase goods from local manufactures, provided that such products meet the required standards/quality. Such, decision is expected to not only to promote local manufactures but also ensure the least lead time in the availability of goods.

2.4 Guidance for Procurement under method in 2.3

i) There are no timelines attached to the Direct Contracting process.

ii) Direct Contracting should be from the most convenient suppliers of repute - already known or new, who has not already incurred a breach in relation to the relevant Procuring Entity.

iii) The required information for the procurement including Price Quotation etc. may be called and accepted through official emails of the Secretary to the relevant Ministry, and confirmation could also be done similarly, only once approval of all CEPC members are in place. CEPC shall take steps to ensure that such a Quotation is duly signed by the Supplier and similarly that the confirmation is signed by all the CEPC Members and the PE

iv) Printed copies of the quotation and confirmation emails/ any other documents shall be printed out and be filed, for purposes of record and future audit purposes.

v) Any negotiation to make the supply more advantageous to the Procuring Entities may undertake only by the CEPC.

vi) The PE must appoint and have in place a robust mechanism to monitor the due completion of the supply as agreed between the Supplier and the PE. The CEPC must be informed of the progress including any delay or breach being caused.

vii) Extending any existing contracts already awarded to procure a greater quantity is also allowed. In such case the price and other terms & conditions may be negotiated by the CEPC, in the backdrop of the prevailing supply constraints and market prices.

3. Increase of Thresholds

3.1 Pharmaceuticals and Medical Devices

Since the emergency/urgent requirement in the present context are mainly Pharmaceuticals, Medical Equipment and Devices, the thresholds under (i) 6.6.4 and (ii) 6.7.2 (a) of the **Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007** are revised as noted hereunder;

1) **The new limits of authority for such procurements of Pharmaceuticals & Medical Devices are as follows under 6.6.4 of the Guidelines**

	Authorized Officer	Increased Threshold
(a)	Secretary to the Ministry of Health/State Ministries under the purview of the Ministry of Health	Up to a maximum limit of **LKR 50 million** or the equivalent thereof in any other foreign currency, per event
(b)	Director General Health Services	Up to a maximum limit of **LKR 25 million** or the equivalent thereof in any other foreign currency, per event
(c)	Director - Medical Supply Division (MSD)	Up to a maximum limit of **LKR 10 million** or the equivalent thereof in any other foreign currency, per event
(d)	Managing Director with approval of the Chairman, State Pharmaceuticals Corporation (SPC)	Up to a maximum limit of **LKR 100 million** or the equivalent thereof in any other foreign currency, per event

2) **The new limits of authority for such urgent procurements of Pharmaceuticals & Medical Devices are as follows under 6.7.2 (a) of the Guidelines**

	Authorized Officer	Increased Threshold
(a)	Secretary to the Ministry of Health/ State Ministries under the purview of the Ministry of Health	Up to a maximum limit of **LKR 4 million** or the equivalent thereof in any other foreign currency, per event

(b)	Director General Health Services	Up to a maximum limit of LKR 2 million or the equivalent thereof in any other foreign currency, per event
(c)	Director - Medical Supply Division (MSD)	Up to a maximum limit of LKR 1 million or the equivalent thereof in any other foreign currency, per event
(d)	Managing Director with approval of the Chairman, State Pharmaceuticals Corporation (SPC)	Up to a maximum limit of LKR 1 million or the equivalent thereof in any other foreign currency, per event

3) 6.7.2 (b) – In the aforesaid circumstance every effort shall be made to procure such products initially from the list of prequalified suppliers/ producers/ manufactures.

4. As Government Institutions and Statutory Bodies are legally empowered execute their transactions through electronic communications, and therefore all PE's strongly advised to use electronic communications including emails, in executing the said procurements in line with the Electronic Transactions Act No 19 of 2006 or as amended from time to time. As such, the PE's must ensure that official email addresses are provided, to the required officers with facilities being in place to facilitate work from home mechanisms.

S. R. Attygalle
Secretary to the Treasury and
Secretary to the Ministry of Finance
The Secretariat
Colombo 01

ඇමුණුම 16

මුදල් අමාත්‍යාංශය
நிதி அமைச்சு
MINISTRY OF FINANCE

මහලේකම් කාර්යාලය, කොළඹ 01.
ශ්‍රී ලංකාව

செயலகம், கொழும்பு 01.
இலங்கை

The Secretariat, Colombo 01.
Sri Lanka

කාර්යාලය / அலுவலகம் / Office: (94)-11-2484500, (94)-11-2484600, (94)-11-2484700
ෆැක්ස් / பெக்ஸ் / Fax: (94)-11-2449823
වෙබ් අඩවිය / வெப் சைட் / Website: www.treasury.gov.lk

මගේ අංකය / எனது இல. / My No.: MF/PF/05/CM/2021/089
ඔබේ අංකය / உமது இல. / Your No.:
දිනය / திகதி / Date: 2021.05. 17

අමාත්‍ය මණ්ඩල සංදේශය

කෝවිඩ් – 19 හදිසි ප්‍රසම්පාදන ක්‍රියාවලිය භදුන්වාදීම (CEPP)

1. හැඳින්වීම

1.1 කෝවිඩ් ආශ්‍රිත ක්‍රියාකාරකම් කඩිනම් කිරීම සඳහා ප්‍රසම්පාදන ක්‍රියාවලිය ලිහිල් කිරීම ඇතුළුව කෝවිඩ් -19 වසංගතයට ඵලදායී හා කාර්යක්ෂම ප්‍රතිචාරයක් සහතික කිරීම වෙනුවෙන් "කෝවිඩ් -19 මහජන සෞඛ්‍ය සේවා කළමනාකරණය සහ ජනතාවට අත්‍යවශ්‍ය දේ සැපයීම" යන මාතෘකාව යටතේ ඉදිරිපත් කරන ලද අමාත්‍ය මණ්ඩල සංදේශ අංක 20/0694/201/016 සඳහා අමාත්‍ය මණ්ඩලය විසින් 2020.04.01 දින අනුමැතිය ලබා දී ඇත. මීට අමතරව, "කෝවිඩ් -19 වසංගතයේ තුන්වන රැල්ල අතරතුර කෝවිඩ් -19 PCR පරීක්ෂණ ධාරිතාව වැඩි කිරීම" යන මාතෘකාව යටතේ සෞඛ්‍ය අමාත්‍යවරයා විසින් ඉදිරිපත් කරන ලද අංක 21/0791/309/040 දරණ අමාත්‍ය මණ්ඩල සංදේශය පදනම් කරගෙන සෞඛ්‍යයට අදාළ ප්‍රසම්පාදනය ලිහිල් කිරීමට අමාත්‍ය මණ්ඩලය විසින් 2021.05.03 දින අනුමැතිය ලබා දෙන ලදි.

1.2 ඒ අනුව, කෝවිඩ් -19 වසංගතයෙන් පැන නැඟිය හැකි හදිසි අවශ්‍යතාවයන් සැලකිල්ලට ගනිමින්, භාණ්ඩාගාර ලේකම් විසින් කෝවිඩ් -19 හදිසි ප්‍රසම්පාදන ක්‍රියාවලිය (CEPP) සඳහා වන මාර්ගෝපදේශ විශේෂයෙන් අදාළ වන සෞඛ්‍ය අමාත්‍යාංශයට, ආරක්ෂක අමාත්‍යාංශයට සහ එම අමාත්‍යාංශ දෙකෙහි විෂය පථය යටතේ පවතින රාජ්‍ය අමාත්‍යාංශ ආවරණය වන පරිදි නිකුත් කර ඇත.

2. කෝවිඩ් - 19 හදිසි ප්‍රසම්පාදන ක්‍රියාවලියට (CEPP) අදාළ මාර්ගෝපදේශ නිකුත් කිරීම සාධාරණීකරණය කිරීම.

2.1 කෝවිඩ් -19 වසංගතයට අදාළ සෞඛ්‍යය ගැටළු කඩිනමින් විසඳා ගැනීම සඳහා කඩිනම් තීරණ ගැනීම සහ එය සහතික කිරීම සඳහා ගනු ලබන ක්‍රියාමාර්ග පමණක් නොව අත්‍යවශ්‍ය භාණ්ඩ අබාධිත ලබා දීම සහතික කිරීම වැනි ජීවනෝපාය සම්බන්ධ කාරණා වලට අදාළ කටයුතු සම්බන්ධයෙන් ද කඩිනම් තීරණ ගැනීම අවශ්‍ය වේ.

2.2 "කෝවිඩ් - 19 හදිසි ප්‍රසම්පාදන ක්‍රියාවලිය (CEPP)" ට අදාළව ඇමුණුම 01 හි දැක්වෙන මාර්ගෝපදේශ භදුන්වා දීමෙන් එන්නත්, වෙනත් වෛද්‍ය අවශ්‍යතා සහ අත්‍යවශ්‍ය භාණ්ඩ මිලදී ගැනීම් සඳහා හදිසි ප්‍රසම්පාදන මාර්ගෝපදේශයන්ට පහසුකම් සැලසීම සඳහා ප්‍රසම්පාදන ක්‍රියාවලිය පහසුවෙන්ම සිදුවීම නිර්දේශ කරනුයේ මෙම පසුබිම් තුළය.

2.3 රටෙහි පවතින හදිසි තත්ත්වය සැලකිල්ලට ගෙන, ඇමුණුම 01 හි සඳහන් කර ඇති පරිදි කෝවිඩ -19 හදිසි ප්‍රසම්පාදන කමිටුව විසින් ගනු ලබන තීරණ අදාල බලධාරීන් විසින් සෑම මසකම අමාත්‍ය මණ්ඩලයට ඉදිරිපත් කරනු ලබන අතර, ප්‍රසම්පාදන අත්පිත්වයේ අභ්‍යන්තර විගණනය විසින් මෙම ක්‍රියාවලියේ ඵලදායීත්වය සාධාරණ බව සනාථ කළ යුතුවේ.

3. අනුමැතිය

ඉහත තත්ත්වයන් යටතේ, ඇමුණුම 01 මඟින් ඉදිරිපත් කර ඇති මාර්ගෝපදේශ සඳහා අමාත්‍ය මණ්ඩලයේ ආවරණ අනුමැතිය ලබා ගැනීමට ඉදිරිපත් කරමි.

මහින්ද රාජපක්ෂ, පා.ම.
මුදල් අමාත්‍ය

Annexure -01

Guidelines for COVID - 19 Related EMERGENCY PROCUREMENTs PROCESS (CEPP)

The purpose of the implementation of the COVID -19 Emergency Procurement Process (CEPP) is to address the issues in the prevailing procurement process in the backdrop of the COVID - 19 pandemic, which is an unprecedented emergency situation. This has compelled the adoption of a practical and speedy Government procurement process, to safeguard public interest, public safety and public health. The introduction of the CEPP is expected to facilitate an effective response in the current context of the current disruptions in the supply chains, consequent scarcities and price fluctuations, in the backdrop of which general procedural compliance will become counterproductive and is likely to create situations where procurement opportunities that are available, will be missed which could then have an inimical impact on the COVID-19 response of the government.

2. Hence, confined to the period the COVID -19 pandemic persists, Procuring Entities (PEs) of Government are authorized to follow the process outlined herein, without having to comply with the standard competitive bidding process that is generally expected to be complied by such Procuring Entities in accordance to the Government Procurement Guidelines 2006.

2.1 Emergency Procurements

In relation to emergency procurements required during the time COVID-19 pandemic prevails, any product or service irrespective of the value and especially with regard to the procurement of Pharmaceuticals, Medical Equipment and Devices, other essential goods or food, a "COVID-19 Emergency Procurement Committee" (CEPC) shall be formed.. The CEPC will act in place of Standing Cabinet Appointed Procurement Committee (SCAPC), Cabinet Appointed Procurement Committee (CAPC) and Cabinet Appointed Negotiating Procurement Committee (CANPC) specified in the Government Procurement Guidelines 2006 and related Manuals/ Circulars. In relation to urgent and emergency procurements, the CEPC may obtain inputs/ advice from technical experts, if it is deemed necessary as Technical Evaluation Committees (TEC) will not be appointed, in line with the paragraph 5.2 of the Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007. The.CEPC will operate, above the thresholds imposed under (i) 6.6.4 and (ii) 6.7.2 (a) of the Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007, as amended in the paragraph 3 of the this Guideline.

The decisions made by the CEPC, when all members of a CEPC have placed their signatures to the related procurement decision shall be considered final, whereby the relevant PE should make the required award of contracts as decided by the CEPC. All such procurements undertaken by the CEPC shall be informed to the relevant Minister/State Minister. The relevant Minister is required to submit a monthly statement of such procurement, for the covering approval of the Cabinet of Ministers. Such statement shall include the Item/s purchased, the supplier, the value and a brief justification of the requirement for such procurement.

2.2 Composition of the COVID-19 Emergency Procurement Committee (CEPC)

1) Secretary to the relevant Ministry/ Secretary to the relevant State Ministry – Chairperson
2) Director General or an officer at an equivalent position of a Treasury Department or the Ministry of Finance as nominated by the Secretary to the Treasury - Member
3) The Head of the related PE or his nominee. - Member

The Head of the PE should make a request to the Secretary to the Treasury requesting a nominee to the CEPC.

When the PE is the relevant Ministry, the Secretary may appoint a senior officer as deemed appropriate to be the third member of the CEPC

To ensure that the process undertaken in reasonably effective in the context of the emergency nature prevailing in the country, the CEPC could invite the Chief Internal Auditor /Internal Auditor (CIA/IA) of the PE to observe the procurement process undertaken. However, once the procurement process is completed the CIA/IA should be provided the relevant documentation to ensure that a reasonably effective procedure has been followed.

2.3 Selection of Procurement Method

Depending on the urgency, the CEPC may select to adopt one of the procurement methods noted hereunder since they are time efficient;

1) Direct Contracting (DC)
2) Single Source Selection (SSS)
3) Shopping (S) having obtained three quotations as applicable to facilitate repeat procurements with least time spent.

It is desirable that when procuring Pharmaceuticals, Medical Equipment and Devices, their availability with the World Health Organization (WHO), United Nations Agencies, Global Drug Facility Inter-Agency Procurement Services Office and the Green Light Committee, be checked. Checking availability with any local manufacturer is also encouraged to promote local manufacturers, provided the CEPC is satisfied that required standard/ quality is met. Every effort shall be made to procure such products initially from the list of prequalified suppliers/ producers/ manufactures. At the same time, every effort must be taken to purchase goods from local manufactures, provided that such products meet the required standards/quality. Such, decision is expected to not only to promote local manufactures but also ensure the least lead time in the availability of goods.

2.4 Guidance for Procurement under method in 2.3

i) There are no timelines attached to the Direct Contracting process.

ii) Direct Contracting should be from the most convenient suppliers of repute - already known or new, who has not already incurred a breach in relation to the relevant Procuring Entity.

iii) The required information for the procurement including Price Quotation etc. may be called and accepted through official emails of the Secretary to the relevant Ministry, and confirmation could also be done similarly, only once approval of all CEPC members are in place. CEPC shall take steps to ensure that such a Quotation is duly signed by the Supplier and similarly that the confirmation is signed by all the CEPC Members and the PE

iv) Printed copies of the quotation and confirmation emails/ any other documents shall be printed out and be filed, for purposes of record and future audit purposes.

v) Any negotiation to make the supply more advantageous to the Procuring Entities may undertake only by the CEPC.

vi) The PE must appoint and have in place a robust mechanism to monitor the due completion of the supply as agreed between the Supplier and the PE. The CEPC must be informed of the progress including any delay or breach being caused.

vii) Extending any existing contracts already awarded to procure a greater quantity is also allowed. In such case the price and other terms & conditions may be negotiated by the CEPC, in the backdrop of the prevailing supply constraints and market prices.

3. Increase of Thresholds

3.1 Pharmaceuticals and Medical Devices

Since the emergency/urgent requirement in the present context are mainly Pharmaceuticals, Medical Equipment and Devices, the thresholds under (i) 6.6.4 and (ii) 6.7.2 (a) of the **Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007** are revised as noted hereunder;

1) **The new limits of authority for such procurements of Pharmaceuticals & Medical Devices are as follows under 6.6.4 of the Guidelines**

	Authorized Officer	Increased Threshold
(a)	Secretary to the Ministry of Health/State Ministries under the purview of the Ministry of Health	Up to a maximum limit of LKR 50 million or the equivalent thereof in any other foreign currency, per event
(b)	Director General Health Services	Up to a maximum limit of LKR 25 million or the equivalent thereof in any other foreign currency, per event
(c)	Director - Medical Supply Division (MSD)	Up to a maximum limit of LKR 10 million or the equivalent thereof in any other foreign currency, per event
(d)	Managing Director with approval of the Chairman, State Pharmaceuticals Corporation (SPC)	Up to a maximum limit of LKR 100 million or the equivalent thereof in any other foreign currency, per event

2) **The new limits of authority for such urgent procurements of Pharmaceuticals & Medical Devices are as follows under 6.7.2 (a) of the Guidelines**

	Authorized Officer	Increased Threshold
(a)	Secretary to the Ministry of Health/ State Ministries under the purview of the Ministry of Health	Up to a maximum limit of LKR 4 million or the equivalent thereof in any other foreign currency, per event

(b)	Director General Health Services	Up to a maximum limit of LKR 2 million or the equivalent thereof in any other foreign currency, per event
(c)	Director - Medical Supply Division (MSD)	Up to a maximum limit of LKR 1 million or the equivalent thereof in any other foreign currency, per event
(d)	Managing Director with approval of the Chairman, State Pharmaceuticals Corporation (SPC)	Up to a maximum limit of LKR 1 million or the equivalent thereof in any other foreign currency, per event

3) 6.7.2 (b) - In the aforesaid circumstance every effort shall be made to procure such products initially from the list of prequalified suppliers/ producers/ manufactures.

4. As Government Institutions and Statutory Bodies are legally empowered execute their transactions through electronic communications, and therefore all PE's strongly advised to use electronic communications including emails, in executing the said procurements in line with the Electronic Transactions Act No 19 of 2006 or as amended from time to time. As such, the PE's must ensure that official email addresses are provided, to the required officers with facilities being in place to facilitate work from home mechanisms.

S. R. Attygalle
Secretary to the Treasury and
Secretary to the Ministry of Finance
The Secretariat
Colombo 01

ඇමුණුම 17

රහසිගතයි

(87)

DG/NP
DG/LA

අමාත්‍ය මණ්ඩල කාර්යාලය
அமைச்சரவை அலுவலகம்
OFFICE OF THE CABINET OF MINISTERS

CABINET DECISION **අමාත්‍ය මණ්ඩල තීරණය** **அமைச்சரவைத் தீர்மானம்**

මගේ අංකය: අමප/21/0883/304/076 2021 මැයි මස 25 දින.

පිටපත්:

ජනාධිපති ලේකම්.
අග්‍රාමාත්‍ය ලේකම්.
රාජ්‍ය ආරක්ෂක හා ආපදා
කළමනාකරණ රාජ්‍ය අමාත්‍යාංශයේ ලේකම්.
ස්වදේශ කටයුතු රාජ්‍ය අමාත්‍යාංශයේ ලේකම්.
ප්‍රාථමික සෞඛ්‍ය සේවා, වසංගත රෝග හා කොවිඩ්
රෝග පාලන කටයුතු රාජ්‍ය අමාත්‍යාංශයේ ලේකම්.
ඖෂධ නිෂ්පාදනය, සැපයීම හා
නියාමන රාජ්‍ය අමාත්‍යාංශයේ ලේකම්.
ආර්ථික පුනර්ජීවනය හා දරිද්‍රතාවය පිටු දැකීම සඳහා වූ
ජනාධිපති කාර්යසාධක බලකායේ සම - ලේකම්වරුන්.
විගණකාධිපති.

ක්‍රියා කළ යුතු:

ආරක්ෂක අමාත්‍යාංශයේ ලේකම්.
මුදල් අමාත්‍යාංශයේ ලේකම්.
සෞඛ්‍ය අමාත්‍යාංශයේ ලේකම්.

කොවිඩ් - 19 හදිසි ප්‍රතිචාරක ක්‍රියාවලිය සඳහා
මාර්ගෝපදේශ හඳුන්වා දීම

(මුදල් ගරු ඇමතිතුමා ඉදිරිපත් කළ 2021-05-17 දිනැති සංදේශය)

2021 මැයි මස 17 දින පැවැත්වුණු අමාත්‍ය මණ්ඩල රැස්වීමේදී එළඹී තීරණයක් අවශ්‍ය කටයුතු සඳහා මේ සමඟ එවා ඇත.

ඩබ්ලිව්.එම්.ඩී.පේ.ප්‍රනාන්දු
අමාත්‍ය මණ්ඩලයේ ලේකම්.

→ 2

33. අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 21/0883/304/076 වූ, **"කොවිඩ් - 19 හදිසි ප්‍රභවපාදන ක්‍රියාවලිය සඳහා මාර්ගෝපදේශ හඳුන්වා දීම"** යන මැයෙන් මුදල් ඇමතිතුමා ඉදිරිපත් කළ 2021-05-17 දිනැති සංදේශය - (අමප අංක 20/0694/201/016 පිළිබඳව වූ 2020-04-01 දිනැති අමාත්‍ය මණ්ඩල තීරණයට අදාළව) ඉහත සඳහන් සංදේශය අමාත්‍ය මණ්ඩලය විසින් සලකා බලනා ලදී. මේ පිළිබඳව සාකච්ඡා කිරීමෙන් අනතුරුව, සංදේශයට ඇමුණුම - 01 ලෙස යා කොට තිබූ කොවිඩ් - 19 හදිසි ප්‍රභවපාදන ක්‍රියාවලිය සඳහා වූ මාර්ගෝපදේශ නිකුත් කිරීම වෙනුවෙන් ආවරණ අනුමැතිය ලබා දීමට තීරණය කරන ලදී.

තවද, මෙම තීරණය සම්මත කරනු ලැබූ සේ සැලකීමටත්, ඒ අනුව අවශ්‍ය කටයුතු සඳහා අදාළ බලධාරීන් වෙත මෙම තීරණය දන්වා යැවීම සඳහා අමාත්‍ය මණ්ඩලයේ ලේකම්ට බලය පැවරීමටත් තීරණය කරන ලදී.

ක්‍රියා කළ යුතු: **ආරක්ෂක අමාත්‍යාංශය** - සංදේශයේ පිටපතක් යා කොට ඇත.
මුදල් අමාත්‍යාංශය
සෞඛ්‍ය අමාත්‍යාංශය - සංදේශයේ පිටපතක් යා කොට ඇත.

පිටපත්: **ජනාධිපති ලේකම්** - සංදේශයේ පිටපතක් යා කොට ඇත.
අග්‍රාමාත්‍ය ලේකම් - සංදේශයේ පිටපතක් යා කොට ඇත.
රාජ්‍ය ආරක්ෂණ හා ආපදා කළමනාකරණ රාජ්‍ය අමාත්‍යාංශය - සංදේශයේ පිටපතක් යා කොට ඇත.
ස්වදේශ කටයුතු රාජ්‍ය අමාත්‍යාංශය - සංදේශයේ පිටපතක් යා කොට ඇත.
ප්‍රාථමික සෞඛ්‍ය සේවා, වසංගත රෝග හා කොවිඩ් රෝග පාලන කටයුතු රාජ්‍ය අමාත්‍යාංශය - සංදේශයේ පිටපතක් යා කොට ඇත.
ඖෂධ නිෂ්පාදනය, සැපයීම හා නියාමන රාජ්‍ය අමාත්‍යාංශය - සංදේශයේ පිටපතක් යා කොට ඇත.
ආර්ථික පුනර්ජීවනය හා දරිද්‍රතාවය පිටු දැකීම සඳහා වූ ජනාධිපති කාර්යසාධක බලකායේ සම - ලේකම්වරුන් - සංදේශයේ පිටපතක් යා කොට ඇත.

33. Cabinet Paper No.21/0883/304/076, a Memorandum dated 2021-05-17 by the Minister of Finance on **"Introducing Guidelines for COVID-19 Emergency Procurement Process (CEPP)"** - (Cabinet decision dated 2020-04-01 on CP No.20/0694/201/016 refers) the above Memorandum was considered by the Cabinet. After discussion, it was decided to grant covering approval for the issuance of the Guidelines for COVID-19 Emergency Procurement Process (CEPP), attached as Annex-01 to the Memorandum.

It was also decided to treat this decision as confirmed and to authorize the Secretary to the Cabinet of Ministers to convey the same to the relevant authorities for necessary action accordingly.

Action by: **My/Defence** - copy of Memorandum annexed.
My/Finance
My/Health - copy of Memorandum annexed.

Copied to: **Secretary to the President** - copy of Memorandum annexed.
Secretary to the Prime Minister - copy of Memorandum annexed.
State Ministry of National Security and Disaster Management - copy of Memorandum annexed.
State Ministry of Home Affairs - copy of Memorandum annexed.
State Ministry of Primary Health Care, Epidemics and Covid Disease Control - copy of Memorandum annexed.
State Ministry of Production, Supply and Regulation of Pharmaceuticals - copy of Memorandum annexed.
Co-Secretaries of the Presidential Task Force for Economic Revival and Poverty Alleviation - copy of Memorandum annexed.

011 2693192, 011 2675011
011 2695367, 011 2694033
011 2675449, 011 2675280

011 2693866
011 2693868
011 2692913

postmaster@health.gov.lk

www.health.gov.lk

සුවසිරිපාය
සුවසිරිපාය
SUWASIRIPAYA

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
MINISTRY OF HEALTH

මගේ අංකය
எனது இல.
My No. MH/AD/01/04/22/2022

ඇමුණුම 18

ඔබේ අංකය
உமது இல.
Your No:

දිනය
திகதி
Date 2022-05-30

අමාත්‍ය මණ්ඩල සංදේශය

අර්බුදකාරී තත්ත්වය තුළ හදිසි අත්‍යාවශ්‍ය ඖෂධ, වෛද්‍ය උපකරණ සහ උපාංග මිලදී ගැනීම

1. පසුබිම

1.1. ලොවෙහි පැවති කෝවිඩ් වසංගත තත්ත්වයෙන් පසුව ශ්‍රී ලංකාව ඉතිහාසයේ දරුණුතම ආර්ථික අර්බුද තත්ත්වයට මුහුණ පාමින් සිටින අතර සෞඛ්‍ය පද්ධතිය තුළ අත්‍යාවශ්‍ය හා තීරණාත්මක ඖෂධ, වෛද්‍ය උපකරණ හා උපාංග වල දැඩි හිඟයක් ඇති වීමේ පෙර නිමිති පහළ වෙමින් පවතී. විදේශ විනිමය සීමා වීම හා ආනයන රෙගුලාසි හේතුවෙන් සැපයුම් දාම ඇණහිට ඇති බැවින් සාමාන්‍ය පරිදි සියළුම රෝහල් වෙත නිසිපතා අවශ්‍ය වන ඖෂධ හා ද්‍රව්‍ය සැපයීම සඳහා ඇණවුම් කිරීමට සෞඛ්‍ය අමාත්‍යාංශයට දුෂ්කරතාවයක් මතු වීමට ඉඩ ඇත.

1.2. ඖෂධ සැපයුම් වලින් බහුතරයක්, ආනයනය මගින් සපයා ගනු ලබන බැවින් විදේශ විනිමය සංචිත අඩු වීම නිසා අත්‍යාවශ්‍ය ඖෂධ බොහෝමයක් රට පුරා පවතින රෝහල් වෙත සැපයීම මේ වන විට අවම වී ඇත.

1.3. කෙසේ වෙතත්, ලෝක බැංකුව හා ආසියානු සංවර්ධන බැංකුව වැනි ආධාර සපයන සංවිධාන විසින් සංවර්ධන ව්‍යාපෘති සඳහා වෙන් කරන ලද මුදලින් යම් ප්‍රමාණයක් සෞඛ්‍ය පද්ධතියේ අඛණ්ඩ ක්‍රියාකාරිත්වය උදෙසා අත්‍යාවශ්‍ය ඖෂධ මිලදී ගැනීම වෙනුවෙන් වෙන් කිරීමට ඉඩ ලබාදී ඇත.

2. විස්තරය හා සාධාරණීකරණය

2.1. නිරන්තර මිළ උච්චාවචනයන් සහ හිඟයන් ඇති කරවමින් වර්තමානයේ අවහිර වූ සැපයුම් දාම උදෙසා කඩිනමින් හා ප්‍රායෝගික ලෙස කොන්ත්‍රාත් ප්‍රදානයන් මගින් ප්‍රතිචාර දැක්වීමෙන් අත්‍යාවශ්‍ය ඖෂධ හා අනෙකුත් තීරණාත්මක අයිතමයන්ගේ සැපයුම් දාම නැවත ස්ථාපිත කළ යුතුය.

2.2. කොවිඩ් වසංගත කත්ත්වය හමුවේ මුදල් අමාත්‍යාංශය විසින් කොවිඩ් 19 හදිසි ප්‍රසම්පාදන ක්‍රියාවලිය සඳහා මාර්ගෝපදේශ හඳුන්වා දෙමින් නිකුත් කළ අංක PFD/PMD/COVID19/Guide/21 හා 2021.05.13 දිනැති චක්‍රලේඛය මගින් සෞඛ්‍ය හා සම්බන්ධ ප්‍රසම්පාදනයන්හි ඇතිකළ ලිහිල් කිරීම්, තීරණාත්මක අයිතමයන්ගේ හිඟය මහහරවා ගැනීමට මහඟු පිටුවහලක් විය.

385, සුවසිරිපාය, පූජ්‍ය බද්දේගම විමලවංශ හිමි මාවත, කොළඹ 10, ශ්‍රී ලංකාව. 385, சுவசிரிபாய, வணக்கத்துக்குரிய பத்தேகம விமலவங்ச தேரோ மாவத்தை, கொழும்பு 10, இலங்
385, Suwasiripaya, Rev. Baddegama Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka.

2.3. එසේම, ඉහත මාර්ගෝපදේශ අනුව දැනටමත් ස්ථාපිත කර ඇති මෙම අමාත්‍යාංශයේ කොවිඩ් 19 හදිසි ප්‍රසම්පාදන කමිටුව මඟින් සෞඛ්‍ය පද්ධතියේ අඛණ්ඩ ක්‍රියාකාරිත්වය උදෙසා පහසුකම් සලසමින් හදිසි ඖෂධ, වෛද්‍ය උපකරණ, උපාංග සහ අනෙකුත් අත්‍යාවශ්‍ය අයිතම මිලදී ගැනීමේ මෙහෙයුම් සිදුකිරීමේ හැකියාවක් ඇත.

3. යෝජනා / නිර්දේශ

3.1. ඉහත කරුණු සළකා බලා මහජන සෞඛ්‍ය, ආරක්ෂාව සහ පොදු යහපත වෙනුවෙන් භාණ්ඩ හිඟය මහහරවා ගැනීම උදෙසා අර්බුධකාරී තත්ත්වය තුළ ඖෂධ, වෛද්‍ය උපකරණ හා උපාංගයන්හි හදිසි මිලදී ගැනීමේ ක්‍රියාවලිය මෙහෙයවීම, බලගැන්වීම සඳහා මෑතකදී හඳුන්වාදුන් අංක **PFD/PMD/COVID19/Guide/21** හා 2021.05.13 දිනැති ප්‍රසම්පාදන මාර්ගෝපදේශ සංග්‍රහය යටතේ ස්ථාපිත කෙරුණු **COVID-19** හදිසි ප්‍රසම්පාදන කමිටුව තවදුරටත් පවත්වා ගනිමින් එහි විෂය පථය පුළුල් කිරීම සඳහා අමාත්‍ය මණ්ඩලයේ අනුමැතිය පතමි.

ඇ/කළේ:-
ආචාර්ය කෙහෙලිය රඹුක්වැල්ල
සෞඛ්‍ය අමාත්‍ය
ආචාර්ය කෙහෙළිය රඹුක්වැල්ල
සෞඛ්‍ය අමාත්‍ය

2022 මැයි 30

ඇමුණුම 19

நிதி, பொருளாதார உறுதிப்பாடு மற்றும் தேசிய கொள்கைகள் அமைச்சு
MINISTRY OF FINANCE, ECONOMIC STABILIZATION & NATIONAL POLICIES

செயலகம், கொழும்பு 01,
இலங்கை.

The Secretariat, Colombo 01,
Sri Lanka.

08

அலுவலகம் Office: 011 - 2484500, 011 - 2484600, 011 - 2484700
தொலைநகல் Fax: 011 - 2449823
இணையதளம் Website: www.treasury.gov.lk

எனது இல. My No. PFD/PMD/CM/2022/JEA/02/152
உமது இல. Your No. CP 22/0714/512/004
திகதி Date: 01.06.2022

Cabinet Memorandum

Observations of the Minister of Finance, Economic Stabilization and National Policies

Ministry/Institution : Health

Subject& Date : Purchasing of Urgently Required Essential Drugs, Medical Equipment and Devices during the crisis situation.

30.05.2022

Proposal/ Request : Approval of the Cabinet of Ministers is sought to expand the scope of the COVID - 19 Emergency Procurement Committee (CEPC) established under the recently introduced procurement guidelines No. PFD/PMD/COVID19/Guide/21 dated 13.05.2021, to empower handling of emergency purchase of Pharmaceuticals, Medical Equipment and Devices during this crisis situation, in order to avoid any shortage and to safeguard public interest, public safety and health.

Observations : In principle, I agree with the proposal considering the prevailing situation in the country. However, it is observed that a new guideline (Guidelines for Health Sector Emergency Procurements Process) comprising the same provision as stipulated in the Guidelines for COVID -19 Related Emergency Procurements Process need to be issued as per the "Annexure A" for a period starting from June to end of December 2022.

Ranil Wickramasinghe, M.P.
Minister of Finance, Economic Stabilization and National Policies

Annexure -A

Guidelines for Health Sector Emergency Procurements Process (HSEPP)

The purpose of the implementation of the Health Sector Emergency Procurements Process (HSEPP) is to address the issues in the prevailing procurement process in the backdrop of the current shortage of urgently required essential Pharmaceuticals, medical equipment and devices, in this unprecedented situation in the country. This has compelled the adoption of a practical and speedy Government procurement process, to safeguard public interest, public safety and public health. The introduction of the HSEPP is expected to facilitate an effective response in the current context of the disruptions in the supply chains, consequent scarcities and price fluctuations, in the backdrop of which general procedural compliance will become counterproductive and is likely to create situations where procurement opportunities that are available, will be missed which could then have an inimical impact on the emergency response of the government.

2. Hence, confined to the period starting from June to end of December 2022, Procuring Entities (PEs) of the Health Sector of Government are authorized to follow the process outlined herein, without having to comply with the standard competitive bidding process that is generally expected to be complied by such Procuring Entities in accordance to the Government Procurement Guidelines 2006.

2.1 Emergency Procurements

In relation to emergency procurements required during the time between June to end of December 2022, any product or service irrespective of the value and especially with regard to the procurement of essential Pharmaceuticals, medical equipment and devices, a "Health Sector Emergency Procurement Committee" (HSEPC) shall be formed. The HSEPC will act in place of Standing Cabinet Appointed Procurement Committee (SCAPC), Cabinet Appointed Procurement Committee (CAPC) and Cabinet Appointed Negotiating Procurement Committee (CANPC) specified in the Government Procurement Guidelines 2006 and related Manuals/ Circulars. In relation to urgent and emergency procurements, the HSEPC may obtain inputs/ advice from technical experts, if it is deemed necessary as Technical Evaluation Committees (TEC) will not be appointed, in line with the paragraph 5.2 of the Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007. The HSEPC will operate, above the thresholds imposed under (i) 6.6.4 and (ii) 6.7.2 (a) of the Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007, as amended in the paragraph 3 of the this Guideline.

The decisions made by the HSEPC, when all members of a HSEPC have placed their signatures to the related procurement decision shall be considered final, whereby the relevant PE should make the required award of contracts as decided by the HSEPC. All such procurements undertaken by the HSEPC shall be informed to the Health Minister. The Health Minister is required to submit a monthly statement of such procurement, for the covering approval of the Cabinet of Ministers. Such statement shall include the Item/s purchased, the supplier, the value and a brief justification of the requirement for such procurement.

2.2 Composition of the Health Sector Emergency Procurement Committee (HSEPC).

1). Secretary to the Health Ministry - Chairperson

2). Director General or an officer at an equivalent position of a Treasury Department or the Ministry of Finance, Economic Stabilization and National Policies as nominated by the Secretary to the Treasury - Member

3). The Head of the related PE or his nominee. - Member

The Head of the PE should make a request to the Secretary to the Treasury requesting a nominee to the HSEPC.

When the PE is the Health Ministry, the Secretary may appoint a senior officer as deemed appropriate to be the third member of the HSEPC.

To ensure that the process undertaken in reasonably effective in the context of the emergency nature prevailing in the country, the HSEPC could invite the Chief Internal Auditor /Internal Auditor (CIA/IA) of the PE to observe the procurement process undertaken. However, once the procurement process is completed the CIA/IA should be provided the relevant documentation to ensure that a reasonably effective procedure has been followed.

2.3 Selection of Procurement Method

Depending on the urgency, the HSEPC may select to adopt one of the procurement methods noted hereunder since they are time efficient;

1) Direct Contracting (DC)
2) Single Source Selection (SSS)
3) Shopping (S) having obtained three quotations as applicable to facilitate repeat procurements with least time spent.

It is desirable that when procuring essential Pharmaceuticals, medical equipment and devices, their availability with the World Health Organization (WHO), United Nations Agencies, Global Drug Facility Inter-Agency Procurement Services Office and the Green Light Committee, be checked. Checking availability with any local manufacturer is also encouraged to promote local manufacturers, provided the HSEPC is satisfied that required standard/ quality is met. Every effort shall be made to procure such products initially from the list of prequalified suppliers/ producers/ manufactures. At the same time, every effort must be taken to purchase goods from local manufactures, provided that such products meet the required standards/quality. Such, decision is expected to not only to promote local manufactures but also ensure the least lead time in the availability of goods.

2.4 Guidance for Procurement under method in 2.3

i) There are no timelines attached to the Direct Contracting process.
ii) Direct Contracting should be from the most convenient suppliers of repute – already known or new, who has not already incurred a breach in relation to the relevant Procuring Entity.
iii) The required information for the procurement including Price Quotation etc. may be called and accepted through official emails of the Secretary to the Health Ministry, and confirmation could also be done similarly, only once approval of all HSEPC members are in place. HSEPC shall take steps to ensure that such a Quotation is duly signed by the Supplier and similarly that the confirmation is signed by all the HSEPC Members and the PE.
iv) Printed copies of the quotation and confirmation emails/ any other documents shall be printed out and be filed, for purposes of record and future audit purposes.
v) Any negotiation to make the supply more advantageous to the Procuring Entities may undertake only by the HSEPC.
vi) The PE must appoint and have in place a robust mechanism to monitor the due completion of the supply as agreed between the Supplier and the PE. The HSEPC must be informed of the progress including any delay or breach being caused.
vii) Extending any existing contracts already awarded to procure a greater quantity is also allowed. In such case the price and other terms & conditions may be negotiated by the HSEPC, in the backdrop of the prevailing supply constraints and market prices.

3. Increase of Thresholds

3.1 Pharmaceuticals and Medical Devices

Since the emergency/urgent requirement in the present context are mainly Pharmaceuticals, Medical Equipment and Devices, the thresholds under (i) 6.6.4 and (ii) 6.7.2 (a) of the **Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007** are revised as noted hereunder;

1) **The new limits of authority for such procurements of Pharmaceuticals & Medical Devices are as follows under 6.6.4 of the Guidelines**

	Authorized Officer	Increased Threshold
(a)	Secretary to the Ministry of Health	Up to a maximum limit of LKR 50 million or the equivalent thereof in any other foreign currency, per event
(b)	Director General Health Services	Up to a maximum limit of LKR 25 million or the equivalent thereof in any other foreign currency, per event
(c)	Director - Medical Supply Division (MSD)	Up to a maximum limit of LKR 10 million or the equivalent thereof in any other foreign currency, per event
(d)	Managing Director with approval of the Chairman, State Pharmaceuticals Corporation (SPC)	Up to a maximum limit of LKR 100 million or the equivalent thereof in any other foreign currency, per event

2) **The new limits of authority for such urgent procurements of Pharmaceuticals & Medical Devices are as follows under 6.7.2 (a) of the Guidelines**

	Authorized Officer	Increased Threshold
(a)	Secretary to the Ministry of Health	Up to a maximum limit of LKR 4 million or the equivalent thereof in any other foreign currency, per event
(b)	Director General Health Services	Up to a maximum limit of LKR 2 million or the equivalent thereof in

		any other foreign currency, per event
(c)	Director - Medical Supply Division (MSD)	Up to a maximum limit of LKR 1 million or the equivalent thereof in any other foreign currency, per event
(d)	Managing Director with approval of the Chairman, State Pharmaceuticals Corporation (SPC)	Up to a maximum limit of LKR 1 million or the equivalent thereof in any other foreign currency, per event

3). 6.7.2 (b) - In the aforesaid circumstance every effort shall be made to procure such products initially from the list of prequalified suppliers/ producers/ manufactures.

4. As Government Institutions and Statutory Bodies are legally empowered execute their transactions through electronic communications, and therefore all PE's strongly advised to use electronic communications including emails, in executing the said procurements in line with the Electronic Transactions Act No 19 of 2006 or as amended from time to time. As such, the PE's must ensure that official email addresses are provided, to the required officers with facilities being in place to facilitate work from home mechanisms.

ඇමුණුම 20

රහසිගතයි

SECRETARY
750
16 JUN 2022
MINISTRY OF HEALTH

අමාත්‍ය මණ්ඩල කාර්යාලය
அமைச்சரவை அலுவலகம்
OFFICE OF THE CABINET OF MINISTERS

CABINET DECISION | අමාත්‍ය මණ්ඩල තීරණය | அமைச்சரவைத் தீர்மானம்

මගේ අංකය: අමප/22/0714/512/004 2022 ජූනි මස 14 දින.

පිටපත්:

ජනාධිපති ලේකම්.
අග්‍රාමාත්‍ය ලේකම්.
විගණකාධිපති.

ක්‍රියා කළ යුතු:

මුදල්, ආර්ථික ස්ථායීකරණ සහ
ජාතික ප්‍රතිපත්ති අමාත්‍යාංශයේ ලේකම්.
සෞඛ්‍ය අමාත්‍යාංශයේ ලේකම්.

17 JUN 2022 Ministry of Health
17 JUN 2022

අර්බුදකාරී තත්ත්වය තුළ හදිසි අත්‍යවශ්‍ය ඖෂධ, වෛද්‍ය උපකරණ සහ උපාංග මිල දී ගැනීම

(සෞඛ්‍ය ගරු ඇමතිතුමා ඉදිරිපත් කළ 2022-05-30 දිනැති සංදේශය)

2022 ජූනි මස 06 දින පැවැත්වුණු අමාත්‍ය මණ්ඩල රැස්වීමේදී එළඹී තීරණයක් අවශ්‍ය කටයුතු සඳහා මේ සමඟ එවා ඇත.

ඩබ්ලිව්.එම්.කේ.ජේ.ප්‍රනාන්දු
අමාත්‍ය මණ්ඩලයේ ලේකම්.

18. අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 22/0734/540/001 වශයෙන් අංකගත කෙරුණු, ගරු අග්‍රාමාත්‍ය සහ මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍ය සහ රාජ්‍ය වියදම් කළමනාකරණය පිළිබඳ අමාත්‍ය මණ්ඩල අනුකාරක සභාවේ සභාපතිතුමා ඉදිරිපත් කළ 2022-06-03 දිනැති සටහනට යා කොට ඇති, 2022-06-01 දින පැවැත්වුණු රාජ්‍ය වියදම් කළමනාකරණය පිළිබඳ අමාත්‍ය මණ්ඩල අනුකාරක සභාවේ නිර්දේශ ඇතුළත් වාර්තාව අමාත්‍ය මණ්ඩලය විසින් සලකා බලනු ලැබුව, එකී වාර්තාවේ ඇතුළත් ඔබ අමාත්‍යාංශයට අදාළ පහත සඳහන් නිර්දේශය අනුමත කරන ලදී.

→ 2

"18.08 අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 22/0714/512/004 වූ, **"අර්බුදකාරී තත්ත්වය තුළ හදිසි අත්‍යවශ්‍ය ඖෂධ, වෛද්‍ය උපකරණ සහ උපාංග මිල දී ගැනීම"** යන මැයෙන් සෞඛ්‍ය ඇමතිතුමා ඉදිරිපත් කළ 2022-05-30 දිනැති සංදේශය - ඉහත සඳහන් සංදේශය මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති ඇමතිතුමාගේ නිරීක්ෂණ සමඟ අමාත්‍ය මණ්ඩල අනුකාරක සභාව විසින් සලකා බලන ලදී. මේ පිළිබඳව සාකච්ඡා කිරීමෙන් අනතුරුව, පහත සඳහන් පරිදි අමාත්‍ය මණ්ඩලය වෙත නිර්දේශ කිරීමට තීරණය කරන ලදී:

(i) මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති ඇමතිතුමාගේ නිරීක්ෂණයන්ට ඇමුණුම - A ලෙස යා කොට තිබූ "සෞඛ්‍ය අංශයේ හදිසි ප්‍රසම්පාදන ක්‍රියාවලිය සඳහා වන මාර්ගෝපදේශ" කඩිනමින් නිකුත් කිරීම පිණිස භාණ්ඩාගාරයේ ලේකම්ට බලය පැවරීම: සහ

(ii) ඉහත (i) හි සඳහන් මාර්ගෝපදේශ නිකුත් කිරීමෙන් අනතුරුව, එකී මාර්ගෝපදේශ අනුගමනය කරමින් ඉදිරියේදී හදිසි අත්‍යවශ්‍ය ඖෂධ, වෛද්‍ය උපකරණ සහ උපාංග මිල දී ගැනීම සඳහා අවශ්‍ය පියවර ගන්නා ලෙස සෞඛ්‍ය අමාත්‍යාංශයේ ලේකම්ට නියම කිරීම.

ක්‍රියා කළ යුතු: **මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය**
සෞඛ්‍ය අමාත්‍යාංශය - ඉහත නිරීක්ෂණ යා කොට ඇත.

පිටපත්: **ජනාධිපති ලේකම්** - සංදේශයේ පිටපතක් හා ඉහත නිරීක්ෂණ යා කොට ඇත.
අග්‍රාමාත්‍ය ලේකම් - සංදේශයේ පිටපතක් හා ඉහත නිරීක්ෂණ යා කොට ඇත.

අමුණුම 21

මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අ
நிதி, பொருளாதார உறுதிப்பாடு
MINISTRY OF FINANCE, ECONOMIC STABILIZATION AND NATIONAL POLICIES

The Secretary to the Cabinet of Ministers
Sri Lanka

PFD/PMD/Health/HSEPP/01/2022

06.2022

Secretary
Ministry of Health

Introducing guidelines for Health Sector Emergency Procurements Process (HSEPP)

The approval of the Cabinet of Ministers has granted on 06.06.2022 to the annexure "A" submitted by the Minister of Finance, Economic Stabilization and National Policies along with the observation to the Cabinet Memorandum No. 22/0714/512/004 dated 01.06.2022 under the heading "Purchasing of Urgently Required Essential Drugs, Medical Equipment and Devices during the crisis situation" presented by the Hon. Minister of Health. By the aforesaid cabinet decision, it has been authorized Secretary to the Treasury to issue Guidelines for Health Sector Emergency Procurement Process (HSEPP).

02. Accordingly, new guidelines have been issued for "Health Sector Emergency Procurements Process (HSEPP)" to facilitate the emergency procurements for purchase of pharmaceuticals, medical equipment and devices, as attached in Annexure A for the period from June 2022 to 31st December 2022.

03. Any clarification with regard to this circular could be obtained from the Director General Public Finance on Tel. 011-2484614.

K.M.M. Siriwardana
Secretary to the Treasury

Copies to:
1. Secretary
2. Secretary to the Prime Minister
3. Secretary to the Cabinet of Ministers
4. Auditor General

Addl. Secy | Procurement
Fwd. N/S
16/06
Secretary
Ministry of Health

Guidelines for Health Sector Emergency Procurements Process (HSEPP)

The purpose of the implementation of the Health Sector Emergency Procurements Process (HSEPP) is to address the issues in the prevailing procurement process in the backdrop of the current shortage of urgently required essential Pharmaceuticals, medical equipment and devices, in this unprecedented situation in the country. This has compelled the adoption of a practical and speedy Government procurement process, to safeguard public interest, public safety and public health. The introduction of the HSEPP is expected to facilitate an effective response in the current context of the disruptions in the supply chains, consequent scarcities and price fluctuations, in the backdrop of which general procedural compliance will become counterproductive and is likely to create situations where procurement opportunities that are available, will be missed which could then have an inimical impact on the emergency response of the government.

2. Hence, confined to the period starting from June to end of December 2022, Procuring Entities (PEs) of the Health Sector of Government are authorized to follow the process outlined herein, without having to comply with the standard competitive bidding process that is generally expected to be complied by such Procuring Entities in accordance to the Government Procurement Guidelines

2.1 Emergency Procurements

In relation to emergency procurements required during the time between June to end of December 2022, any product or service irrespective of the value and especially with regard to the procurement of essential Pharmaceuticals, medical equipment and devices, a "Health Sector Emergency Procurement Committee" (HSEPC) shall be formed. The HSEPC will act in place of Standing Cabinet Appointed Procurement Committee (SCAPC), Cabinet Appointed Procurement Committee (CAPC) and Cabinet Appointed Negotiating Procurement Committee (CANPC) specified in the Government Procurement Guidelines 2006 and related Manuals/ Circulars. In relation to urgent and emergency procurements, the HSEPC may obtain inputs/ advice from technical experts, if it is deemed necessary. Technical Evaluation Committees (TEC) will not be appointed, in line with the paragraph 5.2 of the Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007. The HSEPC will operate, above the thresholds imposed under (i) 6.6.4 and (ii) 6.7.2 (a) of the Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007, as amended in the paragraph 3 of the this Guideline.

The decisions made by the HSEPC, when all members of a HSEPC have placed their signatures to the related procurement decision shall be considered final, whereby the relevant PE should make the required award of contracts as decided by the HSEPC. All such procurements undertaken by the HSEPC shall be informed to the Health Minister. The Health Minister is required to submit a monthly statement of such procurement, for the covering approval of the Cabinet of Ministers. Such statement shall include the Item/s purchased, the number, the value and a brief justification of the requirement for such procurement.

2.2 Composition of the Health Sector Emergency Procurement Committee (HSEPC).

1). Secretary to the Health Ministry - Chairperson
2). Director General or an officer at an equivalent position of a Treasury Department or the Ministry of Finance, Economic Stabilization and National Policies as nominated by the Secretary to the Treasury - Member
3). The Head of the related PE or his nominee - Member

The Head of the PE should make a request to the Secretary to the Treasury requesting a nominee to the HSEPC.

When the PE is the Health Ministry, the Secretary may appoint a senior officer as deemed appropriate to be the third member of the HSEPC.

To ensure that the process undertaken in reasonably effective in the context of the emergency nature prevailing in the country, the HSEPC could invite the Chief Internal Auditor /Internal Auditor (CIA/IA) of the PE to observe the procurement process undertaken. However once the procurement process is completed the CIA/IA should be provided the relevant documentation to ensure that a reasonably effective procedure has been followed.

2.3 Selection of Procurement Method

Depending on the urgency, the HSEPC may select to adopt one of the procurement methods noted hereunder since they are time efficient;

(1) Direct Contracting (DC)
(2) Single Source Selection (SSS)
(3) Shopping (SH) [illegible] modifications as applicable to facilitate [illegible] procurement.

It is desirable that when procuring essential Pharmaceuticals, medical equipment and devices, their availability with the World Health Organization (WHO), United Nations Agencies, Global Drug Facility Inter-Agency Procurement Services Office and the Green Light Committee, be checked. Checking availability with any local manufacturer is also encouraged to promote local manufacturers, provided the HSEPC is satisfied that required standard/ quality is met. Every effort shall be made to procure such products initially from the list of prequalified suppliers/ producers/ manufactures. At the same time, every effort must be taken to purchase goods from local manufactures, provided that such products meet the required standards/quality. Such, decision is expected to not only to promote local manufactures but also ensure the least lead time in the availability of goods.

2.4 Guidance for Procurement under method in 2.3

i) There are no timelines attached to the Direct Contracting process.

ii) Direct Contracting should be from the most convenient suppliers of repute – already known or new, who has not already incurred a breach in relation to the [illegible] Procuring Entity.

iii) The required information for the procurement including Price Quotation etc. may be called and accepted through official emails of the Procuring Entity and confirmation shall also be done similarly, only once approval of all HSEPC members are in place. HSEPC shall take steps to ensure that such a Quotation is duly signed by the Supplier and similarly that the confirmation is signed by all the HSEPC Members and the PE.

iv) Printed copies of the quotation and confirmation emails/ any other documents shall be printed out and be filed, for purposes of record and future audit purposes.

v) Any negotiation to make the supply more advantageous to the Procuring Entities may undertake only by the HSEPC.

vi) The PE must appoint and have in place a robust mechanism to monitor the due completion of the supply as agreed between the Supplier and the PE. The HSEPC must be informed of the progress including any delay or breach being caused.

vii) Extending any existing contracts already awarded to procure a greater quantity is also allowed, in such case the price and other terms & conditions may be negotiated by the HSEPC, in the backdrop of the prevailing supply circumstances and market prices.

3. Increase of Thresholds

(12)

3.1 Pharmaceuticals and Medical Devices

Since the emergency/urgent requirement in the present context are mainly Pharmaceuticals, Medical Equipment and Devices, the thresholds under (i) 6.6.4 and (ii) 6.7.2 (a) of the Guidelines for Procurement of Pharmaceuticals and Medical Devices issued in 2007 are revised as noted hereunder;

1) The new limits of authority for such procurements of Pharmaceuticals & Medical Devices are as follows under 6.6.4 of the Guidelines

	Authorized Officer	Increased Threshold
(a)	Secretary to the Ministry of Health	Up to a maximum limit of LKR 50 million or the equivalent thereof in any other foreign currency, per event
(b)	Director General Health Services	Up to a maximum limit of LKR 25 million or the equivalent thereof in any other foreign currency, per event
(c)	Director - Medical Supply Division (MSD)	Up to a maximum limit of LKR 10 million or the equivalent thereof in any other foreign currency, per event
(d)	Managing Director with approval of the Chairman, State Pharmaceuticals Corporation (SPC)	Up to a maximum limit of LKR 100 million or the equivalent thereof in any other foreign currency, per event

2) The new limits of authority for such urgent procurements of Pharmaceuticals & Medical Devices are as follows under 6.7.2 (a) of the Guidelines

	Authorized Officer	Increased Threshold
(a)	Secretary to the Ministry of Health	Up to a maximum limit of LKR 4 million or the equivalent thereof in any other foreign currency, per event
(b)	Director General Health Services	Up to a maximum limit of LKR 2 million or the equivalent thereof in

		any other foreign currency, per event
(c)	Director - Medical Supply Division (MSD)	Up to a maximum limit of LKR 1 million or the equivalent thereof in any other foreign currency, per event
(d)	Managing Director with approval of the Chairman, State Pharmaceuticals Corporation (SPC)	Up to a maximum limit of LKR 1 million or the equivalent thereof in any other foreign currency, per event

3). 6.7.2 (b) - In the aforesaid circumstance every effort shall be made to procure such products initially from the list of prequalified suppliers/ producers/ manufactures.

. As Government Institutions and Statutory Bodies are legally empowered xecute their transactions through electronic communications, and therefore all PE's strongly advised to use electronic communications including emails, in xecuting the said procurements in line with the Electronic Transactions Act, No 9 of 2006 or as amended from time to time. As such, the PE's must ensure that official email addresses are provided, to the required officers with facilities being, n place to facilitate work from home mechanisms.

K.M.B. Siriwardana
Secretary to the Treasury and
Secretary to the Ministry of Finance

දුරකථන
தொலைபேசி
Telephone
011 2669192, 011 2675011
011 2698507, 011 2694033
011 2675449, 011 2675280

ෆැක්ස්
தொலைநகல்
Fax
011 2693866
011 2693869
011 2692913

විද්‍යුත් තැපෑල
மின்னஞ்சல்
e-mail
postmaster@health.gov.lk

වෙබ් අඩවිය
இணையத்தளம்
Website
www.health.gov.lk

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
MINISTRY OF HEALTH

ඇමුණුම - 1 (5)

මගේ අංකය
எனது இல.
My No.
MH/AD/01/04/22/2022

ඔබේ අංකය
உமது இல.
Your No.
ඇමුණුම 22

දිනය
திகதி
Date
2023.01.31

CABINET MEMORANDOM

Purchasing of Urgently Required Essential Drugs, Medical Equipment and Devices during the crisis situation

1. Background

1.1. This has reference to my Cabinet Memorandum dated 30.05.2022 and the decision thereon No.22/0714/512/004 dated 14.06.2022 regarding the above subject.

1.2. Accordingly, the Cabinet of Ministers granted approval to authorize the Secretary to the Treasury to issue "Guidelines for Health Sector Emergency Procurement Process (HSEPP)" and to direct the Secretary, Ministry of Health to take necessary action to purchase the urgently required essential drugs, medical equipment and devices following the same Guidelines, after considering the observations of the Minister of Finance.

2. Description and Justification

2.1. Adhering to the above Cabinet Decision, the Secretary to the Treasury has issued "Guidelines for Health Sector Emergency Procurement Process (HSEPP)" No.PFD/PMD/Health/HSEPP/01/2022 dated 16.06.2022, for the period from June 2022 to the 31st of December 2022.

2.2. This ministry has implemented nearly LKR 1,390 million worth of procurement for the purchase of drugs, devices and other surgical consumables, under the new guidelines and it has been very helpful to overcome the shortage of some of the critical items, in an expeditious and practical manner.

2.3. However, the current economic downturn situation is expected to be continued further with disrupted supply chain of the essential items. Therefore, the continuous implementation of the provisions of above guidelines is essential for the emergency purchase of pharmaceuticals, devices and other essential items to facilitate uninterrupted health service.

අංක 385, සුවසිරිපාය, පූජ්‍ය බද්දේගම විමලවංස හිමි මාවත, කොළඹ 10, ශ්‍රී ලංකාව. இல. 385, சுவசிரிபாய, வணக்கத்துக்குரிய பத்தேகம விமலவங்ச தேரோ மாவத்தை, கொழும்பு 10, இலங்கை.
No. 385, Suwasiripaya, Rev. Baddegama Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka.

3. Suggestions / Recommendations

3.1. In view of the above, approval of the Cabinet of Ministers is sought to extend the effective time period of "Guidelines for Health Sector Emergency Procurement Process (HSEPP)" until June 30, 2023 to empower handling of emergency purchase of pharmaceuticals, medical equipment, devices, and other surgical consumables, during this crisis, in order to avoid any shortage.

Dr. **Keheliya Rambukwella,**
Minister of Health

31 January, 2023

PCM

මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය
நிதி, பொருளாதார உறுதிப்பாடு மற்றும் தேசியக் கொள்கைகள் அமைச்சு
MINISTRY OF FINANCE, ECONOMIC STABILIZATION AND NATIONAL POLICIES

செயலகம், கொழும்பு 01.
இலங்கை.

The Secretariat, Colombo 01.
Sri Lanka.

தொலைபேசி 011-2446823
Fax

இணையதளம்
Website www.treasury.gov.lk

24-20

MF/PMD/CM/2023/HEA/02/038	உமது இல. Your No	CP 23/0226/610/014	திகதி Date 06.02.2023

Cabinet Memorandum

Observations of the Minister of Finance, Economic Stabilization & National Policies

Ministry/Institution : Health

Subject& Date : Purchasing of Urgently Required Essential Drugs, Medical Equipment and Devices during the crisis situation

31.01.2023

Proposals/ Requests : The approval of the Cabinet of Ministers is sought to extend the effective time period of "Guidelines for Health Sector Emergency Procurement Process (HSEPP)" until June 30, 2023 to empower handing of emergency purchase of pharmaceuticals, medical equipment, devices and other surgical consumables, during this crisis, in order to avoid any shortage.

Observations : When considering the many requests made by the Ministry of Health such as requests of Price Variations, implementation of Unsolicited Proposals to the Ministry of Finance, Economic Stabilization and National Policies. It is observed that, the Procurement Planning and the Procurement Process are delayed due to Weak Coordination within the Institutions and Poor Procurement Planning.

Furthermore, the Cabinet of Ministers has given approval on 12th January 2011 to the Cabinet Memorandum No. 11/0086/504/006 on "Establishment of Standing Cabinet Appointed (Special) Procurement Committees for thirteen Ministries" to appoint the Procurement Planning Committees for Pharmaceuticals. Hence, it is suggested to appoint the said committee with immediate effect.

However, considering the uninterrupted supply of essential Medicines, I have no objection to the proposal in the Cabinet Memorandum.

Ranil Wickremesinghe

Ranil Wickremesinghe
Minister of Finance, Economic Stabilization and National Policies

ඇමුණුම 24

රහසිගතයි

අමාත්‍ය මණ්ඩල කාර්යාලය
அமைச்சரவை அலுவலகம்
OFFICE OF THE CABINET OF MINISTERS

CABINET DECISION අමාත්‍ය මණ්ඩල තීරණය அமைச்சரவைத் தீர்மானம்

මගේ අංකය: අමප/23/0226/610/014

2023 පෙබරවාරි මස 21 දින.

ලැබුණු දිනය
22 FEB 2023
ලේකම් කාර්යාලය
(කාලාපය-1)
සෞඛ්‍ය අමාත්‍යාංශය
Ministry of Health

විෂයපථ:

ජනාධිපති ලේකම්.
අග්‍රාමාත්‍ය ලේකම්.
විගණකාධිපති.

ක්‍රියා කළ යුතු:

මුදල්, ආර්ථික ස්ථායීකරණ සහ
ජාතික ප්‍රතිපත්ති අමාත්‍යාංශයේ ලේකම්.
සෞඛ්‍ය අමාත්‍යාංශයේ ලේකම්.

Secretary
Ministry of Health

අර්බුදකාරී තත්ත්වය තුළ හදිසි අත්‍යවශ්‍ය ඖෂධ, වෛද්‍ය උපකරණ සහ උපාංග මිල දී ගැනීම

(සෞඛ්‍ය ඖෂධ ඇමතිතුමා ඉදිරිපත් කළ 2023-01-31 දිනැති සංදේශය)

2023 පෙබරවාරි මස 13 දින පැවැත්වුණු අමාත්‍ය මණ්ඩල රැස්වීමේදී ලබාගත් තීරණයක් අවශ්‍ය කටයුතු සඳහා මේ සමඟ එවා ඇත.

එස්.ඒ.ඩී.ඩී.ජී.ජේ.ප්‍රනාන්දු
අමාත්‍ය මණ්ඩලයේ ලේකම්.

24. අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 23/0302/640/005 වශයෙන් අංකගත කරනා ලද, ගරු ජනාධිපති සහ මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍ය සහ රාජ්‍ය වියදම් කළමනාකරණය පිළිබඳ අමාත්‍ය මණ්ඩල අනුකාරක සභාවේ සභාපතිතුමා ඉදිරිපත් කළ 2023-02-10 දිනැති සටහනට යා කොට නිබූ, 2023-02-08 දින පැවැත්වුණු රාජ්‍ය වියදම් කළමනාකරණය පිළිබඳ අමාත්‍ය මණ්ඩල අනුකාරක සභාවේ නිර්දේශ ඇතුළත් වාර්තාව අමාත්‍ය මණ්ඩලය විසින් සලකා බලන ලදුව, එකී වාර්තාවේ ඇතුළත් ඔබ අමාත්‍යාංශයට අදාළ පහත සඳහන් නිර්දේශය අනුමත කරන ලදී.

→ 2

"24.20 අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 23/0226/610/0[illegible]
"අර්බුදකාරී තත්ත්වය අවසන් කිරීම, [illegible]
උපකරණ සහ උපාංග මිල දී ගැනීම" යන [illegible]
සෞඛ්‍ය ඇමතිතුමා ඉදිරිපත් කළ 2023-01-31
සංදේශය - (අමප අංක 22/0714/512/004 පිළිබඳ
2022-06-06 දිනැති අමාත්‍ය මණ්ඩල තීරණයට අදාළ
ඉහත සඳහන් සංදේශය මුදල්, ආර්ථික ස්ථායීකරණ
ජාතික ප්‍රතිපත්ති ඇමතිතුමාගේ නිරීක්ෂණ සමග අ
මණ්ඩල අනුකාරක සභාව විසින් සලකා බලන ලදී
පිළිබඳව සාකච්ඡා කිරීමෙන් අනතුරුව, පහත සඳහන් ස
අමාත්‍ය මණ්ඩලය වෙත නිර්දේශ කිරීමට තීරණය
ලදී:

(i) සංදේශයේ 3 ඡේදයෙහි සඳහන් (3.1) යෝජනාව සඳහා අනුමැතිය ලබා දීම; සහ

(ii) මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති ඇමතිතුමා විසින් මේ සම්බන්ධයෙන් ඉදිරිපත් කරනු ලැබ ඇති නිරීක්ෂණවල සඳහන් හා වෙනත් කරුණු සියල්ල සලකා බලා නිසි යෝජනාවක් ඉදිරිපත් කරමින්, ඒ අනුව කටයුතු කිරීම පිණිස සෞඛ්‍ය අමාත්‍යාංශයේ ලේකම්ට නියම කිරීම."

ක්‍රියා කළ යුතු: මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය
සෞඛ්‍ය අමාත්‍යාංශය - ඉහත නිරීක්ෂණ යා කොට ඇත.

පිටපත්: ජනාධිපති ලේකම් - සංදේශයේ පිටපතක් හා ඉහත නිරීක්ෂණ යා කොට ඇත.
අග්‍රාමාත්‍ය ලේකම් - සංදේශයේ පිටපතක් හා ඉහත නිරීක්ෂණ යා කොට ඇත.

දුරකථන
தொலைபேசி
Telephone
011 2669192, 011 2675011
011 2698507, 011 2694033
011 2675449, 011 2675280

ෆැක්ස්
தொலைநகல்
Fax
011 2693866
011 2693869
011 2692913

විද්‍යුත් තැපෑල
மின்னஞ்சல்
e-mail
postmaster@health.gov.lk

වෙබ් අඩවිය
இணையத்தளம்
Website
www.health.gov.lk

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

මගේ අංකය
எனது இல.
My No.

ඔබේ අංකය
உமது இல.
Your No.

දිනය
திகதி
Date

ඇමුණුම :- (ඉ)

ඇමුණුම 25

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
MINISTRY OF HEALTH

අමාත්‍ය මණ්ඩල සංදේශය

අර්බුදකාරී තත්ත්වය තුළ හදිසි අත්‍යාවශ්‍ය ඖෂධ, වෛද්‍ය උපකරණ සහ උපාංග මිලදී ගැනීම

1. හැඳින්වීම

1.1. උක්ත කරුණ සම්බන්ධයෙන් වන මාගේ 2023.01.31 දිනැති අමාත්‍ය මණ්ඩල සංදේශය සහ ඒ පිළිබඳව ලබාදුන්, අංක අමස/23/0226/610/014 හා 2023.02.13 දිනැති අමාත්‍ය මණ්ඩල තීරණය හා බැඳේ.

1.2. ඒ අනුව, මූදල් අමාත්‍යතුමාගේ නිරීක්ෂණ සළකා බැලීමෙන් අනාතුරුව අර්බුධකාරී තත්ත්වය තුළ හාණ්ඩ හිඟය මහඟරවා ගැනීම උදෙසා ඖෂධ, වෛද්‍ය උපකරණ, උපාංග සහ අනෙකුත් ශල්‍ය පාරිභෝජ්‍ය ද්‍රව්‍යයන්ගේ හදිසි මිලදී ගැනීමේ ක්‍රියාවලිය මෙහෙයවීම බලගැන්වීම සඳහා "සෞඛ්‍ය අංශයේ හදිසි ප්‍රසම්පාදන ක්‍රියාවලිය සඳහා වන මාර්ගෝපදේශ" බලපැවැත්වෙන කාලසීමාව 2023 ජූනි මස 30 දින දක්වා දීර්ඝ කිරීමට අමාත්‍ය මණ්ඩලය අනුමැතිය ලබාදෙන ලදී.

2. විස්තරය හා සාධාරණීකරණය

2.1. මෙම අමාත්‍යාංශය තව්මාර්ගෝපදේශ යටතේ ශ්‍රී ලංකාවේ සෞඛ්‍ය සේවා ආයතන සඳහා අවශ්‍ය හදිසි අත්‍යාවශ්‍ය ඖෂධ, උපාංග සහ අනෙකුත් ශල්‍ය අයිතම, රසායනාගාර අයිතම, විකිරණශීලී අයිතම සහ පාරිභෝජ්‍ය ද්‍රව්‍ය මිලදී ගැනීම සඳහා ශ්‍රී ලංකා රුපියල් බිලියන 8ක පමණ මිරිසාකමකින් යුතු ප්‍රසම්පාදන ක්‍රියාත්මක කර ඇති අතර සමහර තීරණාත්මක අයිතමයන්ගේ හිඟය කඩිනමින් හා ප්‍රායෝගික අයුරින් මහඟරවා ගැනීමට එය මහඟු පිටුවහලක් වීය.

2.2 අවශ්‍යතාවය, හදිසිතාව සහ ප්‍රමාණවත් සැපයුමක් නොමැතිනම් හෝ වෛද්‍ය සැපයුම් අංශයේ නොග ශූන්‍ය වීම මත පදනම්ව, රාජ්‍ය ඖෂධ නීතිගත සංස්ථාව සෞඛ්‍ය අංශයේ හදිසි

අංක 385, සුවසිරිපාය, පූජ්‍ය බද්දේගම විමලවංශ ගිමි මාවත, කොළඹ 10, ශ්‍රී ලංකාව. இல. 385, சுவசிரிபாய, வண்ணக்கத்துக்குரிய பத்தேகம விமலவங்ச தேரோ மாவத்தை, கொழும்பு 10, இலங்கை.
No. 385, Suwasiripaya, Rev. Baddegama Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka.

ප්‍රසම්පාදන කමිටුව හරහා අවශ්‍ය ඖෂධ, ශල්‍ය අයිතම, රසායනාගාර අයිතම, විකිරණශීලී අයිතම සහ පාරිභෝජ්‍ය ද්‍රව්‍ය සැපයීමට ඉල්ලීම් කරයි.

2.3. කෙසේ වුවද, අත්‍යාවශ්‍ය අයිතමයන්ගේ සැපයුම්දාම අවහිරතා සමඟින් වර්ථමාන ආර්ථික පසුබෑම තවදුරටත් පවතින අතර එය සම්පූර්ණයෙන් යථා තත්ත්වයට පත්ව නොමැත. එම නිසා සැපයුම්දාමය විධිමත් කිරීමට ඖෂධ, වෛද්‍ය උපකරණ, උපාංග සහ අනෙකුත් අත්‍යාවශ්‍ය අයිතමයන්ගේ හදිසි මිලදී ගැනීම මඟින් අඛණ්ඩ සෞඛ්‍ය සේවාව සැපයීම සඳහා උක්ත මාර්ගෝපදේශයන්හි ප්‍රතිපාදන තවදුරටත් ක්‍රියාත්මක කළහැකි වීම අත්‍යාවශ්‍ය වේ.

2.4. ඉල්ලීම්වල ස්වභාවය අනුව ප්‍රසම්පාදන ක්‍රියාවලියේ කාල රාමුව අවම කිරීම සහ රජයට මූල්‍යමය වශයෙන් ප්‍රතිලාභ ලබා දෙන සෞඛ්‍ය අංශයේ හදිසි ප්‍රසම්පාදන ක්‍රියාවලිය සඳහා වන මාර්ගෝපදේශ විධිවිධාන් ඉතා වැදගත් වේ. තවද, සෞඛ්‍ය අංශයේ හදිසි ප්‍රසම්පාදන කමිටුව හරහා සිදුකළ හදිසි ප්‍රසම්පාදන මඟින් පසුගිය මාස හය තුළ වෛද්‍ය සැපයුම් අංශයේ අවශ්‍ය අවම තොග මට්ටම් පවත්වා ගැනීමට ඉමහත් සහයෝගයක් ලබා දී ඇති බව නිරීක්ෂණය වී ඇත.

3. යෝජනා / නිර්දේශ

3.1. ඉහත කරුණු සළකා බලා සුපුරුදු ප්‍රසම්පාදන ක්‍රියාවලිය (අමාත්‍ය මණ්ඩලය පත්කළ ස්ථාවර ප්‍රසම්පාදන කමිටුව, අමාත්‍යාංශ ප්‍රසම්පාදන කමිටුව හා දෙපාර්තමේන්තුගත ප්‍රසම්පාදන කමිටුව) එහි උපරිම මට්ටමින් ස්ථාපිත වන තුරු අර්බුධකාරී තත්ත්වය තුළ හාණ්ඩ හිඟය මඟහරවා ගැනීම උදෙසා ඖෂධ, වෛද්‍ය උපකරණ, උපාංග, රසායනාගාර අයිතම සහ අනෙකුත් ශල්‍ය පාරිභෝජ්‍ය ද්‍රව්‍යයන්හි හදිසි මිලදී ගැනීමේ ක්‍රියාවලිය මෙහෙයවීම බලගැන්වීම සඳහා "සෞඛ්‍ය අංශයේ හදිසි ප්‍රසම්පාදන ක්‍රියාවලිය සඳහා වන මාර්ගෝපදේශ" බලපැවැත්වෙන කාලසීමාව 2023 දෙසැම්බර් මස 31 දින දක්වා දීර්ඝ කිරීමට අමාත්‍ය මණ්ඩලයේ අනුමැතිය පතමි.

ආචාර්ය කෙහෙළිය රඹුක්වැල්ල
සෞඛ්‍ය අමාත්‍ය

2023 ජූනි 19

මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය
நிதி, பொருளாதார உறுதிப்பாடு மற்றும் தேசியக் கொள்கைகள் அமைச்சு
MINISTRY OF FINANCE, ECONOMIC STABILIZATION AND NATIONAL POLICIES

නිවාඩ්ස්ති කාර්යාලය, කොළඹ 01, ශ්‍රී ලංකාව
செயலகம், கொழும்பு 01, இலங்கை.
The Secretariat, Colombo 01, Sri Lanka.

කාර්යාලය / அலுவலகம் / Office: 011-2484500, 011-2484600, 011-2484700
ෆැක්ස් / தொலைநகல் / Fax: 011-2449823
වෙබ් අඩවිය / இணையதளம் / Website: www.treasury.gov.lk

මගේ අංකය / எனது இல / My No: PFD/PMD/CM/2023/HEA/02/228
ඔබේ අංකය / உமது இல / Your No: CP 23/1168/610/014-I
දිනය / திகதி / Date: 28. 06.2023

Cabinet Memorandum

Observations of the Minister of Finance, Economic Stabilization and National Policies

Ministry/Institution : Health

Subject& Date : Purchasing of Urgently Required Essential Drugs and Medical Equipment and Devices during the crises situation

19.06.2023

Proposals/ Requests : The approval of the Cabinet of Ministers is sought to extend the effective time period of " Guidelines for the Health Sector Emergency Procurement Process (HSEPP)" until 31 December 2023 to empower handing of emergency purchase of pharmaceuticals, medical equipment, devises, Laboratory items and other surgical consumables during this crisis in order to avoid any shortage until the usual procurement process (Standing Cabinet Appointed Procurement Committee, Ministry Procurement Committee and Departmental Procurement Committee) gets established at its' maximum level.

Observations : I observe that, the Guidelines for Health Sector Emergency Procurement Process (HSEPP) has been implemented since June 2022.

I further, observe that most of the conditions that have instigated the introduction of the aforesaid Health Sector Emergency Procurement Guidelines have been eased out to a reasonable level by now. Purchase of drugs and other medical supplies utilizing emergency procurement provisions will not only enhance procurement costs but also will lead to deviations from the recognized procurement best practices.

In the circumstances in place of extending the validity of the Emergency Procurement Guidelines, it is advisable that

authority be given to the Chief Accounting Officer of the Health Ministry to make appropriate changes to the Procurement Conditions such as procurement time frame, bid security and performance bond as and when necessary with the approval of the National Procurement Commission.

Ranil Wickremesinghe
Minister of ~~Finance,~~ Economic Stabilization and National Policies

ඇමුණුම 27

රහසිගතයි

අමාත්‍ය මණ්ඩල කාර්යාලය
அமைச்சரவை அலுவலகம்
OFFICE OF THE CABINET OF MINISTERS

CABINET DECISION අමාත්‍ය මණ්ඩල තීරණය அமைச்சரவைத் தீர்மானம்

මගේ අංකය: අමප/23/1168/610/014-I 2023 ජූලි මස 11 දින.

පිටපත්:

අග්‍රාමාත්‍ය ලේකම්.
විගණකාධිපති.

ක්‍රියා කළ යුතු:

ජනාධිපති ලේකම්.
මුදල්, ආර්ථික ස්ථායීකරණ සහ
ජාතික ප්‍රතිපත්ති අමාත්‍යාංශයේ ලේකම්.
සෞඛ්‍ය අමාත්‍යාංශයේ ලේකම්.

ලේකම්
සෞඛ්‍ය අමාත්‍යාංශය

අර්බුදකාරී තත්ත්වය තුළ හදිසි අත්‍යවශ්‍ය ඖෂධ, වෛද්‍ය උපකරණ සහ උපාංග මිල දී ගැනීම

(සෞඛ්‍ය ගරු ඇමතිතුමා ඉදිරිපත් කළ 2023-06-19 දිනැති සංදේශය)

2023 ජූලි මස 04 දින පැවැත්වුණු අමාත්‍ය මණ්ඩල රැස්වීමේදී එළඹී තීරණයක් අවශ්‍ය කටයුතු සඳහා මේ සමඟ එවා ඇත.

ඩබ්ලිව්.එම්.ඩී.ජේ.ප්‍රනාන්දු
අමාත්‍ය මණ්ඩලයේ ලේකම්.

31. අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 23/1223/640/022 වශයෙන් අංකගත කරන ලද, ගරු ජනාධිපති සහ මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍ය සහ රාජ්‍ය වියදම් කළමනාකරණය පිළිබඳ අමාත්‍ය මණ්ඩල අනුකාරක සභාවේ සභාපතිතුමා ඉදිරිපත් කළ 2023-06-28 දිනැති සටහනට යා කොට තිබූ, 2023-06-28 දින පැවැත්වුණු රාජ්‍ය වියදම් කළමනාකරණය පිළිබඳ අමාත්‍ය මණ්ඩල අනුකාරක සභාවේ නිර්දේශ ඇතුළත් වාර්තාව අමාත්‍ය මණ්ඩලය විසින් සලකා බලනු ලදී.

එකී වාර්තාවේ ඇතුළත් ඔබ අමාත්‍යාංශයට අදාළ පහත සඳහන් නිර්දේශය අමාත්‍ය මණ්ඩලය විසින් අනුමත කරන ලදී:

→2

"31.10 අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 23/1168/610/014-I වූ, **"අර්බුදකාරී තත්ත්වය තුළ හදිසි අත්‍යවශ්‍ය ඖෂධ, වෛද්‍ය උපකරණ සහ උපාංග මිල දී ගැනීම"** යන මැයෙන් සෞඛ්‍ය ඇමතිතුමා ඉදිරිපත් කළ 2023-06-19 දිනැති සංදේශය - (අමප අංක 23/0226/610/014 පිළිබඳව වූ 2023-02-13 දිනැති අමාත්‍ය මණ්ඩල තීරණයට අදාළව) ඉහත සඳහන් සංදේශය මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති ඇමතිතුමාගේ නිරීක්ෂණ සහ සංදේශයේ සඳහන් යෝජනාව පිළිබඳව සෞඛ්‍ය ඇමතිතුමා විසින් මෙම රැස්වීමේදී සිදු කරන ලද වැඩිදුර කරුණු පැහැදිලි කිරීම් සමඟ අමාත්‍ය මණ්ඩල අනුකාරක සභාව විසින් සලකා බලන ලදී. මේ පිළිබඳව සාකච්ඡා කිරීමෙන් අනතුරුව, පහත සඳහන් පරිදි අමාත්‍ය මණ්ඩලය වෙත නිර්දේශ කිරීමට තීරණය කරන ලදී:

(I) සංදේශයේ 3 ඡේදයෙහි සඳහන් (3.1) යෝජනාව සඳහා අනුමැතිය ලබා දීම;

(II) පහත සඳහන් කරුණු පිළිබඳව අධ්‍යයනය කර නිර්දේශ සහිත වාර්තාවක්, අමාත්‍ය මණ්ඩලය වෙත එක් (01) මාසයක කාලසීමාවක් තුළ ඉදිරිපත් කිරීම සඳහා ක්ෂේත්‍රයේ ප්‍රවීණයන්ගෙන් සමන්විත කමිටුවක් පත් කිරීම පිණිස ජනාධිපති ලේකම්ට බලය පැවරීම:

(i) දේශීය වශයෙන් නිෂ්පාදනය කළ නොහැකි මෙරටට අවශ්‍ය ගුණාත්මක ඖෂධ සහ පාරිභෝජ්‍ය වෛද්‍යමය උපාංග වඩාත් තරගකාරී මිල ගණන්වලට ප්‍රසම්පාදනය කිරීම පිණිස දැනට පවතින බාධාවන් කවරේද යන්න;

→ 3

(ii) එකී බාධාවන් ඉවත් කරමින් වඩාත් සරල සහ විනිවිදභාවයකින් යුතුව ගුණාත්මක ඖෂධ සහ පාරිභෝජ්‍ය වෛද්‍යමය උපාංග මිල දී ගැනීම සඳහා අනුගමනය කළ යුතු ක්‍රමවේදය/ ක්‍රමවේද කවරේද යන්න;

(iii) 2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ විධිවිධානවලට අනුගතව ඉහත (ii)හි පරිදි කටයුතු කිරීම සඳහා පහසුකම් සැපයීමට හැකි වන අයුරින් ජාතික ඖෂධ නියාමන අධිකාරියේ කටයුතු ප්‍රතිසංවිධානය කිරීම සම්බන්ධයෙන් සලකා බැලිය යුතු කරුණු කවරේද යන්න;

(iv) රාජ්‍ය ඖෂධ නීතිගත සංස්ථාව සහ රාජ්‍ය ඖෂධ නිෂ්පාදන නීතිගත සංස්ථාව යන ආයතනවල සහ ඖෂධ, පාරිභෝජ්‍ය වෛද්‍යමය උපාංග හා ශල්‍ය වෛද්‍ය උපකරණ ප්‍රසම්පාදනයට අදාළව සෞඛ්‍ය අමාත්‍යාංශයේ සහ වෛද්‍ය සැපයීම් අංශයේ කාර්යභාරය වඩාත් කාර්යක්ෂමව හා ඵලදායීව ඉටු කිරීම පිණිස ගත යුතු ක්‍රියාමාර්ග කවරේද යන්න; සහ

(v) ඉහත සඳහන් කරුණුවලට අතිරේකව අමාත්‍ය මණ්ඩලයේ අවධානය යොමු කළ යුතු වෙනත් කරුණු කිසිවක් වේ නම් එම කරුණු කවරේද යන්න."

→ 4

ක්‍රියා කළ යුතු:	**ජනාධිපති ලේකම්** - සංදේශයේ පිටපතක් හා ඉහත නිරීක්ෂණ යා කොට ඇත.
	මූල්‍ය, ආර්ථික ස්ථායීකරණ සහ ජාතික **ප්‍රතිපත්ති අමාත්‍යාංශය**
	සෞඛ්‍ය අමාත්‍යාංශය - ගරු ඇමතිතුමාගේ අවධානයට යොමු කිරීම පිණිස - ඉහත නිරීක්ෂණ යා කොට ඇත.
පිටපත:	**අග්‍රාමාත්‍ය ලේකම්** - සංදේශයේ පිටපතක් හා ඉහත නිරීක්ෂණ යා කොට ඇත.

දුරකථන) 0112669192 , 0112675011
தொலைபேசி) 0112698507 , 0112694033
Telephone) 0112675449 , 0112675280

ෆැක්ස්) 0112693866
பெக்ஸ்) 0112693869
Fax) 0112692913

විද්‍යුත් තැපෑල) postmaster@health.gov.lk
மின்னஞ்சல் முகவரி)
e-mail)

වෙබ් අඩවිය) www.health.gov.lk
இணையத்தளம்)
website)

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

මගේ අංකය)
எனது இல) SM/PSRP/08/IND/CRD/2022 Vol III
My No.)

ඔබේ අංකය)
உமது இல)
Your No.)

දිනය)
திகதி) 01.09.2022
Date)

(133)

ඇමුණුම 28

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
Ministry of Health

Deputy Director General (Medical Supplies Division),
Ministry of Health.

Time line of importing pharmaceuticals under the Indian Credit Line

A meeting was held with the officials of Indian Credit Facility Coordination Unit (ICFCU) of Treasury on the progress of Pharmaceutical Sector under the Indian Credit Line on 01st September 2022, and there, it was clarified that all the **pharmaceuticals imported through the Indian Credit Line should have reached Sri Lanka by 31st January 2023**.

Considering the above,

1. Please take action to change the date of expected delivery of all the items imported under the Indian Credit Line to a date on or before 31st January 2023.

2. Please send any new orders which can be accommodated under the Indian Credit Line (which are to be delivered before 31st January 2023), to State Pharmaceutical Corporation (SPC) to start immediate action on procurement and supply.

Your urgent attention and action on this regard is highly appreciated.

Dr. S.C. Wickramasinghe
Chairman,
Pharmaceutical Sub Committee for Indian Credit Line

12 SEP 2022
Medical Supplies Division Colombo 10

Copies:
1. Secretary, Ministry of Health – *for information please*
2. Director General of Health Services – *for information please*
3. Chairman, State Pharmaceuticals Corporation – *for information and necessary actions please*
4. General Manager, State Pharmaceuticals Corporation – *for information and necessary actions please*
5. Director (Medical Supplies Division) – *for information and necessary actions please*
6. All Assistant Directors of Medical Supplies Division – *for information and necessary actions please*

දූරකථනය) 0112669192 , 0112675041
தொலைபேசி) 0112698507 , 0112694033
Telephone) 0112675449 , 0112675280

ෆැක්ස්) 0112693866
பெக்ஸ்) 0112693869
Fax) 0112692913

විද්‍යුත් තැපෑල) postmaster@health.gov.lk
மின்னஞ்சல் முகவரி)
e-mail)

වෙබ් අඩවිය) www.health.gov.lk
இணையத்தளம்)
website)

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

මගේ අංකය)
எனது இல)
My No.) SM/PSRP/01/MSD/2021

ඔබේ අංකය)
உமது இல)
Your No.)

දිනය)
திகதி) 23. 09. 2022
Date)

ඇමුණුම 29

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
Ministry of Health

Dr D.R.K. Herath
Deputy Director General
Medical Supplies Division

Medical Supplies Division
23 SEP 2022
MEDICAL SUPPLIES DIVISION COLOMBO 10.

Emergency Procurement through Private Suppliers using Indian Credit Line

This is to informed you that it was decided at the meeting chaired by Hon. Minister of Health, procure below one month stock level drugs using Indian credit line through private suppliers.

Therefore, you are requested to place the order to the State Pharmaceutical Corporation (SPC) in sufficient for three months period enabling to procure through emergency procurement method at Ministry of Health. It is further informed that order quantity should be decided without concerning pending orders at the moment due to two months delay in the process of procurement by SPC.

Additional Secretary
(Production, Supply & Regulation of Pharmaceuticals)
Ministry of Health
23 SEP 2022

Dr R.M.S.K. Rathnayake

Additional Secretary (Production, Supply and Regulation of Pharmaceuticals)

Ministry of Health

Cc: Director (MSD)

This is very important & urgent. Pl. Prepare list for below one month Pharmaceutical items. Prepare cover sheet including (SPMC / LM) common all non reviewing items. Pl. Prepare orders to the list & place SPC on today/ separate Pl. maintain file

ඇමුණුම 30

දුරකථන / தொலைபேசி / Telephones } 694113, 694114, 686528-30

විදුලි පණිවුඩ / தந்தி / Telegrams } රජ ඖෂධ මැදිරිය MEDSTORES

ෆැක්ස් / பக்ஸ் / Fax } 941-697096

කේබල් / கடல் வழித்தந்தி / Cables } GOVTDRUG

මගේ අංකය / எனது இல. / My No. } 2022/SPC/V/P/09/2022

ඔබේ අංකය / உமது இல. / Your No. }

වෛද්‍ය සැපයීම් අංශය
(සෞඛ්‍ය සේවා දෙපාර්තමේන්තුව)
வைத்திய விநியோகப்பகுதி
(சுகாதார சேவைத் திணைக்களம்)
MEDICAL SUPPLIES DIVISION
(Department of Health Services)

අංක 357, බද්දේගම වීමලවංශ මාවත, කොළඹ 10, ශ්‍රී ලංකාව.
இல. 357, பத்தேகம விமலவன்ச மாவத்தை, கொழும்பு 10, இலங்கை.
No. 357, Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka.

තැ. පෙ. / P.O.Box } 1679

දිනය/திகதி/Date : 26th September 2022

Chairman
State Pharmaceuticals Corporation

Emergency Procurement through Private Suppliers using Indian Credit Line

Additional Secretary (Production, Supply and Regulation of Pharmaceuticals) has instructed to place the orders with SPC for 03 months requirement for the following below one month stock level drugs without considering the positions of pending orders placed with all sources such as SPC, ADB, AIIB, World Bank in order to procure using Indian Credit Line through private Suppliers.(Copy of the letter is attached herewith)

The following Government order lists are submitted for necessary arrangements please.

	Order List No	SR No	Item Description	Order Qty	Value(Rs.)
1	2022/SPC/V/C/P/00633	00404004	Epoetin Inj. 10,000 IU	12,000	21,129,360.00
2	2022/SPC/V/C/P/00633	00404002	Epoetin Inj. 4000IU PFS	350,000	121,184,000.00
3	2022/SPC/V/C/P/00633	00405301	Human Albumin Sol. 20%, 50mL	100,000	498,070,000.00
4	2022/SPC/V/C/P/00633	00107403	Liposomal Amphotericin B	6,250	155,994,812.50
5	2022/SPC/V/C/P/00633	00402201	Protein Hydrolysate Inj. 100mL	3,000	2,792,400.00
6	2022/SPC/V/C/P/00633	01500701	Sevoflurane 250mL Bot.	2,250	27,312,232.50
7	2022/SPC/V/C/P/00633	00106501	Sodium Stibogluconte Inj.	200	10,306,246.00
8	2022/SPC/V/C/P/00638	00105801	Levofloxacin Tab. 500mg	45,000	321,750.00
9	2022/SPC/V/C/P/00638	00105701	Ofloxacin Tab. 200 mg	60,000	1,240,800.00
10	2022/SPC/V/C/P/00638	00103501	Vancomycin Inj. 500mg Vial	48,000	5,486,400.00
11	2022/SPC/V/C/P/00641	01205401	Cyclosporin Cap. 25mg	100,000	1,510,000.00
12	2022/SPC/V/C/P/00641	01205402	Cyclosporin Cap. 50mg	225,000	4,236,750.00
13	2022/SPC/V/C/P/00641	01500401	Etomidate Inj. 20mg/10mL	875	993,352.50
14	2022/SPC/V/C/P/00641	01204201	Everolimus Tab. 0.25mg	75,000	11,505,000.00
15	2022/SPC/V/C/P/00641	01205601	Tacrolimus Cap. 0.5mg	250,000	2,210,000.00
16	2022/SPC/V/C/P/00641	01205602	Tacrolimus Cap. 1mg	1,125,000	18,967,500.00
17	2022/SPC/V/C/P/00661	00801001	Mesalazine tab. 400mg	45,000	1,450,800.00
18	2022/SPC/V/C/P/00666	00902901	Bimatoprost Ophthalmic Susp.	45,000	9,347,400.00
19	2022/SPC/V/C/P/00667	00903001	Brinzolamide Eye drop 1%, 5mL	20,000	9,151,000.00
20	2022/SPC/V/C/P/00671	00107903	Aciclovir IV Infu. 250mg Vial	66,000	6,923,400.00
21	2022/SPC/V/C/P/00671	00107101	Fluconazole Cap. 50mg	270,000	1,733,400.00
22	2022/SPC/V/C/P/00671	00107102	Fluconazole Inj. 200mg in	10,500	740,145.00

342

	Order List No	SR No	Item Description	Order Qty	Value(Rs.)
23	2022/SPC/V/C/P/00676	00102102	Meropenem Inj. 1g Vial	450,000	268,168,500.00
24	2022/SPC/V/C/P/00685	00403501	Hydroxocobalamine Inj. 1mg/1mL	35,000	14,218,050.00
25	2022/SPC/V/C/P/00686	00407201	Total Parenteral Nutrition in	6,250	44,920,812.50
26	2022/SPC/V/C/P/00688	00205701	Alteplase 20mg Vial	225	24,571,631.25
27	2022/SPC/V/C/P/00693	01208501	Abiraterone Acetate Tab.	68,750	19,583,437.50
28	2022/SPC/V/C/P/00693	01201703	Cytarabine Inj.	1,500	5,547,015.00
29	2022/SPC/V/C/P/00693	01210101	Mesna Inj. 200mg	7,500	3,906,225.00
30	2022/SPC/V/C/P/00694	00103203	Clindamycin Inj. 300mg/2mL Amp	375,000	66,990,000.00
31	2022/SPC/V/C/P/00695	00301101	Flupenthixol Inj 40mg/2mL Amp.	11,250	5,006,812.50
32	2022/SPC/V/C/P/00695	00304401	Lamotrigine Tab 25mg	600,000	3,108,000.00
33	2022/SPC/V/C/P/00695	00306701	Quetiapine Tab. 25mg	600,000	2,106,000.00
34	2022/SPC/V/C/P/00695	00303403	Tramadol HCl Inj. 100mg/2mL	25,000	368,000.00
35	2022/SPC/V/R/P/00632	01200801	Bleomycin sulphate for Inj.	625	1,950,000.00
36	2022/SPC/V/R/P/00632	01201601	Capecitabine Tab. 500mg	250,000	11,350,000.00
37	2022/SPC/V/R/P/00632	01200201	Chlorambucil Tab. 2mg	7,500	2,577,375.00
38	2022/SPC/V/R/P/00632	01201001	Daunorubicin HCl for Inj. 20mg	1,500	1,450,470.00
39	2022/SPC/V/R/P/00632	01201103	Doxorubicin HCl	4,500	3,697,200.00
40	2022/SPC/V/R/P/00632	01202701	Etoposide Cap.100mg	1,200	607,884.00
41	2022/SPC/V/R/P/00632	01202702	Etoposide Inj. 100mg Vial	3,000	2,371,200.00
42	2022/SPC/V/R/P/00632	01202002	Gemcitabine Inj. 1g Vial	4,000	2,889,600.00
43	2022/SPC/V/R/P/00632	01200401	Ifosfamide1g Vial+Mesna 100mg	2,500	4,333,775.00
44	2022/SPC/V/R/P/00632	01202803	Lecucovorin Cal. Inj.	13,750	4,576,000.00
45	2022/SPC/V/R/P/00632	01202204	Methotrexate Inj. 1g/10mL Vial	2,100	5,654,229.00
46	2022/SPC/V/R/P/00632	01202201	Methotrexate Tab. 2.5mg	1,875,000	3,843,750.00
47	2022/SPC/V/R/P/00632	01202501	Vinblastine Sulphate Inj.	500	553,150.00
48	2022/SPC/V/R/P/00632	01202401	Vincristine Sulphate Inj.	5,750	1,871,970.00
49	2022/SPC/V/R/P/00634	00200701	Amiodarone Tab. 100mg	500,000	3,170,000.00
50	2022/SPC/V/R/P/00634	00205404	Aspirin Enteric-coated Tab75mg	65,000,000	46,800,000.00
51	2022/SPC/V/R/P/00634	00200102	Digoxin Inj. 500 mcg/2mL Amp.	1,200	562,980.00
52	2022/SPC/V/R/P/00634	00203901	Dobutamine Inj. 250mg/20mL	37,500	15,296,625.00
53	2022/SPC/V/R/P/00634	00204701	Enoxaparin Inj. 4000IU/0.4mL	200,000	144,902,000.00
54	2022/SPC/V/R/P/00634	00204702	Enoxaparin Inj.6000IU/0.6mL	250,000	220,287,500.00
55	2022/SPC/V/R/P/00634	00204201	Ephedrine Inj. 30mg/1mL Amp.	45,000	31,226,400.00
56	2022/SPC/V/R/P/00634	00200302	Furosemide (Frusemide) Inj.	625,000	5,481,250.00
57	2022/SPC/V/R/P/00634	00203002	Glyceryl Trinitrate	11,500	12,576,055.00
58	2022/SPC/V/R/P/00634	00203001	Glyceryl Trinitrate Tab 0.5mg	4,500,000	6,930,000.00
59	2022/SPC/V/R/P/00634	00200501	Mannitol IV Infu. 20%, 250mL	25,000	3,575,500.00
60	2022/SPC/V/R/P/00634	00205903	Tranexamic acid Inj. 500mg/5mL	120,000	4,078,800.00
61	2022/SPC/V/R/P/00634	00205902	Tranexamic Acid Tab/Cap 500mg	450,000	5,620,500.00
62	2022/SPC/V/R/P/00635	00000801	Morphine Tab. 10mg	210,000	15,380,400.00
63	2022/SPC/V/R/P/00635	00001102	Pethidine HCl Inj.	45,000	34,987,950.00
64	2022/SPC/V/R/P/00636	00400701	Potassium Chloride (ER) Tab.	2,500,000	4,375,000.00
65	2022/SPC/V/R/P/00637	00107901	Aciclovir Tab. 200mg	525,000	1,953,000.00
66	2022/SPC/V/R/P/00637	00102301	Doxycycline Cap. 100mg	1,500,000	6,420,000.00
67	2022/SPC/V/R/P/00640	00703502	Alendronate Sodiu. Tab. 70mg	137,500	895,125.00
68	2022/SPC/V/R/P/00640	01205201	Azathioprine Tab. 50mg	625,000	2,481,250.00
69	2022/SPC/V/R/P/00640	01502003	Bupivacaine 0.5%+Glucose 8%	68,750	14,443,000.00
70	2022/SPC/V/R/P/00640	01502001	Bupivacaine Inj. 0.5%/ 10mL	45,000	21,902,400.00

	Order List No	SR No	Item Description	Order Qty	Value(Rs.)
71	2022/SPC/V/R/P/00640	00701602	Dexamethasone Inj. 8mg/2mL	250,000	3,327,500.00
72	2022/SPC/V/R/P/00640	00701401	Fludrocortisone Tab. 0.1mg	50,000	3,732,500.00
73	2022/SPC/V/R/P/00640	00701502	Hydrocortisone Tab. 10mg	375,000	7,635,000.00
74	2022/SPC/V/R/P/00640	00702401	Hydroxyprogesterone Inj.	5,000	1,852,750.00
75	2022/SPC/V/R/P/00640	01500202	Ketamine HCl Inj. 500mg/10mL	1,500	9,043,995.00
76	2022/SPC/V/R/P/00640	01502201	Lidocaine 2% + Adrenalin	45,000	3,249,900.00
77	2022/SPC/V/R/P/00640	01502105	Lidocaine HCl Gel 2%,	62,500	3,873,750.00
78	2022/SPC/V/R/P/00640	01302001	Oxybutynine Tab. 2.5mg	62,500	605,625.00
79	2022/SPC/V/R/P/00640	00701301	Propylthiouracil Tab. 50mg	62,500	1,100,000.00
80	2022/SPC/V/R/P/00640	01301502	Tamsulosin Cap. 0.4 mg	1,500,000	9,810,000.00
81	2022/SPC/V/R/P/00642	00500104	Salbutamol Inj. 5mg/5mL	1,500	4,001,400.00
82	2022/SPC/V/R/P/00643	00107401	Amphotericin Inj. 50mg Vial	625	1,810,925.00
83	2022/SPC/V/R/P/00643	00602801	Anti D(Rho)Immunoglobulin	3,750	33,247,500.00
84	2022/SPC/V/R/P/00643	00602501	Anti Rabies Human	1,250	13,742,625.00
85	2022/SPC/V/R/P/00643	01501101	Atracurium Besylate Inj.	250,000	21,350,000.00
86	2022/SPC/V/R/P/00643	00700601	Biphasic Isophane Insulin	450,000	164,124,000.00
87	2022/SPC/V/R/P/00643	00404801	Desferrioxamine Inj. 500mg	112,500	99,805,500.00
88	2022/SPC/V/R/P/00643	01300102	Ergometrine Inj. 500mcg/1mL	8,750	4,595,500.00
89	2022/SPC/V/R/P/00643	00204601	Heparin Inj. 25,000 I.U/5mL	75,000	54,930,750.00
90	2022/SPC/V/R/P/00643	00603201	Human Immunoglobulin IV	5,000	38,519,800.00
91	2022/SPC/V/R/P/00643	00603205	Human Immunoglobulin IV	22,500	676,274,625.00
92	2022/SPC/V/R/P/00643	00603202	Human Immunoglobulin IV	5,500	149,033,280.00
93	2022/SPC/V/R/P/00643	00700701	Insulin	12,500	4,325,625.00
94	2022/SPC/V/R/P/00643	00700801	Insulin Soluble (Human) Inj.	30,000	11,727,300.00
95	2022/SPC/V/R/P/00643	01502104	Lidocaine Topical aerosol	1,000	2,296,320.00
96	2022/SPC/V/R/P/00643	00205201	Protamine Sulphate Inj.	2,000	592,880.00
97	2022/SPC/V/R/P/00643	00402202	Protein Hydrolysate Inj.	2,500	2,371,675.00
98	2022/SPC/V/R/P/00643	00703001	Tetracosactrin Inj.	500	8,923,605.00
99	2022/SPC/V/R/P/00643	00703401	Vasopressin Inj. 20 I.U. in	5,500	12,337,380.00
100	2022/SPC/V/R/P/00644	00500801	Budesonide Respiratory Susp.	25,500	2,170,815.00
101	2022/SPC/V/R/P/00645	00501502	Adrenaline/Epinephrin Inj.	210,000	5,082,000.00
102	2022/SPC/V/R/P/00646	00500204	Fluticasone+Salmeterol MDI	7,500	2,314,800.00
103	2022/SPC/V/R/P/00647	00900201	Fusidic acid Eye Drop 1%(S.R.)	37,500	9,404,625.00
104	2022/SPC/V/R/P/00648	00500205	Fluticasone+Salmeterol MDI	225,000	73,919,250.00
105	2022/SPC/V/R/P/00649	00500403	Ipratropium Bromide	30,000	4,012,800.00
106	2022/SPC/V/R/P/00650	00800502	Metoclopramide Inj.10mg/2mL	450,000	4,396,500.00
107	2022/SPC/V/R/P/00651	00902201	Hydroxypropylmethyl Cellulose	18,750	4,779,375.00
108	2022/SPC/V/R/P/00652	00800803	Omeprazole Sodium Inj. 40mg	300,000	8,088,000.00
109	2022/SPC/V/R/P/00653	00902101	Fluorescein Sodium Inj.	750	312,000.00
110	2022/SPC/V/R/P/00654	00801201	Bisacodyl Tab. 5mg	750,000	375,000.00
111	2022/SPC/V/R/P/00655	00904101	Moxifloxacin HCl ophthalmic	35,000	1,715,350.00
112	2022/SPC/V/R/P/00656	00801401	Iso-Os.bowel clens.prep.	36,000	13,431,600.00
113	2022/SPC/V/R/P/00657	00904302	Tobramycin 0.3% +Dexamethasone	2,000	200,000.00
114	2022/SPC/V/R/P/00658	00802601	Sodium Biphosphate 1.6g+Sodium	25,500	5,266,005.00
115	2022/SPC/V/R/P/00659	01401001	Allopurinol Tab. 100mg	900,000	2,142,000.00
116	2022/SPC/V/R/P/00662	01102201	Silversulphadiazine Cream	5,000	3,039,400.00
117	2022/SPC/V/R/P/00663	01103101	Selenium Sulphide Lotion	7,500	3,315,600.00
118	2022/SPC/V/R/P/00664	00903201	Nepafenac Ophthalmic Susp.	11,250	11,250,000.00

	Order List No	SR No	Item Description	Order Qty	Value(Rs.)
119	2022/SPC/V/R/P/00665	00904901	Natamycin Ophthalmic	5,000	1,752,400.00
120	2022/SPC/V/R/P/00668	00901401	Tropicamide Eye Drops 1%,	1,250	96,075.00
121	2022/SPC/V/R/P/00669	00901302	Cyclopentolate Eye drop 1%,	1,250	357,500.00
122	2022/SPC/V/R/P/00670	00901001	Prednisolone Acetate Eye drop	42,500	1,790,100.00
123	2022/SPC/V/R/P/00672	00101502	Cefotaxime for Inj. 1g Vial	250,000	16,190,000.00
124	2022/SPC/V/R/P/00672	00101704	Ceftriaxone for Inj. 1g Vial	437,500	17,801,875.00
125	2022/SPC/V/R/P/00672	00101403	Cefuroxime Tab. 500mg	1,125,000	40,286,250.00
126	2022/SPC/V/R/P/00673	00101602	Ceftazidime for Inj. 1g Vial	70,000	7,697,200.00
127	2022/SPC/V/R/P/00674	00401202	Sodium Chloride 0.45% &	20,000	1,677,200.00
128	2022/SPC/V/R/P/00677	00401903	Magnesium Sulphate Inj. 50%	22,500	4,026,600.00
129	2022/SPC/V/R/P/00678	00402801	Pyridoxine Tab. 10mg	72,000	2,516,400.00
130	2022/SPC/V/R/P/00679	00402802	Pyridoxine Tab. 25mg	500,000	965,000.00
131	2022/SPC/V/R/P/00680	00403001	Calcitriol Cap. 250ng	2,000,000	5,500,000.00
132	2022/SPC/V/R/P/00681	00403101	Alfacalcidol Cap. 0.25mcg	8,250,000	28,380,000.00
133	2022/SPC/V/R/P/00682	00403202	Phytomenadione Inj.	75,000	8,865,750.00
134	2022/SPC/V/R/P/00683	00406702	Cholecalciferol	600,000	11,574,000.00
135	2022/SPC/V/R/P/00687	00404901	Disposable, IV giving sets	2,100,000	76,251,000.00
136	2022/SPC/V/R/P/00689	00902001	Balanced Salt, Solu. 500mL	8,750	4,622,800.00
137	2022/SPC/V/R/P/00690	01206701	Anastrozole Tab. 1mg	500,000	4,660,000.00
138	2022/SPC/V/R/P/00690	01203201	Asparaginase Inj.	300	2,121,600.00
139	2022/SPC/V/R/P/00690	01207001	Bicalutamide Tab. 50mg	82,500	2,852,025.00
140	2022/SPC/V/R/P/00690	01203602	Carboplatin Inj. 450mg/45mL	4,750	14,743,572.50
141	2022/SPC/V/R/P/00690	01203702	Cisplatin Inj. 50mg/50mL Vial	5,500	3,551,515.00
142	2022/SPC/V/R/P/00690	01203301	Dacarbazine Inj. 200mg	1,500	1,794,000.00
143	2022/SPC/V/R/P/00690	01204802	Docetaxel Inj. 80mg/2mL Vial	4,000	3,531,360.00
144	2022/SPC/V/R/P/00690	01207901	Exemestane Tab. 25mg	15,500	558,000.00
145	2022/SPC/V/R/P/00690	01204403	Imatinib mesilate	62,500	7,312,500.00
146	2022/SPC/V/R/P/00690	01204401	Imatinib Mesilate Tab/Cap	137,500	52,240,375.00
147	2022/SPC/V/R/P/00690	01205002	Irinotecan Inj. 100mg/5mL Vial	1,500	2,201,265.00
148	2022/SPC/V/R/P/00690	01206301	Lenalidomide Cap. 5mg	22,500	2,508,750.00
149	2022/SPC/V/R/P/00690	01206901	Letrozole Tab. 2.5mg	37,500	261,375.00
150	2022/SPC/V/R/P/00690	01207402	Octreotide Inj. 50mcg in	20,000	12,966,000.00
151	2022/SPC/V/R/P/00690	01203803	Oxaliplatin Inj. 100mg in 20mL	4,000	4,758,400.00
152	2022/SPC/V/R/P/00690	01204904	Paclitaxel Inj.	2,250	5,452,807.50
153	2022/SPC/V/R/P/00690	01204901	Paclitaxel Inj. 30mg/5mL	25,000	8,563,000.00
154	2022/SPC/V/R/P/00690	01203901	Procarbazine Cap. 50mg	600	228,858.00
155	2022/SPC/V/R/P/00690	01205701	Rituximab Inj.	1,750	9,641,765.00
156	2022/SPC/V/R/P/00690	01205702	Rituximab Inj.	2,250	48,583,552.50
157	2022/SPC/V/R/P/00690	01206802	Tamoxifen Tab. 20mg	450,000	2,128,500.00
158	2022/SPC/V/R/P/00690	01203402	Temozolomide Cap. 250mg	1,200	221,412.00
159	2022/SPC/V/R/P/00690	01206401	Thalidomide Cap. 100mg	42,500	1,237,600.00
160	2022/SPC/V/R/P/00691	00305201	Benztropine Inj. 2mg/2mL Amp.	450	5,148,000.00
161	2022/SPC/V/R/P/00691	00304202	Clobazam Tab.10mg	1,250,000	3,275,000.00
162	2022/SPC/V/R/P/00691	00302402	Clomipramine HCl Tab. 25mg	500,000	3,080,000.00
163	2022/SPC/V/R/P/00691	00305001	Co-careldopa Tab. 25mg/100mg	187,500	4,636,875.00
164	2022/SPC/V/R/P/00691	00305002	Co-Careldopa Tab. 25mg/250mg	1,400,000	18,438,000.00
165	2022/SPC/V/R/P/00691	00300104	Diazepam Rectal Sol.	1,000	747,860.00
166	2022/SPC/V/R/P/00691	00300803	Haloperidol Inj. 5mg/1mL Amp.	15,000	265,800.00
167	2022/SPC/V/R/P/00691	00302101	Lithium Carbonate Tab. 250mg	1,750,000	4,952,500.00

	Order List No	SR No	Item Description	Order Qty	Value(Rs.)
168	2022/SPC/V/R/P/00691	00300602	Methylphenidate HCl Tab 10mg	500,000	5,395,000.00
169	2022/SPC/V/R/P/00691	00301902	Olanzapine Tab.10mg	4,000,000	3,720,000.00
170	2022/SPC/V/R/P/00691	00303103	Ondansetron Inj. 8mg/4mL	225,000	2,799,000.00
171	2022/SPC/V/R/P/00691	00303604	Phenobarbital Inj. 200mg/1mL	4,500	1,487,565.00
172	2022/SPC/V/R/P/00691	00303704	Phenytoin Inj. 250mg/5mL Amp.	12,000	58,063,320.00
173	2022/SPC/V/R/P/00691	00303703	Phenytoin Sodium Tab. 100 mg	3,000,000	5,760,000.00
174	2022/SPC/V/R/P/00691	00302001	Risperidone Tab.2mg	6,250,000	10,375,000.00
175	2022/SPC/V/R/P/00691	00302801	Sertraline Tab. 50mg	2,500,000	9,175,000.00
176	2022/SPC/V/R/P/00691	00304001	Sodium Valproate Tab. 100mg	3,000,000	8,280,000.00
177	2022/SPC/V/R/P/00691	00304002	Sodium Valproate Tab. 200mg	17,500,000	36,925,000.00
178	2022/SPC/V/R/P/00691	00302901	Venlafaxine HCl Cap. (ER)	700,000	3,024,000.00
179	2022/SPC/V/R/P/00691	00302902	Venlafaxine HCl Cap. (ER) 75mg	1,625,000	8,791,250.00
180	2022/SPC/V/R/P/00696	01200901	Dactinomycin for Injection	375	1,117,350.00
181	2022/SPC/V/R/P/00697	00201901	Sildenafil Tab. 50mg	375,000	5,973,750.00
182	2022/SPC/V/R/P/00699	00800404	Domperidone Suppository 30mg	3,750	579,600.00
			Total		**4,150,108,652.75**

The "conditions of supply" applicable for the emergency orders are attached herewith.

CONDITIONS OF SUPPLY

1. **The product should have minimum of 12 months shelf life at the time of delivery at Medical Supplies Division or if deviated, prior approval should be obtain from Director, Medical Supplies Division.**

2. To be supplied as per the delivery schedule indicated in the order list.

3. Description of Item, Date of Manufacture, Date of expiry, Batch No, Name and address of manufacturer should be clearly marked on the outer covering containing the item and on the outer cover of the carton/box.

4. Offers for any other economically viable pack sizes different from the specified pack sizes are acceptable with the prior approval of Director, Medical Supplies Division.

5. MSD Order List No, SPC indent No/Purchase order No, SR No, Description and storage condition of Item shall be indicated in all Supply Invoices.

6. Storage condition of the items should be clearly indicated in the inner most and outer most carton labels.

7. Cold chain should be maintained according to the manufacturer's instructions during storage, transport and delivery.

8. Delivery of the items is to be made to Medical Supplies Division warehouses at above address free of charge.

9. **Withdrawal from use of items due to quality failures:**

   a). In case of batch withdrawal due to quality failure, the supplier/manufacturer shall reimburse the value of entire batch quantity supplied.

338

Y	Y	12905008	Cranioplasty Mesh, 20cm x 20cm8FG,Ti, with screws.
Y	Y	12905008	Cranioplasty Mesh, 20cm x 20cm8FG,Ti, with screws.
Y	Y	12905101	Mesh bender (reconstruction Mesh bender)
Y	Y	12906001	System includ. 4-6mmCervical Interbody cages.

b). In case of product withdrawal due to quality failure, the supplier /manufacturer shall reimburse the value of entire product quantity supplied.

c). In the event of either **a)** or **b)** above the supplier/manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

10. Standards - Any other Pharmaceutical Standard accepted by Cosmetics, Devices and Drugs Regulatory Authority in Sri Lanka for registration of a pharmaceutical item is also acceptable.

11. In the event that item is awarded to unregistered bidder, the NOL/PUL issued by NMRA should be submitted when item is delivered. If not, payment will not be released for the delivered item.

12. In the event of failing to supply the item within the delivery schedule given the SPC indent/purchase order the items will not be accepted. However, if the item is still required by Medical Supplies Division and decides to accept the same, a penalty of 0.1% of the total value per day up to 7 days(total of 0.7% for 1st 7days of late delivery), 0.3% per total value per day from 8th to 14th (another 2.1% for 7 days from from 8th to 14th day of late delivery),0.5% per total value per day from 15th to 21st day(another 3.5% for the period from 15th to 21st day of late delivery) for the lapsed period will be deducted from your payment as liquidated damage.

In case of an item delivered after 3 weeks, if the item is still required MSD reserves the right to accept maximum penalty of 10-% of the total value will be imposed.

13. In addition to the condition given herein any other relevant conditions as per the tender document issued by SPC are also applicable.

Thank you

Yours faithfully

Dr. D. R. K. HERATH
Deputy Director General (Medical Supplies)
Medical Supplies Division
Ministry of Health Nutrition & Indigenous Medicine
Colombo 10.

Deputy Director General (Med. Supp.)
Medical Supplies Division

Cc

1. Secretary-Ministry of Health - f.i.
2. DGHS - f.i.
3. Additional Secretary (Production, Supply and Regulation of Pharmaceuticals)- f.i.

தலைமை தொலைபேசி
Telephone
011 2669192, 011 26750
011 2698507, 011 269403
011 2675449, 011 267528

ෆැක්ස්
தொலைநகல்
Fax
011 2693866
011 2693869
011 2692913

විද්‍යුත් තැපෑල
மின்னஞ்சல்
e-mail
postmaster@health.gov.lk

වෙබ් අඩවිය
இணையத்தளம்
Website
www.health.gov.lk

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

මගේ අංකය
எனது இல.
My No.
HH/AD/01/04/41/2022

ඔබේ අංකය
உமது இல.
Your No.
ඇමුණුම 31

දිනය
திகதி
Date
2022-09-26

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
MINISTRY OF HEALTH

අමාත්‍ය මණ්ඩල සංදේශය

ශ්‍රී ලංකාව තුළ අබණ්ඩ වෛද්‍ය සැපයීම් සේවාවක් පවත්වාගෙන යාම.

1. පසුබිම

1.1 සෞඛ්‍ය අමාත්‍යාංශය සහ එහි ආයතන එනම් වෛද්‍ය සැපයුම් අංශය, ශ්‍රී ලංකා රාජ්‍ය ඖෂධ නිෂ්පාදන සංස්ථාව, ශ්‍රී ලංකා රාජ්‍ය ඖෂධ නිතීගත සංස්ථාව හා ජාතික ඖෂධ නියාමන අධිකාරිය මඟින් ඖෂධ හා පරිභෝජ්‍ය ද්‍රව්‍ය ප්‍රසම්පාදනය, සෞඛ්‍ය අංශ සඳහා බෙදාහැරීම සහ නියාමනය සම්බන්ධයෙන් සම්පූර්ණයෙන්ම වගකීම දරණ අතර රෝගීන් වෙත ලබා දීම දක්වා ගුණාත්මක බව හා සැපයීම අධීක්ෂණය කරනු ලබයි.

1.2 ශ්‍රී ලංකාවේ සෞඛ්‍ය සේවා ආයතන සඳහා අවශ්‍ය ඖෂධ, ශල්‍ය ද්‍රව්‍ය, රසායනාගාර ද්‍රව්‍ය, විකිරණ ද්‍රව්‍ය සහ පරිභෝජ්‍ය ද්‍රව්‍ය සැපයීම සඳහා ශ්‍රී ලංකා රජය වාර්ෂිකව රු. බිලියන 65 ක් පමණ වැය කරනු ලැබේ. පවතින විදේශ විනිමය අර්බුදය හමුවේ වෛද්‍ය සැපයුම් ජාලය ඇඩි බලපෑමකට ලක් වී ඇති අතර වෛද්‍ය සැපයීම් හිඟය වර්ධනය වෙමින් පවතී.

1.3 සෞඛ්‍ය අමාත්‍යාංශය විසින් වෛද්‍ය සැපයුම් ලබා ගැනීම සඳහා ඉන්දියානු ණය යෝජනා ක්‍රමය, ආසියානු සංවර්ධන බැංකුව, ලෝක බැංකුව සහ ආසියානු යටිතල පහසුකම් ආයෝජන බැංකුව යන ආයතන මඟින් ලබාදෙන ණය ආධාර උපයෝගී කරගෙන ඇති අතර අවශ්‍ය වෛද්‍ය සැපයීම් තවදුරටත් ලබා ගැනීම සඳහා බහුවිධ ණය යෝජනා ක්‍රම සහ ණය සපයන ආයතන සම්බන්ධ කරගනිමින් ගත හැකි සියලු ක්‍රියාමාර්ග මේ වනවිට ගෙන ඇත.

2. විස්තරය හා සාධාරණීකරණය

2.1 වෛද්‍ය සැපයුම් සඳහා රජයේ ප්‍රධාන ප්‍රසම්පාදන නියෝජිතයා වශයෙන් රාජ්‍ය ඖෂධ නිතිගත සංස්ථාවයි. රාජ්‍ය ඖෂධ නිතිගත සංස්ථාවේ වෛද්‍ය සැපයීම් ප්‍රසම්පාදන ක්‍රියාවලියට අදාළ පරිපාලනමය ක්‍රියාවලිය හරහා වෛද්‍ය සැපයීම් ආනයනය කිරීම සඳහා සැලකිය යුතු කාලයක් ගතවේ.

සුවසිරිපාය, පූජ්‍ය බද්දේගම විමලවංශ හිමි මාවත, කොළඹ 10, ශ්‍රී ලංකාව. 385, சுவசிரிபாய, வணக்கத்துக்குரிய பத்தேகம விமலவங்ச தேரோ மாவத்தை, கொழும்பு 10, இலங்கை.

2.2 වර්තමානයේ වෛද්‍ය සැපයීම් අංශය තුල පවත්නා වෛද්‍ය සැපයීම්වල තොග මට්ටම ඉතා අවම මට්ටමක පවතී. මේ එනවිට වෛද්‍ය සැපයීම් අංශය තුල ඖෂධ වර්ග 182, ශල්‍ය ද්‍රව්‍ය සහ පරිභෝජ්‍ය උපකරණ 4739ක්, විකිරණශීලී අයිතම 15ක් සහ අත්‍යාවශ්‍ය රසායනාගාර අයිතම 582ක් මසක අවශ්‍යතාවයට වඩා අඩු මට්ටමක පවතී. එසේම ඉදිරි මාස තුන ඇතුලත තවත් බොහෝ අයිතම වල තොග මට්ටම ශුන්‍ය වනු ඇත. තවද, ඖෂධ වර්ග 17ක් සහ ශල්‍ය ද්‍රව්‍ය සහ පරිභෝජ්‍ය ද්‍රව්‍ය 3791 ක ආයතනික තොග මට්ටම් ද දැනටමත් ශුන්‍ය වී ඇත. මේ නිසා ඉදිරි සති 3 තුල දිවයිනේ සෞඛ්‍ය සේවා ආයතනවල දැඩි වෛද්‍ය සැපයුම් හිඟයක් ඇතිවීමේ තර්ජනයක් මතුව තිබේ.(සවිස්තරාත්මක වාර්තාව : ඇමුණුම අංක 01)

2.3 වත්මන් විදේශ විනිමය අර්බුදය තුල අවශ්‍ය වෛද්‍ය සැපයුම් මිලදී ගැනීම සඳහා සෞඛ්‍ය අමාත්‍යාංශය විසින් මූලික අරමුදල් මාර්ගය ලෙස ඉන්දියානු ණය යෝජනා ක්‍රමය භාවිතා කර ඇත. වෛද්‍ය සැපයීම් ආනයනය කිරීමට රාජ්‍ය ඖෂධ නීතිගත සංස්ථාව වෙත වෙන්කරන ලද ඇමෙරිකානු ඩොලර් මිලියන 94.99 න් මේ වන විට භාවිත කර ඇත්තේ ඇමෙරිකානු ඩොලර් මිලියන 48.6ක් පමණි. (2022 සැප්තැම්බර් 23 වන විට ඉන්දියානු ණය යෝජනා ක්‍රමයේ උපයෝජනයේ සවිස්තරාත්මක වාර්තාව - ඇමුණුම් අංක 02)

2.4 මුදල්, ආර්ථික ස්ථායිකරණ හා ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය මගින් (අංක MF/ICFU/HEALTH/MISC දරණ 2022.09.02 දිනැති ලිපිය - ඇමුණුම අංක 03) ඉන්දීය ණය අරමුදල මෙම වසර අවසානයේදී අවලංගු වන බව දන්වා ඇති අතර ඒ හේතුවෙන් 2022 දෙසැම්බර් මස 31 දිනට ප්‍රථමයෙන් එය උපයෝජනය කළ යුතුව ඇත. මුදල් අමාත්‍යාංශයේ ඉන්දීය ණය පහසුකම් සම්බන්ධීකරණ අංශය (ICFC) සහ ඉන්දීය මහ කොමසාරිස් කාර්යාලයෙහි පවත්නා පරිපාලනමය හා අනුමැතිය ලබාගැනීමේ ක්‍රියාවලිය සඳහා ගතවන කාලය සැලකිල්ලට ගෙන මුදල්, ආර්ථික ස්ථායිකරණ හා ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය දැඩිව උපදෙස් ලබා දී ඇත්තේ ප්‍රසම්පාදන ක්‍රියාවලිය 2022 සැප්තැම්බර් 30 වනවිට නිම් කිරීමටය. ඉන්දීය ණය අරමුදලේ පවත්නා ඌණ උපයෝජන තත්ත්වය මුදල්, ආර්ථික ස්ථායිකරණ හා ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය මගින් ඉස්මතු කර ඇති අතර ඖෂධ සඳහා දැනට ඉන්දීය ණය යෝජනා ක්‍රමයෙන් වෙන් කර ඇති මුදල් 2022 ණය අරමුදල අවලංගු වීමට පෙර පෞද්ගලික අංශයේ නියෝජිතවරුන්ට ඖෂධ ආනයනය කිරීමට යොදවන ලෙස උපදෙස් දී ඇත.

2.5 රාජ්‍ය ඖෂධ නීතිගත සංස්ථාව මඟින් සාමාන්‍ය පරිදි සිදුකරන වෛද්‍ය සැපයීම් වල ප්‍රසම්පාදන කටයුතු හරහා ඖෂධ හා උපාංග ලැබෙනුයේ මාස තුනක් වැනි දීර්ඝ කාලයකට පසුවය.

2.6 පවත්නා විනිමය අර්බුදය පෞද්ගලික සෞඛ්‍ය සේවා වලටද අහිතකර ලෙස බලපා ඇති අතර ඒ හේතුවෙන් ඖෂධ හිඟයක් මෙන්ම ඖෂධ වල මිල ගණන්ද සැලකිය යුතු ලෙස ඉහළ ගොස් ඇත.

2.7 වෛද්‍ය සැපයීම් වල පවත්නා හිඟය සමාජීය, දේශපාලන හා මානුෂිය අර්බුධයක් බවට පත් වීමට ඉඩ ඇත.

3. යෝජිත විසඳුම්

3.1 වෛද්‍ය සැපයුම් අංශයේ අවශ්‍යතාවය සහ හදිසි තත්ත්වය මත පදනම්ව ඉන්දියානු ණය යෝජනා ක්‍රමය යටතේ ඉතිරි අරමුදල් භාවිතා කරමින් හදිසි ප්‍රසම්පාදන ලෙස ඖෂධ නියාමන අධිකාරියේ අනුමැතිය යටතේ වෛද්‍ය සැපයුම් ආනයනය කිරීමට පුද්ගලික අංශයේ ආනයනික නියෝජිතයින්ට අවසර ලබාදීම.

3.2 ඉන්දියානු ණය යෝජනා ක්‍රමය භාවිතා කර ඖෂධ ආනයනය කරන පුද්ගලික අංශයේ නියෝජිතයින්ගෙන් මාස 03 කට ප්‍රමාණවත් වෛද්‍ය සැපයුම් තොග මිලදී ගැනීම.

3.3 ඖෂධ නියාමන අධිකාරියේ ලියාපදිංචි නොමැති අයිතම අර්බුධකාරී තත්ත්වය හමුවේ ආනයනය කිරීම ප්‍රමාදවීම් අවම කිරීම සඳහා ආනයනය කිරීමට පෙර නිසි ලෙස ලියාපදිංචිය නිදහස් කිරීමේ ක්‍රියාවලියකට යටත් විය යුතුය. (Waiver of Registration)

3.4 වෛද්‍ය සැපයුම් සඳහා සෞඛ්‍ය අමාත්‍යාංශයේ මිල කමිටුව විසින් භාවිතා කරනු ලබන මිල තීරණය කිරීමේ පවතින ක්‍රමවේදයම භාවිතා කිරීම.

4. අපේක්ෂිත අනුමැතිය

රජයේ සෞඛ්‍ය ආයතන වල පවත්නා උග්‍ර වෛද්‍ය සැපයීම් හිඟය මග හරවා ගනිමින් අඛන්ඩ වෛද්‍ය සැපයුම් සේවාවක් පවත්වා ගැනීමට සෞඛ්‍ය අමාත්‍යාංශය පහත යෝජනා සඳහා අමාත්‍ය මණ්ඩල අනුමැතිය අපේක්ෂා කෙරේ.

4.1 වෛද්‍ය සැපයුම් අංශයේ හදිසි අවශ්‍යතාවය මත පදනම්ව ඉන්දියානු ණය ආධාර ක්‍රමය යටතේ ඉතිරි අරමුදල් භාවිතා කරමින් හදිසි ප්‍රසම්පාදන ලෙස ඖෂධ නියාමන අධිකාරියේ අනුමැතිය යටතේ වෛද්‍ය සැපයුම් ආනයනය කිරීමට පුද්ගලික අංශයේ ආනයනික නියෝජිතයින්ට අවසර ලබාදීම.

4.2 සෞඛ්‍ය අමාත්‍යාංශයේ මිල කමිටුව විසින් තීරණය කර ඇති පවත්නා මිලදී ගැනීමේ යාන්ත්‍රණයට යටත්ව ඉන්දීය ණය යෝජනා අරමුදල භාවිත කරමින් වෛද්‍ය සැපයීම් ආනයනය කරනු ලබන පෞද්ගලික ආනයන නියෝජිතයින්ගෙන් මාස තුනකට ප්‍රමාණවත් වෛද්‍ය සැපයීම් තොග මිලදී ගැනීමට වෛද්‍ය සැපයීම් අංශයට අනුමැතිය ලබා දීම.

ආ/කළේ:-
ආචාර්ය කෙහෙලිය රඹුක්වැල්ල
සෞඛ්‍ය අමාත්‍ය
ආචාර්ය කෙහෙළිය රඹුක්වැල්ල
සෞඛ්‍ය අමාත්‍ය

2022 සැප්තැම්බර් මස 26 දින දී ය.

ඇමුණුම 32

/10 2022 8:51 AM FAX

කාර්යාලය
அலுவலகம்
Office
2422438,

ෆැක්ස් අංක
ෆැක්සලෙනකල් ඉල.
Fax Nos.
2323730
2389150
2389151

වෙබ් අඩවිය
இணையத்தளம்
Web Site
www.cabinetoffice.gov.lk

ඊ-මේල්
மின்னஞ்சல்
E-mail
info@cabinetoffice.gov.lk

අමාත්‍ය මණ්ඩල කාර්යාලය
அமைச்சரவை அலுவலகம்
OFFICE OF THE CABINET OF MINISTERS

ලොයිඩ්ස් ගොඩනැගිල්ල, ශ්‍රීමත් බැරොන් ජයතිලක මාවත, කොළඹ 01.
லொயிட்ஸ் கட்டடம், சேர் பாரோன் ஜயதிலக்க மாவத்தை, கொழும்பு 01.
Lloyd's Building, Sir Baron Jayathilaka, Mawatha, Colombo 01.

මගේ අංකය
எமது இல.
My No.
22/1523/610/018

ඔබේ අංකය
உமது இல.
Your No.

දිනය
திகதி
Date
2022-10-04

රහසිගතයි

SECRETARY
1373517
05 OCT 2022
Ministry of Health

4005
10 OCT 2022
සෞඛ්‍ය අමාත්‍යාංශය
Division of Production Supply & Regulation of Pharmaceuticals

එස්.ජේ.එස්. චන්ද්‍රගුප්ත මහතා
ලේකම්
සෞඛ්‍ය අමාත්‍යාංශය
ෆැක්ස්: 2692913

අමාත්‍ය මණ්ඩල තීරණය

2022-10-03 දින පැවති අමාත්‍ය මණ්ඩල රැස්වීමේ වාර්තාවේ විෂය අංක (27) හි උද්ධෘතයක් පහත දැක්වේ.

විෂය අංක: (27)

අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 22/1523/610/018 වූ, "ශ්‍රී ලංකාව තුළ අඛණ්ඩ වෛද්‍ය සැපයීම් සේවාවක් පවත්වාගෙන යාම" යන මැයෙන් සෞඛ්‍ය ඇමතිතුමා ඉදිරිපත් කළ 2022-09-26 දිනැති සංදේශය - මෙම රැස්වීමේදී සභාගත කරන ලද ඉහත සඳහන් සංදේශය, ඒ පිළිබඳව සෞඛ්‍ය ඇමතිතුමා විසින් සිදු කරන ලද වැඩිදුර කරුණු පැහැදිලි කිරීම් සමඟ සලකා බලන ලදී. මේ පිළිබඳව සාකච්ඡා කිරීමෙන් අනතුරුව, සංදේශයේ 4 ඡේදයෙහි සඳහන් (4.1) සහ (4.2) යෝජනා සඳහා අනුමැතිය ලබා දීමට තීරණය කරන ලදී.

තවද, මෙම තීරණය සම්මත කරනු ලැබූ සේ සැලකීමටත්, ඒ අනුව අවශ්‍ය කටයුතු සඳහා අදාළ බලධාරීන් වෙත මෙම තීරණය දන්වා යැවීම සඳහා අමාත්‍ය මණ්ඩලයේ ලේකම්ට බලය පැවරීමටත් තීරණය කරන ලදී.

ක්‍රියා කළ යුතු: මූදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය - සංදේශයේ පිටපතක් යා කොට ඇත.
සෞඛ්‍ය අමාත්‍යාංශය
වෙළෙඳ, වාණිජ හා ආහාර සුරක්ෂිතතා අමාත්‍යාංශය - සංදේශයේ පිටපතක් යා කොට ඇත.

පිටපත්: ජනාධිපති ලේකම් - සංදේශයේ පිටපතක් යා කොට ඇත.
අග්‍රාමාත්‍ය ලේකම් - සංදේශයේ පිටපතක් යා කොට ඇත.

Addl. Secy / Pharma
Addl. Secy / Admin I
Fwd p/l
Secretary
Ministry of Health

ඩබ්ලිව්.එම්.ඩී.ජේ. ප්‍රනාන්දු
අමාත්‍ය මණ්ඩලයේ ලේකම්

2329620
අතිරේක ලේකම්
மேலதிகச் செயலாளர்
Additional Secretary
2431004
ජ්‍යෙෂ්ඨ සහකාර ලේකම්
சிரேட்ட உதவிச் செயலாளர்
Senior Assistant Secretary
2325279
2422276
3136199

318

Approved

INTERNAL MEMO

Ministry of Health

To :- Secretary

From :- Additional secretary (MOH) , Medical officer (Procurement)

File Number :- PSRP/08/EOI/General/2022

Subject :- Invitation for Expressions of Interest to import and supply of vital and essential pharmaceuticals to Sri Lanka under the Indian Credit Line for 3 months.

Date :- 27.09.2022

With reference to the meeting held on 22.09.2022 with the Honorable minister of health and suppliers of pharmaceuticals regarding the import and supply of vital and essential pharmaceuticals to Sri Lanka under the Indian Credit Line for 3 months.

According to above decision and the requirement insisted by the Medical Suppliers Division, we have prepared Expressions of Interest (EOI) document to invite suppliers to import and supply of vital and essential drugs to Sri Lanka.

Seek approval

1. To approve the EOI document.
2. To folate this document through E- Procurement portal PROMISE.lk and web site of the Health Ministry.

-END-

(317)

(13-B)

Approved 29/11/17 Recommended 29/11/17

Secretary/Addl. Sec. (SMOH)/MO (P)

Please refer the minute No. 01 and folio No. 13

EOIs will be closed at 11.00 am on 03.10.2022 as scheduled. Accordingly, the following EOI Opening Committees are nominated and forwarded your approval please.

EOI Opening Committee – 01	**Capacity (Chairman/Member)**
Mrs. R.N. Wickramarachchi Senior Assistant Secretary, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health	Chairman
Mrs. S.U.S. Rajapaksha Development Officer, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health	Member

EOI Opening Committee – 02	**Capacity (Chairman/Member)**
Mrs. W.M.G.M. Wijesooriya Chief Accountant, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health	Chairman
Mrs. J.D.A.S. Senarathne Development Officer, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health	Member

EOI Opening Committee – 03	**Capacity (Chairman/Member)**
Mr. R.D. Asanka Mithrirathne Director (Planning), Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health.	Chairman
Miss. W.A.Y. Sewwandi Development Officer (Procurement) Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health.	Member

EOI Opening Committee – 04	**Capacity (Chairman/Member)**
Mrs. J.P.S. Dissanayake Senior Assistant Secretary Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health.	Chairman
Miss. K.T.I. De Silva Development Officer, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health	Member

EOI Opening Committee – 05	Capacity (Chairman/Member)
Mr. Niran M. Manage Accountant, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health	Chairman
Mrs. M.H.S.T. Thisera Development Officer, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health	Member

EOI Opening Committee – 06	Capacity (Chairman/Member)
Mrs. A.R.P.D.Rajapaksha Administrative Officer, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health	Chairman
Mrs. M.D.C.Manchanayake Development Officer, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health	Member

Alternative

EOI Opening Committee	Capacity (Chairman/Member)
Mrs. D.H.R.N.Hemathunga Internal Auditor, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health.	Chairman
Mrs. A.S.A.P. Silva Development Officer, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health	Member

EOI Opening Committee	Capacity (Chairman/Member)
Dr. B.L.D.Jayanath Medical Officer (Procurement) Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health.	Chairman
Mrs. H.P.D. Priyanthika Development Officer, Production, Supply and Regulation of Pharmaceutical Unit, Ministry of Health	Member

(12)

315

Ministry of Health

Invitation for Expressions of Interest to import and supply of vital and essential pharmaceuticals to Sri Lanka under the Indian Credit Line for 3 months.

27th September 2022

(314)

Table of contents

313

Introduction

The Ministry of Health is responsible for the supply of essential pharmaceuticals and surgical items to government hospitals and healthcare institutes in Sri Lanka.

The organisation is seeking invitee's response to the invitation for the supply of vital and essential pharmaceuticals to Sri Lanka under the Indian Credit Line for 3 months as outlined in Part A.

The organisation seeks to gain a more detailed understanding of the supplier market and range of solutions that may be available. Hence, this Expression of Interest (EOI) process may be the first stage of a multi-stage procurement process.

Structure of the invitation

This Invitation comprises the following sections:

- Introduction – contains an overview of the structure of the documents.
- Part A – The Invitation

  About this Invitation provides establishment details about the procurement opportunity.

312

Part A – The invitation

Part A.1 – About this invitation

1.Establishment details

Organisation name: Ministry of Health

2.Organisation contact

Project manager	
Name:	Mr. S. Janaka Sri Chandragupta
Position title:	Secretary – Ministry of Health
Contact details:	Ministry of Health, 385, Ven. Baddegama Wimalawansa Thero Mawatha, Colombo 10.

Second contact person	
Name:	Dr. R.M.S.K.Rathanayake
Position title:	Additional Secretary Ministry of Health
Contact details:	"Osu Piyasa", Ministry of Health, 5th floor, HQ Building, T.B. Jaya Mawatha, Colombo 10, Sri Lanka. TP:0112103211 Fax 0112082162

3.Lodgement details

Internet lodgement	
Website address	www.health.gov.lk / www.promise.lk

4.Indicative timetable

Please note: this timetable provides invitees with an indication of the timing of the EOI process. The timetable is indicative only and may be changed by the organisation.

Activity	Date
Closing time for invitee's response	3rd October 2022 at 11.00 AM
Intended completion date of short-listing process	Within two days from 3rd October 2022
Intended completion date of evaluation of invitee's responses	7th October 2022

B11

**Note:

- Separate EOI for each drug needed to be submitted along with following documents and each EOI needed to be submitted in separate envelops with the generic name of the drug and SR number marked at top left corner of each envelop.
  Documents to be submitted
  - NMRA registration.
  - Intends of previous supplies of the same drug.
  - Business Registration (number and certificate).

- Sealed responses may be personally deposited in the box available for this purpose at **the office of Additional Secretary, "Osu Piyasa", Ministry of Health, 5th floor, HQ Building, T.B. Jaya Mawatha, Colombo 10, Sri Lanka on or before closing date and time.**

- Responses to Expressions of Interest will be opened **at 12.00 noon on Wednesday, October 3, 2022** at the above address and one representative from each supplier is invited to participate in the opening.

5. Evaluation criteria

An invitee's response will be evaluated against:

(a) The evaluation criteria identified in the table below; and

(b) the overall proposition presented in the invitee's response.

Mandatory requirements	Complies
1. The supplier should have a valid registration at NMRA to import the drug to Sri Lanka from the exporter. But considering the price factor lowest offers without NMRA registration may be selected and Waiver of Registration (WOR) could be considered.	Yes/No

Suppliers who are not registered in NMRA, should submit following documents along with the EOI for the Waiver of Registration,

- Request Letter from the Applicant
- Completed Waiver of Registration Application (This application could be downloaded from this link - https://www.nmra.gov.lk/images/2020/Medicine_Application/Application-for-WOR-medicine.pdf)
- Certificate of Analysis (COA) of the relevant product
- Certificate of Pharmaceutical Product (COPP)
- Commercial invoice / Proforma Invoice
- Product Information Leaflet
- Labels of the product
- Quotation Document

2. The drug should be of an Indian origin.	Yes/No
3. Price of the drug.	
4. Immediate date that the company can import the drug to Sri Lanka with the amount.	
5. Amount of the drug the company can import within **three months** (if one company cannot import the entire amount, another company can be given a chance to import the balance amount).	
6. Delivery Schedule	
7. Shelf life	

Other evaluation criteria
(a)The cost of each drug will be decided by the pricing committee after considering all costs and taxes involved for importing the drug and the profit margin of supplier.
(b)Price to be quoted in USD and it should be C & F USD Air freight /C&F USD Sea freight or both.
(c) Previous or current supplier without any quality failure/ complain.
(d) If one supplier is unable to supply the required full quantity, importation of balance quantity, price and the supplier will be decided by the procurement entity.

(9)

(309)

Form of Mandatory Requirements
Price schedule

Name of the Supplier - .....

Address of the Supplier - .....

Name and Address of the Manufacture Supplier -
.....
.....

SR No (As mentioned in annexure I)	Description of Item	Pack Size Offered	Quantity Offered	Origin of the drug **(Drug should be an Indian Origin)**	Immediate date that the company can import the drug to Sri Lanka with the amount	Amount of the drug that company can import within **three months**	Probable Delivery Schedule	Availability of NMRA registration	Delivery Price to MSD Stores **(C & F USD Air freight /C&F USD Sea freight)**		Shelf life
									Unit Price (USD)	Total Price (USD)	

Name of Supplier :.....

Signature of Supplier : .....

(With Name and Designation of Signatory) : .....

Postal Address of Supplier :.....

Official Stamp:

Telephone No:..... Fax No :.....E-mail : .....

** This format must be filled by the supplier.

**Note:

Monthly estimated supply has been annexed herewith (Annexure I)

308

Annexure I

Priority Group 01

No	SR No	Item	Monthly Requirement
1	00000801	Morphine sulphate Tablet 10mg	70,000
2	00001102	Pethidine hydrochloride Injection 75mg ampoule	15,000
3	00100901	Co-amoxiclav Tablet 375mg	583,333
4	00101403	Cefuroxime Tablet 500mg	375,000
5	00101502	Cefotaxime Injection 1g Vial	83,333
6	00102102	Meropenem Injection 1g vial	150,000
7	00103501	Vancomycin hydrochloride Injection 500mg Vial	16,000
8	00105701	Ofloxacin Tablet 200 mg	20,000
9	00105801	Levofloxacin Tablet 500mg	15,000
10	00106501	Sodium stibogluconte Injection 10g/100mL Vial	67
11	00107102	Fluconazole Injection 200mg in 100mL Vial	3,500
12	00107401	Amphoteracin Injection 50mg Vial	208
13	00107403	Liposomal Amphotericin B Injection 50mg for I.V. use	2,083
14	00107903	Aciclovir Injection 250mg Vial	22,000
15	00200102	Digoxin Injection 500mcg in 2mL ampoule	400

16	00200302	Furosemide(Frusemide) Injection 20mg in 2mL ampoule	208,333
17	00200701	Amiodarone Tablet 100mg	166,667
18	00203002	Glyceryl trinitrate (Nitroglycerin) Injection 50mg in 10mL	3,750
19	00204601	Heparin Injection 25,000 I.U.in 5mL Vial	25,000
20	00205404	Aspirin Enteric coated Tablet 75mg	21,370,275
21	00205903	Tranexamic acid Injection 500mg in 5mL ampoule	40,000
22	00300104	Diazepam rectal solution 5mg in 2.5mL Tube	333
23	00301101	Flupenthixol decanoate Injection 40mg in 2mL Ampoule	3,750
24	00301902	Olanzapine Tablet 10mg	1,333,333
25	00302001	Risperidone Tablet 2mg	2,083,333
26	00302901	venlafaxine extended release Capsules 37.5mg	233,333
27	00302902	Venlafaxine Hydrochloride extended release Capsules 75mg	541,667
28	00303103	Ondansetron Inj. 8mg in 4mL ampoule	75,000
29	00303604	Phenobarbital Injection 200mg/mL	1,500
30	00303703	Phenytoin Sodium Tablet 100 mg	1,000,000
31	00303704	Phenytoin sodium Injection 250mg in 5mL Ampoule	4,000
32	00304001	Sodium Valproate Tablet 100mg	1,000,000
33	00304202	Clobazam Tablet 10mg	416,667
34	00304401	Lamotrigine Tablet 25mg	200,000
35	00305002	Co-Careldopa Tablet 25/250mg	466,667
36	00305201	Benztropine Injection 2mg in 2mL Ampoule	150
37	00306701	Quetiapine Tablet 25mg	200,000
38	00400701	Potassium Chloride Tablet 600mg	833,333

39	00402202	Protein Hydrolysate Inj. 10% w/v in 500mL bottle(Amino acids solution)	833
40	00402801	Pyridoxine Tablet 10mg	24,000
41	00403001	Calcitriol Capsule 250ng	666,667
42	00403202	Phytomenadione Injection 1mg in 0.5mL Ampoule	25,000
43	00403501	Hydroxocobalamine Injection 1mg in 1mL Ampoule	11,667
44	00404004	Epoetin Injection 10,000 IU Vial / Pre-filled syringe	4,000
45	00404801	Desferrioxamine Injection 500 mg	37,500
46	00406702	Cholecalciferol Capsule/Tablet 1000 IU (25 micrograms)	200,000
47	00500104	Salbutamol Injection 5mg in 5mL ampoule	500
48	00500204	Fluticasone propionate 125mcg with Salmeterol xinafoate 25mcg / metered dose,120 dose unit	2,500
49	00500403	Ipratropium bromide respiratory solution, 250mcg in 1mL, 15mL Bottle	10,000
50	00500801	Budesonide respiratory suspension 0.5mg in 2mL respule	8,500
51	00602501	Antirabies human Immunoglobulin 300 I.U. Vial	417
52	00603201	Human immunoglobulin for intravenous use 1g Vial	1,667
53	00603202	Human Immunoglobulin for intravenous use 2.5g - 3.0g in Vial	1,833
54	00701301	Propylthiouracil Tablet 50mg	20,833
55	00701401	Fludrocortisone Acetate Tablet 0.1mg	16,667
56	00701502	Hydrocortisone Tablets 10mg	125,000
57	00701602	Dexamethasone Injection 8mg in 2mL Ampoule	83,333

58	00702401	Hydroxyprogesterone Injection 250mg in 1mL ampoule	1,667
59	00703001	Tetracosactrin Inj.250microgram/1mL	167
60	00703502	Alendronate sodium Tablets 70mg	45,833
61	00800404	Domperidone suppository 30mg	1,250
62	00800803	Omeprazole sodium Inj. 40mg	100,000
63	00801001	Mesalazine Tablet 400mg	15,000
64	00801401	Iso-osmotic bowel cleansing preparation (Polyethylene glycol 58g-60g)	12,000
65	00901001	Prednisolone acetate eye drops 1%,5mL Vial	14,167
66	00901401	Tropicamide Eye Drops 1% 5mL-15mL Vial	417
67	00902001	Balanced salt solution 500mL plastic bottle	2,917
68	00902101	Fluorescein sodium Injection 10% in 2mL-5mL vial	250
69	00902201	Hydroxypropylmethylcellulose ophthalmic solution for intraocular use 2%, 3ml-5ml prefilled syringe	6,250
70	00902901	Bimatoprost ophthalmic suspension 300mcg/mL,3mL vial	15,000
71	00903001	Brinzolamide eye drops 1%,in 5mL dropper bottle	6,667
72	00904101	Moxifloxacin hydrochloride ophthalmic solution 0.5%, 5mL vial	11,667
73	00904302	Tobramycin 0.3% with Dexamethasone 0.1% eye drops, 5ml-10ml dropper bottle	667
74	00904901	Natamycin ophthalmic suspension 5% in 5ml-15ml vial	1,667
75	01102001	Clobetasol propionate Ointment 0.05%,15g tube	33,333
76	01102201	Silversulphadiazine cream 1%,500g Jar	1,667
77	01200201	Chlorambucil Tablet 2mg	2,500

78	01200401	Ifosfamide Injection 1g vial with Mesna Injection 100mg in 1mL, 3 ampoules in one set	833
79	01201601	Capecitabine Tablet 500mg	83,333
80	01201703	Cytarabine Injection 1g in 10mL vial	500
81	01202002	Gemcitabine hydrochloride Injection 1g vial	1,375
82	01202201	Methotrexate Tablet 2.5mg	625,000
83	01202401	Vincristine sulphate Injection 1mg vial	1,917
84	01202501	Vinblastine Sulphate Injection 10mg vial	167
85	01202701	Etoposide Capsule 100mg	400
86	01202702	Etoposide Injection 100mg vial	1,000
87	01202803	Lecucovorin Calcium (Folinic acid) Injection 10mg /mL in 5mL vial/ampoule.	4,583
88	01203402	Temozolomide Capsule 250mg	400
89	01203702	Cisplatin Injection 50mg Vial	1,833
90	01203803	Oxaliplatin Injection(as liophilized powder) 100mg vial	1,333
91	01203901	Procarbazine Capsule 50mg	200
92	01204401	Imatinib Mesilate Capsule 100mg	45,833
93	01204802	Docetaxel Injection 80mg vial	1,333
94	01204904	Paclitaxel Injection 260mg	750

303

95	01205002	Irinotecan hydrochloride trihydrate Injection 100mg in 5mL vial	500
96	01205201	Azathioprine Tablet 50mg	208,333
97	01205401	Cyclosporin Capsule 25mg	33,333
98	01205402	Cyclosporin Capsule 50mg	75,000
99	01205702	Rituximab Injection 500mg in 50mL vial	750
100	01206301	Lenalidomide Capsules 5mg	7,500
101	01206701	Anastrozole Tablet 1mg	166,667
102	01206901	Letrozole Tablet 2.5mg	12,500
103	01207001	Bicalutamide Tablet 50mg	27,500
104	01208501	Abiraterone acetate Tablet 250mg	22,917
105	01210101	Mesna Injection 200mg in 2mL	2,500
106	01300102	Ergometrine maleate injection 500mcg in 1mL ampoule	2,917
107	01302001	Oxybutynine Hydrocloride Tablet 2.5mg	20,833
108	01401001	Allopurinol Tablet 100mg	300,000
109	01500202	Ketamine hydrocloride injection 500mg in 10mL vial	500
110	01500401	Etomidate injection 20mg in 10mL vial	292
111	01500701	Sevoflurane for inhalational anaesthesia 250mL bottle	750
112	01502104	Lignocaine spray 10%, 50mL bottle	333
113	01502105	Lignocaine anhydrous gel 2% in 30g tubes	20,833
114	00303403	Tramadol hydrochloride Injection 100mg in 2mL Ampoule	8,333
115	00205701	Alteplase(Recombinent Tissue type plasminogen activator) 20mg vial	75

302

116	01205701	Rituximab Injection 100mg in 10mL vial	583
117	00404002	Epoetin Inj.4000IU Pre-filled syringe	116,667
118	00200501	Mannitol 20% I.V.Infusion in 250 mL bottle	8,333
119	01201001	Daunorubicin Hydrochloride Injection 20mg vial	500
120	00800502	Metoclopramide Inj.10mg in 2mL	150,000
121	00101704	Ceftriaxone Injection 1g Vial	145,833
122	00300602	Methylphenidate Hydrochloride Tablet 10mg	166,667
123	00304002	Sodium valproate Tablet 200mg	5,833,333
124	00500109	Salbutamol respiratory solution 0.5% in 15mL vial	20,000
125	00102301	Doxycycline hydrochloride Capsule 100mg	500,000
126	01204901	Paclitaxel Injection 30mg in 5mL vial	8,333
127	01101901	Fluocinolone cream 0.025% ,15g tube	8,333
128	00903201	Nepafenac ophthalmic suspension 0.1%, 3ml-5ml	3,750
129	00500205	Fluticasone propionate 250mcg with Salmeterol xinafoate 25mcg / metered dose,120 dose unit	75,000
130	00403101	Alfacalcidol Capsule 250microgram	2,750,000
131	00401202	Sodium chloride 0.45% & Dextrose 5% for intravenous infusion 500mL Bottle	6,667
132	00205201	Protamine sulphate Injection 50mg in 5mL vial	667
133	00900201	Fusidic acid Eye Drop 1%(S.R.)	12,500

134	01502003	Bupivacaine hydrochloride inj. 0.5% with Glucose 8% in 4mL amp in pre-sterililized theatre pack for spinal anaesthesia	22,917
135	00205902	Tranexamic Acid Tablet/Capsule 500mg	150,000
136	00103203	Clindamycin phosphate Inj.300mg/2mL	125,000
137	00901801	Acetazolamide Tablet 250mg	100,000
138	00405301	Human Albumin Solution BP/USP/Ph Eur 20% in 50mL bottle	33,333
139	00203901	Dobutamine Injection 250mg in 20mL vial	12,500
140	00802601	Sodium Biphosphate 1.6gand Sodium phosphate 0.6g enema in 10mL,120mL bottle.	8,500
141	00107101	Fluconazole Capsule 50mg	90,000
142	01203301	Dacarbazine (as Cittrate) Injection 200mg vial	500
143	01206802	Tamoxifen Tablet 20mg	150,000
144	01206401	Thalidomide Capsules 100mg	14,167
145	01502201	Lignocaine 2% with Adrenalin 1:80,000 injection 30mL vial	15,000
146	01301502	Tamsulosin Capsule 0.4 mg	500,000
147	01200901	Actinomycin D Injection 500mirogram vial	125
148	00602801	Anti D.(Rho) Immunoglobulin (human) Injection 300mcg in 1.5mL vial	1,250
149	01200801	Bleomycin sulphate Injection 15000 units vial	208

150	01502001	Bupivacaine hydrochloride injection 0.5% in 10mL ampoule with sterile wrap	15,000
151	00700601	Biphasic Isophane Insulin Injection (Human) 30% Soluble/70% Isophane	150,000
152	00302101	Lithium Carbonate Tablet 250mg	583,333
153	01207402	Octreotide Injection 50microgram in 1mL ampoule	6,667
154	00407201	Total Parenteral Nutrition in 500mL-1,500mL multiple component in collapsible bag	2,083
155	00107901	Aciclovir Tablet 200mg	175,000
156	00101602	Ceftazidime Injection 1g Vial	23,333
157	01300202	Oxytocin Injection 5 I.U. in 1mL ampoule	141,667
158	00700801	Insulin Soluble (Human)1000IU in 10 vial	10,000
159	00201901	Sildenafil Tablet 50mg	125,000
160	00204701	Enoxaparin Injection 40mg in 0.4mL prefilled syringe	66,667
161	00204201	Ephedrine Injection 30mg/mL	15,000
162	01205601	Tacrolimus Capsule 0.5mg	83,333
163	00703401	Vasopressin Injection 20 I.U. in 1mL ampoule	1,833
164	00401903	Magnesium sulphate Injection 50% in 10mL ampoule	7,500
165	01204201	Everolimus Tablet 0.25mg	25,000
166	01501101	Atracurium besylate injection 25mg in 2.5mL ampoule	83,333
167	00302402	Clomipramine Hydrochloride Tablet 25 mg	166,667
168	01205602	Tacrolimus Capsule 1mg	375,000
169	01201103	Doxorubicin hydrochloride Injection 2mg/mL 25mL vial	1,500

170	00204702	Enoxaparin Injection 60mg in 0.6mL in prefilled Syringe	83,333
171	01203602	Carboplatin Injection 450mg in 45mL vial	1,583
172	00700701	Insulin Isophane(human)1000IU/10mL	4,167
173	01202204	Methotrexate Injection 1g vial	700
174	00603205	Human immunoglobulin for intravenous use 5g - 6g vial	7,500
175	01203201	Asparaginase Injection 10,000IU vial	100
176	00300803	Haloperidol Injection 5mg in 1mL Ampoule	5,000
177	00302801	Sertraline Tablet 50mg	833,333
178	00801201	Bisacodyl Tablet 5mg	250,000
179	01204403	Imatinib Mesilate Capsule/Tablet 400mg	20,833
180	00402702	Thiamine hydrochloride Injection 100mg in 2mL ampoule	33,333
181	00402201	Protein hydrolysate Injection 100mL Bottle	1,000
182	00305001	Co-careldopa Tablet 25/100mg	62,500
183	00901702	Timolol maleate Eye Drops 0.5%, 5mL vial	8,333
184	01200304	Cyclophosphamide Injection 1g vial	1,000
185	01206101	Filgrastim Injection 300mcg in 0.5mL/1mL, prefilled syringe/vial	14,167
186	00300201	Chlordiazepoxide Tablet 10mg	100,000
187	01202801	Lecucovorin Calcium (Folinic acid)Tablet 15mg	2,000
188	01204601	Sorafenib Tablet 200mg	11,500

Priority Group 02

No	SR No	Item	Monthly Requirement
1	00400303	Iron Drops 50mg/mL, in 15mL dropper bottle	13,333
2	00901302	Cyclopentolate hydrochloride eye drops 1.0% 5mL-15mL dropper bottle	417
3	01103101	Selenium sulphide lotion 2.5% 60mL bottle	2,500
4	00402802	Pyridoxine Hydrochloride Tablet 25mg	166,667
5	00206105	Dried,Factor VIII fraction 200-350IU vial with von Willebrand factor	642
6	01207901	Exemestane Tablet 25mg	5,167
7	00706201	Dutasteride Capsule 0.5 mg	2,500
8	01501001	Glycopyrrolate injection 200microgram in 1mL vial	2,000
9	01207301	Goserelin acetate implant 3.6mg (in syringe applicator)	1,167
10	00901501	Tropicamide 0.8% with phenylephrine hydrochloride 5% eye drops 5mL-15mL dropper bottle	3,333
11	00201201	Carvedilol Tablet 6.25mg	2,083,333
12	00000301	Fentanyl Citrate Injection 100mcg in 2mL ampoule.	60,000
13	00000807	Morphine sulphate Injection 15mg ampoule	50,000
14	00406202	Calcium polystyrene sulphonate 15g-17g powder sachet	10,000
15	00201502	Labetalol hydrochloride Injection 100mg in 20mL Ampoule	2,333

16	00301001	Fluphenazine decanoate Injection 25mg in 1mL Ampoule	18,333
17	00206005	Dried factor VII fraction 1000 micrograms -2500 micrograms vial	33,333
18	00100902	Co-amoxiclav Tablet 625mg	2,500,000
19	00500107	Salbutamol aerosol Inhaler 100mcg/metered dose, 200 dose Unit	75,000
20	00305901	Levetiracetam Tablet 500 mg	500,000
21	01502102	Lignocaine hydrochloride injection 2% w/v in 20mL vial	25,000
22	00403203	Phytomenadione Injection 10mg in 1mL Ampoule	10,000
23	00701805	Methylprednisolone sodium Succinate Injection for IV use 1g Vial	3,333
24	01202101	Mercaptopurine Tablet 50mg	13,333
25	01000701	Xylometazoline hydrochloride Nasal drops 0.1% in 10mL dropper bottle	2,333
26	00400702	Potassium chloride Injection 15% in 10mL Ampoule	39,167
27	00302701	Fluoxetine hydrochloride Capsule 20mg	1,166,667
28	00703202	Somatropin for InjectionBP/USP 2IU-30IU	25,000
29	00600101	Tetanus toxoid Vaccine 0.5mL(single dose) ampoule	66,667
30	01601201	Methylene blue 1% w/v injection 10mL ampoule	250
31	00703701	Zoledronic acid Injection 4mg in 5mL vial	1,667
32	00206201	Dried,Factor IX Fraction 500 IU-600IU vial	500
33	00200702	Amiodarone Injection 150mg in 3mL ampoule	3,333
34	00303702	Phenytoin Sodium Tablet 50mg	120,358
35	01201202	Epirubicin hydrochloride Injection 50mg vial	667

36	00200101	Digoxin Tablet 0.25 mg	183,333
37	00500404	Ipratropium bromide 20mcg/dose 200 metered doses aerosol inhaler	6,500
38	01501801	Naloxone injection 400mcg in 1mL ampoule	750
39	00207501	Cadioplegia infusion(St. Thomas Solution)	308
40	01301401	Misoprostol Tablet 200 micrograms	15,000
41	00401004	Sodium chloride for intravenous infusion 3%, 500mL bottle	5,833

Priority Group 03

No	SR No	Item	Monthly Requirement
1	00404001	Epoetin Injection 2,000 IU Vial/Pre-filled syringe	16,667
2	00306601	Pregabalin Capsule 75 mg	208,333
3	01203501	Hydroxyurea Capsule 500mg	66,667
4	00102502	Gentamicin Sulphate Injection 80mg in 2mL Ampoule	35,000
5	00101406	Cefuroxime Injection 750mg Vial	166,667
6	01500302	Propofol IV infusion 50mL ampoule/vial	8,333
7	00103002	Clarithromycin lactobionate for IV infusion 500mg vial	4,500
8	00303104	Ondansetron Tablet 4mg	50,000
9	00204001	Dopamine Injection 200mg in 5mL ampoule	10,417

ඇමුණුම 34

දුරකථන) 0112669192 , 0112675011
தொலைபேசி) 0112698507 , 0112694033
Telephone) 0112675449 , 0112675280

ෆැක්ස්) 0112693866
பெக்ஸ்) 0112693869
Fax) 0112692913

විද්‍යුත් තැපෑල)postmaster@health.gov.lk
மின்னஞ்சல் முகவரி)
e-mail)

වෙබ් අඩවිය) www.health.gov.lk
இணையத்தளம்)
website)

iqjisrsmdh
சுவசிரிபாய
SUWASIRIPAYA

මගේ අංකය &
எனது இல &
My No. & PSRP/08/EOI/General/2022

ඔබේ අංකය &
உமது இல)
Your No. &

දිනය &
திகதி &
Date & 30 .09.2022

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
Ministry of Health

Mrs.U. S. K. Denawaththa (Additional Secretary (Admin) / MOH)	-Chairman
Dr.A.T.Sudarshana (Deputy Director /MSD)	-Member
Dr.Jayanath Buthpitiya (Medical Officer(Procurement)/MOH)	-Member
Mrs.D.H.R.N.Pemathunga (Internal Auditor/MOH)	-Member
Ms.P.D.Solomon (Assistant Director - Pharmaceutical I/MSD)	-Member

Appointment of Expression of Interest (EOI) Evaluation committee to Import and Supply of Vital and Essential Pharmaceuticals to Sri Lanka under the Indian Credit line for 3 months.

I wish to inform that you have been appointed as the Chairman / a Member of EOI evaluation committee to evaluate the EOIs submitted by suppliers to import and supply of vital and essential pharmaceuticals to Sri Lanka under the Indian Credit Line for 3 months.

Accordingly, the EOI Evaluation Committee meeting is scheduled to be held **at 9.00 AM on 6th and 7th October 2022 at the office of Additional Secretary, "Osu Piyasa", 5th Floor, HQ Building, T.B.Jaya Mawatha, Colombo 10.**

You are kindly requested to attend the above committee on time and extend your support to make the EOI evaluation success.

Please note that the items under this EOIs are urgently required.

S. Janaka Sri Chandraguptha
Secretary
Ministry of Health
"Suwasiripaya"
385, Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10.

o/c S. Janaka Sri Chandraguptha
Secretary,
Ministry of Health

ඇමුණුම 35

SAVORITE
PHARMACEUTICALS PVT. LTD.
(A Govt. Recognized One Star Export House)

21st October 2022,
Honorable Health Minister
Suwasiripaya, No 385, Rev.
Baddegama Wimalawansa Thero,
Mawatha,
Colombo 10, Sri Lanka

Subject: Supply of Essential Medicines

Dear Sir,

Furtherance to our meeting on 20th October 2022, we have the following below mentioned products ex-stock along with the delivery timelines mentioned.

We are an export company and a Government recognized Export house and are in existence for over 12 years. We are currently exporting to more than 40 countries.

Below is the attached list of products with their tentative delivery schedules:

lo	New SR NO	Item	Unit	Requirement for 03 months	CIF Price	Packing	Delivery time
1	00101502	Cefotaxime Inj. 1g Vial	Vial	250,000	4	Pack of 10 injection	Delivery in 45-65 days
2	00101704	Ceftriaxone Inj. 1g	Vial	437,500	4	Pack of 10 injection	Delivery in 45-65 days
3	00107201	Itraconazole Cap. 100mg	Cap	360,000	4.4	10x10 (100 tablets pack)	Delivery in 45-65 days
4	00200302	Furosemide (Frusemide) Inj 20mg/2ml	Amp	625,000	0.11	per ampoule	Delivery by 22nd November
5	00203702	Verapamil HCl Inj. 5mg/2ml	Amp	3,750	0.4	per ampoule	Delivery in 45-65 days

Corporate Office: 703-704 Atlantis Heights, Opposite Vadodara Central, Sarabhai Compound, Vadodara-390007 (Gujarat) INDIA.
• +91 265 3501184 • +91 265 3501185 • e.mail: savoritepharma@gmail.com • info@savoritepharma.com • www.savoritepharma.com

L70

SAVORITE®
PHARMACEUTICALS PVT. LTD.
(A Govt. Recognized One Star Export House)

6	00301901	Olanzapine Tab:5mg	Tab	1,875,000	1.85	10x10 (100 tablets pack)	Ready by 22nd November
7	00301902	Olanzapine Tab.10mg	Tab	4,000,000	2.3	10x10 (100 tablets pack)	Delivery in 45-65 days
8	00302902	Venlafaxine HCl Cap. E.R. 75mg	Cap	1,625,000	3.3	10x10 (100 tablets pack)	Delivery in 45-65 days
9	00303103	Ondansetron Inj. 8mg in 4mlampoule	Amp	225,000	0.71	per ampoule	Delivery by 22nd November
10	00303703	Phenytoin Sodium Tab. 100 mg	Tab	3,000,000	2.3	10x10 (100 tablets pack)	Delivery in 45-65 days
11	00303704	Phenytoin sodium Inj. 250mgin 5ml	Amp	12,000	0.26	per ampoule	Delivery in 45-65 days
12	00305002	Co-Careldopa Tab. 25/250mg	Tab	1,400,000	9.5	10x10 (100 tablets pack)	Delivery in 45-65 days
13	00403202	Phytomenadione Injection1mg/0.5ml	Amp	75,000	0.22	per ampoule	Delivery in 45-65 days
14	00501002	Montelukast Sodium Tab. 10mg	Tab	450,000	2.45	10x10 (100 tablets pack)	Delivery in 45-65 days
15	00701301	Propylthiouracil tablet 50mg	Tab	62,500	7.75	10x10 (100 tablets pack)	Delivery in 45-65 days
16	00706301	Finasteride tablet 5mg	Tab	112,500	2.85	10x10 (100 tablets pack)	Delivery in 45-65 days
17	00800502	Metoclopramide Inj.10mg/2ml	Amp	450,000	0.1	per ampoule	Ready by 22nd Novmber
18	00901201	Atropine sulphate Eye Drops1% 5ml	Vial	2,500	0.2	Per Drop	Delivery in 45-65 days

Corporate Office: 703-704 Atlantis Heights, Opposite Vadodara Central, Sarabhai Compound, Vadodara-390007 (Gujarat) INDIA.
• +91 265 3501181 • +91 265 3501185 • e.mail: savoritepharma@gmail.com • info@savoritepharma.com • www.savoritepharma.com

SAVORITE®
PHARMACEUTICALS PVT. LTD.
(A Govt. Recognized One Star Export House)

19	00901401	Tropicamide Eye Drops 1% ,5ml	Vial	1,250	0.7	Per Drop	Delivery in 45-65 days
20	01105701	Mometasone furoate 0.1%,5gtube	Tube	12,500	0.35	Per Cream	Delivery in 45-65 days
21	00102102	Meropenem Inj. 1g vial	Vial	450,000	3.25	Per injection with WFI	Delivery in 45-65 days
22	01301502	Tamsulosin capsule 0.4 mg	Cap	1,500,000	2.65	10x10 (100 tablets pack)	Delivery in 45-65 days
23	00107901	Acidovir Tab. 200mg	Tab	525,000	2.85	10x10 (100 tablets pack)	Delivery in 45-65 days
24	00105801	Levofloxacin Tab. 500mg	Tab	45,000	6.15	10x10 (100 tablets pack)	Delivery in 45-65 days
25	00203501	Nifedipine ER Tab.20mg	Tab	22,500,000	2.25	10x10 (100 tablets pack)	Delivery in 45-65 days
26	00204701	Enoxaparin Inj.40mg/0.4ml PF.Syringe	PF.Syr	200,000	3.2	Per PFS	Delivery in 45-65 days
27	00201201	Carvedilol Tab. 6.25mg	Tab	6,250,000	1.3	10x10 (100 tablets pack)	Delivery in 45-65 days
28	01105702	Mometasone Furoate 0.1%,15gtube	Tube	10,000	0.5	Per tube	Delivery in 45-65 days
29	00204702	Enoxaparin Inj.60mg/0.6mlPF.Syringe	PF.Syr	250,000	3.7	Per PFS	Delivery in 45-65 days
30	00306601	Pregabalin capsule 75 mg	Cap	625,000	2.9	10x10 (100 tablets pack)	Ready by 22nd november
31	00201502	Labetalol HCl Inj. 100mg/20ml	Amp	7,000	7.85	Per injection	Delivery in 45-65 days
32	00302701	Fluoxetine hydrochloride Cap.20mg	Cap	3,500,000	2.35	10x10 (100 tablets pack)	Delivery in 45-65 days

Corporate Office: 703-704 Atlantis Heights, Opposite Vadodara Central, Sarabhai Compound, Vadodara-390007 (Gujarat) INDIA.
• +91 265 3501184 • +91 265 3501185 • e.mail: savoritepharma@gmail.com • info@savoritepharma.com • www.savoritepharma.com

(163)

SAVORITE®
PHARMACEUTICALS PVT. LTD.
(A Govt. Recognized One Star Export House)

33	01102402	Mupirocin 2% cream 5g tube	Tube	5,000	0.8	Per tube	Delivery in 45-65 days
34	00200101	Digoxin Tab 0.25 mg	Tab	550,000	1.95	10x10 (100 tablets pack)	Delivery in 45-65 days
35	00501001	Montelukast Sodium chewableTab. 5mg	Tab	300,000	2.35	10x10 (100 tablets pack)	Delivery in 45-65 days
36	00201202	Carvedilol Tab. 12.5mg	Tab	750,000	2.75	10x10 (100 tablets pack)	Delivery in 45-65 days
37	00800701	Ranitidine HCl Inj. 50mg/2mlamp	Amp	300,000	0.09	per ampoule	Ready by 15th November
38	00204401	Noradrenaline Inj. 4mg/2ml	Amp	300,000	0.28	Per ampoule	Ready by 20th November

Conditions of supply

1) The payment is to be through Indian Credit Line allocated for Sri Lanka, which should be supported by a letter of confirmation from the ministry of finance/health.
2) We undertake total responsibility for the quality of the product, in the event of any product failure, we shall recall or replace the total quantity of the batch. We shall also provide you with NABL approved third party laboratory report for the product mentioned.
3) We will supply stocks that have minimum 75% shelf life as per the requirements of Sri Lanka
4) The packs will have Generic Name mentioned in English and the PIL in English. Some packs may contain apart from these other languages.
5) The lead time is mentioned above for each product.

Kindly consider our offer and oblige.

Best Regards,

SAVORITE PHARMACEUTICALS PVT. LTD. VADODARA

Virat Maheshwari
Savorite Pharmaceuticals Private Limited

Corporate Office: 703-704 Atlantis Heights, Opposite Vadodara Central, Sarabhai Compound, Vadodara-390007 (Gujarat) INDIA.
T: +91 265 3501184 F: +91 265 3501185 • e-mail: savoritepharma@gmail.com • info@savoritepharma.com • www.savoritepharma.com

ඇමුණුම 36

SA
PHARMACEUTICALS PVT. LTD.
(A Govt. Recognized One Star Export House)

(161)

28th October 2022,
DDG/ Medical Supplies Division
Ministry of Health
No 357, Rev. Baddegama
Wimalawansha Thero,
Colombo 10 Sri Lanka

Subject: Supply of Essential Medicines

Dear Sir,

Furtherance to our meeting on 20th October 2022, we have the following below mentioned products ex-stock along with the delivery timelines mentioned.

We are an export company and a Government recognized Export house and are in existence for over 12 years. We are currently exporting to more than 40 countries.

Below is the attached list of products with their tentative delivery schedules:

No	New SR NO	Item	Unit	Requirement for 03 months	CIF Price	Packing	Delivery time
1	00101502	Cefotaxime Inj. 1g Vial	Vial	250,000	4	Pack of 10 injection	Delivery in 45-65 days
2	00101704	Ceftriaxone Inj. 1g	Vial	437,500	4	Pack of 10 injection	Delivery in 45-65 days
3	00107201	Itraconazole Cap. 100mg	Cap	360,000	4.4	10x10 (100 tablets pack)	Delivery in 45-65 days
4	00200302	Furosemide (Frusemide) Inj.20mg/2ml	Amp	625,000	0.11	per ampoule	Delivery in 45-65 days

Corporate Office: 703-704 Atlantis Heights, Opposite Vadodara Central, Sarabhai Compound, Vadodara-390007 (Gujarat) INDIA.
+91 265 3501184 +91 265 3501185 • e.mail: savoritepharma@gmail.com • info@savoritepharma.com • www.savoritepharma.com

160

5	00203702	Verapamil HCl Inj. 5mg/2ml	Amp	3,750	0.4	per ampoule	Delivery in 45-65 days
6	00301901	Olanzapine Tab.5mg	Tab	1,875,000	1.85	10x10 (100 tablets pack)	Delivery in 45-65 days
7	00301902	Olanzapine Tab.10mg	Tab	4,000,000	2.3	10x10 (100 tablets pack)	Delivery in 45-65 days
8	00302902	Venlafaxine HCl Cap. E.R. 75mg	Cap	1,625,000	3.3	10x10 (100 tablets pack)	Delivery in 45-65 days
9	00303103	Ondansetron Inj. 8mg in 4mlampoule	Amp	0.21 225,000	0.14	per ampoule	Delivery in 45-65 days
10	00303703	Phenytoin Sodium Tab. 100 mg	Tab	3,000,000	2.3	10x10 (100 tablets pack)	Delivery in 45-65 days
11	00303704	Phenytoin sodium Inj. 250mgin 5ml	Amp	12,000	0.26	per ampoule	Delivery in 45-65 days
12	00305002	Co-Careldopa Tab. 25/250mg	Tab	1,400,000	9.5	10x10 (100 tablets pack)	Delivery in 45-65 days
13	00403202	Phytomenadione Injection1mg/0.5ml	Amp	75,000	0.22	per ampoule	Delivery in 45-65 days
14	00501002	Montelukast Sodium Tab. 10mg	Tab	450,000	2.45	10x10 (100 tablets pack)	Delivery in 45-65 days
15	00701301	Propylthiouracil tablet 50mg	Tab	62,500	7.75	10x10 (100 tablets pack)	Delivery in 45-65 days

159

16	00706301	Finasteride tablet 5mg	Tab	112,500	2.85	10x10 (100 tablets pack)	Delivery in 45-65 days
17	00800502	Metoclopramide Inj.10mg/2ml	Amp	450,000	0.1	per ampoule	Delivery in 45-65 days
18	00901201	Atropine sulphate Eye Drops1% 5ml	Vial	2,500	0.2	Per Drop	Delivery in 45-65 days
19	00901401	Tropicamide Eye Drops 1% ,5ml	Vial	1,250	0.7	Per Drop	Delivery in 45-65 days
20	01105701	Mometasone furoate 0.1%,5gtube	Tube	0.35 12,500	0.26	Per Cream	Delivery in 45-65 days
21	00102102	Meropenem Inj. 1g vial	Vial	3.25 450,000	3.1	Per injection	Delivery in 45-65 days
22	01301502	Tamsulosin capsule 0.4 mg	Cap	1,500,000	2.65	10x10 (100 tablets pack)	Delivery in 45-65 days
23	00107901	Aciclovir Tab. 200mg	Tab	525,000	2.85	10x10 (100 tablets pack)	Delivery in 45-65 days
24	00105801	Levofloxacin Tab. 500mg	Tab	45,000	6.15	10x10 (100 tablets pack)	Delivery in 45-65 days
25	00203501	Nifedipine ER Tab.20mg	Tab	22,500,000	2.25	10x10 (100 tablets pack)	Delivery in 45-65 days
26	00204701	Enoxaparin Inj.40mg/0.4ml PF.Syringe	PF.Syr	200,000	3.2	Per PFS	Delivery in 45-65 days
27	00201201	Carvedilol Tab. 6.25mg	Tab	6,250,000	1.3	10x10 (100 tablets pack)	Delivery in 45-65 days
28	01105702	Mometasone Furoate 0.1%,15gtube	Tube	0.5 10,000	0.38	Per tube	Delivery in 45-65 days

(158)

29	00204702	Enoxaparin Inj.60mg/0.6mlPF.Syringe	PF.Syr	3·7 250,000	2.6	Per PFS	Delivery in 45-65 days
30	00306601	Pregabalin capsule 75 mg	Cap	625,000	2.9	10x10 (100 tablets pack)	Delivery in 45-65 days
31	00201502	Labetalol HCl Inj. 100mg/20ml	Amp	7·85 7,000	5.8	Per injection	Delivery in 45-65 days
32	00302701	Fluoxetine hydrochloride Cap.20mg	Cap	3,500,000	2.35	10x10 (100 tablets pack)	Delivery in 65 days
33	01102402	Mupirocin 2% cream 5g tube	Tube	0·8 5,000	0.6	Per tube	Delivery in 45-65 days
34	00200101	Digoxin Tab 0.25 mg	Tab	550,000	1.95	10x10 (100 tablets pack)	Delivery in 45-65 days
35	00501001	Montelukast Sodium chewableTab. 5mg	Tab	300,000	2.35	10x10 (100 tablets pack)	Delivery in 45-65 days
36	00201202	Carvedilol Tab. 12.5mg	Tab	750,000	2.75	10x10 (100 tablets pack)	Delivery in 45-65 days
37	00800701	Ranitidine HCl Inj. 50mg/2mlamp	Amp	300,000	0.09	per ampoule	Delivery in 45-65 days
38	00204401	Noradrenaline Inj. 4mg/2ml	Amp	300,000	0.28	Per ampoule	Delivery in 45-65 days

(157).

Conditions of supply

1) The payment is to be through Indian Credit Line allocated for Sri Lanka, which should be supported by a letter of confirmation from the ministry of finance/health.
2) We undertake total responsibility for the quality of the product, in the event of any product failure, we shall recall or replace the total quantity of the batch. We shall also provide you with NABL approved third party laboratory report for the product mentioned.
3) We will supply stocks that have minimum 75% shelf life as per the requirements of Sri Lanka. The time period of the delivery will be 45 to 65 days and shall be considered after the confirmation from Indian credit line.
4) The packs will have Generic Name mentioned in English and the PIL in English. Some packs may contain apart from these other languages.
5) The lead time is mentioned above for each product.
6) Partial shipment should be allowed & accepted for payment.
7) Our Bank details are as follows :-

BENEFICIARY NAME	:- SAVORITE PHARMACEUTICALS PVT LTD
BANK NAME	:- AXIS BANK LTD., BARODA
BRANCH NAME	:- BARODA
ACCOUNT NUMBER	:- 919020044678761
SWIFT CODE	:- AXISINBB013

Kindly consider our offer and oblige.

Best Regards

SAVORITE PHARMACEUTICALS PVT. LTD. VADODARA

Virat Maheshwari
Savorite Pharmaceuticals Private Limited

011 2669182, 011 2675011
011 2698507, 011 2694033
011 2675449, 011 2675280

011 2693866
011 2693869
011 2692913

postmaster@health.gov.lk

www.health.gov.lk

මගේ අංකය
எனது இல.
My No.

ඔබේ අංකය
உமது இல.
Your No.

දිනය
திகதி
Date

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
MINISTRY OF HEALTH

අමාත්‍ය මණ්ඩල සංදේශය

ශ්‍රී ලංකාව තුළ අඛණ්ඩ වෛද්‍ය සැපයීම් සේවාවක් පවත්වා ගෙන යාම

1.0 පසුබිම

1.1 ශ්‍රී ලංකාවේ සෞඛ්‍ය ආයතන වෙත ඖෂධ සහ පාරිභෝජන භාණ්ඩ ප්‍රසම්පාදනය, බෙදා හැරීම හා නියාමනය සහ ඒවායේ ගුණාත්මකභාවය සහ රෝගීන් දක්වා සැපයීම අධීක්ෂණය කිරීම පිළිබඳ පූර්ණ වගකීම, සෞඛ්‍ය අමාත්‍යාංශය සහ ඊට අයත් ආයතන වන වෛද්‍ය සැපයුම් අංශය, රාජ්‍ය ඖෂධ නීතිගත සංස්ථාව, රාජ්‍ය ඖෂධ නිෂ්පාදන සංස්ථාව සහ ජාතික ඖෂධ නියාමන අධිකාරිය සතු වේ.

1.2 ශ්‍රී ලංකාවේ සෞඛ්‍ය ආයතන සඳහා අවශ්‍ය ඖෂධ, ශල්‍ය වෛද්‍ය උපකරණ, රසායනාගාර උපකරණ, විකිරණශීලී උපකරණ සහ පාරිභෝජන භාණ්ඩ (වෛද්‍ය සැපයුම්) සැපයීම සඳහා ශ්‍රී ලංකා රජය වාර්ෂිකව රුපියල් බිලියන 65 ක් පමණ වැය කරනු ලබයි. පවත්නා විදේශ විනිමය අර්බුදය, රට තුළ ඖෂධ නිහයන් නිර්මාණය කරමින් වෛද්‍ය සැපයුම් දාමයට අහිතකර ලෙස බලපා ඇත.

1.3 මෙම අරමුණ සඳහා සෞඛ්‍ය අමාත්‍යාංශය විසින් ඉන්දියානු ණය යෝජනා ක්‍රමය, ආසියානු සංවර්ධන බැංකු අරමුදල්, ලෝක බැංකු අරමුදල් සහ ආසියානු යටිතල පහසුකම් ආයෝජන බැංකු අරමුදල් භාවිත කොට ඇති අතර අවශ්‍ය වෛද්‍ය සැපයීම් ලබා ගැනීම පිණිස බහු ණය යෝජනා ක්‍රම සහ පරිත්‍යාගශීලී ආයතන සම්බන්ධීකරණය කිරීමට ගත හැකි සෑම ප්‍රයත්නයන් මෙන්ම අවශ්‍ය ක්‍රියාමාර්ග අමාත්‍යාංශය විසින් ගෙන ඇත.

2.0 විස්තරය හා සාධාරණීකරණය

2.1 වෛද්‍ය සැපයීම් සඳහා රජයේ ප්‍රධානම ප්‍රසම්පාදන නියෝජිත ආයතනය වන්නේ රාජ්‍ය ඖෂධ නීතිගත සංස්ථාවයි. රාජ්‍ය ඖෂධ නීතිගත සංස්ථාවේ වෛද්‍ය සැපයුම් ප්‍රසම්පාදන ක්‍රියාවලියට අදාල පරිපාලන ක්‍රියාවලිය හේතුවෙන් වෛද්‍ය සැපයීම් ආයතනය සඳහා සැලකිය යුතු කාල සීමාවක් ගතවනු ඇත.

සුවසිරිපාය, කැලණිවැල්ල මාවත, කොළඹ 10, ශ්‍රී ලංකාව. 385, கலனிவெல்ல மாவத்தை, கொழும்பு 10, இலங்கை
385, Suwasiripaya, Kelaniwala Mawatha, Colombo 10, Sri Lanka

2.2 වෛද්‍ය සැපයුම් අංශය තුළ වෛද්‍ය සැපයුම් වල දැනට පවතින තොග අවදානම් මට්ටමක පවතී. මේ අවස්ථාව වන විට (2022 ඔක්තෝබර් මස 17 වන විට) වෛද්‍ය සැපයුම් අංශයේ ඖෂධ 151 ක, ශල්‍ය වෛද්‍ය උපකරණ සහ පාරිභෝජන භාණ්ඩ 5278 ක, විකිරණශීලී උපකරණ 18 ක සහ නිත්‍ය සහ අනුපූරක රසායනාගාර උපකරණ 850 ක තොග ශූන්‍ය මට්ටමක පවතී. ඉදිරි සති 3ක කාල සීමාව තුළ තවත් බොහෝ උපකරණ වල තොග අවසන් වනු ඇති බවට අපේක්ෂා කෙරේ.

2.3 තවත් ඖෂධ 21 ක සහ ශල්‍ය වෛද්‍ය උපකරණ සහ පාරිභෝජන භාණ්ඩ 2002 ක රෝහල් (ආයතනික) තොග මට්ටම් දැනටමත් ශූන්‍යව පවතී. මෙම හේතුව නිසා ඉදිරි සති තුනක කාල සීමාව තුළ රටේ සෞඛ්‍ය ආයතන තුළ උග්‍ර වෛද්‍ය සැපයුම් හිඟයක් නිර්මාණය වීමේ දැඩි අවධානමක් පවතී. (හිඟ අයිතම පිළිබඳ සම්පූර්ණ විස්තරයක් ඇමුණුම 1 වශයෙන් මීට යා කොට ඇත)

2.4 මැනුම් අමුද්‍රව්‍ය සහ නිර්වින්දන ඖෂධ වැනි අත්‍යාවශ්‍ය ශල්‍ය වෛද්‍ය උපකරණ වල තොග මට්ටම් අවසන් වීම සහ ඉනා අවම මට්ටමක පැවතීම, ඉදිරි සති තුනක කාල සීමාව තුළ ශල්‍යාගාර වල ක්‍රියාකාරීත්වය මුළුමනින්ම අක්‍රීය කරනු ඇතැයි අපේක්ෂා කෙරේ. (ඇමුණුම 2)

2.5 වත්මන් විදේශ විනිමය අර්බුදය තුළ අත්‍යාවශ්‍ය වෛද්‍ය සැපයුම් මිළ දී ගැනීම සඳහා සෞඛ්‍ය අමාත්‍යාංශය විසින් ප්‍රධානතම අරමුදල් සලසා ගැනීමේ ක්‍රමය වශයෙන් ඉන්දියානු ණය යෝජනා ක්‍රමය භාවිත කර ඇත. රාජ්‍ය ඖෂධ නීතිගත සංස්ථාව වෙත වෙන් කරන ලද ඇමරිකානු ඩොලර් මිලියන 114.9 ක මුදලින් මේ වන විට ඇමරිකානු ඩොලර් මිලියන 68.5 ක මුදලක් පමණක් එකී සංස්ථාව විසින් භාවිත කොට ඇත. (2022 සැප්තැම්බර් 14 වන විට වෛද්‍ය සැපයීම සඳහා ඉන්දියානු ණය යෝජනා ක්‍රමය භාවිත කිරීම පිළිබඳ සම්පූර්ණ විස්තරයක් මීට ඇමුණුම 3 වශයෙන් යා කොට ඇත.)

2.6 ඉන්දියානු ණය යෝජනා ක්‍රමය සහ අනෙකුත් අරමුදල් ක්‍රම භාවිත කර දින 45 ක් ඇතුළත ශ්‍රී ලංකාව වෙත මාස 03 ක කාලයක් සඳහා ප්‍රමාණවත් වන වෛද්‍ය සැපයීම් තොග ලබා දීම සඳහා The Savorite Pharmaceuticals (Pvt) Ltd (703, Atlantis Heights, Sarabhai Compound, Vadiwadi Road, Vadodara- 39007 Gujarat, India.) ආයතනය විසින් එකඟතාව පළ කොට ඇත. (ඇමුණුම 4)

2.7 වත්මන් විදේශ විනිමය අර්බුදය තුළ අවශ්‍ය වෛද්‍ය සැපයුම් මිලදී ගැනීම සඳහා සෞඛ්‍ය අමාත්‍යාංශය විසින් මූලික අරමුදල් මාර්ගය ලෙස ඉන්දියානු ණය යෝජනා ක්‍රමය භාවිතා කර ඇත.ඒ යටතේ මුදල් අමාත්‍යාංශයේ ඉන්දීය ණය පහසුකම් සම්බන්ධීකරණ අංශය (ICFC) සහ ඉන්දීය මහකොමසාරිස් කාර්යාලයෙහි පවත්නා පරිපාලනය හා අනුමැතිය ලබාගැනීමේ ක්‍රියාවලිය සඳහා මේ වනවිට ලිපිගොනු දහසකට වඩා වැඩි ප්‍රමාණයක් ඉදිරිපත් කර ඇති අතර අවශ්‍ය අනුමැතිය ලබාගැනීම් සඳහා දීර්ඝ කාලයක් ගත වන බව නිරීක්ෂණය වේ. එබැවින් සෞඛ්‍ය අංශ සඳහා අත්‍යවශ්‍ය ඖෂධ, ශල්‍ය පරිභෝජ්‍ය ද්‍රව්‍ය (Surgical items) හා ප්‍රතික්‍රියාකාරක (reagents) කඩිනමින් සපයා ගැනීමේ බරපතල ගැටළුවක් උද්ගත වී ඇති බව ද නිරීක්ෂණය වී ඇත.

3.0 යෝජිත විසඳුම

3.1 වෛද්‍ය සැපයුම් අංශයේ හදිසි තත්වය සහ දැඩි අවශ්‍යතාව මත පදනම්ව, ඉන්දියානු ණය යෝජනා ක්‍රමය යටතේ පවතින ඉතිරි අරමුදල් සහ වෙනත් අරමුදල් ක්‍රම භාවිත කරමින් මාස 3 ක කාලසීමාවක් සඳහා ප්‍රමාණවත් වෛද්‍ය සැපයුම් ආනයනය කිරීම සඳහා The Savorite Pharmaceuticals (Pvt) Ltd වැනි තෝරාගත් පෞද්ගලික අංශයේ ඖෂධ ආනයනය කරනු ලබන හෝ නිපදවනු ලබන ආයතන වෙත අවසර ලබාදීම.

3.2 ඉන්දියානු ණය යෝජනා ක්‍රමය සහ ශ්‍රී ලංකා රජයේ අරමුදල් ඇතුළු වෙනත් අරමුදල් ක්‍රම භාවිත කර තෝරාගත් සැපයුම් කරුවන් ගෙ එකඟවී ඇති කාලසීමාවක් තුළ ආනයනය කරන ලද තොග සඳහා වන පිරිවැය සඳහා වන ගෙවීම් සිදු කිරීම.

3.3 මෙම අර්බුදකාරී කාලසීමාව තුළ සිදුවන ප්‍රමාදයන් අවමකර ගැනීම සඳහා රාජ්‍ය ඖෂධ නීතිගත සංස්ථාවේ ලියාපදිංචිය නොමැති අයිතම ආනයනය කිරීමට ප්‍රථම එකී සංස්ථාවේ නිසි ලියාපදිංචි ක්‍රියාවලියකට භාජනය විය යුතුය.

4.0 අපේක්ෂිත අනුමැතිය

4.1 රජයේ සෞඛ්‍ය ආයතනවල උග්‍ර වෛද්‍ය සැපයීම් හිඟයන් ඇතිවීම වලක්වා ගැනීම සඳහා අවශ්‍ය වෛද්‍ය සැපයුම් සේවාවක් පවත්වා ගැනීම පිණිස, සෞඛ්‍ය අමාත්‍යාංශය විසින් පහත සඳහන් යෝජනා සඳහා අනුමැතිය අපේක්ෂා කෙරේ.

4.1.1 වෛද්‍ය සැපයුම් අංශයේ හදිසි තත්ත්වය සහ අවශ්‍යතාවය මත පදනම්ව, ඉන්දියානු ණය යෝජනා ක්‍රමයේ ඉතිරිව පවතින අරමුදල් සහ වෙනත් අරමුදල් ක්‍රම භාවිත කරමින් මාස තුනක කාලයක් සඳහා ප්‍රමාණවත් රාජ්‍ය ඖෂධ නීතිගත සංස්ථාවේ අනුමත වෛද්‍ය සැපයුම් ආනයනය කිරීම සඳහා The Savorite Pharmaceuticals (Pvt) Ltd ආයතනයට සහ වෙනත් තෝරාගත් සැපයුම් කරුවන් වෙත අවසර ලබා දීම සඳහා.

4.1.2 ඉන්දියානු ණය යෝජනා ක්‍රමය සහ වෙනත් අරමුදල් ක්‍රම භාවිත කරමින්, එකඟවනු ලබන ගෙවීම් සැලැස්මකට අනුව ගෙවීම් සිදුකිරීම සඳහා The Savorite Pharmaceuticals (Pvt) Ltd ආයතනය සහ වෙනත් තෝරාගත් සැපයුම් කරුවන් සමග ගිවිසුමක් අත්සන් නැවීම පිණිස අවසර ලබාදීම සඳහා.

ඇ/කෑළු:
ආචාර්ය කෙහෙලිය රඹුක්වැල්ල
සෞඛ්‍ය අමාත්‍ය

ආචාර්ය කෙහෙලිය රඹුක්වැල්ල
සෞඛ්‍ය අමාත්‍ය
2022 ඔක්තෝබර් 25 වන දින දිය.

ඇමුණුම 38

කාර්යාලය
அலுவலகம்
Office
2422438

ෆැක්ස් අංක
தொலைநகல் இல.
Fax Nos.
2323730
2389150
2389151

වෙබ අඩවිය
இணையத்தளம்
Web Site

ඊ-මේල්
மின்னஞ்சல்
E-mail
info@cabinetoffice.gov.lk

අමාත්‍ය මණ්ඩල කාර්යාලය
அமைச்சரவை அலுவலகம்
OFFICE OF THE CABINET OF MINISTERS

ලොයිඩ්ස් ගොඩනැගිල්ල, ශ්‍රීමත් බරෝන් ජයතිලක මාවත, කොළඹ 01.
லொயிட்ஸ் கட்டடம், சேர் பாரோன் ஜயதிலக்க மாவத்தை, கொழும்பு 01.
Lloyd's Building, Sir Baron Jayathilaka, Mawatha, Colombo 01.

මගේ අංකය
எனது இல.
My No.
22/1693/610/024

ඔබේ අංකය
உமது இல.
Your No.

දිනය
திகதி
Date
2022-10-26

එස්.ජේ.එස්. චන්ද්‍රගුප්ත මහතා
ලේකම්
සෞඛ්‍ය අමාත්‍යාංශය
ෆැක්ස්: 2692913

අමාත්‍ය මණ්ඩල තීරණය

2022-10-25 දින පැවති අමාත්‍ය මණ්ඩල රැස්වීමේ වාර්තාවේ විෂය අංක (23) හි උද්ධෘතයක් සහන දැක්වේ.

විෂය අංක: (23)

අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 22/1693/610/024 වූ, "ශ්‍රී ලංකාව තුළ අඛණ්ඩ වෛද්‍ය සැපයීම් සේවාවක් පවත්වාගෙන යාම" යන මැයෙන් සෞඛ්‍ය ඇමතිතුමා ඉදිරිපත් කළ 2022-10-25 දිනැති සංදේශය - (අමප අංක 22/1523/610/018 පිළිබඳව වූ 2022-10-03 දිනැති අමාත්‍ය මණ්ඩල තීරණයට අදාළව) මෙම රැස්වීමේදී සභාගත කරන ලද ඉහත සඳහන් සංදේශය, ඒ සම්බන්ධයෙන් සෞඛ්‍ය ඇමතිතුමා විසින් සිදු කරන ලද වැඩිදුර කරුණු පැහැදිලි කිරීම් සමඟ අමාත්‍ය මණ්ඩලය විසින් සලකා බලන ලදී. මේ පිළිබඳව සාකච්ඡා කිරීමෙන් අනතුරුව, පහත සඳහන් පරිදි තීරණය කරන ලදී:

(i) සංදේශයේ 4.0 ඡේදයෙහි 4.1 අනුඡේදය යටතේ සඳහන් (4.1.1) සහ (4.1.2) යෝජනා සඳහා ප්‍රතිපත්තිමය වශයෙන් අනුමැතිය ලබා දීම; සහ

(ii) මෙම කරුණු පිළිබඳව අවසන් තීරණයකට එළඹීමට හැකි වනු පිණිස, ඉහත සංදේශයේ සඳහන් යෝජනා සම්බන්ධයෙන් මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති ඇමතිතුමාගේ නිරීක්ෂණ රාජ්‍ය වියදම් කළමනාකරණය පිළිබඳ අමාත්‍ය මණ්ඩල අනුකාරක සභාවේ මීළඟ රැස්වීමට ඉදිරිපත් කිරීමට අවශ්‍ය පියවර ගන්නා ලෙස එම අමාත්‍යාංශයේ ලේකම්ට නියම කිරීම.

කවද, මෙම තීරණය ක්‍රියාත්මක කරනු ලැබූ ලේ පැලකීමටත්, ඒ අනුව අවශ්‍ය කටයුතු සඳහා අදාළ බලධාරීන් වෙත මෙම තීරණය දන්වා යැවීම සඳහා අමාත්‍ය මණ්ඩලයේ ලේකම්ට බලය පැවරීමටත් තීරණය කරන ලදී.

ලේකම්
සෞඛ්‍ය අමාත්‍යාංශය

ලේකම්
செயலாளர்
Secretary
2329620

අතිරේක ලේකම්
மேலதிகச் செயலாளர்
Additional Secretary
2431004

ජ්‍යෙෂ්ඨ සහකාර ලේකම්
சிரேட்ட உதவிச் செயலாளர்
Senior Assistant Secretary
2325279
2422276
3136199

Anex I

373

ක්‍රියා කළ යුතු: **අමාත්‍ය මණ්ඩලයේ ලේකම්**

මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය - ගරු ඇමතිතුමාගේ අවධානයට යොමු කිරීම පිණිස - සංදේශයේ පිටපතක් යා කොට ඇත.

සෞඛ්‍ය අමාත්‍යාංශය - ගරු ඇමතිතුමාගේ අවධානයට යොමු කිරීම පිණිස.

වෙළෙඳ, වාණිජ හා ආහාර සුරක්ෂිතතා අමාත්‍යාංශය - සංදේශයේ පිටපතක් යා කොට ඇත.

පිටපත්: **ජනාධිපති ලේකම්** - සංදේශයේ පිටපතක් යා කොට ඇත.
අග්‍රාමාත්‍ය ලේකම් - සංදේශයේ පිටපතක් යා කොට ඇත.

ඩබ්ලිව්.එම්.සී.ජේ. ප්‍රනාන්දු
අමාත්‍ය මණ්ඩලයේ ලේකම්

ඇමුණුම 39

දුරකථන / தொலைபேசி / Telephones } 694113, 694114, 686528-30

විදුලි පණිවුඩ / தந்தி / Telegrams } රජ වෛද්‍යකම් මෙඩ්ස්ටෝස් / MEDSTORES

ෆැක්ස් / ඵக்ஸ் / Fax } 941-697096

කේබල් / கடிதத்தின் / Cables } GOVTDRUG

ඔබේ අංකය / உமது இல. / Your No.

වෛද්‍ය සැප
(සෞඛ්‍ය සේවා අදහාර්තමේන්තුව)
வைத்திய விநியோகப்பகுதி
(சுகாதார சேவைத் திணைக்களம்)
MEDICAL SUPPLIES DIVISION
(Department of Health Services)

අංක 357, බද්දේගම විමලවංශ මාවත, කොළඹ 10, ශ්‍රී ලංකාව.
இல. 357, பத்தேகம விமலவங்ச மாவத்தை, கொழும்பு 10, இலங்கை.
No. 357, Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka

තැ. පෙ. / தபெ / P.O.Box } 1679

01/11/2022

දිනය/திகதி/Date : .....

Director
Assistant Director (Pharmaceutical- I, ii)
Assistant Director (Surgical- I, ii)
Assistant Director (Lab - I, ii)

Special Procurement Action to be taken under the current crisis situation.

01 In view of the urgency of short supply items , under mentioned special procurement actions have been approved by Cabinet of Ministers for immediate implementation.

i. Special procurement process via an EOI from local suppliers (process already completed by Additional Secretary (PSRP)) , for 3 months requirement of hundred eighty four (184) items .

Reference : Cabinet Memorandum 22/1523/610/018 – of 2022.10.03, approved number 22/1693/610/024 approved date 2022.10.26

ii. Special procurement via unsolicited supply proposal (received by Honorable Minister of Health & evaluated by additional secretary (MSD)), from an Indian supply argent , evaluated by Addl. Secretary-MSD for 03 month requirement of 38 urgent items

Reference : Cabinet Memorandum MH/AD/01/04/41/2022 of 2022.09.26, Cabinet Approval number 22/1523/610/018 of 2022.10.04

02 In respect of (i) above, please initiate MSD local supply order lists under the "V" category, in parallel to the emergency "V" orders placed with SPC for 3 months or the quantity in the letter awarding the EOI based tender (letter Ref. No. PSRP/08/EOI/Acc/2022). It is to be done without considering the stock in hand and balance due on past orders.

The relevant stock control (supply) officer may initiate a common order file in creating this EOI based order list and send a D/ MSD approved hard copy of same to accountant (supply)/MSD for further processing .

03 In respect of (ii) above Secretary Health has instructed , to place the order for 3 months of the 38 urgent items that are selected from the list of items offered in the proposal of the Indian Party.

Relevant stock control officer (supply), may initiate a common order file for this unsolicited proposal based orders of the 38 items (Annex I) for 03 months in the list of items , evaluated and selected by Adl. Secretary (PSRP)

in addition to placing the MSMIS order online , a hard copy of the relevant order list approved by D/MSD shall be send to accountant (supply /MSD), for further processing to generate the PO .

Dr. D.R.K.Herath
Deputy Director General (MSD)

Dr. D. R. K. HERATH
Deputy Director General (Medical Supplies)
Medical Supplies Division
Ministry of Health Nutrition & Indigenous Medicine
Colombo 10.

PC-M

මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය
நிதி, பொருளாதார உறுதிப்பாடு மற்றும் தேசியக் கொள்கைகள் அமைச்சு
MINISTRY OF FINANCE, ECONOMIC STABILIZATION AND NATIONAL POLICIES

මහලේකම් කාර්යාලය, කොළඹ 01,
ශ්‍රී ලංකාව

செயலகம், கொழும்பு 01,
இலங்கை.

The Secretariat, Colombo 01,
Sri Lanka.

05-08

කාර්යාලය
அலுவலகம்
Office
011-2484500
011-2484600
011-2484700

ෆැක්ස්
தொலைநகல்
Fax
011-2449823

වෙබ් අඩවිය
இணையதளம்
Website
www.treasury.gov.lk

මගේ අංකය
எனது இல
My No
PFD/PMD/CM/2022/HEA/02/300

ඔබේ අංකය
உமது இல
Your No
CP 22/1693/610/024

දිනය
திகதி
Date
02.11.2022

Cabinet Memorandum

Observations of the Minister of Finance, Economic Stabilization and National Policies

Ministry/Institution : Health

Subject& Date : Maintenance of Uninterrupted Supply of Medical Supplies to Sri Lanka

25.10.2022

Proposals/ Requests : Approval of the Cabinet of Ministers is sought for the following proposals;

1. Permit the Savorite Pharmaceuticals (Pvt) Ltd and other selected suppliers to import NMRA – approved medical supplies adequate for 3 months using the remaining funds of the Indian Credit Line and other funding resources based on the urgency and requirement of the MSD.

2. Permit Ministry of Health to sign an agreement with Savorite Pharmaceuticals (Pvt) Ltd and other selected suppliers to pay back in an agreed payment plan, utilizing the ICL and other funding resources.

Observations : It is observed that, according to the Cabinet Memorandum some vital and essential drugs are out of stock in the Medical Supply Division and some drugs will be out of stock within three weeks. Therefore, considering the national requirement for drugs, I have no objection to proposals Nos. 4.1.1 and 4.1.2, subject to the followings;

a. The proposed supplier mentioned in the Cabinet Memorandum is selected on an unsolicited basis. Therefore, prices and quality of medical supplies should be reviewed and negotiated by the Cabinet Appointed Negotiation Committee (CANC) or Health Sector Emergency Procurement Committee (HSEPC) which is already appointed to the Ministry of Health to obtain realistic and reasonable prices on par with the market rates and also the quality of the drugs.

b. The Ministry of Health should follow the procedures which are applicable for private sector pharmaceutical suppliers who import drugs on behalf of the State Pharmaceutical Corporation under the Indian Credit Line Scheme for the proposed supplier.

c. The Ministry of Health and the proposed supplier enter into an agreement regarding prices and quality of drugs before the importation.

d. If there are any private sector supplier who comes under unsolicited basis to provide medical supplies under the Indian Credit Line, the Ministry of Health should follow the process of a, b and c above for them. Further, if funds utilize other than the Indian Credit Line, the appropriate Procurement Guidelines should be followed by the Ministry of Health.

e. It is observed that, the State Pharmaceutical Corporation (SPC) needs longer lead time to import medical supplies. Considering the current situation of shortage of drugs, SPC should develop an in-house mechanism to address this emergency situation by reducing the lead time for procurement process with the approval of the relevant authorities.

f. Also, the Ministry of Health should develop a proper monitoring and coordinating mechanism within the institutions come under the purview of the Ministry to overcome such unnecessary delays in the procurement process.

g. Further, the Ministry of Health should follow the appropriate procurement planning process by keeping lead time and buffer stock to avoid shortage of any medical supplies in future.

Ranil Wickremesinghe
Minister of Finance, Economic Stabilization and National Policies

ඇමුණුම 41

රහසිගතයි

අමාත්‍ය මණ්ඩල කාර්යාලය
அமைச்சரவை அலுவலகம்
OFFICE OF THE CABINET OF MINISTERS

CABINET DECISION අමාත්‍ය මණ්ඩල තීරණය அமைச்சரவைத் தீர்மானம்

මගේ අංකය: අමප/22/1693/610/024 2022 නොවැම්බර් මස 22 දින.

පිටපත්:

ජනාධිපති ලේකම්.
අග්‍රාමාත්‍ය ලේකම්.
විගණකාධිපති.

ක්‍රියා කළ යුතු:

මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යාංශයේ ලේකම්.
සෞඛ්‍ය අමාත්‍යාංශයේ ලේකම්.
වෙළෙඳ, වාණිජ හා ආහාර සුරක්ෂිතතා අමාත්‍යාංශයේ ලේකම්.

ශ්‍රී ලංකාව තුළ අඛණ්ඩ වෛද්‍ය සැපයීම සේවාවක් පවත්වාගෙන යාම

(සෞඛ්‍ය ගරු ඇමතිතුමා ඉදිරිපත් කළ 2022-10-25 දිනැති සංදේශය)

2022 නොවැම්බර් මස 14 දින පැවැත්වුණු අමාත්‍ය මණ්ඩල රැස්වීමේදී ඵලඹී තීරණයක් අවශ්‍ය කටයුතු සඳහා මේ සමඟ එවා ඇත.

ඩබ්ලිව්.එම්.ඩී.ජේ.ප්‍රනාන්දු
අමාත්‍ය මණ්ඩලයේ ලේකම්.

05. අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 22/1769/640/012 වශයෙන් අංකගත කරන ලද, ගරු ජනාධිපති සහ මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍ය සහ රාජ්‍ය වියදම් කළමනාකරණය පිළිබඳ අමාත්‍ය මණ්ඩල අනුකාරක සභාවේ සභාපතිතුමා ඉදිරිපත් කළ 2022-11-03 දිනැති සටහනට යා කොට තිබූ, 2022-11-02 දින පැවැත්වුණු රාජ්‍ය වියදම් කළමනාකරණය පිළිබඳ අමාත්‍ය මණ්ඩල අනුකාරක සභාවේ නිර්දේශ ඇතුළත් වාර්තාව අමාත්‍ය මණ්ඩලය විසින් සලකා බලනා ලදුව, එකී වාර්තාවේ ඇතුළත් ඔබ අමාත්‍යාංශයට අදාළ පහත සඳහන් නිර්දේශය අනුමත කරන ලදී.

→2

"05.08 අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 22/1693/610/024 වූ, **"ශ්‍රී ලංකාව තුළ අඛණ්ඩ වෛද්‍ය සැපයීම් සේවාවක් පවත්වාගෙන යාම"** යන මැයෙන් සෞඛ්‍ය ඇමතිතුමා ඉදිරිපත් කළ 2022-10-25 දිනැති සංදේශය - (ඉහත සංදේශය පිළිබඳව වූ 2022-10-25 දිනැති අමාත්‍ය මණ්ඩල තීරණයට අදාළව) ඉහත සඳහන් සංදේශය මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති ඇමතිතුමාගේ නිරීක්ෂණ සමඟ අමාත්‍ය මණ්ඩල අනුකාරක සභාව විසින් සලකා බලනු ලදී. මේ පිළිබඳව සාකච්ඡා කිරීමෙන් අනතුරුව, එකී නිරීක්ෂණවල පළමු ඡේදයේ (අ) සිට (උ) දක්වා වන අනුඡේදයන්හි සඳහන් පරිදි කටයුතු කිරීමට යටත්ව, සංදේශයේ 4.0 ඡේදයේ 4.1 අනුඡේදයෙහි සඳහන් (4.1.1) සහ (4.1.2) යෝජනා සඳහා අනුමැතිය ලබා දීම අමාත්‍ය මණ්ඩලය වෙත නිර්දේශ කිරීමට තීරණය කරන ලදී."

තවද, මෙම තීරණය සම්මත කරනු ලැබූ සේ සැලකීමටත්, ඒ අනුව අවශ්‍ය කටයුතු සඳහා අදාළ බලධාරීන් වෙත මෙම තීරණය දන්වා යැවීම සඳහා අමාත්‍ය මණ්ඩලයේ ලේකම්ට බලය පැවරීමටත් තීරණය කරන ලදී.

ක්‍රියා කළ යුතු: **මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය**
සෞඛ්‍ය අමාත්‍යාංශය - ඉහත නිරීක්ෂණ යා කොට ඇත.
වෙළෙඳ, වාණිජ හා ආහාර සුරක්ෂිතතා අමාත්‍යාංශය - සංදේශයේ පිටපතක් හා ඉහත නිරීක්ෂණ යා කොට ඇත.

පිටපත්: **ජනාධිපති ලේකම්** - සංදේශයේ පිටපතක් හා ඉහත නිරීක්ෂණ යා කොට ඇත.
අග්‍රාමාත්‍ය ලේකම් - සංදේශයේ පිටපතක් හා ඉහත නිරීක්ෂණ යා කොට ඇත.

දුරකථන) 0112669192 , 0112675011
தொலைபேசி) 0112698507 , 0112694033
Telephone) 0112675449 , 0112675280

ෆැක්ස්) 0112693866
பெக்ஸ்) 0112693869
Fax) 0112692913

විද්‍යුත් තැපෑල)postmaster@health.gov.lk
மின்னஞ்சல் முகவரி)
e-mail)

වෙබ් අඩවිය) www.health.gov.lk
இணையத்தளம்)
website)

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதாரஅமைச்சு
Ministry of Health

මගේ අංකය) PSRP/08/EOI/General/2022
எனது இல
My No.)

ඔබේ අංකය)
உமது இல)
Your No.)

දිනය)
திகதி) 2022-11-30
Date)

405

ඇමුණුම 42

Dr. R.M.S.K. Rathnayake
Additional Secretary
Division of Production, Supply and Regulation of Pharmaceuticals

Conducting of procurement process of Health Sector Emergency Procurement Committee

The Ministry of Health is responsible for the supply of essential pharmaceuticals surgical items and laboratory consumables to government hospitals and healthcare institutes in Sri Lanka. The Government of Sri Lanka annually spends about SLR 65 billion to supply required pharmaceuticals, surgical items, laboratory items, radiological items, and consumables required for healthcare institutions. Due to the existing forex crisis, medical supplies supply chain has badly affected and developing shortages.

02. The current stock levels of medical supplies inside the Medical Supplies Division (MSD) are alarming. Because of this, there is an inevitable threat of developing a severe shortage of medical supplies in Healthcare Institutions in the country which could lead to a significant failure in the healthcare delivery system.

03. To maintain the uninterrupted supply of medical supplies and to avoid acute shortages of medical supplies in government healthcare, Ministry of Health has appointed a Health Sector Emergency Procurement Committee in accordance with the guidelines for Health Sector Emergency Procurement Process (HSEPP) No-PFD/PMD/Health/HSEPP/01/2022 dated 16/06/2022 issued by the Ministry of Finance of the Government of Sri Lanka.

04. It is essential to maintain an efficient and effective Health Sector Emergency Procurement Process in order to maintain uninterrupted supply chain. It is well known factor that, the previous State Ministry of Production Supply and Regulation of Pharmaceuticals has conducted procurement related activities of Standing Cabinet Appointed Procurement Committee (SCAPC), Ministry Procurement Committee (MPC) and specially procurement activities of Covid -19 Emergency Procurement Process (CEPP).

05. Since, staff and other resources available at the Division of Production, Supply and Regulation of Pharmaceuticals which functions under the Ministry of Health, it has been decided to authorize to conduct procurements procured under Health Sector Emergency Procurement Process.

S. Janaka Sri Chandraguptha
Secretary

S. Janaka Sri Chandraguptha
Secretary
Ministry of Health
"Suwasiripaya",
385, Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10, Sri Lanka.

Copies: 1. Additional Secretary (Procurement), Ministry of Health
2. Chairman, State Pharmaceuticals Corporation.
3. Deputy Director General, Medical Supplies Division

For your information and necessary action pl.

දුරකථන) 0112669192 , 0112675011
தொலைபேசி) 0112698507 , 0112694033
Telephone) 0112675449 , 0112675280

ෆැක්ස්) 0112693866
பெக்ஸ்) 0112693869
Fax) 0112692913

විද්‍යුත් තැපෑල)postmaster@health.gov.lk
மின்னஞ்சல் முகவரி)
e-mail)

වෙබ් අඩවිය) www.health.gov.lk
இணையத்தளம்)
website)

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

මගේ අංකය & PSRP/08/EOI/General/2022
எனது இல
My No. &

ඔබේ අංකය &
உமது இல)
Your No. &

දිනය &
திகதி &
Date & 21 .11.2022

ඇමුණුම 43

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதாரஅமைச்சு
Ministry of Health

Dr.B.L.D.Jayanath,
Medical Officer In charge (Procurement unit),
Division of Production, Supply and Regulation of Pharmaceuticals (PSRP).
Ministry of Health,
Colombo 10.

Conducting of Procurement Process of Health Sector Emergency Procurement Committee.

This has reference with the letter no. PSRP/08/EOI/General/2022 dated 20.11.2022 sent by the Secretary, Ministry of Health regarding above matter.

The Ministry of Health has decided to give authority to conduct procurements, procured under Health Sector Emergency Procurement Process under my leadership and supervision.

It is well known factor that, the previous State Ministry of Production Supply and Regulation of Pharmaceuticals (SMPSRP) has conducted all procurement related activities of Standing Cabinet Appointed Procurement Committee (SCAPC), Ministry Procurement Committee (MPC) and specially procurement activities of Covid -19 Emergency Procurement Process (CEPP) with the well-trained Medical Officers and staff available at the procurement unit of the previous state ministry.

I specially observed that you had been attached to the procurement unit of previous state ministry as a Procurement Manager with qualification of Higher National Diploma in Public Procurement and Contract Administration (HN-DIPPCA) awarded by SLIDA from 5th July 2021. Since then, you have overseen the procurement activities of Covid -19 Emergency Procurement Process successfully and rendered commendable and highly satisfactory service.

Since, above staff and other resources available at the Division of Production, Supply and Regulation of Pharmaceuticals which functions under the Ministry of Health, you are hereby appointed to take over the duties of procurement officer attached to the procurement unit and assign following duties of Health Sector Emergency Procurement Process on the basis of service need in order to conduct the emergency procurement activities under my supervision.

(82)

(397)

- Coordinating the preparation of Bidding documents.
- Coordinating Tender calling process.
- Coordinating bid opening process.
- Coordinating the Technical Evaluation Committees.
- Coordinating Health Sector Emergency Procurement Committee (HSEPC).
- Coordinating the preparation of HSEPC decisions.
- Preparation of cabinet memorandum and note to the cabinet related to the HSEPP.
- Supervision of the staff allocated to the procurement unit of former state ministry of production, supply and regulations of pharmaceuticals.

Additional Secretary
(Production, Supply &
Regulation of Pharmaceuticals)
Ministry of Health

Dr.R.M.S.K.Rathnayake

Additional Secretory,

Division of Production, Supply and Regulation of Pharmaceuticals

Ministry of Health.

Cc:

1. Additional Secretary – Procurement, Ministry of Health -FYI
2. Director General- Health Services, Ministry of Health -FYI
3. Chairman – State Pharmaceutical Corporation -FYI
4. Deputy Director General- Medical Services II, Ministry of Health -FYI
5. Deputy Director General- NCD Unit, Ministry of Health -FYI
6. Deputy Director General- Medical supplies Division -FYI
7. Director - Medical Services II, Ministry of Health -FYI

Senior Assistant Director

All Assistant Director (Pharmaceuticals)

Obtaining Approval through normal Channels for Procurement as an unsolicited proposal of M/s Kuasikh Therapeutics (P) LTD, Chennai, India

As per the instruction given by the Hon. Minister of Health on 01st December 2022 in a meeting with Secretary, Ministry of Health, Additional Secretary (PSRP) and DGHS at his office, please proceed as above to obtain approvals and procurement of 28 items in the proposal with the cabinet approval to be obtained by Additional Secretary(PSRP).

Director

Medical Supplies Division

Dr. A. T. SUDARSHANA
Director
Ministry of Health
Medical Supplies Division
No. 357, Deans Road.
Colombo 10.

Asst. Director - Pharmaceuticals
02 DEC 2022
Medical Supplies Division
Colombo 10

Hscop, Allsco / supply,
fna
02/12/2022

අමුණුම 45

KAUSIKH THERAPEUTICS (P) LTD.

Regd Off : New No. 21, Old No. 12, Durairaj Street, Palavanthangal, Chennai - 600 114.
Factory : Plot No. 6 & 7, Paraniputhur Village, Gerugambakkam, Chennai - 602 101.
Website : ktplchennai.com
Telefax : 2382 0370 / 0490
Tel. : 2382 0673 / 0674
e-mail : kausic@vsnl.net

Exporter:
Kausikh Therapeutics (P) Ltd.
Fac: Plot No.6 & 7 Paraniputhur Road.
Gerugambakkam
Chennai - 600128. GST No.33AABCK5176D1ZT
Telefax: 91 44 2382 0370 / 0490.

Consignee:
M/s. State Pharmaceuticals Corporation of Srilanka
75, Sir Baron Jayatilaka Mawatha
Colombo-1, Srilanka.

Asst. Director - Pharmaceuticals
02 DEC 2022
Medical Supplies Division
Colombo 10.

Invoice No. & Date
KTPL/048 Dt.30.11.2022

Buyer's Bank Name & Address

Buyer other than consignee :

Country or Origin of Goods
India

Terms of Delivery and Payment
LC 90 DAYS

Vessal / Flight No.	Port of Lading - Chennai
Port of Discharge Colombo	Final Destination Colombo

Sl.No	Brand Name (If Applicable)	Generic Name (If Applicable	Forma	Pack Size	Total Quantity (Boxes)	Unit FOB rate US $ / Pack	Total Value (In USD)
1		Levofloxacin 500mg tabs	TABS	10x10 A/A	450	$ 4.96	$ 2,232.00
2		Cholecalciferol 1000 IU tabs	TABS	10x10 A/A	6000	$ 0.89	$ 5,340.00
3		Ofloxacin 200mg tabs	TABS	10x10 B	600	$ 1.91	$ 1,146.00
4		Tamsulosin caps 0.4mg	CAPS	10x10 B	15000	$ 1.66	$ 24,900.00
5		Pyridoxine HCL 25mg tabs	TABS	10x10 B	5000	$ 0.41	$ 2,050.00
6		Sildenafil 50mg tabs	TABS	10x2x4 B	4688	$ 1.49	$ 6,985.12
7		Carvedilol 6.25mg tabs	TABS	10x10 B	62500	$ 0.60	$ 37,500.00
8		Allopurinol 100mg	TABS	10x10 B	9000	$ 0.91	$ 8,190.00
9		Ondansetron 4mg tabs	TABS	10x10 B	1500	$ 0.85	$ 1,275.00
10		Cefuroxime Syp 125mg/5ml	BOT	100ml	1500	$ 0.88	$ 1,320.00
11		Fluconazole Caps 200mg	CAPS	1S	10500	$ 0.12	$ 1,260.00
12		Diclofenac Sodium 25mg tabs	TABS	10x10 B	18000	$ 0.46	$ 8,280.00
13		Itraconazole caps 100mg	CAPS	10x10 A/A	3600	$ 2.80	$ 10,080.00
14		Azithromycin 250mg tabs	TABS	10x10 B	7500	$ 5.04	$ 37,800.00
15		Ibuprofen 200mg tabs	TABS	10x10 B	75000	$ 0.78	$ 58,500.00
16		Desloratadine 5mg tabs	TABS	10x10 A/A	6000	$ 1.11	$ 6,660.00
17		Montelukast Sodium tabs 10mg	TABS	10x10 A/A	4500	$ 1.48	$ 6,660.00
18		Nifedipine ER tabs 20mg	TABS	10x10 B	225000	$ 0.57	$ 1,28,250.00
19		Loperamide Hcl tabs 2mg	TABS	10x10 B	225	$ 0.62	$ 139.50
20		Montelukast Sodium Chewable tabs 5mg	TABS	10x10 B	3000	$ 0.89	$ 2,670.00
21		Carvedilol tabs 12.5mg	TABS	10x10 B	7500	$ 0.81	$ 6,075.00
22		Cefixime tabs 200mg	TABS	10x10 A/A	750	$ 6.29	$ 4,717.50
23		Metoclopramide tabs 10mg	TABS	10x10 B	2550	$ 0.60	$ 1,530.00
24		Aspirin tabs 300mg	TABS	10x10 B	5000	$ 1.03	$ 5,150.00
25		Erythromycin Succinate Syp 125mg/5ml	BOT	100ml	10500	$ 0.69	$ 7,245.00
26		Cefuroxime tabs 500mg	TABS	10x10 A/A	11250	$ 13.60	$ 1,53,000.00
27		Cefalexin dispersible tabs 125mg	TABS	10x10 B	2500	$ 2.13	$ 5,325.00
28		Bisacodyl 5mg tabs	TABS	10x10 B	7500	$ 0.49	$ 3,675.00
				Total FOB			$ 5,37,955.12

(Total Value US$ 5,37,955.12 *US$ FIVE LAKHS THIRTY SEVEN THOUSAND NINE HUNDRED AND FIFTY FIVE AND CENTS TWELVE ONLY*
Delivery : Within 60 days of receipt of Confirmed Order and advance.
Bank/Branch Name : ICICI BANK, ANNANAGAR BRANCH A/C.No.168305001686
Swift Code to be filled in field 57A : ICICINBBCTS

For *KAUSIKH* THERAPEUTICS (P) LTD

DIRECTOR

Declaration:
We declare that thisProforma invoice shows the goods described and that all particulars are true and correct.

දුරකථන தொலைபேசி Telephone
011 2669192, 011 2675011
011 2698507, 011 2694033
011 2675449, 011 2675280

ෆැක්ස් தொலைநகல் Fax
011 2693866
011 2693869
011 2692913

විද්‍යුත් තැපෑල மின்னஞ்சல் e-mail
postmaster@health.gov.lk

වෙබ් අඩවිය இணையத்தளம் Website
www.health.gov.lk

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

මගේ අංකය எனது இல. My No.
MHADIO1104/141
2022

ඔබේ අංකය உமது இல. Your No.
ඇමුණුම 46

දිනය திகதி Date
2022.12.05

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
MINISTRY OF HEALTH

අමාත්‍ය මණ්ඩල සටහන

ශ්‍රී ලංකාව තුළ අඛණ්ඩ වෛද්‍ය සැපයීම් සේවාවක් පවත්වා ගෙන යාම

1.0 පසුබිම

1.1 වර්තමානයේ ශ්‍රී ලංකාවේ පවතින විදේශ විනිමය අර්බුදය හේතුවෙන් ශ්‍රී ලංකාවට අත්‍යවශ්‍ය වෛද්‍ය සැපයීම් අවශ්‍ය අවම ප්‍රමාණ වලින් ආනයනය කිරීමේ ගැටලුවකට සෞඛ්‍ය අමාත්‍යාංශය මුහුණ දී ඇත.

1.2 අමප අංක 22/1693/610/024 හා 2022.10.25 දිනැති අමාත්‍ය මණ්ඩල සංදේශයට අනුකූලව, ඉන්දියානු ණය යෝජනා ක්‍රමය සහ අනෙකුත් අරමුදල් භාවිතා කර, ශ්‍රී ලංකාව වෙත මාස 03 කට අවශ්‍ය වෛද්‍ය සැපයීම් තොග දින 45 ක් තුළ තෝරාගත් යැපයුම්කරුවන් මඟින් ලබා ගැනීමට අනුමැතිය ඉල්ලා සිටින ලදී.

1.3 තව ද 2022.11.14 දිනැති අමාත්‍ය මණ්ඩල තීරණයෙන් උක්ත අමාත්‍ය මණ්ඩල සංදේශයේ යෝජනා සඳහා මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යතුමාගේ නිරීක්ෂණ සමඟ අමාත්‍ය මණ්ඩල අනුකාරක සභාව විසින් සලකා බලා අනුමැතිය ලබා දී ඇත. (ඇමුණුම 01)

2.0 විස්තරය හා සාධාරණීකරණය

2.1 මේ අවස්ථාව වන විට (2022 ඔක්තෝබර් මස 17 වන විට) වෛද්‍ය සැපයුම් අංශයේ ඖෂධ 151 ක, ශල්‍ය වෛද්‍ය උපකරණ සහ පාරිභෝජන භාණ්ඩ 5278 ක, විකිරණශීලී උපකරණ 18 ක සහ නීත්‍ය සහ අනුපූරක රසායනාගාර උපකරණ 850 ක තොග ශූන්‍ය මට්ටමක පවතී. ඉදිරි සති 3ක කාල සීමාව තුළ කඩිත් බොහෝ උපකරණ වල තොග අවසන් වනු ඇති බවට අපේක්ෂා කෙරේ.

2.2 තව ද ඖෂධ 21 ක සහ ශල්‍ය වෛද්‍ය උපකරණ සහ පාරිභෝජන භාණ්ඩ 2002 ක රෝහල් (ආයතනික) තොග මට්ටම් දැනටමත් ශූන්‍යව පවතී. එමෙන්ම මැහුම් අමුද්‍රව්‍ය සහ නිර්වින්දන ඖෂධ වැනි අත්‍යාවශ්‍ය ශල්‍ය වෛද්‍ය උපකරණ වල තොග මට්ටම් අවසන් වීම සහ ඉතා අවම මට්ටමක පවතින බව ද නිරීක්ෂණය කරමී.

2.3 වත්මන් විදේශ විනිමය අර්බුදය තුළ අත්‍යාවශ්‍ය වෛද්‍ය සැපයුම් මිලදී ගැනීම සඳහා සෞඛ්‍ය අමාත්‍යාංශය විසින් ප්‍රධානතම අරමුදල් සලසා ගැනීමේ ක්‍රමය වශයෙන් ඉන්දියානු ණය යෝජනා ක්‍රමය භාවිත කර ඇත. රාජ්‍ය ඖෂධ නීතිගත සංස්ථාව වෙත වෙන් කරන ලද ඇමරිකානු ඩොලර් මිලියන 114.9 ක මුදලින් මේ වන විට ඇමරිකානු ඩොලර් මිලියන 68.5 ක මුදලක් පමණක් එකී සංස්ථාව විසින් භාවිත කොට ඇත.

2.4 ඉන්දියානු ණය යෝජනා ක්‍රමය සහ අනෙකුත් අරමුදල් ක්‍රම භාවිත කර දින 45 ක් ඇතුළත ශ්‍රී ලංකාව වෙත මාස 03 ක කාලයක් සඳහා ප්‍රමාණවත් වන වෛද්‍ය සැපයීම් තොග ලබා දීම සඳහා KAUSIKH THERAPEUTICS (P) LTD (New No: 21, 'Old No: 12, Durairaj Street, Palavanthangal, Chennai.) ආයතනය විසින් එකඟතාව පළ කොට ඇත. ඔහු විසින් සපයනු ලබන වෛද්‍ය සැපයුම් වර්ග 28 ඇමුණුම 02 ත් දක්වා ඇත.

3.0 අමාත්‍යාංශය විසින් ගෙන ඇති ක්‍රියාමාර්ග

3.1 රජයේ සෞඛ්‍ය ආයතනවල උග්‍ර වෛද්‍ය සැපයීම් හිඟයන් ඇතිවීම වලක්වා ගැනීම සඳහා අඛණ්ඩ වෛද්‍ය සැපයුම් සේවාවක් පවත්වා ගැනීම පිණිස, සෞඛ්‍ය අමාත්‍යාංශය විසින් පහත සඳහන් පරිදි කටයුතු කිරීමට අවශ්‍ය වන බවට අමාත්‍ය මණ්ඩලයේ අවධානයට ලක් කරනු ලැබේ.

3.1.1 වෛද්‍ය සැපයුම් අංශයේ හදිසි තත්ත්වය සහ අවශ්‍යතාවය මත පදනම්ව, ඉන්දියානු ණය යෝජනා ක්‍රමයේ ඉතිරිව පවතින අරමුදල් සහ වෙනත් අරමුදල් ක්‍රම භාවිත කරමින් මාස තුනක කාලයක් සඳහා ප්‍රමාණවත් රාජ්‍ය ඖෂධ නීතිගත සංස්ථාවේ අනුමත වෛද්‍ය සැපයුම් ආනයනය කිරීම සඳහා KAUSIKH THERAPEUTICS (P) LTD ආයතනයට අවසර ලබා දීම.

3.1.2 ඉන්දියානු ණය යෝජනා ක්‍රමය සහ වෙනත් අරමුදල් ක්‍රම භාවිත කරමින්, එකඟවනු ලබන ගෙවීම් සැලැස්මකට අනුව ගෙවීම් සිදුකිරීම සඳහා මෙන්ම වෛද්‍ය සැපයීමේ ගුණාත්මක බව සහ මිල පිළිඳව KAUSIKH THERAPEUTICS (P) LTD ආයතනය සමග ගිවිසුම් අත්සන් තැබීම.

ඇ/කළේ:-
ආචාර්ය කෙහෙලිය රඹුක්වැල්ල
සෞඛ්‍ය අමාත්‍ය
ආචාර්ය කෙහෙලිය රඹුක්වැල්ල
සෞඛ්‍ය අමාත්‍ය
2022 දෙසැම්බර්.05.... වන දින දිය.

2 පිටුව

ඇමුණුම 47

රහසිගතයි

අමාත්‍ය මණ්ඩල කාර්යාලය
அமைச்சரவை அலுவலகம்
OFFICE OF THE CABINET OF MINISTERS

CABINET DECISION අමාත්‍ය මණ්ඩල තීරණය அமைச்சரவைத் தீர்மானம்

මගේ අංකය: අමප/22/1993/610/024-I 2022 දෙසැම්බර් මස 13 දින.

පිටපත්:

ජනාධිපති ලේකම්.
අග්‍රාමාත්‍ය ලේකම්.
විගණකාධිපති.

ක්‍රියා කළ යුතු:

මූදල්, ආර්ථික ස්ථායීකරණ සහ
ජාතික ප්‍රතිපත්ති අමාත්‍යාංශයේ ලේකම්.
සෞඛ්‍ය අමාත්‍යාංශයේ ලේකම්.
වෙළෙඳ, වාණිජ හා ආහාර සුරක්ෂිතතා අමාත්‍යාංශයේ ලේකම්.

ශ්‍රී ලංකාව තුළ අඛණ්ඩ වෛද්‍ය සැපයීම සේවාවක් පවත්වාගෙන යාම්

(සෞඛ්‍ය ගරු ඇමතිතුමා ඉදිරිපත් කළ 2022-12-05 දිනැති අමාත්‍ය මණ්ඩල සටහන)

2022 දෙසැම්බර් මස 05 දින පැවැත්වුණු අමාත්‍ය මණ්ඩල රැස්වීමේදී එළඹී තීරණයක් අවශ්‍ය කටයුතු සඳහා මේ සමඟ එවා ඇත.

ඩබ්ලිව්.එම්.ඩී.ජේ.ප්‍රනාන්දු
අමාත්‍ය මණ්ඩලයේ ලේකම්.

36. අමාත්‍ය මණ්ඩල පත්‍රිකා අංක 22/1993/610/024-I වූ, **"ශ්‍රී ලංකාව තුළ අඛණ්ඩ වෛද්‍ය සැපයීම් සේවාවක් පවත්වාගෙන යාම"** යන මැයෙන් සෞඛ්‍ය ඇමතිතුමා ඉදිරිපත් කළ 2022-12-05 දිනැති අමාත්‍ය මණ්ඩල සටහන - (අමප අංක 22/1693/610/024 පිළිබඳව වූ 2022-11-14 දිනැති අමාත්‍ය මණ්ඩල තීරණයට අදාළව) මෙම රැස්වීමේදී සභාගත කරන ලද ඉහත සඳහන් අමාත්‍ය මණ්ඩල සටහන, එහි සඳහන් කරුණු පිළිබඳව සෞඛ්‍ය ඇමතිතුමා විසින් සිදු

→2

කරන ලද වැඩිදුර පැහැදිලි කිරීම් සමඟ අමාත්‍ය මණ්ඩලය විසින් සලකා බලන ලදී. මේ පිළිබඳව යාකච්ඡා කිරීමෙන් අනතුරුව, මෙම විෂයය සම්බන්ධයෙන්ම වූ අමප අංක 22/1693/610/024 වගයෙන් අංකගත කරන ලද 2022-10-25 දිනැති අමාත්‍ය මණ්ඩල සංදේශයට අදාළව මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති ඇමතිතුමා විසින් ඉදිරිපත් කරන ලද 2022-11-02 දිනැති නිර්දේශයන්ට අනුගතව කටයුතු කිරීමට යටත්ව, සටහනේ 3.0 ඡේදයේ 3.1 අනුඡේදයෙහි (3.1.1) සහ (3.1.2) යටතේ දක්වා ඇති පරිදි පියවර ගැනීම පිණිස අනුමැතිය ලබා දීමට තීරණය කරන ලදී.

තවද, මෙම තීරණය සම්මත කරනු ලැබූ සේ සැලකීමටත්, ඒ අනුව අවශ්‍ය කටයුතු සඳහා අදාළ බලධාරීන් වෙත මෙම තීරණය දන්වා යැවීම සඳහා අමාත්‍ය මණ්ඩලයේ ලේකම්ට බලය පැවරීමටත් තීරණය කරන ලදී.

ක්‍රියා කළ යුතු: මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය - සටහනේ පිටපතක් යා කොට ඇත.
ගෞරව අමාත්‍යාංශය
වෙළඳ, වාණිජ හා ආහාර සුරක්ෂිතතා අමාත්‍යාංශය - සටහනේ පිටපතක් යා කොට ඇත.

පිටපත්: ජනාධිපති ලේකම් - සටහනේ පිටපතක් යා කොට ඇත.
අග්‍රාමාත්‍ය ලේකම් - සටහනේ පිටපතක් යා කොට ඇත.

MINUTES OF THE 84TH BOARD MEETING OF THE NATIONAL MEDICINES REGULATORY AUTHORITY HELD ON THE 16TH OF SEPTEMBER 2022 AT 1.30 PM, AT THE OFFICE OF THE CHAIRMAN, W A D RAMANAYAKE MAWATHA OFFICE, COLOMBO 02

I. Present

1.	Prof. S D Jayaratne	Chairman
2.	Dr. Vijith Gunasekera	CEO
3.	Dr. Pradeep de Silva	Member
4.	Dr. Kosala Karunaratne	Member
5.	Mr. Manoj Gamage	Member
6.	Mr. Supul Wijesinghe	Member (Via Zoom)
7.	Mr. Chathura Mohottigedara	Member
8.	Mr. Priyantha Serasinghe	Member

II. Excused

1.	Dr. Asela Gunawardena	Member

III. On Invitation

1.	Mr. Ajith Priyadarshana	Director NMQAL

84.0 Preliminaries

84.0.1 Welcome of the Members to the 84th Board Meeting

The Chairman welcomed all the Members to the 84th Board Meeting.

84.1 Confirmation of the Minutes

84.1.1 **Confirmation of the Minutes of the 83rd Board Meeting**

The Minutes of the 83rd Board Meeting held on 19th August 2022, which has been previously circulated among the members, was tabled and confirmed by the Board, subject to the following amendments:

Page No. 07 – 83.4.1 **APPROVAL FOR THE SUGGESTED CRITERIA FOR THE CLEARANCE OF BACKLOG OF RE-REGISTERED MEDICINE PRODUCT APPLICATIONS**

"The Chairman briefed the Board about the background of the Board Paper. Dr. Pradeep de Silva mentioned that the respective manufacturer should disclose new or current development of therapeutic use with the application, if there are any such.

Decision

The Board approved the amended procedure for the clearance of backlog of already registered medicine products, as mentioned in the Board Paper. Further, the respective manufacturer should disclose new or current development of therapeutic use, if there are any such."

84.5 Note to the Board

84.5.1 DISCIPLINARY ACTION WAS TAKEN FOR TWO DRIVERS AND ONE KKS

The Chairman briefed the Board regarding the background of the subject.

Decision

The Board noted and approved as per the details presented.

84.5.2 NOTIFICATION OF APPROVED SPECIAL PROCEDURE FOR INTERNAL FAST TRACK PATHWAY FOR WAIVER OF REGISTRATION ISSURENCE FOR PROCUREMENTS FROM INDIAN CREDIT LINE (ICL), ASIAN DEVELOPMENT BANK (ADB), WORLD BANK (WB) AND ASIAN INFRASTRUCTURE INVESTMENT BANK (AIIB)

The Chairman briefed the Board regarding the background of the subject.

Decision

The Board noted and approved as per the details presented. However, the Board Members felt that NMRA have no responsibility with the quality-failed medicines imported under this scheme, and it will rest with the accepting and donating agencies.

MINUTES OF THE 85TH BOARD MEETING OF THE NATIONAL MEDICI REGULATORY AUTHORITY HELD ON THE 21ST OF OCTOBER 2022 AT 1.30 PM, AT THE OFFICE OF THE CHAIRMAN, W A D RAMANAYAKE MAWATHA OFFICE, COLOMBO 02

I. Present

1.	Prof. S D Jayaratne	Chairman
2.	Dr. Vijith Gunasekera	CEO
3.	Dr. Pradeep de Silva	Member
4.	Dr. Pradeep Kumarasinghe de Silva	Member
5.	Mr. Manoj Gamage	Member (Via Zoom)
6.	Mr. Supul Wijesinghe	Member (Via Zoom)
7.	Mr. Chathura Mohottigedara	Member

II. Excused

1.	Dr. Asela Gunawardena	Member
2.	Mr. Priyantha Serasinghe	Member

III. Absent

1.	Dr. Kosala Karunaratne	Member

IV. On Invitation

1.	Ms. Yamuna Karunarathne	Accountant
2.	Ms. Manoja Alwesra	Administrative Officer

85.0 Preliminaries

85.0.1 Welcome of the Members to the 85th Board Meeting

The Chairman welcomed all the Members to the 85th Board Meeting.

85.1 Confirmation of the Minutes

85.1.1 Confirmation of the Minutes of the 84th Board Meeting

The Minutes of the 84th Board Meeting held on 16th September 2022, which has been previously circulated among the members, was tabled and confirmed by the Board, subject to the following amendments:

Page No. 05 – 84.4.4 **APPROVAL TO FOLLOW REGULATORY RELIANCE PRINCIPLE FOR REGISTRATION OF GENERAL MEDICAL DEVICES WHICH ARE APPROVED BY WHO OR NMRA REFERENCE COUNTRIES SUCH AS USA, UK, AUSTRALIA, CANADA, JAPAN, NETHERLAND, GERMANY, DENMARK, NORWAY, SWITZERLAND, SWEDEN, FRANCE, ITALY**

"The Chairman briefed the Board about the background of the Board Paper.

regulatory authorities have been selected as per the document published by Pan American Health Organisation (PAHO) / WHO for Reliance For Emergency Use Authorisation of Medicines and Other Health Technologies in a Pandemic)

iii. to include Medicine and Healthcare products Regulatory Agency (MHRA), UK as reference authority for in vitro diagnostic medical devices

iv. to inform the administrative decision to the members of Medical Devices Evaluation Committee (MDEC) for recommending one year provisional registration"

The above decision has been amended to read as follows:

"***Decision***

The Board approved the following:

i. to implement the approval granted by previous NMRA Board (Board Paper No. 73.4.16, date of Board Meeting 15th October 2021) to follow regulatory reliance principle for registration of in vitro diagnostic medical devices

ii. to exempt the sample analysing / performance testing by expert panels for registration of in vitro diagnostic medical devices (IVD medical devices) which are approved by WHO or WHO reference regulatory authorities such as Therapeutic Goods Administration (TGA), Australia, Health Canada, Food and Drug Administration (FDA), USA, Ministry of Health, Labour and Welfare, Japan and Health Science Authority (HSA), Singapore. (Reference regulatory authorities have been selected as per the document published by Pan American Health Organisation (PAHO) / WHO for Reliance For Emergency Use Authorisation of Medicines and Other Health Technologies in a Pandemic)

iii. to include Medicine and Healthcare products Regulatory Agency (MHRA), UK as reference authority for in vitro diagnostic medical devices

iv. to inform the administrative decision to the members of Medical Devices Evaluation Committee (MDEC) for recommending one or two years provisional registration"

Page No. 08 – 84.5.2 NOTIFICATION OF APPROVED SPECIAL PROCEDURE FOR INTERNAL FAST TRACK PATHWAY FOR WAIVER OF REGISTRATION ISSURENCE FOR PROCUREMENTS FROM INDIAN CREDIT LINE (ICL), ASIAN DEVELOPMENT BANK (ADB), WORLD BANK (WB) AND ASIAN INFRASTRUCTURE INVESTMENT BANK (AIIB)

"The Chairman briefed the Board regarding the background of the subject.

Decision

The Board noted and approved as per the details presented. However, the Board Members felt that NMRA have no responsibility with the quality-failed medicines imported under this scheme, and it will rest with the accepting and donating agencies."

The above decision has been amended to read as follows:

"*Decision*

*The Board noted and approved as per the details presented. However, the Board Members felt that NMRA have no responsibility with the quality-failed medicines imported under this scheme, and it will rest with the **accepting agencies**."*

85.2 **Matters arising from previous Minutes**

85.2.1 AMENDMENT TO NOTE TO THE BOARD NO. 84.5.2 DATED 16/09/2022

The Board noted and approved the amended payment criteria as given in the Amendment to Note to the Board No. 84.5.2 dated 16/09/2022.

The Board also noted and approved the special conditions included in the Amendment to Note to the Board No. 84.5.2 dated 16/09/2022, for approving Waiver of Registration (WOR) applications regarding foreign-funded emergency procurements, considering the current economic crisis and shortage of medicines in the country.

85.3 **Reporting of Monthly Financial Status and Related Matters**

The Board noted all details of the Monthly Financial Statements for the month of August 2022. The Accountant informed the Board that currently, seventy five (75) million rupees is maintained in the Saving Account of NMRA, and the excess amount is deposited in a Fixed Deposit every Friday for a twenty five percent (25%) interest rate.

The Accountant also informed the Board that the Budget Plan and Action Plan will be submitted to the next Board Meeting.

MINUTES OF THE 86TH BOARD MEETING OF THE NATIONAL MEDICINES REGULATORY AUTHORITY HELD ON THE 18TH OF NOVEMBER 2022 AT 1.30 PM, AT THE OFFICE OF THE CHAIRMAN, W A D RAMANAYAKE MAWATHA OFFICE, COLOMBO 02

I. Present

1.	Prof. S D Jayaratne	Chairman
2.	Dr. Vijith Gunasekera	CEO
3.	Dr. Pradeep de Silva	Member
4.	Dr. Pradeep Kumarasinghe de Silva	Member
5.	Dr. Kosala Karunaratne	Member
6.	Mr. Manoj Gamage	Member (Via Zoom)
7.	Mr. Supul Wijesinghe	Member
8.	Mr. Chathura Mohottigedara	Member
9.	Mr. Priyantha Serasinghe	Member

II. Excused

1.	Dr. Asela Gunawardena	Member

86.0 Preliminaries

86.0.1 Welcome of the Members to the 86th Board Meeting

The Chairman welcomed all the Members to the 86th Board Meeting.

86.1 Confirmation of the Minutes

86.1.1 Confirmation of the Minutes of the 85th Board Meeting

The Minutes of the 85th Board Meeting held on 21st October 2022, which has been previously circulated among the members, was tabled and confirmed by the Board, subject to the following amendments:

Page No. 03 – 84.5.2 **NOTIFICATION OF APPROVED SPECIAL PROCEDURE FOR INTERNAL FAST TRACK PATHWAY FOR WAIVER OF REGISTRATION ISSURENCE FOR PROCUREMENTS FROM INDIAN CREDIT LINE (ICL), ASIAN DEVELOPMENT BANK (ADB), WORLD BANK (WB) AND ASIAN INFRASTRUCTURE INVESTMENT BANK (AIIB)**

"The Chairman briefed the Board regarding the background of the subject.

Decision

The Board noted and approved as per the details presented. However, the Board Members felt that NMRA have no responsibility with the quality-failed medicines imported under this scheme, and it will rest with the accepting and donating agencies."

The above decision has been amended to read as follows:

"*Decision*

The Board noted and approved as per the details presented. However, the Board Members felt that NMRA have no responsibility with the quality-failed medicines imported under this scheme, and it will rest with the accepting agencies.
The Board also decided to include Japan International Corporation Agency (JICA) and any other institution approved by Secretary, Ministry of Health."

Page No. 05 - 85.4.1 **TO ASSIGN RR NUMBER FOR RE-REGISTRATION DOSSIERS AFTER RECEIVING FULL REGISTRATION AND CONTINUE THE PREVIOUS DOSSIER FOR THE RENEWAL OF PREVIOUS PROVISIONAL REGISTRATION WITHIN ONE YEAR FROM THE DATE OF EXPIRY WITH THE PAYMENT FOR PROCESSING FEES OF NEW APPLICATIONS**

"The Chairman briefed the Board about the background of the Board Paper. The Chief Executive Officer informed the Board that the mandatory documents for the re-registration application are delayed due to various reasons. Therefore, the supplier company submits a new dossier for evaluation. In order to make the evaluation process easier, the previous application number will be assigned to the new dossier submitted by the local agent, with a processing fee, if submitted within one year. If the file is submitted after one year, it will be considered as a new file. The date of renewal of registration could be at the expiry of previous registration.

Decision
The Board approved assigning the previous application number to the file submitted by the local agent for evaluation, within one year, with a processing fee. The Board also approved files submitted after one year to be considered as a new file."

The above decision has been amended to read as follows:
"***Decision***

1. ***The Board approved to assign RR file number for the re-registration dossiers submitted within one year period after expiry of previous full registration. The processing fee should be charged as the same processing fee of new dossier for all dossiers which do not submit within stipulated time specified in NMRA Act Section 64 (1).***
2. ***The Board approved to continue the previous dossiers when applying for renewal of previous provisional registration within one year period after expiry of previous provisional registration. However, the processing fee need to be charged as the same processing fee of new dossier for applications which are not submitted within stipulated time specified in NMRA Act Section 64 (1).***"

86.2 **Matters arising from previous Minutes**

85.5.2 **DETERMINE THE INITIAL PRICE OF MEDICINES, MEDICAL DEVICES AND BORDERLINE PRODUCTS AND ADVISE THE MINISTER ON SUBSEQUENT PRICE REVISIONS**

MINUTES OF THE 87TH BOARD MEETING OF THE NATIONAL MEDICINES REGULATORY AUTHORITY HELD ON THE 29TH OF DECEMBER 2022 AT 6.30 PM, AT ROOM 12A, MONARCH IMPERIAL, SRI JAYAWARDENEPURA KOTTE

අමු ඇමු 51

I. Present

1.	Prof. S D Jayaratne	Chairman
2.	Dr. Vijith Gunasekera	CEO
3.	Dr. Pradeep Kumarasinghe de Silva	Member
4.	Dr. Kosala Karunaratne	Member (Via Zoom)
5.	Mr. Manoj Gamage	Member
6.	Mr. Supul Wijesinghe	Member
7.	Mr. Chathura Mohottigedara	Member (Via Zoom)

II. Excused

1.	Dr. Asela Gunawardena	Member
2.	Dr. Pradeep de Silva	Member
3.	Mr. Priyantha Serasinghe	Member

III. On Invitation

1.	Mr. Santhusitha Ovitigala	Assistant Director / ICT
2.	Ms. Yamuna Karunaratna	Accountant
3.	Ms. Manoja Alweera	Administrative Officer
4.	Mr. Sumudu Sulochana	Development Officer / ICT
5.	SLT-Mobitel Team	

87.0 Preliminaries

87.0.1 **Welcome of the Members to the 87th Board Meeting**

The Chairman welcomed all the Members to the 87th Board Meeting.

87.1 **Confirmation of the Minutes**

87.1.1 **Confirmation of the Minutes of the 86th Board Meeting**

The Minutes of the 86th Board Meeting held on 18th November 2022, which has been previously circulated among the members, was tabled and confirmed by the Board, subject to the following amendments:

Page No. 03 – 85.6.2 LETTER VIA REGISTERED POST BY KISH LABORATORIES (PVT) LTD

"The Chairman mentioned that the Antigen Test kit supplied by Kish Laboratories (Pvt) Ltd has been used completely by the hospitals. But he said that Medical Devices Evaluation Sub Committee (MDESC) will write to Medical Supplies Division (MSD) to verify whether there are any left. CEO mentioned that the procedure of testing may have been done according to a different kit supplied to Medical Supplies Division (MSD). The Board instructed the Chief Executive Officer to find out what the testing procedure was from the Microbiologist and the Director of

87.4.8 BUSINESS INTERNET LINE

The Chief Executive Officer highlighted the difficulties of working with Lanka Government Network (LGN) Wifi connection provided by the Information Communication Technology Agency (ICTA). Assistant Director ICT highlighted the bandwidth issues of ADSL and Fibre Optic connections.

Decision

The Board instructed the Chief Executive Officer to inquire from Telecom about available internet connection packages with suitable bandwidth, verify the prices, and present to the next Board.

87.4.9 TO NOTIFY THE BOARD OF DIRECTORS OF THE NMRA FOR THE WAIVER OF REGISTRATION REQUESTED BY MSD FOR PHARMACEUTICALS MANUFACTURED SUPPLIED FROM SAVOURITE PHARMACEUTICAL PVT LTD, INDIA

The Chairman briefed the Board that the Cabinet of Ministers has approved the supply of pharmaceuticals from this supplier and the Ministry of Health has requested NMRA to give a waiver of registration.

Decision

The Board endorsed that NMRA cannot take any responsibility for quality-failures and other related issues. The Board decided that the paragraph used in other No Objection Letters and Waiver of Registration letters as a disclaimer should be more detailed and comprehensively-worded.

The Board decided to add "The NMRA will not take responsibility for safety, efficacy, and quality of the products." to the existing paragraph, used as a disclaimer in No Objection Letters and Waiver of Registration letters.

87.5 Note to the Board

87.5.1 NOTIFICATION OF APPROVED LIST OF ISSUED WOR FOR PROCUREMENTS FROM INDIAN CREDIT LINE (ICL), ASIAN DEVELOPMENT BANK (ADB), WORLD BANK (WB) AND ASIA INFRASTRUCTURE INVESTMENT BANK (AIIB)

The Chief Executive Officer briefed the Board regarding the background of the Note to the Board.

Decision

The Board noted and approved as per the details presented.

The Board decided to include the existing paragraph used as a disclaimer in No Objection Letters and Waiver of Registration letters with the addition of "The NMRA will not take responsibility for safety, efficacy, and quality of the products." to letters issued for donations received from Indian Credit Line (ICL), Asian development Bank (ADB), World Bank (WB) and Asia Infrastructure Investment Bank (AIIB).

ඇමුණුම 53

ඖෂධ මණ්ඩල නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எங்கள் இல. My No.	NMRA/EA/WOR/MED/ICL/MSD/ 185/22	ඔබේ අංකය உங்கள் இல. Your No.	දිනය திகதி Date 30...../12/2022

The Controller General of Import & Export
Department of Import & Export Control
Colombo 01

GRANTING PERMISSION TO IMPORT AND CUSTOMS CLEARANCE OF A CONSIGNMENT OF MEDICINE UNDER THE CATEGORY OF WAIVER OF REGISTRATION

Name of medicine	:	Bupivacaine 0.5% w/v + Glucose 8% w/v Injection (Bupivacaine Hydrochloride Injection 0.5% with Glucose 8% in 4ml Ampoule in pre-sterilized theatre pack for spinal anaesthesia)
Manufacturer	:	Divine Laboratories (Pvt) Ltd, India
Quantity	:	68,750 Ampoules
PA Order No	:	ICL/EOI/P1/134/2022 dated 04-11-2022
PO No	:	129063
Local agent	:	Slim Pharmaceuticals (Pvt) Ltd

GRN
2023/2/13

This is to inform you that the National Medicines Regulatory Authority hereby granted permission under the category of waiver of registration of pharmaceuticals to import and customs clearance of the consignment of the aforesaid product on the request made by the Regulatory Affairs Officer, Slim Pharmaceuticals (Pvt) Ltd, No. 67/1/1, Norris Canal Road, Colombo 10.

This approval is granted in accordance with the power vested on the NMRA in the section 109 of the National Medicines Regulatory Authority Act No 5 of 2015 and shall be in force during the period stated in this letter unless earlier suspended or cancelled.

.....
Chief Executive Officer
National Medicines Regulatory Authority

CC:
1. Add. Secretary/ Ministry of Health- f.i
2. DGHS- f.i.
3. Director General of Customs- f. i. & n.a
4. Director MSD- This medicine was not evaluated by the NMRA. Therefore, please note that quality, safety and efficacy of these products are responsibility of yours. Also obtain a Certificate of Analysis (COA) of finished product for each batch of pre shipment samples issued by the manufacturer. Please ensure that this item is used only for the said purpose and not marketed
5. Slim Pharmaceuticals (Pvt) Ltd - Also obtain a Certificate of Analysis (COA) of finished product for each batch of pre shipment samples issued by the manufacturer. Please note that it is required to be registered this product with the NMRA before importing the next consignment.
6. Chief F & DI / NMRA- For Continuous monitoring and please note that this approval has been issued to supply the item only to State Sector Health Institutions.

NB:
This letter is valid only for this consignment and is valid for a period of twelve weeks from the date of issue. No extension will be granted and this permission will expire at the end of twelve weeks.

+94 11 269 51 73 | +94 11 269 88 96/7 +94 11252 33 85 www.nmra.gov.lk info@nmra.gov.lk
NMRA, No. 120, Norris Canal Road, Colombo 10, Sri Lanka.

checked by (PH) 29/12/2022

ඇමුණුම 54

Telephones : 686528-30

විදුලි පණිවුඩ කාර්යාලය
Telegrams : MEDSTORES

ෆැක්ස්
Fax : 941-697096

කේබල්
Cables : GOVTDRUG

මගේ අංකය
My No.

ඔබේ අංකය
Your No. : MSU/B/MSD/C/2/23/02

(සෞඛ්‍ය සේවා දෙපාර්තමේන්තුව)
සායත්තාංශය
(சுகாதார சேவைத் திணைக்களம்)
MEDICAL SUPPLIES DIVISION
(Department of Health Services)

අංක 357, බද්දේගම වීමලවංශ මාවත, කොළඹ 10, ශ්‍රී ලංකාව.
இல. 357, பத்தேகம விமலவன்ச மாவத்தை, கொழும்பு 10, இலங்கை.
No. 357, Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka.

තැ. පෙ.
P.O.Box : 1679

දිනය/திகதி: 2023.06.19

විගණන අධිකාරි

ජාතික විගණන උප කාර්යාලය,

වෛද්‍ය සැපයීම් අංශය,

කොළඹ 10.

<u>හදිසි මිලදී ගැනීම සඳහා ලියාපදිංචියෙන් නිදහස් කිරීමේ සහතිකය (WOR) ලබා ගෙන ඇති සැපයුම්කරුවන්ගේ ඖෂධ වල තත්වය සම්බන්ධයෙන් වෛද්‍ය සැපයීම් අධ්‍යක්ෂකගේ වගකීම පිළිබඳ පරීක්ෂාව.</u>

උක්ත කරුණ සම්බන්ධයෙන් ඔබේ අංක MSU/B/MSD/C/2/23/02 හා 2023.06.07 දිනැති ලිපිය හා බැඳේ.

වෛද්‍ය සැපයීම් අංශය මගින් අදාල ඖෂධ ඇණවුම් (Order) පමණක් සිදු කරන අතර එහි ප්‍රභවිපාදන හා තාක්ෂණික ඇගයීම සම්බන්ධයෙන් වෛද්‍ය සැපයීම් අංශය කටයුතු නොකරනු ඇත.

ඖෂධ වල තත්වය, ආරක්ෂාව හා ප්‍රත්‍යක්ෂභාවය(Safety, quality& efficacy සම්බන්ධයෙන් වගකිව යුතු නීති රාමුව අදාල වනුයේ ජාතික ඖෂධ නියාමන අධිකාරිය (NMRA) වන බැවින් අදාල ලියාපදිංචිය නිදහස් කිරීමේ සහතිකය (WOR) ලබා දීම සම්පූර්ණ වගකීමද එම ආයතනය සතු වනු ඇත.

මේ තත්වය යටතේ වෛද්‍ය සැපයීම් අධ්‍යක්ෂක වන මා හට ඒ සම්බන්ධව වගකීම දැරීමට නොහැකි වන අතර එම කොන්දේසි මාගේ එකඟතාවයෙන් තොරව ජාතික ඖෂධ නියාමන අධිකාරිය (NMRA) විසින් යොදා ඇත. මේ සම්බන්ධයෙන් ගරු අමාත්‍යතුමා,සෞඛ්‍ය ලේකම්තුමා, සෞඛ්‍ය සේවා අධ්‍යක්ෂ ජෙනරාල්තුමා වාචිකව දැනුම් දෙන ලදි.

ඒ අනුව අදාල වගකීම් පැවරීම, WOR ඉල්ලීම් කරන නිළධාරීන්/ ආයතනය වෙත පැවරීම වෙනස් කළ යුතු බව CEO/Chairman NMRA වෙතට වාචිකව දැනුම් දෙන ලදි.

වෛද්‍ය එච්.එම්.එස්. විතුමනායක
අධ්‍යක්ෂ
වෛද්‍ය සැපයීම් අංශය
පුස්ස බද්දේගම විමලවංශ මහ මාවත,
කොළඹ 10.

වෛද්‍ය සැපයීම් අංශය,

Expression of Interest (EOI) to Import and Supply of Vital and Essential pharmaceuticals to Sri Lanka under the Indian Credit line for 3 months

Awarded suppliers according to the EOI Evaluation done by the Committee on 6.10.2022 at9.00 AM

Reference No.	SR Number	Name of the drug	Required quantity for 3 months	Name of the Supplier	Awarded Quantity	Awarded Price		Remarks	Contact Details
						Unit Price (USD)	Total Price (USD)		
10	00107102	Fluconazole Injection 200mg in 100mL Vial	10500	1. Unicura International (Pvt) Ltd	10500	0.42 per vial	4,410.00	Recommend to award to supplier Unicura International (Pvt) Ltd with WOR	011-3620802
11	00107401	Amphotericin Injection 50mg Vial	624	1. Unicura International (Pvt) Ltd	624	5.29 per vial	3,300.96	Recommend to award to supplier Unicura International (Pvt) Ltd with WOR	011-3620802

EOI Evaluation Committee

Name	Capacity	Signature
Mrs. U.S.K.Denawatta (Additional Secretary-Admin/MOH)	Chairman	
Dr.A.T.Sudarshana (Deputy Director/MSD)	Member	
Dr.Jayanath Bathpitiya (MO/ Procurement/MOH)	Member	
Mrs.D.H.R.N.Pemathunga (Internal Auditor/MOH)	Member	
Ms.P.D.Solomon (Assistant Director- Pharma/ MSD)	Member	U. P. Dsouza.

MINISTRY OF HEALTH
MINUTE OF HEALTH SECTOR EMERGENCY PROCUREMENT COMMITTEE

NATURE OF THE ROCUREMENT COMMITTEE	HSEPC	PROCUREMNT ENTITY		Medical Supplies Division, Ministry of Health	
MEETING NO.	HSEPC Special Meeting	DATE	13.10.2022 & 18.10.2022	PURPOSE	Awarding
ITEM NO.		01 -188			
TITLE OF PROCUREMENT		Import and supply of vital and essential pharmaceuticals to Sri Lanka through Private suppliers under the Indian Credit Line for 3 months.			
SR NO. / ITEM NO.		Annex- II			
QUANTITY					

PRESENT

Members of the HSEPC		Others
Mr. S. Janaka Sri Chandraguptha	-Chairperson	1. Dr.R.M.S.K.Rathanayake (Additional Secretary, MOH)
Mr. P.A.S. Athula Kumara	-Member	2. Mr.Y.L.M.Navavi (Additional Secretary/Procurement, MOH)
Mr. Sarath Liyanage	-Member	3. Mrs.U.S.K.Denawatta (Additional Secretary/Admin, MOH)
		4. Dr.A.T.Sudarshana (Director, MSD)
		5. Mrs.D.H.R.N.Pemathunga (Internal Auditor,MOH)
		6. Dr.Jayanath Buthpitiya (Mo/Procurement,MOH)
		7. Ms.P.D.Solamon (Assistant Director/Pharma I, MSD)
		8. Mr.H.A.Nuwan (DO/Procurement,MOH)
		9. Mrs.R.H.S.H.Ranasinghe (DO/Procurement/MOH)
		10. Ms.H.K.T.Dabare (DO/Procurement/MOH)
		11. Ms.W.A.Y Sewwandi (DO/Procurement/MOH)
		12. Mrs.S.U.S.Rajapaksha (DO/Procurement/MOH)

→ මේ අවස්ථාවේදී රාජ කුමාරංකල මහතා (රාජ අමාත්‍යාංශය නියෝජිත සභ කළමනාකරු)

ICL/EOI/P1/45/2022	00404801	Desferrioxamine Injection 500 mg	112500	ABC Pharma Services Pvt Ltd	112500	7.15	804,375.00	6.99	786,375.00

05. HSEPC Observations

4.1 HSEPC observed that this requirement needs to be fulfilled immediately based on the necessity, urgency and inadequate supply with zero stocks in the Medical Supply Division of the Ministry of Health.

4.2 HSEPC went through the Evaluation report and observed that the evaluation committee has recommended suppliers for each item specially after considering the offered price and the delivery schedule.

4.3 HSEPC further observed that the evaluation committee has recommended to offer Waiver of Registration (WOR) for unregistered suppliers in National Medicines Regulatory Authority (NMRA) who have been recommended for awarding.

06.HSEPC Decision

Considering necessity, urgency and inadequate supply with zero stocks in the Medical Supply Division of these items, HSEPC decided to award items mentioned in **Annex- V** to substantially responsive suppliers with total awarded quantities, awarded unit price and total price under each item in USD.

Further HSEPC decided to purchase these items eighter through Indian Credit Line or Direct purchasing.

NAME	CAPACITY	AGREE / DISAGREE	SIGNATURE
Mr. S. Janaka Sri Chandraguptha Secretary, Ministry of Health	Chairman	Agreed	
Mr. P.A.S.Athula Kumara Director General, Department of Public Enterprises	Member	Agreed	
Mr. Sarath Liyanage Chariman, State Pharmaceutical Corporation	Member	Agree	

425

දුරකථන) 0112669192 , 0112675011
தொலைபேசி) 0112698507 , 0112694033
Telephone) 0112675449 , 0112675280

ෆැක්ස්) 0112693866
பெக்ஸ்) 0112693869
Fax) 0112692913

විද්‍යුත් තැපෑල)postmaster@health.gov.lk
மின்னஞ்சல் முகவரி)
e-mail)

වෙබ් අඩවිය) www.health.gov.lk
இணையத்தளம்)
website)

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
Ministry of Health

මගේ අංකය &
எனது இல &
My No. & PSRP/08/EOI/Acc/2022

ඇමුණුම 57

ඔබේ අංකය
உமது இல
Your No. &

දිනය &
திகதி & 20-10-2022
Date &

Director,
NovaChem Lanka PVT Ltd

Acceptance of Expressions of Interest to import and supply of vital and essential pharmaceuticals to Sri Lanka under the Indian Credit Line for 3 months

This is to inform you that, you have been selected to import the pharmaceuticals under the Indian Credit Line facility. (Details of awarded pharmaceuticals to your institution are given in Annexure I.)

1. You are hereby strictly instructed to adhere to all the conditions and regulations related to the purchase of medical supplies using the Indian Credit Line.
2. You are hereby strictly instructed to adhere to the agreed timeline and should take all required actions to import them as quickly as possible.
3. The Medical Supplies Division (MSD) will buy back a quantity sufficient for the 3 months consumption and MSD is responsible for the payments.
4. Purchaser reserves the right to call for free replacement of goods supplied with inadequate residual shelf life, or reject such consignment and refrain from its clearance from the port.
5. All quality problems/complaints should be confirmed by the National Medicines Regulatory Authority (NMRA) / Technical Advisory Committee (TAC) of Sri Lanka / or any other Authority as decided by the Ministry of Health of Sri Lanka.
6. In case of withdrawals due to quality failure, suppliers should ensure that the value of entire quantity either the withdrawn batched or product would be total reimbursed with an additional 25% of the total value concerned as an administrative cost.

නො.385 පූජ්‍ය බද්දේගම විමලවංශ හිමි මාවත ,කොළඹ 10 .385, வணக்கத்துக்குரிய பத்தேகமவிம லவங்ச தேரோ மாவத்தை, கொழும்பு 10.
385, Rev. Baddegama Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka.

7. Conditions of supply from MSD

- The product should have minimum of 12 months shelf life at the time of delivery at Medical Supplies Division or if deviated, prior approval should be obtained from Director, Medical Supplies Division.
- To be supplied as per the delivery schedule agreed in EOI in the order list.
- Description of item, Date of Manufacture, Date of Expiry, Batch No., Name and Address of Manufacturer should be clearly marked on the outer covering containing the item and on the outer cover of the carton/ box.
- Offers for any other economically viable pack sizes different from the specified pack sizes are acceptable with the prior approval of Director, Medical Supplies Division.
- Storage conditions of the items should be clearly indicated in the inner most and outer most carton labels.
- Cold chain should be maintained according to the manufacturer's instructions during storage, transport and delivery.
- Delivery of the items is to be made to Medical Supplies Division warehouses free of charge.
- Withdrawal from use of items due to quality failures:
  a) In case of batch withdrawal due to quality failure, the supplier / manufacturer shall reimburse the value of entire batch quantity supplied.
  b) In case of product withdrawal due to quality failure, the supplier / manufacturer shall reimburse the value of entire product quantity supplied.
  c) In the event of either **a) or b)** above the supplier / manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.
- Standards- Any other Pharmaceuticals Standard accepted by Cosmetics, Devices and Drugs Regulatory Authority in Sri Lanka for registration of a pharmaceutical item is also acceptable.
- In the event of that item is awarded to unregistered bidder, the NOL/ PUL/ WOR issued by NMRA should be submitted when item is delivered. If not, payment will not be released for the delivered item.
- In the event of failing to supply the item within the delivery schedule given in the agreed EOI / purchase order the items will not be accepted. However, if the item is still required by Medical Supplies Division and decides to accept the same, a penalty of 0.1% of the total value per day up to 7 days (total of 0.7% for 1st 7 days of late delivery), 0.3% per total value per day up 8th to 14th (another 2.1% for 7 days from 8th to 14th day of late delivery), 0.5% per total value per day from 15th to 21st day of late delivery(another 3.5%

for the period 15th to 21st day of late delivery) for the lapsed period will be deducted from your payment as liquidated damage.

In case of an item delivered after 3 weeks, if the item is still required MSD reserves the right to accept maximum penalty of 10-% of the total value will be imposed.

Your contribution to avoid any future shortage of medical supplies in Sri Lanka is greatly appreciated.

Thank you,

S. Janaka Sri Chandraguptha
Secretary
Ministry of Health

S. Janaka Sri Chandraguptha
Secretary
Ministry of Health
"Suwasiripaya"
385, Rev. Baddegama Wimalawansa Thero Mawatha
Colombo 10.

Copies –

1. Additional Secretary - Production, Supply & Regulation of Pharmaceuticals
2. Director General of Health Services
3. Deputy Director General - MSD
4. Director (MSD)
5. Chairman – SPC
6. Chief Executive Officer- NMRA

No	Reference No	Order list Number	SR Number	Name of the drug	Awarded Quantity	Name of the Awarded Supplier	Name of the Manufacturer	Name of the Shipping Line	Unit Price	Total Price	Awarding decision and total delivery price to MSD
1	ICL/EOI/P1/23/2022	-	00301101	Flupenthixol decanoate Injection 40mg in 2mL Ampoule	11250	NovaChem Lanka PVT Ltd	Pharmafabrikon Unit II	-	1.8	20250	Recommended to award lowest responsive supplier M/S NovaChem Lanka PVT Ltd at a unit cost of USD 1.8 for 11250 units at atotal cost of C&F USD Twenty thousand two hundred and fifty(20250) only with Waiver of registration.

දුරකථන) 0112669192 , 0112675011
தொலைபேசி) 0112698507 , 0112694033
Telephone) 0112675449 , 0112675280

ෆැක්ස්) 0112693866
பெக்ஸ்) 0112693869
Fax) 0112692913

විද්‍යුත් තැපෑල)postmaster@health.gov.lk
மின்னஞ்சல் முகவரி)
e-mail)

වෙබ් අඩවිය) www.health.gov.lk
இணையத்தளம்)
website)

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதாரஅமைச்சு
Ministry of Health

මගේ අංකය)PSRP/08/EOI/General/2022
எனது இல)
My No.)

ඔබේ අංකය
உமது இல)
Your No.

දිනය) 28.10.2022
திகதி)
Date)

ඇමුණුම 58

Dr.D.R.K.Herath,
Deputy Director General,
Medical Supplies Division.

Emergency Procurement through Private Suppliers using Indian Credit Line.

I wish to inform you that the Ministry of Health has taken following decisions in accordance with the decision of the Cabinet of Ministers on 26th September 2022 for the cabinet Memorandum No. 22/1523/610/018 on "Maintenance of uninterrupted supply of medical supplies to Sri Lanka" to maintain the uninterrupted supply of medical supplies and to avoid acute shortages of medical supplies in government healthcare.

- Permit the private sector pharmaceutical importing agents to import NMRA-approved medical supplies as emergency procurements using the remaining funds of the Indian Credit line based on the urgency and requirement of the MSD. (Items without NMRA registration must undergo a proper Waiver of Registration Process at the NMRA before importing to reduce any delays during this crisis.).
- Permit MSD to buy back medical supplies sufficient for 3 months from the imported stocks of private sector pharmaceutical importing agents who utilized the ICL adhering to the existing buyback pricing mechanism as decided by the pricing committee of the Ministry of Health.

Following above decision and according to the order lists placed by, Medical Supplies Division, the Ministry of Health has decided to invite Expressions of Interest (EOI) from suppliers to import and supply of vital and essential drugs to Sri Lanka. Prepared EOI document was published through E- Procurement portal PROMISE.lk and web site of the Health Ministry on 27th September 2022.

Received EOI's were evaluated through an evaluation committee and the recommendations of evaluation committee were subjected to the approval of the Health Sector Emergency Procurement Committee (HSEPC).

Considering necessity, urgency and inadequate supply with zero stocks in the Medical Supply Division of these pharmaceutical items, HSEPC decided to award items mentioned in **Annex-I** to substantially responsive suppliers with total awarded quantities, awarded unit price and total price under each item in USD.

Accordingly, the Ministry of Health has issued a letter of acceptance to selected suppliers, including the terms and conditions of supply. **Annex-II.**

In order to continue this process, you are hereby instructed to issue purchase orders for above mentioned selected suppliers, including following conditions.

1. Purchasing of each item can be done through Indian Credit Line or any other convenient method for both parties.
2. Whether to accept the awarded quantity as one lot or partially.
   I. If it is one lot, it should be clearly mentioned the duration or exact date from the date of purchase order.
   II. If it is partially, it should be indicated the minimum quantity and the duration. (Delivery Schedule).
3. If the registration is not submitted by a particular supplier, there should be a clear demarcation of the responsibilities. (Whether it is done by the ministry or supplier).
4. Whether to accept a Performance Bond or not.
   Duration and the amount of the Performance Bond should be decided according to the delivery schedule and as per the need of emergency situation.
5. Penalty Criteria for late deliveries and quantity failures.
   As per the emergency conditions, whether to consider the waiving off penalties with justifying the reasons for delays.
6. The payments to be done in 45 days. In delays, 3% monthly charge for the due amount to be borne by the ministry.
7. Since this is a three months stock, an assurance with regards to the short shelf life needs to be taken from the supplier.
8. Important documents, which should be submitted along with the invoice.

S. Janaka Sri Chandragupta

Secretary,

Ministry of Health.

o/c

o/c

Cc: Director (MSD)

SH / Adl. Sec.(PSRP) / DDG(MSD) /DMSD /CA(MSD) /Acct(S)

Refer Folio (1-63)

Reference: Cabinet Memorandum 22/1523/610/018 of 04th October 2022.

The special procurement process via an EOI from local suppliers to "Maintenance of uninterrupted supply of medical supplies to Sri Lanka" approved by above mentioned cabinet memorandum and EOI process already completed by Additional Secretary (Production, Supply & Regulation of Pharmaceuticals) for purchasing three months requirement of hundred eighty eight (188) items(**Annexure V** pages 36-49).

In accordingly, Meeting held on 31st October 2022 in Pharmaceuticals Productions, Supply and regulations Unit and Chaired by Dr.R.M.S.K Rathnayake (Add. Secretary / PSRP) to DDG (MSD) instructed to issue the purchase orders from Medical Supplies Division, subject to the allocation transfer from SPC for EOI selected 188 items. Accordingly, your approval is sought to issue the purchase orders by Medical Supplies Division to suppliers of those 188 items.

Hence your approval is requested, for emergency purchase of the item listed in Annexure (V) to maintain uninterrupted supply to avoid acute shortages of medical supplies in government hospitals.

as below;

1. Approval to issue purchase orders in **USD** and make payments using ICL or other sources.
2. Approval to issue the purchase orders subject to the transfer allocations to Medical Supplies Division from the State Pharmaceuticals Corporation (SPC).
3. Issue the purchase orders without a purchase agreement and a performance bond.

02/11/22

2023/10/26

CERTIFIED TRUE C

ඇමුණුම 60

දුරකථන / தொலைபேசி / Telephones } 694113, 694114, 686528-30

විදුලි පණිවුඩ / தந்தி / Telegrams } රජ බෙහෙත් / மெட்ஸ்ரோர்ஸ் / MEDSTORES

ෆැක්ස් / பக்ஸ் / Fax } 941-697096

කේබල් / கடல் வழித்தந்தி / Cables } GOVTDRUG

මගේ අංකය / எனது இல. / My No. } DDG/MSD/EM.PU/Gen/2022

ඔබේ අංකය / உமது இல. / Your No. }

වෛද්‍ය සැපයීම් අංශය
(සෞඛ්‍ය සේවා දෙපාර්තමේන්තුව)
வைத்திய விநியோகப்பகுதி
(சுகாதார சேவைத் திணைக்களம்)
MEDICAL SUPPLIES DIVISION
(Department of Health Services)

අංක 357, බද්දේගම විමලවංශ මාවත, කොළඹ 10, ශ්‍රී ලංකාව.
இல. 357, பத்தேகம விமலவங்ச மாவத்தை, கொழும்பு 10, இலங்கை.
No. 357, Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka.

පෝ. පෙ. / தபெ / P.O.Box } 1679

දිනය/திகதி/Date : 2023/11/06

කළමණාකරු,
CIC Hoding pvt ltd/Zyrex Pharmacrutical pvt ltd/Trimed Pharmaceutical pvt ltd/
Chamee Chemist/Novachem Lanka pvt ltd/Medmart Pharama pvt ltd/
S.J.Enter prises pvt ltd/Asian health drug stor pvt ltd/Imperial Life Scinces pvt ltd/
Tabrane Healthcare pvt ltd/George steuart healt pvt ltd/Soft care International pvt ltd/
Slim Pharmaceutical pvt ltd/Advitech International pvt ltd/Isoleze Biotech Pharma pvt ltd/
ABC Pharma pvt ltd/Unicura International pvt ltd/TMI Solution pvt ltd/
Pharma Associate pvt ltd/Hemas Pharmaceutical pvt ltd/
Ceyoka pvt ltd/Yaden International pvt ltd

<u>ඉන්දියානු ණය යෝජනා ක්‍රමය යටතේ ඖෂධ මිලදී ගැනීම සඳහා ඇණවුම් ලබා දීම - 2023 වර්ෂය.</u>

ඉහත වැඩ සටහන යටතේ ඖෂධ මිලදී ගැනීම සඳහා ඔබ ආයතනය වෙත ඇණවුම් ලබා දී මීට අමුණා ඇති Annexure -i හා Annexure - ii හි සඳහන් ඖෂධ වලට අදාල සියලු ඇණවුම් නියමිත දිනට සැපයීමට නොහැකි වීම මත අවලංගු කළ බව මෙයින් කාරුණිකව දන්වා සිටිමි.

මෙමගින් ඔබ ආයතනයට සිදුවන අපහසුතාවය සම්බන්ධයෙන් කණගාටුව ප්‍රකාශ කරමි.

අධ්‍යක්ෂ (වෛද්‍ය සැපයීම්)
වෛද්‍ය සැපයීම් අංශය.

වෛද්‍ය එම්.එම්.ජේ. විතුමණ්ඩපය
අධ්‍යක්ෂ
වෛද්‍ය සැපයීම් අංශය
සුවය වද්දෙගම විමලවංශ මාවත,
කොළඹ 10.

පිටපත්:- 01. නියෝජ්‍ය අධ්‍යක්ෂ ජනරාල් - වෛද්‍ය සැපයීම්. දැ.පි.(Annexure i/ii)
02. සහකාර අධ්‍යක්ෂ - ඖෂධ දැ.පි හා අවශ්‍ය කටයුතු සඳහා. (Annexure i/ii)
03. මහාග පාලන නිලධාරි - දැ.පි. හා අවශ්‍ය කටයුතු සඳහා. (Annexure i/ii)

Annexure - 1

NO	MSD PO No	MSD Order List Number	SR Number	Name of the Supplier	Name of the drug	Awarded Quantity	Deliver Schedule As Per The PO	Delivered Quantity 2023-04-04	Balance Quantity
01	129048	2022/MSD/V/R/P/00072	00500204 (40) X	CIC Holdings Pvt Ltd	Fluticasone propionate 125mcg with Salmeterol xinafoate 25mcg / metered dose,120 dose unit	7,500	05-12-2022 - 7,500	-	7,500
02	129055	2022/MSD/V/R/P/00067	00001102 (2) X	Zyrex Pharmaceuticals (Pvt) Ltd	Pethidine hydrochloride Injection 75mg ampoule	45,000	05-12-2022 - 22,500 02-02-2022 - 22,500	-	45,000
03	129058	2022/MSD/V/R/P/00081	00602501 (43) X	ABC Pharma Services Pvt. Ltd.	Antirabies Human Immunoglobulin 300I.U vial	1,250	31-01-2023 - 1,250	-	1,250
04	129060	2022/MSD/V/R/P/00081	00205201 (96) X	Slim Pharmaceuticals PVT Ltd	Protamine sulphate Injection 50mg in 5mL vial	2,000	28-12-2022 - 667 10-02-2023 - 1,333	-	2,000
	129061	2022/MSD/V/R/P/00072	00800502 (89) X	Trimed Pharma (Pvt) Ltd	Metoclopramide Inj.10mg in 2mL	450,000	24-11-2022 - 150,000 24-12-2022 - 150,000 19-01-2023 - 150,000	-	450,000
06	129066	2022/MSD/V/R/P 00085	00402702 X (136)	Trimed Pharma (Pvt) Ltd	Thiamine hydrochloride Injection 100mg in 2mL ampoule	100,000	24-11-2022 - 33,333 22-11-2022 - 33,333 19-01-2023 - 33,334	-	100,000
07	129067	2022/MSD/V/R/P/00081	00402202 (33) X	Slim Pharmacutical s (Pvt) Ltd	Protein Hydrolysate Inj. 10% w/v in 500mL bottle(Amino acids solution)	2,499	27-02-2023 - 2,499	-	2,499
08	129068	2022/MSD/V/R/P/00081	01501101 X (124)	Trimed Pharma (Pvt) Ltd	Atracurium besylate injection 25mg in 2.5mL ampoule	249,999	24-11-2022 - 83,333 22-12-2022 - 83,333 19-01-2023 - 83,333	-	249,999
09	129072	2022/MSD/V/R/P/00074	00901702 X (139)	Trimed Pharma (Pvt) Ltd	Cyclophosphamide Injection 1g vial	3,000	24-11-2022 - 3000	-	3,000
10	129073	2022/MSD/V/R/P/00076	01502105 (87) X	Softcare International (Pvt) Ltd.	Lignocaine anhydrous gel 2% in 30g tubes	62,500	03-01-2023 - 62,500	-	62,500
1	129074	2022/MSD/V/C/P/00073	00103203 X (140)	Trimed Pharma (Pvt) Ltd	Clindamycin phosphate Inj.300mg/2mL	375,000	24-11-2022 - 125,000 22-12-2022 - 125,000 19-01-20223 - 125,000	-	375,000

	129075	2022/MSD/V/R/P/00081	00404801 (38)	ABC Pharma Services Pvt. Ltd.	Desferrioxamine 500mg Vials	112,500	26-12-2022 - 112,500	-	112,500
13	129076	2022/MSD/V/R/P/00083	00303103 (23)	Trimed Pharma (Pvt) Ltd	Ondansetron Inj. 8mg in 4mL ampoule	225,000	24-11-2022 - 75,000 22-12-2022 - 75,000 19-01-2023 - 75,000	-	225,000
14	129077	2022/MSD/V/R/P/00074	01206701 (79)	Softcare International (Pvt) Ltd.	Anastrozole Tablet 1mg	500,000	08-11-2022 - 500,000	-	500,000
15	129078	2022/MSD/V/R/P/00076	01502001 (110)	Trimed Pharma (Pvt) Ltd	Bupivacaine hydrochloride injection 0.5% in 10mL ampoule with sterile wrap	45,000	24-11-2022 - 15,000 22-12-2022 - 15,000 19-01-2023 - 15,000	-	45,000
16	129079	2022/MSD/V/R/P/00081	01300202 (116)	Trimed Pharma (Pvt) Ltd	Oxytocin Injection 5 I.U. in 1mL ampoule	425,001	24-11-2022 -141,667 22-12 2022 - 141,667 19-01-2023 - 141,667	-	425,001
17	129089	2022/MSD/V/R/P/00076	1302001 (83)	Unicura International (Pvt) Ltd	Oxybutynine Hydrocloride Tablet 2.5mg	62,499	24-11-2022 - 20,833 15-12-2022 - 20,833 05-01-2023 - 20,833	-	62,499
	129091	2022/MSD/V/R/P/00074	01204403 (135)	Softcare International (Pvt) Ltd.	Imatinib Mesilate Capsule/Tablet 400mg	62,500	04-11-2022 - 57,500 08-11-2022 - 5,000	-	62,500
19	129094	2022/MSD/V/R/P/00083	00302801 (133)	TMI solutions Pvt Ltd	Sertraline Tablet 50mg	2,500,000	05-12-2022 - 833,333 06-02-2023-1,666,6667	-	2,500,000
20	129097	2022/MSD/V/R/P/00081	00107401 (9)	Unicura International (Pvt) Ltd	Amphoteracin Injection 50mg Vial	624	24-11-2022 - 208 15-12-2022 - 208 05-01-2023 - 208	200	424
21	129098	2022/MSD/V/R/P/00074	01204601 (142)	Softcare International (Pvt) Ltd.	Sorafenib Tablet 200mg	34,500	08-11-2022 - 34,500	-	34,500
22	129099	2022/MSD/V/R/P/00072	00500104 (39)	Unicura International (Pvt) Ltd	Salbutamol Injection 5mg in 5mL ampoule	1,500	24-11-2022 - 500 15-12-2022 - 500 05-01-2022 - 500	-	1,500
23	129101	2022/MSD/V/R/P/00064	00403202 (35)	Unicura International (Pvt) Ltd	Phytomenadione Injection 1mg in 0.5mL Ampoule	75,000	24-11-2022 - 25,000 15-12-2022 - 25,000 05-01-2023 - 25,000	75,000	-
2	129103	2022/MSD/V/R/P/00074	01203602 (129)	Softcare International (Pvt) Ltd.	Carboplatin Injection 450mg in 45mL vial	4,749	04-12-2022 - 4,749	-	4,749

	129105	2022/MSD/V/R/P /00064	00401903 (122)	TMI solutions Pvt Ltd	Magnesium sulphate Injection 50% in 10mL ampoule	22,500	05-12-2022 - 7,500 06-02-2023 - 15,000	-	22,500
26	129107	2022/MSD/V/R/P /00074	01203301 (104)	Unicura International (Pvt) Ltd	Dacarbazine (as Cittrate) Injection 200mg vial	1,500	24-11-2022 - 500 15-12-2022 - 500 05-01-2023 - 500	-	1,500
27	129108	2022/MSD/V/C/P /00082	00303403 (88)	Unicura International (Pvt) Ltd	Tramadol hydrochloride Injection 100mg in 2mL Ampoule	24,999	24-11-2022 - 8,333 15-12-2022 - 8,333 05-01-2023 - 8,333	-	24,999
28	129110	2022/MSD/V/R/P /00074	01206301 (98)	Softcare International (Pvt) Ltd.	Lenalidomide Capsules 5mg	22,500	08-11-2022 - 22,500	-	22,500
29	129111	2022/MSD/V/R/P /00074	01203201 (131)	Unicura International (Pvt) Ltd	Asparaginase Injection 10,000IU vial	300	24-11-2022 - 100 15-12-2022 - 100 05-01-2023 - 100	-	300
30	129112	2022/MSD/V/R/P /00083	00302402 (125)	TMI solutions Pvt Ltd	Clomipramine Hydrochloride Tablet 25 mg	500,001	05-12-2022 - 166,667 06-02-2023 - 333,334	-	500,001
436	129113	2022/MSD/V/R/P /00074	01204401 (72)	Softcare International (Pvt) Ltd.	Imatinib Mesilate Capsule 100mg	137,500	08-11-2022 - 6,000 04-12-2022 - 131,500	-	137,500
32	129114	2022/MSD/V/R/P /00074	01201103 (127)	Unicura International (Pvt) Ltd	Doxorubicin hydrochloride Injection 2mg/mL 25mL vial	4500	24-11-2022 - 1,500 15-12-2022 - 1,500 05-01-2023 - 1,500	-	4,500
33	129115	2022/MSD/V/R/P /00074	01204904 (73)	Softcare International (Pvt) Ltd.	Paclitaxel Injection 260mg	2,250	08-11-2022 - 2,250	-	2,250
34	129116	2022/MSD/V/C/P /00084	1205602 (126)	TMI solutions Pvt Ltd	Tacrolimus Capsule 1mg	1,125,000	05-12-2022 - 375,000 06-02-2023 - 750,000	-	1,125,000
35	129117	2022/MSD/V/R/P /00088	00901702 (138)	Unicura International (Pvt) Ltd	Timolol maleate Eye Drops 0.5%, 5mL vial	25,000	24-11-2022 - 8,500 15-12-2022 - 8,500 05-01-2023 - 8,500	-	25,000
36	129119	2022/MSD/V/R/P /00074	01207001 (81)	Softcare International (Pvt) Ltd.	Bicalutamide Tablet 50mg	82,500	08-11-2022 - 2,000 04-12-2022 - 80,500	-	82,500
37	129123	2022/MSD/V/R/P /00074	01206901 (80)	Softcare International (Pvt) Ltd.	Letrozole Tablet 2.5mg	37,500	08-11-2022 - 37,500	-	37,500
38	129126	2022/MSD/V/R/P /00064	00402801 (34)	TMI solutions Pvt Ltd	Pyridoxine Tablet 10mg	72,000	05-12-2022 - 24,000 06-02-2023 - 48,000	-	72,000

	129127	2022/MSD/V/R/P/00088	009010801 (101)	Advitech International (Pvt) Ltd	Acetazolamide Tablet 250mg	300,000	18-11-2022 - 100,000 16-12-2022 - 100,000 13-01-2023 - 100,000	-	300,000
40	129128	2022/MSD/V/R/P/00074	01202002 (66)	Unicura International (Pvt) Ltd	Gemcitabine hydrochloride Injection 1g vial	4,125	24-11-2022 - 1,375 15-12-2022 - 1,375 05-01-2023 - 1,375	-	4,125
41	129131	2022/MSD/V/R/P/00069	00902201 (57)	Unicura International (Pvt) Ltd	Hydroxypropylmethylcellulose ophthalmic solution for intraocular use 2%, 3ml-5ml prefilled syringe	18,750	24-11-2022 - 6,250 15-12-2022 - 6,250 05-01-2023 - 6,250	-	18,750
42	129132	20222/MSD/V/R/P/00076	00701502 (98)	TMI solutions Pvt Ltd	Hydrocortisone Tablets 10mg	375,000	05-12-2022 - 125,000 06-02-2023 - 250,000	-	375,000
43	129133	2022/MSD/V/R/P/00076	01502201 (104)	TMI solutions Pvt Ltd	Lignocaine 2% with Adrenalin 1:80,000 injection 30mL vial	45,000	05-12-2022 - 15,000 06-02-2023 - 30,000	-	45,000
44	129134	2022/MSD/V/R/P/00074	01202702 (69)	Unicura International (Pvt) Ltd	Etoposide Injection 100mg vial	3,000	24-11-2022 - 1,000 24-12-2022 - 1,000 05-01-2023 - 1,000	-	3,000
45	129135	2022/MSD/V/C/P/00073	00107102 (8)	Unicura International (Pvt) Ltd	Fluconazole Injection 200mg in 100mL Vial	10,500	24-11-2022 - 3,500 15-12-2023 - 3,500 05-01-2023 - 3,500	-	10,500
46	129141	2022/MSD/V/C/P/00086	00903001 (59)	TMI solutions Pvt Ltd	Brinzolamide eye drops 1%,in 5mL dropper bottle	20,001	05-12-2022 - 6,667 06-02-2023 - 13,334	-	20,001
47	129144	2022/MSD/V/RP/00074	01200801 (109)	Unicura International (Pvt) Ltd	Bleomycin sulphate Injection 15000 units vial	624	24-11-2022 - 200 15-12-2022 - 200 05-01-2023 -224	-	624
48	129145	2022/MSD/V/C/P/00079	00801001 (53)	TMI solutions Pvt Ltd	Mesalazine Tablet 400mg	45,000	05-12-2022 - 15,000 06-02-2023 - 30,000	-	45,000
49	129150	2022/MSD/V/C/P/00073	00107101 (103)	TMI solutions Pvt Ltd	Fluconazole Capsule 50mg	270,000	05-12-2022 - 90,000 06-02-2023 - 180,000	-	270,000
50	129151	2022/MSD/V/R/P/00074	01202204 (130)	Unicura International (Pvt) Ltd	Methotrexate Injection 1g vial	2,100	24-11-2022 - 700 15-12-2022 - 700 05-01-2023 - 700	-	2,100

51	129155	2022/MSD/V/R/P /00074	01202401 (69)	Unicura International (Pvt) Ltd	Vincristine sulphate Injection 1mg vial	5,750	24-11-2022 - 1,917 15-12-2022 - 1,917 05-01-2023 - 1,916	-	5,750
52	129156	2022/MSD/V/R/P /00083	00300803 (132)	TMI solutions Pvt Ltd	Haloperidol Injection 5mg in 1mL Ampoule	15,000	05-12-2022 - 5,000 06-02-2023 - 10,000	-	15,000
53	129160	2022/MSD/V/R/P /00074	01202701 (66)	Unicura International (Pvt) Ltd	Etoposide Capsule 100mg	1,200	24-11-2022 - 400 15-12-2022 - 400 05-01-2023 - 400	-	1,200
54	129163	2022/MSD/V/R/P /00074	01206802 (105)	TMI solutions Pvt Ltd	Tamoxifen Tablet 20mg	450,000	05-12-2022 - 150,000 06-02-2023 - 300,000	-	450,000
55	129164	2022/MSD/V/R/P /00083	00302901 (21)	TMI Solutions Pvt Ltd	venlafaxine extended release Capsules 37.5mg	699,999	05-12-2022 - 233,333 06-02-2023 - 466,666	-	699,999
56	129165	2022/MSD/V/R/P /00069	00904302 (61)	Unicura International (Pvt) Ltd	Tobramycin 0.3% with Dexamethasone 0.1% eye drops, 5ml-10ml dropper bottle	2,001	24-11-2022 - 667 15-12-2022 - 667 05-01-20223 - 667	-	2,001
57	129166	2022/MSD/V/R/P /00083	00305002 (30)	Unicura International (Pvt) Ltd	Co-Careldopa Tablet 25/250mg	1,400,001	24-11-2022 - 466,667 15-12-2022 - 466,667 05-01-2023 - 466,667	-	1,400,001
58	129167	2022/MSD/V/R/P /00072	00500801 (42)	Unicura International (Pvt) Ltd	Budesonide respiratory suspension 0.5mg in 2mL respule	25,500	24-11-2022 - 8,500 15-12-2022 - 8,500 05-01-2023 - 8,500	-	25,500
59	129168	2022/MSD/V/R/P /00076	00701401 (49)	Unicura International (Pvt) Ltd	Fludrocortisone Acetate Tablet 0.1mg	50,000	24-11-2022 - 16,667 15-12-2022 - 16,667 05-01-2023 - 16,666	-	50,000
60	129170	2022/MSD/V/R/P /00074	01202803 (70)	Unicura International (Pvt) Ltd	Lecucovorin Calcium (Folinic acid) Injection 10mg /mL in 5mL vial/ampoule.	13,750	24-11-2022 - 4,583 15--11-2022 - 4583 05-01-2023 - 4584	-	13,750
61	129171	2022/MSD/V/R/P /00083	00302902 (22)	TMI Solutions Pvt Ltd	Venlafaxine Hydrochloride extended release Capsules 75mg	1,625,001	05-12-2022 - 541,667 06-02-2023 -1,083,334	-	1,625,001

62	129172	2022/MSD/V/R/P/00074	01200201 (65)	Unicura International (Pvt) Ltd	Chlorambucil Tablet 2mg	7,500	24-11-2022 - 2,500 15-12-2022 - 2,500 05-01-2022 - 2,500	-	7,500
63	129174	2022/MSD/V/R/P/00072	00801201 (134)	TMI solutions Pvt Ltd	Bisacodyl Tablet 5mg	750,000	05-12-2022 - 250,000 06-02-2023 - 500,00	-	750,000
64	129175	2022/MSD/V/C/P/00084	01205401 (75)	TMI solutions Pvt Ltd	Cyclosporin Capsule 25mg	99,999	05-12-2022 - 33,333 06-02-2023 - 66,666	-	99,999
65	129176	2022/MSD/V/R/P/00072	01401001 (84)	TMI solutions Pvt Ltd	Allopurinol Tablet 100mg	900,000	05-12-2022 - 300,000 06-02-2022 - 600,000	-	900,000
66	129177	2022/MSD/V/R/P/00076	01205201 (74)	TMI solutions Pvt Ltd	Azathioprine Tablet 50mg	624,999	05-12-2022 - 208,333 06-02-2023 - 416,666	-	624,999
67	129178	2022/MSD/V/C/P/00075	00403501 (36)	TMI solutions Pvt Ltd	Hydroxocobalamine Injection 1mg in 1mL Ampoule	35,001	05-12-2022 - 11,667 06-02-2023 - 23,334	-	35,001
	129179	2022/MSD/V/R/P/00064	00403101 (95)	TMI solutions Pvt Ltd	Alfacalcidol Capsule 250microgram	8,250,000	05-12-2022-2,750,000 06-02-2023-5,500,000	-	8,250,000
69	129180	2022/MSD/V/R/P/00064	00400701 (32)	TMI solutions Pvt Ltd	Potassium Chloride Tablet 600mg	2,499,999	05-12-2022 - 833,333 06-02-2023- 1,666,666	-	2,499,999
70	129181	2022/MSD/V/R/P/00083	00304002 (91)	TMI solutions Pvt Ltd	Sodium valproate Tablet 200mg	17,499,999	05-12-2022-5,833,333 06-02-2023-11,666,666	-	17,499,999
71	129182	2022/MSD/V/R/P/00066	00201901 (117)	TMI solutions Pvt Ltd	Sildenafil Tablet 50mg	375,000	05-12-2022 - 125,000 06-02-2023 - 250,000	-	375,000
72	129183	2022/MSD/V/R/P/00083	00303703 (25)	TMI solutions Pvt Ltd	Phenytoin Sodium Tablet 100 mg	3,000,000	05-12-2022-1,000,000 06-02-2023-2,000,000	-	3,000,000
73	129184	2022/MSD/V/R/P/00083	00303704 (26)	TMI solutions Pvt Ltd	Phenytoin sodium Injection 250mg in 5mL Ampoule	12,000	05-12-2022 - 4,000 06-02-2023 - 8,000	-	12,000
74	129185	2022/MSD/V/C/P/00082	00304401 (29)	TMI solutions Pvt Ltd	Lamotrigine Tablet 25mg	600,000	05-12-2022 - 200,000 06-02-2023 - 400,000	-	600,000

75	129186	2022/MSD/V/R/P /00069	00901001 (54)	TMI solutions Pvt Ltd	Prednisolone acetate eye drops 1%,5mL Vial	42,501	05-12-2022 - 14,167 06-02-2023 - 28,334	-	42,501
76	129187	2022/MSD/V/C/P /00086	00902901 (56)	TMI solutions Pvt Ltd	Bimatoprost ophthalmic suspension 300mcg/mL,3mL vial	45,000	05-12-2022 - 15,000 06-02-2023 - 30,000	-	45,000
77	129188	2022/MSD/V/C/P /00084	01205601 (120)	TMI solutions Pvt Ltd	Tacrolimus Capsule 0.5mg	250,000	05-12-2022 - 83,333 06-02-2023 - 166,667	-	250,000
78	129189	2022/MSD/V/R/P /00066	00204701 (118)	TMI solutions Pvt Ltd	Enoxaparin Injection 40mg in 0.4mL prefilled syringe	200,000	05-12-2022 - 66,667 06-02-2023 - 133,333	-	200,000
79	129190	2022/MSD/V/R/P /00057	00101602 (115)	TMI solutions Pvt Ltd	Ceftazidime Injection 1g Vial	69,999	05-12-2022 - 23,333 06-02-2023 - 46,666	-	69,999
80	129191	2022/MSD/V/R/P /00077	00107901 (114)	TMI solutions Pvt Ltd	Aciclovir Tablet 200mg	525,000	05-12-2022 - 175,000 06-02-2023 - 350,000	-	525,000
81	129192	2022/MSD/V/R/P /00066	00200701 (14)	TMI Solution Pvt Ltd	Amiodarone Tablet 100mg	500,001	05-12-2022 - 166,667 06-02-2023 - 333,334	-	500,001
82	129193	2022/MSD/V/R/P /00083	00302101 (111)	TMI solutions Pvt Ltd	Lithium Carbonate Tablet 250mg	1,749,999	05-12-2022 - 583,333 06-02-2023-1,166,666	-	1,749,999
83	129194	2022/MSD/V/C/P /00084	01205402 (76)	TMI solutions Pvt Ltd	Cyclosporin Capsule 50mg	225000	05-12-2022 - 75,000 06-02-2023 - 150,000	-	225,000
84	129197	2022/MSD/V/R/P /00066	00205902 (99)	Advitech International (Pvt) Ltd	Tranexamic Acid Tablet/Capsule 500mg	450,000	21-11-2022 - 150,000 19-12-2022 -150,000 16-01-2023-150,000	-	450,000
85	129201	2022/MSD/V/R/P /00074	01207402 (85)	Advitech International (Pvt) Ltd	Octreotide Injection 50microgram in 1mL ampoule	20,000	21-11-2022 - 6,667 19-12-2022 - 13,333	-	20,000
86	129202	2022/MSD/V/C/P /00087	01102001	Advitech International (Pvt) Ltd	Clobetasol propionate Ointment 0.05%,15g tube	100,000	21-11-2022 - 33,333 19-12-2022 - 33,333 16-01-2023 - 33,334	-	100,000
87	129204	2022/MSD/V/R/P /00072	00800803 (52)	Advitech International (Pvt) Ltd	Omeprazole sodium Inj. 40mg	300,000	21-11-2022 - 100,000 19-12-2022 - 100,000 16-01-2023 - 100,000	-	300,000

88	129206	2022/MSD/V/R/P /00076	00702401	Advitech International (Pvt) Ltd	Hydroxyprogesterone Injection 250mg in 1mL ampoule	5,000	21-11-2022 - 5,000	-	5,000
89	129210	2022/MSD/V/R/P /00069	00904101	Advitech International (Pvt) Ltd	Moxifloxacin hydrochloride ophthalmic solution 0.5%, 5mL vial	35,000	21-11-2022 - 11,667 19-12-2022 - 11,667 16-01-2023 - 11,666	-	35,000
90	129212	2022/MSD/V/C/P /00073	00103501 (5)	Advitech International (Pvt) Ltd	Vancomycin hydrochloride Injection 500mg Vial	48,000	21-11-2022 - 16,000 12-12-2023 - 16,000 09-01-2023 - 16,000	-	48,000
91	129215	2022/MSD/V/R/P /00081	00204601 (16)	Advitech International (Pvt) Ltd	Heparin Injection 25,000 I.U.in 5mL Vial	75,000	21-11-2022 - 25,000 12-12-2022 - 25,000 09-01-2023 - 25,000	-	75,000
92	129216	2022/MSD/V/R/P /00066	00205903 (17)	Advitech International (Pvt) Ltd	Tranexamic acid Injection 500mg in 5mL ampoule	120,000	21-11-2022 - 40,000 12-12-2022 - 40,000 09-01-2023 - 40,000	-	120,000
93	129217	2022/MSD/V/R/P /00057	00101502 (3)	Advitech International (Pvt) Ltd	Cefotaxime Injection 1g Vial	249,999	21-11-2022 - 83,333 12-12-2020 - 83,333 09-01-2023 - 83,333	-	249,999
94	129219	2022/MSD/V/C/P /00056	00102102 (4)	Advitech International (Pvt) Ltd	Meropenem Injection 1g vial	450,000	21-11-2022 - 150,000 12-12-2022 - 150,000 09-01-2023 - 150,000	-	450,000
95	129220	2022/MSD/V/R/P /00069	01102201	Advitech International (Pvt) Ltd	Silversulphadiazine cream 1%,500g Jar	5,001	21-11-2022 - 5,0001	-	5,001
96	129221	2022/MSD/V/R/P /00069	00903201 (93)	Advitech International (Pvt) Ltd	Nepafenac ophthalmic suspension 0.1%, 3ml-5ml	11,250	28-11-2022 - 11,250	-	11,250
97	129222	2022/MSD/V/C/P /00075	00407201 (113)	Advitech International (Pvt) Ltd	Total Parenteral Nutrition in 500mL-1,500mL multiple component in collapsible bag	6,249	28-11-2022 - 6,249	-	6,249
98	129223	2022/MSD/V/R/P /00057	00101704 (90)	Advitec International Pvt. Ltd.	Ceftriaxone Injection 1g Vial	218,750	11-11-2022 -145,833 19-12-2022 - 72,917	-	218,750
99	129224	2022/MSD/V/C/P /00073	00105701 (6)	Advitech International (Pvt) Ltd	Ofloxacin Tablet 200 mg	60,000	21-11-2022 - 20,000 12-12-2022 - 20,000 09-01-2023 - 20,000	-	60,000
100	129225	2022/MSD/V/C/P /00073	00105801 (7)	Advitech International (Pvt) Ltd	Levofloxacin Tablet 500mg	45,000	21-11-2022 - 15,000 12-12-2022 - 15,000 09-01-2023 - 15,000	-	45,000

101	129226	2022/MSD/V/R/P/00076	01301502	Advitech International (Pvt) Ltd	Tamsulosin Capsule 0.4 mg	1,500,000	28-11-2022 - 500,000 26-12-2022 - 500,000 23-01-2023 - 500,000	-	1,500,000
102	130755	2022/MSD/V/R/P/00099	00303604 (24)	Yaden international Pvt Ltd	Phenobarbital Injection 200mg/mL	4,500	06-12-2022 - 4,500	-	4,500
103	130756	2022/MSD/V/R/P/00099	00304202	Yaden International (Pvt) Ltd	Clobazam Tablet 10mg	400,000	06-12-2022 - 400,000	-	400,000
104	130769	2022/MSD/V/R/P/00096	00900201 (97)	Yaden International PVT Ltd	Fusidic acid Eye Drop 1%(S.R.)	37,500	06-12-2022 - 37,500	-	37,500
105	130965	2022/MSD/V/R/P/00072	00500205 (94)	Softlogic Pharmaceuticals PVT Ltd	Fluticasone propionate 250mcg with Salmeterol xinafoate 25mcg / metered dose,120 dose unit	225,000	24-02-2023 -225,000	-	225,000
106	131084	2022/MSD/V/R/P/00102	00203002 (15)	Pharma Associates	Glyceryl trinitrate (Nitroglycerin) Injection 50mg in 10mL	11,250	23-12-2022 - 5,000 23-02-2023 - 6,250	-	11,250
107	131086	2022/MSD/V/R/P/00099	00304202 (27)	Pharma Associates	Clobazam Tablet 10mg	850,000	26-12-2022 - 12,500 24-02-2023 - 837,500	-	850,000
108	131088	2022/MSD/V/R/P/00099	00300201 (148)	Pharma Associates	Chlordiazepoxide Tablet 10mg	300,000	15-01-2023 - 300,000	-	300,000
109	131091	2022/MSD/V/R/P/00095	00500403 (41)	Chameee chemist	Ipratropium bromide respiratory solution, 250mcg in 1mL, 15mL Bottle	30,000	06-02-2023 - 30,000	-	30,000
110	131160	2022/MSD/V/R/P/00103	00500109 (92)	Chamee Chemist	Salbutamol respiratory solution 0.5% in 15mL vial	60,000	06-02-2023 - 60,000	-	60,000
111	131163	2022/MSD/V/R/P/00108	00403203 (151)	Novachem Lanka (Pvt) Ltd	Phytomenadione Injection 10mg in 1mL Ampoule	30,000	30-01-2023 - 30,000	-	30,000
112	131165	2022/MSD/V/C/P/00109	00301001 (149)	Novachem Lanka PVT Ltd	Fluphenazine decanoate Injection 25mg in 1mL Ampoule	55,000	30-12-2022 - 20,000 31-01-2023 - 35,000	-	55,000
113	131169	2022/MSD/V/R/P/00118	00000801 (1)	Yarden International (Pvt) Ltd	Morphine sulphate Tablet 10mg	210,000	09-12-2022 - 210,000	-	210,000
114	131586	2022/MSD/V/R/P/00104	01203803 (71)	Medmart Pharma (Pvt) Ltd.	Oxaliplatin Injection(as liophilized powder) 100mg vial	4,000	4,000 - 28-02-2023	-	4,000

115	131588	2022/MSD/V/R/P/00107	301902	S.J. Enterprises Pvt Ltd	Olanzapine Tablet 10mg	4,000,000	16-12-2022-1,333,333 06-01-2023-1,333,333 03-02-2023-1,333,334	-	4,000,000
116	131594	2022/MSD/V/R/P/00114	00500107 (150)	Unicura International (PVT) Ltd	Salbutamol aerosol Inhaler 100mcg/metered dose, 200 dose Unit	225,000	16-12-2022 - 75,000 06-01-2023 - 75,000 03-02-2023 - 75,000	-	225,000
117	131615	2022/MSD/V/R/P/00110	1207301 (145)	Unicura International (PVT) Ltd	Goserelin acetate implant 3.6mg (in syringe applicator)	3500	23-12-2022 - 1,170 13-01-2023 - 1,170 03-02-2023 - 1,160	-	3,500
118	131618	2022/MSD/V/R/P/00066	00200302	Asia Health Drug Store Pvt Ltd	Furosemide(Frusemide) Injection 20mg in 2mL ampoule	625,000	02-01-2023 - 625,000	-	625,000
119	131627	2022/MSD/V/R/P/00110	01202101 (152)	Imperial Life Sciences (Pvt) Ltd.	Mercaptopurine Tablet 50mg	39,999	16-12-2022 - 39,999	-	39,999
120	131628	2022/MSD/V/R/P/00111	00000301 (147)	Zyrex Pharmaceuticals (PVT) Ltd	Fentanyl Citrate Injection 100mcg in 2mL ampoule.	180000	31-12-2022 - 90,000 31-01-2023 - 90,000	-	180,000
121	131630	2022/MSD/V/R/P/00110	01207901 (144)	Softcare International (PVT) Ltd	Exemestane Tablet 25mg	15,500	30-12-2022 - 15,500	-	15,500
122	131632	2022/MSD/V/R/P/00110	1205702	Isolez Biotech Pharma AG Ltd	Rituximab Injection 500mg in 50mL vial	2,250	07-12-2022 - 2,250	-	2,250
123	132848	2022/MSD/V/R/P/00097	00101403	Tabrane Healthcare (Pvt) Ltd	Cefuroxime Tablet 500mg	1,125,000	19-12-2022 - 100,000 31-01-2023- 1,025,000	-	1,125,000
124	132850	2022/MSD/V/R/P/00106	00406702	Tabrane Pharmaceuticals (Pvt) Ltd	Cholecalciferol Capsule/Tablet 1000 IU (25 micrograms)	600,000	13-01-2023 - 600,000	-	600,000
125	132856	2022/MSD/V/C/P/00105	01201703	Tabrane Pharmaceuticals (Pvt) Ltd	Cytarabine Injection 1g in 10mL vial	1,500	13-01-2023 - 1,500	-	1,500
126	132859	2022/MSD/V/C/P/00092	01208501	Softcare International (Pvt) Ltd.	Abiraterone acetate Tablet 250mg	68,750	19-12-2022 - 3,500 13-01-2023 - 65,250	-	68,750

127	132865	2022/MSD/V/R/P/	01205002	Isolez Biotech Pharma AG Ltd	Irinotecan hydrochloride trihydrate Injection 100mg in 5mL vial	1,500	20-12-2022 - 1,500	-		1,5(
128	149933	2022/MSD/V/R/P /00106	00406702	Yaden International Pvt Ltd	Cholecalciferol (Colecalciferol) Cap/Tab 1000IU (25mcg)	600,000				600,0(
129	149928	2022/MSD/V/R/P /00066	00200701	Yaden International Pvt Ltd	Amiodarone Tab. 100mg	500,000				500,0(
130	149935	2022/MSD/V/R/P /00083	00303703	Yaden International Pvt Ltd	Phenytoin Sodium Tab. 100 mg	3,000,000				3000,0(
131	147300	2022/MSD/V/R/P /00081	00703401	Yaden International Pvt Ltd	Vasopressin Inj. 20 I.U. in 1mL Amp.	5,500				5,5(
132	147290	2022/MSD/V/R/P /00072	00500104	Yaden International Pvt Ltd	Salbutamol Inj. 5mg/5mL Amp.	1,500				1,5(
133	147292	2022/MSD/V/R/P /00076	00701502	Yaden International Pvt Ltd	Hydrocortisone Tab. 10mg	375,000				375,0(
134	147297	2022/MSD/V/R/P /00082	00303403	Yaden International Pvt Ltd	Tramadol HCl Inj. 100mg/2mL Amp.	25,000				25,0(
135	147285	2022/MSD/V/R/P /00075	00403501	Yaden International Pvt Ltd	Hydroxocobalamine Inj. 1mg/1mL Amp.	35,000				35,0(
136	147291	2022/MSD/V/R/P /00076	00701401	Yaden International Pvt Ltd	Fludrocortisone Tab. 0.1mg	50,000				50,0(
137	147294	2022/MSD/V/R/P /00079	00801001	Yaden International Pvt Ltd	Mesalazine tab. 400mg	45000				45,0(
138	147301	2022/MSD/V/R/P /00083	00302402	Yaden International Pvt Ltd	Clomipramine HCl Tab. 25mg	500,000				500,0(
139	147298	2022/MSD/V/R/P /00069	00903201	Yaden International Pvt Ltd	Nepafenac Ophthalmic Susp. 0.1%,3mL - 5mL Vial	11,250				11,2:

140	147274	2022/MSD/V/R/P /00064	00400701	Yaden International Pvt Ltd	Potassium Chloride (ER) Tab. 600mg	2,500,000				2,500,000
141	147299	2022/MSD/V/R/P /00074	01200801	George Steuart health pvt ltd	Bleomycin sulphate for Inj. 15 000 units vial	624				624
142	147270	2022/MSD/V/R/P /00066	00200302	Novachem Lanka (Pvt) Ltd	Furosemide (Frusemide) Inj. 20mg/2mL Amp.	625,000				625,000

158

154

Annexure -11

	MSD PO No	MSD Order List Number	SR Number	Name of the Supplier	Name of the drug	Awarded Quantity	Balance Quantity
1	135759	2023/MSD/V/R/P/00038	603205	Isolez Biotech Pharma AG Ltd	Human Immunoglobulin 5g-6g Vial	22,500	18,515
2	129059	2022/MSD/V/R/P/00066	00200102	Slim Pharmaceuticals Pvt Ltd	Digoxin Injection 500mcg in 2mL ampoule	1,200	460
3	130763	2022/MSD/V/R/P/00096	00901401	Yaden International (Pvt) Ltd	Tropicamide Eye Drops 1% 5mL-15mL Vial	1,250	1
4	129080	2022/MSD/V/C/P/00091	00404004	ABC Pharma Services Pvt. Ltd.	Epoetin Injection 10,000 IU Vial / Pre-filled syringe	12,000	2,000
5	129081	2022/MSD/V/C/P/00091	00405301	ABC Pharma Services Pvt. Ltd.	Human Albumin Solution BP/USP/Ph Eur 20% in 50mL bottle	99,999	33,166
6	129102	2022/MSD/V/R/P/00069	00904901	Unicura International (Pvt) Ltd	Natamycin ophthalmic suspension 5% in 5ml-15ml vial	5,001	140
7	129121	2022/MSD/V/R/P/00066	00204702	TMI solutions Pvt Ltd	Enoxaparin Injection 60mg in 0.6mL in prefilled Syringe	249,999	68,999
8	131090	2022/MSD/V/R/P/00099	00302001	Pharma Associates	Risperidone Tablet 2mg	6,250,000	136,400

9	130757	2022/MSD/V/R/P/00100	00701301	Yaden International Pvt Ltd	Propylthiouracil Tablet 50mg	62,500	40
10	149936	2022/MSD/V/R/P/00083	00302801	Hemas Pharmaceutical Pvt Ltd	Sertraline Tab. 50mg	2,500,000	1,157,900
11	147296	2022/MSD/V/R/P/00076	01502105	Ceyoka (Pvt) Ltd	Lidocaine HCl Gel 2%, 30g Tube	62,500	32,010
12	147295	2022/MSD/V/R/P/00069	00904901	Ceyoka (Pvt) Ltd	Natamycin Ophthalmic Susp. 5% in 5mL-15mL Dropper Bot.	5,001	140

Memorandum

Reference to folio 01, list of items supplied by logistic company (one star - export house by the name of Savorite pharmaceutical private limited - India in collaboration with its' in-house manufacturing facility of Ronald pharmaceuticals private limited - India) has been scrutinized with the list of annually estimated & supplied pharmaceuticals of MSD.

As per the details provided in folio 01, oral solids and liquids are manufactured and supplied on order basis, using in-house facilities of Ronald pharmaceuticals, where as other dosage forms are supplied by Savorite pharmaceutical (pvt) ltd.
Eg: Cream/Gel/Ointment, drops, inhalers, prefill syringes or injectables and powder satches

After scrutinizing the list in folio 01,with estimated list of MSD items, possibility of obtaining 39 items (please see folio.02) from the Indian supply agent "Savorite pharmaceutical (pvt) ltd" , has been positively identified as a new source of supply, to fulfill our emergency requirements (< 03 months), within a shortest possible time (< 45 days). This has become necessary in view of the slow progress and less than expected outcome of the foreign funded procurements such as ICL, ADB and AIIB.

Recommendations:

1. Recommends to explore the possibility of obtaining up to 03 month requirement of the urgently needed items in folio 02 that are supplied by the above mentioned Indian supply agent from ex-stocks or manufacture & supply basis, in less than 45 days .

2. This being a direct quotation (not in keeping with the normal procurements guidelines) based procurement on an unsolicited proposal of a Indian supply agent, it may need special approvals to proceed sighting the current state of affair as an emergency situation.
   Eg: Cabinet approval

3. Being a first time supplier, with no historical performance records of his products, some sort of a financial security, on the product quality assurance, has to be obtained or a suitable alternative arrangement has to be worked out with the supplier to mitigate the quality related risk of losses.

4. In view of the present FOREX issues, convenient and workable arrangement has to be negotiated with the supplier to finance the supplies and the settlement of payments.
   Eg; using Indian credit line, a special Loan facility/credit facility for the purchases.

This is forwarded regarding the offer in folio 01,first received from the Ministers' office and as per the instructions of Hon. Minister of Health in the meeting held on 17.10.2022, with the participations of Chairman (SPC), DGHS, Secretary of Health, DDG (MSD) and MSD representatives.

Senior Assistant Director
Medical Supplies Division

Director / SAD.

This is reference to meeting with the participation of Hon. Minister, S/H, DGHS, DDG MSD, & MSD staff members regarding current crisis of drug supply seen in the country.

It has been requed to explore the possibility of purchasing these drugs from the supplier for three months required.

S/H, DGHS, DDG MSD

Forwarded 2022/10/19

Sir.

Pl. see the memorandum prepared by MSD.

This is for your instruction ad approval please

Dr. A. T. SUBARSHANA
Director
Ministry of Health
Medical Supplies Division

19/10/2022

අමුණුම 62

19 OCT 2022
D.G.H.S.

Sec. Health

This is discussed with the MOH yesterday to overcome the drug shortage of MSD

Shall prepared very clear guidelines on

(1) procurement method
(2) - pricing matter
(3) - Quality Assurance of the pharmaceuticals By SPC/NMRA
(4) - an Equal of Quality Issues - method of ~~[illegible]~~ awarding - No Loss/
(5) Minimum order quantity

20 22/10/20

we should ~~be~~ followed unsolicited procurement procedure.

20 110

Secretary
Ministry of Health

SECRETARY
20 OCT 2022
MINISTRY OF HEALTH

தொலைபேசி) 0112669192 , 0112675011
தொலைபேசி) 0112698507 , 0112694033
Telephone) 0112675449 , 0112675280

தொலைநகல்) 0112693866
தொலைநகல்) 0112693869
Fax) 0112692913

மின்னஞ்சல் முகவரி)
postmaster@health.gov.lk
மின்னஞ்சல் முகவரி)
e-mail)

இணைய தளம்) www.health.gov.lk
இணையத்தளம்)
website)

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
Ministry of Health

மகை அங்கய) DDG/MSD/COM/2022
எனது இல)
My No.)

ඔබේ අංකය)
உமது இல
Your No.)

திகதி)
Date)2022.10.31

ඇමුණුම 63

Savorite Pharmaceuticals (PVT) Ltd.
Govt. Recognised One Star Export House
INDIA.

Urgently Required Pharmaceuticals to Maintaining Continuous Supply in Sri Lanka

Herewith, I am sending the order list of urgently required Pharmaceuticals (38 Items), for immediate supply.

Your kind co-operation in this regard is much appreciated.

S. Janaka Sri Chandraguptha
Secretary
Ministry of Health

S. Janaka Sri Chandraguptha
Secretary
Ministry of Health
"Suwasiripaya"
385, Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10.

copy handed over to the supplier on 01/11/2022.

ඇමුණුම 64

දුරකථන 694113
ෆැක්ස් 694114
Telephones 686528-30

විදුලි පණිවුඩ රස සේවකයේ
Telegrams MEDSTORES

ෆැක්ස් 941-697096
Fax

කේබල් GOVTDRUG
Cables

මගේ අංකය DDG/MSD/COM/2022
My No.

ඔබේ අංකය
Your No.

සෞඛ්‍ය සැපයිම් අංශය
(සෞඛ්‍ය සේවා දෙපාර්තමේන්තුව)
සෞඛ්‍යය මාධ්‍යයාකූලපාලනී
(සෞඛ්‍ය සේවයේ අධ්‍යක්ෂ කාර්යාලය)
MEDICAL SUPPLIES DIVISION
(Department of Health Services)

අංක 357, බද්දේගම වීඤ්ඤාණ මාවත, කොළඹ 10, ශ්‍රී ලංකාව.
இல. 357, பத்தேகம விஸ்வாவன்ன மாவத்த, கொழும்பு 10, இலங்கை.
No. 357, Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka.

පෝ. පෙ.
ප.පෙ. 1579
P.O.Box

දිනය/திகதி/Date : 2022.12.17

Additional Secretary (PSRP)
Ministry of Health
Colombo

Procurement via unsolicited proposal of M/s. Kausikh Therapeutics (P) Ltd, Chennai, India under the Indian Credit Line funding facility

This has reference to the instruction given by Hon. Minister of Health on 01/12/2022 to Director MSD in a meeting with Secretary, Health Additional Secretary (PSRP) and DGHS at the minister's office regarding the purchase three months requirement of 28 items. The relevant unsolicited proposal was received by the Hon. Minister from Kausikh Therapeutics (P) Ltd, Chennai, India.(Ref. Internal Memo dated 02/12/2022 of Director/MSD).

After reviewing the latest supply positions of the above mentioned 28 items, with the relevant MSD staff, it has been decided to proceed with the above proposal using Indian Credit Line (ICL) funding facility, to procure up to six months requirement. It was related to the increased allocation of ICL funds (for medicines by USD 53 Million) and lack of adequate local funding for SPC/DHS pending orders.

In the comparison of unit prices of the unsolicited bid, with the last DHS tender prices provided by DGM (Pharma)/SPC on 17/12/2022 by email, following conclusions were made ;

a) Prices offered for thirteen items (Annexure I) are less than the last SPC/DHS tender price. Therefore, it can be recommended for consideration by the pricing committee and the emergency procurement committee to purchase six months requirement under the above unsolicited proposal, with the Cabinet approval.
b) Prices offered for fifteen items (Annexure II) are higher than the last tender price of SPC/DHS. Therefore, it has to be negotiated with the supplier to bring down the prices before considering the same to purchase six months requirement.

This is for your kind perusal and necessary future action please

Dr. D. R. K. HERATH
Deputy Director General (Medical Supplies)
Medical Supplies Division
Ministry of Health Nutrition & Indigenous Medicine
Colombo 10.

Deputy Director General
Medical Supplies Division

Copy:- 1.Secretary, Ministry of Health - f.i.
2. DGHS - f.i.
3. Director / MSD - f.i.
4. All AD (Pharmaceuticals) - f.i. & n.a.

Price comparision of unsolicited bid price with the last tender price provided by SPC on 17/12/2022(DGM(Pharma) by email. (Anneure I)

a) List of offered items with bid price less than SPC provided last tender price.

No	New SR NO	VEN	Item	Unit	Requirement for 03 months	MSMIS standard unit cost(Rs.)	Value(Rs.)	Value(USD) Ex.@ Rs.365.00	Kausikh Terapeutics (P) Ltd offered value(USD)	Kausikh Terapeutics (P) Ltd offered unit price value(USD)	SPC provided latest tender price(USD/LKR)	Difference (USD)
1	00102903	N	Erythromycin Syr. 125 mg/5ml,100ml	Bot	10,500	175.33	1,840,965.00	5,044	7,245.00	0.6900	0.9500	0.2600
2	00406702	E	Cholecalciferol capsule/tablet1000 IU(25 mcg)(Colecalciferol)	Cap	600,000	19.29	11,574,000.00	31,710	5,340.00	0.0089	0.0984	0.0895
3	00107201	N	Itraconazole Cap. 100mg	Cap	360,000	11.45	4,122,000.00	11,293	10,080.00	0.0280	0.0475	0.0195
4	00802201	N	Loperamide HCl Tab/Cap 2mg	Tab	22,500	7.07	159,075.00	436	139.50	0.0062	0.0225	0.0163
5	00105701	E	Ofloxacin Tab. 200 mg	Tab	60,000	20.68	1,240,800.00	3,399	1,146.00	0.0191	0.0330	0.0139
6	00303104	E	Ondansetron tablet 4mg	Tab	150,000	6.17	925,500.00	2,536	1,275.00	0.0085	0.0200	0.0115
7	00201202	N	Carvedilol Tab. 12.5mg	Tab	750,000	2.17	1,627,500.00	4,459	6,075.00	0.0081	0.0180	0.0099
8	00402802	E	Pyridoxine HCl Tab. 25mg	Tab	500,000	1.93	965,000.00	2,644	2,050.00	0.0041	0.0100	0.0059
9	01301502	E	Tamsulosin capsule 0.4 mg	Cap	1,500,000	6.54	9,810,000.00	26,877	24,900.00	0.0166	0.0207	0.0041
10	00501001	N	Montelukast Sodium chewableTab. 5mg	Tab	300,000	13.14	3,942,000.00	10,800	2,670.00	0.0089	0.0110	0.0021
11	01401001	E	Allopurinol tablet.100mg	Tab	900,000	2.38	2,142,000.00	5,868	8,190.00	0.0091	0.0107	0.0016
12	00800501	N	Metoclopramide tablet 10mg	Tab	255,000	2.65	675,750.00	1,851	1,530.00	0.0060	0.0075	0.0015
13	00203501	N	Nifedipine ER Tab.20mg	Tab	22,500,000	0.56	12,600,000.00	34,521	128,250.00	0.0057	0.0062	0.0005

Note : Since the above comparitsion is purely based on SPC provided last tender price, a comprehensive price evaluation for acceptability, with other relevant data (by a the Pricing committee) , is recommended.

b) List of offered items with bid price higher than SPC provided last tender price.

(Annexure II)

No	New SR NO	VEN	Item	Unit	Requirement for 03 months	MSMIS standard unit cost(Rs.)	Value(Rs.)	Value(USD) Ex.@ Rs.365.00	Kausikh Terapeutics (P) Ltd offered value(USD)	Kausikh Terapeutics (P) Ltd offered unit price value(USD)	SPC provided latest tender price(USD/LKR)	Difference(USD)
1	00201201	E	Carvedilol Tab. 6.25mg	Tab	6,250,000	1.61	10,062,500.00	27,568	37,500.00	0.0060	0.0059	-0.0001
2	01400301	N	Diclofenac sodium Tab. 25 mg	Tab	1,800,000	0.7001	1,260,180.00	3,453	8,280.00	0.0046	0.0044	-0.0002
3	00103101	N	Azithromycin Tab.250mg	Tab	750,000	9.46	7,095,000.00	19,438	37,800.00	0.0504	0.0500	-0.0004
4	00801201	E	Bisacodyl tablet 5mg	Tab	750,000	0.5	375,000.00	1,027	3,675.00	0.0049	0.0043	-0.0006
5	01400201	N	Ibuprofen tablet 200mg	Tab	7,500,000	1.2	9,000,000.00	24,658	58,500.00	0.0078	0.0055	-0.0023
6	00501002	N	Montelukast Sodium Tab. 10mg	Tab	450,000	3.24	1,458,000.00	3,995	6,660.00	0.0148	0.0120	-0.0028
7	00303201	N	Aspirin Tab. 300mg	Tab	500,000	1.41	705,000.00	1,932	5,150.00	0.0103	0.0063	-0.0040
8	00502201	N	Desloratadine tablet 5mg	Tab	600,000	1.46	876,000.00	2,400	6,660.00	0.0111	0.0070	-0.0041
9	00101303	N	Cefalexin dispersible tablet125mg	Tab	250,000	3.55	887,500.00	2,432	5,325.00	0.0213	0.0167	-0.0046
10	00201901	E	Sildenafil Tab. 50mg	Tab	375,000	15.93	5,973,750.00	16,366	6,985.12	0.0186	0.0100	-0.0086
11	00105801	E	Levofloxacin Tab. 500mg	Tab	45,000	7.15	321,750.00	882	2,232.00	0.0496	0.0397	-0.0099
12	00101403	E	Cefuroxime Tab. 500mg	Tab	1,125,000	35.81	40,286,250.00	110,373	153,000.00	0.1360	0.1180	-0.0180
13	00101802	N	Cefixime Tablet 200mg	Tab	75,000	15.65	1,173,750.00	3,216	4,717.00	0.0629	0.0405	-0.0224
14	00107103	N	Fluconazole Cap. 200mg	Cap	10,500	21.67	227,535.00	623	1,260.00	0.1200	0.0772	-0.0428
15	00101404	E	Cefuroxime Syr.125mg/5ml, 100ml bot.	Bot	1,500	298.55	447,825.00	1,227	1,320.00	0.88	0.82	-0.06
Grand Total							**131,774,630.00**	**361,026**	**537,954.62**			

Note : Since the above comparition is purely based on SPC provided last tender price, a comprehensive price evaluation for acceptability, with other relevant data (by a the Pricing committee) , is recommended.

ජාතික උපදේශක කමිටුව සම්බන්ධයෙන් පනතේ දැනැවි විධිවිධාන දොළවීම.

37. මේ පනතේ 5, 6, 7, 8, 9, 10, 11, 12 සහ 13 වන වගන්තිවල විධිවිධාන අවශ්‍ය වෙනස්කිරීම් සහිතව ජාතික උපදේශක කමිටුවේ සභාපතිවරයා, සාමාජිකයන් සහ කමිටුවේ කටයුතු පවත්වාගෙන යාම සඳහා මෙන්ම ඒ සම්බන්ධයෙන් ද අදාළ විය යුතු ය.

III වන කොටස

ජාතික ඖෂධ තත්ත්ව ආරක්ෂණ පර්යේෂණාගාරය

ජාතික ඖෂධ තත්ත්ව ආරක්ෂණ පර්යේෂණාගාරය පිහිටුවීම.

38. (1) (මෙහි ඉහත්මතු "එන්එම්කිව්ඒඑල්" යනුවෙන් සඳහන් කරනු ලබන) මෙම පනතේ කාර්ය සඳහා ජාතික ඖෂධ තත්ත්ව ආරක්ෂණ පර්යේෂණාගාරය යනුවෙන් හඳුන්වනු ලබන අංශයක් පිහිටුවනු ලැබිය යුතු ය.

(2) (අ) නියමිත දිනයට පෙරාතුව ම වූ දිනයේ අමාත්‍යවරයාගේ අමාත්‍යාංශය යටතේ ක්‍රියාත්මකව පවතින ජාතික ඖෂධ තත්ත්ව ආරක්ෂණ පර්යේෂණාගාරය නියමිත දිනයේ සිට බලපැවැත්වෙන පරිදි අධිකාරිය වෙත පවරා ගනු ලැබිය සුනු අතර මෙම පනතේ කාර්ය සඳහා එන්එම්කිව්ඒඑල් ලෙස සලකනු ලැබිය යුතු ය.

(ආ) ජාතික ඖෂධ තත්ත්ව ආරක්ෂණ පර්යේෂණාගාරය වෙත පවරනු ලැබ, නියමිත දිනයේ දී ඒ වන විට අවසන් කර නැති සියලු පරීක්ෂණ පැවරුම් සහ වේනත් කටයුතු නියමිත දිනයේ සිට බලපැවැත්වෙන පරිදි එන්එම්කිව්ඒඑල් ආයතනය විසින් ඉටු කිරීම සහ අවසන් කිරීම කළ යුතු ය.

(ඇ) ජාතික ඖෂධ තත්ත්ව ආරක්ෂණ පර්යේෂණාගාරයේ යම් නිලධරයකු හෝ සේවා නියුක්තකයකු නියමිත දින සිට බලපැවැත්වෙන පරිදි එන්එම්කිව්ඒඑල් හි සේවා නියුක්ත විය හැකි අතර 1998 අංක 53 දරන ශ්‍රී ලංකා ජාතික ජල ජීවී විභා සංවර්ධන අධිකාරිය පනතේ 16, 17, 18 සහ 19 වන වගන්තිවල විධිවිධාන අවශ්‍ය වෙනස් කිරීම් සහිතව එම නිලධරයා හෝ සේවානියුක්තිකයා සම්බන්ධයෙන් අදාළ විය යුතු ය.

එන්එම්කිව්ඒඑල් හි කර්තව්‍යය.

39. (1) එන්එම්කිව්ඒඑල් හි කර්තව්‍යය වනුයේ:—

(අ) (i) ලියාපදිංචිය සඳහා වූ ඉල්ලීම් සමග ඉදිරිපත් කරන ලද ද්‍රව්‍ය;

(5) පාරිභෝගිකයාට තමාගේ කැමැත්ත පරිදි අදාළ ඖෂධයක් මිලදී ගැනීමට හැකිවන පරිදි ඔසුසලේ ඇති, එම ඖෂධයට අදාළ විවිධ වෙළඳනාම සහිත හෝ රහිත වර්ගීය ඖෂධ සහ ඒවායේ මිල ගණන් ඖෂධවේදියා විසින් පාරිභෝගිකයාට දැනුම් දිය යුතු ය.

(6) මිලදී ගැනීම සිදුකරන අවස්ථාවේදී ඔසුසලේ ඇති අදාළ වර්ගීය ඖෂධයට අදාළ වෙළඳ නාම සහිත හෝ රහිත ඖෂධ සඳහා ඒවායේ මිල ගණන් පාරිභෝගිකයාට දැනුම්දීම පැහැර හරිනු යම් ඖෂධවේදියකු මේ පනත යටතේ වරදක් සිදු කරනු ලැබිය යුතු ය.

මේ කොටසේ විධිවිධාන උල්ලංඝනය කිරීම වරදක් බව.

57. මේ පනතේ මේ කොටසේ නිශ්චිතව දක්වා ඇති විධිවිධාන උල්ලංඝනය කරන යම් තැනැත්තකු වරදක් සිදු කරනු ලැබිය යුතු ය.

IV වන කොටස

ඖෂධ ලියාපදිංචි කිරීම සහ බලපත්‍ර ලබාදීම

ඖෂධ ලියාපදිංචි කිරීම ආදිය සඳහා අවශ්‍යතා.

58. (1) කිසිදු තැනැත්තකු විසින් යම් ඖෂධයක් අධිකාරියෙ ලියාපදිංචි නොකර සහ අධිකාරියෙන් බලපත්‍රයක් ලබා නොගෙ නිෂ්පාදනය කිරීම හෝ ආනයනය කිරීම නොකළ යුතු ය.

(2) කිසිදු තැනැත්තකු විසින් අධිකාරියෙන් බලපත්‍රයක් ලබ නොගෙන යම් ඖෂධයක් ගබඩා කිරීම, එකලස් කිරීම, නැවැ ඇසුරුම් කිරීම, බෙදාහැරීම, ප්‍රවාහනය කිරීම හෝ විකිණීම නොකළ යුතු ය.

(3) (1) වන හෝ (2) වන උපවගන්තිවල නිශ්චිතව දක්වා ඇ විධිවිධාන උල්ලංඝනය කරන යම් තැනැත්තකු වරදක් සිදු කරු ලැබිය යුතු ය.

ඖෂධයක් ලියාපදිංචි කිරීම සඳහා වූ ඉල්ලීම.

59. (1) යම් ඖෂධයක් නිෂ්පාදනය කිරීමට හෝ ආනයන කිරීමට අදහස් කරන යම් තැනැත්තකු විසින් එම ඖෂධය ලියාපදි කිරීම සඳහා වූ ඉල්ලීමක් නියමිත ආකෘති පත්‍රය අනුව අධිකාරි වෙත ඉදිරිපත් කළ යුතු ය.

IV වන කොටස

සීමාස්ථ නිෂ්පාදන ලියාපදිංචි කිරීම සහ බලපත්‍ර ලබාදීම

සීමාස්ථ නිෂ්පාදන ලියාපදිංචි කිරීම ආදිය සඳහා වූ අවශ්‍යතා.

101. (1) කිසිම තැනැත්තකු විසින් යම් සීමාස්ථ නිෂ්පාදනයක් අධිකාරියේ ලියාපදිංචි නොකර සහ අධිකාරියෙන් තත්කාර්ය සඳහා බලපත්‍රයක් ලබා නොගෙන නිෂ්පාදනය කිරීම හෝ ආනයනය කිරීම නොකළ යුතු ය.

(2) කිසිම තැනැත්තකු විසින් අධිකාරියේ බලපත්‍රයක් ලබා නොගෙන යම් සීමාස්ථ නිෂ්පාදනයක් ගබඩා කිරීම, එකලස් කිරීම, නැවත ඇසුරුම් කිරීම, බෙදාහැරීම, ප්‍රවාහනය කිරීම හෝ විකිණීම සිදු නොකළ යුතු ය.

(3) (1) වන හෝ (2) වන උපවගන්තිවල විධිවිධාන උල්ලංඝනය කරන යම් තැනැත්තකු විසින් වරදක් සිදු කරනු ලැබේ.

සීමාස්ථ නිෂ්පාදන ලියාපදිංචි කිරීම ආදිය සඳහා වූ ඉල්ලීම.

102. (1) යම් සීමාස්ථ නිෂ්පාදනයක් ආනයනය කිරීමට, විකිණීමට, නිෂ්පාදනය කිරීමට, සැකසීමට හෝ බෙදාහැරීමට අදහස් කරන යම් තැනැත්තකු විසින් එම සීමාස්ථ නිෂ්පාදනය ලියාපදිංචි කිරීම සඳහා වූ ඉල්ලීමක් නියමිත ආකෘති පත්‍රය අනුව අධිකාරිය වෙත ඉදිරිපත් කළ යුතු ය.

(2) එම ඉල්ලීම පත්‍රය සමග එම සීමාස්ථ නිෂ්පාදනය පිළිබඳ නියමිත විස්තර, සාම්පල සහ නියමිත ලියාපදිංචි ගාස්තුව ද ඉදිරිපත් කරනු ලැබිය යුතු ය.

(3) (අ) සීමාස්ථ නිෂ්පාදන ලියාපදිංචි කිරීම සහ බලපත්‍ර සඳහා ලැබෙන සෑම ඉල්ලීමක්ම ලේඛනගත කළ යුතු ලේඛනයක් අධිකාරිය විසින් පවත්වාගෙන යා යුතු ය.

(ආ) එම ලේඛනයේ ඇතුළත් කළ යුතු විස්තර නියමිත පරිදි විය යුතු ය.

(4) ඉල්ලීමක් ලැබීමේ දී අධිකාරිය විසින් එම ඉල්ලීමේ පිටපතක් සහ සීමාස්ථ නිෂ්පාදනයේ සාම්පල සහ සියලු විස්තර -

(අ) සාධාරණ මිලකට මහජනතාවගේ සෞඛ්‍ය ආරක්ෂණ අවශ්‍යතාවලට අදාළ ප්‍රත්‍යක්ෂ, ආරක්ෂා සහිත සහ නිවැරදි

නියෝග.

121. මේ පනතේ මේ කොටසේ විධිවිධාන සියල්ල හෝ ඉන් යම් විධිවිධානයක් බලාත්මක කිරීම සඳහා අමාත්‍යවරයා විසින් නියෝග කරනු ලැබිය හැකි ය.

II වන කොටස

අභියාචනා

අභියාචනා.

122. (1) (අ) මේ පනත යටතේ අධිකාරිය විසින් ගනු ලැබූ යම් තීරණයකින් අතෘප්තියට පත් යම් තැනැත්තකු විසින් එම තීරණය දැනුම් දීමයක් ඇතුළත එම තීරණය නැවත සලකා බැලීම සඳහා අධිකාරිය වෙත ලිඛිත අභියාචනයක් ඉදිරිපත් කළ හැකි ය.

(ආ) අධිකාරිය විසින් එකී අභියාචනය පිළිබඳ තීරණය ප්‍රායෝගිකව් තැකි ඉක්මනින් අභියාචක වෙත දැනුම් දිය යුතු ය.

(2) අභියාචක, අධිකාරියේ තීරණයෙන් අතෘප්තියට පත්වන අවස්ථාවක, එම තීරණයට එරෙහිව 123 වන වගන්තිය යටතේ පත්කරන ලද අභියාචන කමිටුව වෙත අභියාචනයක් ඉදිරිපත් කරනු ලැබිය හැකි ය.

අභියාචන කමිටුව.

123. (1) මේ පනත ප්‍රකාරව ඉදිරිපත් කරනු ලබන අභියාචන අසා තීරණය කිරීම සඳහා අමාත්‍යවරයා විසින් අභියාචන කමිටුවක් පත් කරනු ලැබිය යුතු ය.

(2) අභියාචන කමිටුව පහත දැක්වෙන තැනැත්තන්ගෙන් සමන්විත විය යුතු ය.-

(අ) අභියාචන කමිටුවේ සභාපතිවරයා විය යුතු ශ්‍රී ලංකා ශ්‍රේෂ්ඨාධිකරණයේ හෝ අභියාචනාධිකරණයේ විශ්‍රාමලත් විනිශ්චයකාරවරයන් අතරින් පත් කරගනු ලබන සාමාජිකයකු;

(ආ) සෞඛ්‍ය ලේකම්වරයා; සහ

(ඇ) වෛද්‍ය ක්ෂේත්‍රයේ විශිෂ්ට දක්ෂතා පෙන්නුම්කර ඇති විශ්‍රාමලත් විශේෂඥ වෛද්‍යවරුන් අතරින් පත් කරනු ලබන සාමාජිකයෙක්.

GUIDELINES

FOR

PROCUREMENT OF PHARMACEUTICALS & MEDICAL DEVICES

2006

NATIONAL PROCUREMENT AGENCY

1. GENERAL PRINCIPLES

1.1 All Pharmaceuticals procured must fulfill **Quality, safety and Efficacy** criteria. All Medical Devices procured should satisfy **Quality, safety, Performance, Effectiveness and Efficacy** criteria.

1.2 The strategic objectives of procurement of Pharmaceuticals & Medical Devices should be :

- procure the most cost-effective Pharmaceuticals and Medical Devices in the right quantities ;
- ensure supplier reliability with respect to service and quality;
- arrange timely delivery to avoid shortages and stock outs; and
- achieve the lowest possible evaluated cost.

2. REGISTRATION

2.1 All Pharmaceuticals and Medical Devices to be procured by the PE shall be registered with the Cosmetics, Devices and Drugs Regulatory Authority of Sri Lanka.

2.2 The PE shall request the prospective bidders to attach a notarially certified copy of the original registration certificate and any re-registration certificates where applicable to the bid documents. Submission of back-dated registration certificates after bid opening shall be rejected.

2.3 For products which are imported to Sri Lanka, the registration should also be valid until at least six (06) months after the last consignment of the Pharmaceuticals and/or the Medical Devices to be procured are due to be received in Sri Lanka. . For products which are manufactured in Sri Lanka, the registration should be valid for at least six (06) months after the last consignment of the Pharmaceuticals and or the Medical Devices to be procured are received by the PE.

2.4 If the bidder submits evidence that the Bidder's authorized local agent has applied for re-registration at least six months before the date of expiry of the current registration, as per the relevant gazette notification, this shall be deemed sufficient to satisfy the requirements of registration.

2.5 No contract shall be awarded to any bidder unless the bidder is in possession of a valid certificate of registration at the time of the award of contract.

2.6 The requirement of registration stipulated above may be waived off in exceptional circumstances which is referred to as Emergency and Urgent Procurements under section 6.6 and 6.7 upon the issuance of a "no objection"

2020-2021 වර්ෂ තුළ පවත්වන ලද ඖෂධ වට්ටෝරු සමාලෝචන කමිටුව විසින් ප්‍රතිශෝධිත රජයේ රෝහල් තුළ භාවිතා කළ යුතු නව ඖෂධ ලැයිස්තුව

විද්‍යාලය / Collage ----------	ඖෂධ සංඛ්‍යාව ----------
2.1 Medicines used in Infectious Diseases	216
2.2 Medicines used in Cardiovascular Diseases	150
2.3 Medicines acting on the Central Nervous System	170
2.4 Medicines affecting Nutrition and blood	155
2.5 Medicines used in the treatments of Respiratory Diseases	114
2.6 Vaccines and Immunological Products	52
2.7 Medicines used in the treatment of Endocrine system	94
2.8 Medicines acting on the Gastro Intestinal Tract	64
2.9 Medicines acting on Eye	73
2.10 Medicines used in the treatments of diseases of Ear, Nose & Oropharynx	31
2.11 Medicines acting on the Skin	110
2.12 Medicines used in Malignant Diseases	190
Other items relevant to Malignant diseases	30
2.13 Medicines used in the Renal Diseases	86
2.14 Medicines used in the treatments of Musculoskeletal Diseases	66
2.15 Medicines used in Anesthesia	125
2.16 Antidotes	17
	1,743

The Revision of Pharmaceutical Formulary for Government Healthcare Institutions 2020/2021

MEDICAL SUPPLIES DIVISION
Ministry of Health

MSD

(33)

File No :- MSD/QA/FR/20/21

To :- In-charge (Quality Assurance Unit)

Subject :- The final report of the Revision of Pharmaceuticals formulary for Government Healthcare Institutions 2020/2021, recommended by the Formulary Revision Committee 2020/2021 (Folio 01-229 & i-ix)

Forwarded for your recommendation and signature please.

Signature - .....
Name - Y.N.L. Abeywardana
Designation - SCO(QA)-02
Date - 27.06.2022

Signature - .....
Name - M.M.P. Madumadavi
Designation - SCO(QA)-04
Date - 27.06.2022

To :- Assistant Director (P)-II

Subject :-

Recommended / ~~Not Recommended.~~

Signature - .....
Name - S. U. Karawita
Designation - IC (QA)
Date - 27.06.2022

To :- Director (Medical Supplies Division)

Subject :-

Recommended / ~~Not Recommended.~~

Signature - .....
Name - L.C. Wanniarachchi
Designation - AD(P)-II
Date - 27 06.2022

To :- Deputy Director General (Medical Supplies)

Subject :-

Recommended / Not Recommended.

Dr. CHANDANA WIJESINGHE
(MBBS,MD.PhD)
Director (covering up)
Medical Supplies Division
Rev. Baddegama Wimalawansa Mawatha
Colombo 10.

Signature - .....
Name - Dr. Chandana Wijesinghe
Designation - Director (MSD)
Date - 06.2022

To :- Director General of Health Service.

Subject :-

Recommended / Not Recommended.

Dr. S.C. WICKRAMASINGHE
Deputy Director General
(Medical Supplies Division) Covering up
Medical Supplies Division
Ministry of Health
Colombo 10.

Signature - .....
Name - Dr. C. Wickramasinghe
Designation - DDG (MS)
Date -

(32)

To :- Secretary (Ministry of Health)

Subject :-

Recommended / Not Recommended.

28 JUN 2022

D. G. H. S.

Dr. ASELA GUNAWARDENA
Director General of Health Services
Ministry of Health
"Suwasiripaya"
385, Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10.

Signature - .....
Name - Dr. Asela Gunawardena
Designation - DGHS
Date - 28/6/22

Approved / Not Approved

S. Janaka Sri Chandragupta
Secretary
Ministry of Health
"Suwasiripaya"
385, Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10.

Signature - .....
Name-
Designation - Secretary (Ministry of Health)
Date - 06/07/2022

SECRETARY
05 JUL 2022
Ministry of Health

DDG (Medical Supplies)
06 JUL 2022
MEDICAL SUPPLIES
DIVISION
COLOMBO 10.

(31)

The Revision of Pharmaceutical Formulary for Government Healthcare Institutions 2020/2021

The members of the Core Committee- The Revision of Pharmaceutical Formulary- 2020/2021

No.	Name of the committee member	Signature and Seal
1	Dr. Chandana Wijesinghe Director, Medical Supplies Division (Committee Chairman)	Dr. CHANDANA WIJESINGHE (MBBS,MD,PhD) Director (covering up) Medical Supplies Division Rev. Baddegama Wimalawansa Thero Mw; Colombo 10.
2	Professor Rohini Fernandopulle, Senior Professor in Pharmacology	Rdopulle 7/6/2022 Senior Professor in clinical pharmacolog
3	Professor Gita Fernando, Emeritus Professor of Pharmacology	
4	Professor Shalini Sri Ranganathan, Professor in Pharmacology	PROF SHALINI SRI RANGANATHAN MBBS (Sri Lanka), MD (Sri Lanka) PhD (Cardiff, UK) MRCP (UK) DCH (Sri Lanka), Dip Med Tox (Cardiff, UK) Professor in Pharmacology & Specialist in Paediatrics (Reg. No:11008) Faculty of Medicine, University of Colombo.
5	Professor Chamari Weeraratne, Professor in Pharmacology	Prof. C. L. Weeraratne Head / Pharmacology DEPARTMENT OF PHARMACOLOGY COLOMBO 08. FACULTY OF MEDICINE
6	Professor Priyanga Ranasinghe, Professor in Pharmacology	
7	Professor Panduka Karunanayake, Professor in Clinical Medicine	

8	Professor Raveen Hanwelle, Professor of Psychiatry	
9	Dr. Lakkumar Fernando, Senior Consultant Paediatrician	02/06/22 Consultant Paediatrician DGH Negombo.
10	Dr. Ruwanthi Perera, Consultant Paediatrician	Consultant Paediatrician CSTH 02/06/2022
11	Dr. Pradeep Kumarasinghe De Silva, Consultant Physician	Dr. Pradeep Kumarasinghe de Silva M.B.B.S (Colombo) M.D (Medicine) FCCP Consultant Physician National Hospital of Sri Lanka Colombo SLMC Reg No. 9983
12	Dr. Gayan Ekanayake, Consultant Plastic Surgeon	Dr. Gayan Ekanayake Consultant Plastic and Reconstructive Surgeon
13	Dr. Thushan Benaragama, Consultant Plastic Surgeon	Dr. THUSHAN BENARAGAMA (MBBS, MS) Consultant Plastic and Reconstructive Surgeon. NATIONAL HOSPITAL OF SRI - LANKA COLOMBO.
14	Dr. U.P.D. Ratnasisri, Consultant obstetrician	Dr. U.D.P. Ratnasiri MBBS (SL) - MS (Obs & Gyn) FRCOG (UK) Consultant Obstetrician & Gynaecologist
15	Dr. Kumudini Ranathunga, Consultant Anesthesiologist	DR. MRS. K. RANATUNGA MD. FRCA CONSULTANT ANAESTHATIST
16	Dr. Manoj Edirisooriya, Consultant Anesthesiologist	

(29)

Nominated other relevant Core committee members for Formulary Revision (Pharmaceuticals) 2020/2021

Professor Ishan De Zoysa, Consultant Gastroenterological Surgeon

Dr. Dilcep de Silva, Specialist in Health Economics

Dr. Samanmalee Gunasekara, Consultant Microbiologist

Dr. Dushani Jayawardhana, Consultant Microbiologist

Dr. Stanley Amarasekera, Consultant cardiologist and Cardiac interventionalist

Dr. Duminda Samarasinghe, Consultant Paediatric Cardiologist

Dr. Sunethra Senanayake, Consultant Neurologist

Dr. Senaka Bandusena, Consultant Neurologist

Dr. Nishadya Ranasinghe, Consultant Haematologist

Dr. Sanjeewa Pathirage, Consultant Haematologist

Dr. Geethal Perera, Consultant Pulmonologist

Dr. Ishanth Perera, Consultant Pulmonologist

Dr. Kanthi Nanayakkara, Consultant Vaccinologist

Dr. Noel Somasundaram, Consultant Endocrinologist

Dr. Manilka Sumanatilleke, Consultant Endocrinologist

Dr. Sanjeewa Aryasingha, Consultant Gastroenterologist

Dr. Muditha Kulathunga, Consultant Eye Surgeon

Dr. Kapila Banduthilake, Consultant Vitreoretinal surgeon

Dr. Chandra Jayasooriya, Consultant Otorhinolaryngologist

Dr. Amal Fernando, Consultant Otorhinolaryngologist

Dr. Janaka Akarawita, Consultant Dermatologist

Dr. Dananjaya Ariyawansa, Consultant Dermatologist

Dr. Damayanthi Peiris, Consultant Oncologist

Dr. A. J. Hilmi, Consultant Oncologist

Dr. Aruna Priyantha Hewageegana, Consultant Nephrologist

Dr. Vindya Gunasekara, Consultant Paediatric Nephrologist

(28)

iv. Manjula Wijewardena, Consultant Urologist

v. W.A. Susantha De Silva, Consultant Urologist

vi. Ruwinda Munidasa, Consultant Rheumatology & Rehabilitation

vii. Manika de Silva, Consultant Rheumatologist

13. Common comments which apply to all Pharmaceutical categories

13.1 Formulary Revision Committee suggestions

1 Medicines will be supplied under their 'International Non-proprietary Name' (INN), or 'generic' name. The use of generic names serves to promote purchasing and prescribing by generic name.

2 Non-formulary items are not allowed and should refer to Formulary Revision Committee for the approval when needed.

3 NMRA unregistered products are not allowed to be in the formulary.

4 Not to purchase unregistered products until they get registered at NMRA.

5 NMRA unregistered products are not allowed to Local purchase by institutions.

6 When including new item to the formulary, Pharmaco-economical evaluation should be done.

7 All unregistered new items which are approved in the formulary revision, will be included to the formulary after completing the NMRA registration.

8 Decided to consider the ceiling price (which is given by the NMRA) at the procurement committee for each tender (Note: Do not exceed the maximum retail price issued by NMRA).

9 All colleges are requested to prepare a treatment guideline mentioning 1st line, 2nd line and 3rd line medications in order to ensure the availability of these formulary items.

13.2 MSD suggestions

1 Newly requested pharmaceutical items will be discussed at Formulary Revision Committee meeting, if only those products are registered at NMRA.

2 MSD not provides medicines in their brand names.

3 All offered pharmaceutical items shall be evaluated in the Technical Evaluation Committee by consultant/s from relevant college/s at the procurement level in order to assure the quality and appropriateness of the purchased product.

ඇමුණුම 69

දුරකථන
தொலைபேசி
Telephones
694113
694114
686528-30

විදුලි පණිවුඩ
தந்தி
Telegrams
රජ ඖෂධ
மெட்ஸ்ரோர்ஸ்
MEDSTORES

ෆැක්ස්
பக்ஸ்
Fax
941-697096

සංකේත
கடவுச் சீட்டுத்தந்தி
Cables
GOVTDRUG

මගේ අංකය
எனது இல.
My No.
MSD/QA-02/FRC/NMRA-01

ඔබේ අංකය
உமது இல.
Your No.

වෛද්‍ය සැපයීම්
(සෞඛ්‍ය සේවා දෙපාර්තමේන්තුව)
සෞඛ්‍ය වින්‍යෝගය්‍යකුති
(சுகாதார சேவைத் திணைக்களம்)
MEDICAL SUPPLIES DIVISION
(Department of Health Services)

අංක 357, බෙදගම වීරසේවන මාවත, කොළඹ 10, ශ්‍රී ලංකාව.
இல. 357, பத்தேகம வீரசேவன மாவத்தை, கொழும்பு 10, இலங்கை.
No. 357, Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka

තැ. පෙ.
தபெ
P.O.Box
1679

දිනය/திகதி/Date : 24 .11.2022

Chief Executive Officer
National Medicines Regulatory Authority,
No 120,
Norris Canal Road,
Colombo 10

Informing the decisions of Formulary Revision (Pharmaceuticals) 2020/2021 relevant to NMRA

The pharmaceuticals in the formulary were revised by the Formulary Revision Committee (FRC) 2020/2021. The final report which was approved by the Secretary in Health services, Ministry of Health, has published on MSD website (The Link: https://msd.gov.lk/index.php/downloads/formulary-revision-reports/fr-2020-2021).

Following decisions were taken at the committee which are related to the NMRA medicines registration procedure.

1. Medicines will be supplied under their 'International Non-proprietary Name' (INN) or 'Generic Name'. The use of Generic names serves to promote purchasing and prescribing by Generic name.
2. NMRA unregistered products are not allowed to be in the formulary, to purchase by SPC and to Local purchase by institutions.
3. All unregistered new items which were recommended by the Formulary Revision Committee, will be included to the formulary after completing the NMRA registration.
4. Decided to consider the ceiling price (which is given by the NMRA) at the procurement committee for each tender.
   [Note: Do not exceed the Maximum Retail Price (MRP) issued by NMRA].
5. All colleges are requested to prepare a treatment guideline mentioning 1st line, 2nd line and 3rd line medications in order to ensure the availability of these formulary items.

25

243

Unregistered items which were already included in the formulary and recommended new items (not included since not registered) to include to the formulary are categorized under the following topics. Please prioritize these as given below order at the registration.

1. The list of items to inform NMRA for giving priority for registration (Attachment 1)
2. The list of items to inform NMRA to increase the number of registrations (Attachment 2)
3. The list of items to inform NMRA to register under Orphan category (Attachment 3)
4. The list of recommended new items (not included to the formulary since not registered) (Attachment 4)

Further to the above, the following decisions were taken by the committee which are relevant to NMRA registration is attached in Attachment 5 for your notice and necessary arrangements.

Your fullest support in this endeavor is very much appreciated.

Thank you.

Dr. A. T. SUDARSHANA
Director
Ministry of Health
Medical Supplies Division
No. 357, Deans Road,
Colombo 10.

O/C Director
Medical Supplies Division

Attachment 1

The list of items to inform NMRA for giving priority for registration

No.	SR No.	Item
1	00100803	Flucloxacillin Injection, 1g vial
2	00203002	Glyceryl trinitrate (Nitroglycerin) Injection 50mg in 10mL
3	00406901	Magnesium Glycinate Tablet 400mg (200mg of elemental Magnesium)
4	00704502	Triamcinolone acetonide (preservative free) Injection 40mg in 1mL vial
5	00802801	L-Ornithine L- Aspartate Injection 5g in 10mL ampoule
6	00802801	L-Ornithine L- Aspartate Injection 5g in 10mL ampoule
7	01105001	Tretinoin cream 0.025% 15g tube
8	01201902	Fluorouracil Injection 250mg in 10mL vial
9	01201904	Fluorouracil Injection 1g in 20mL vial
10	01202102	Mercaptopurine Oral Suspension 20mg/mL, 100mL bottle
11	01202601	Vinorelbine Injection 50mg vial
12	01202603	Vinorelbine Tablet 30mg
13	01202703	Etoposide Capsule 50mg
14	01202803	Lecucovorin Calcium (Folinic acid) Injection 10mg /mL in 5mL vial/ampoule.
15	01203001	Bortezomib Injection 1mg vial
16	01203002	Bortezomib Injection 2mg vial
17	01203202	Crisantaspase Injection 10,000IU vial
18	01204201	Everolimus Tablet 0.25mg

No.	SR No.	Item
19	01207401	Octreotide long acting Injection 20mg vial with solvent
20	01207403	Octreotide long acting Injection 30mg vial with solvent
21	01208301	Cladribine Injection 10mg in 10mL vial
22	01208601	Cabazitaxel Injection 60 mg / 1.5 mL vial
23	01209101	Mitotane Tablets 500mg
24	01210001	Vandetanib Tablet 100mg
25	01210701	Ceritinib Capsule 150mg
26	01210801	Atezolizumab Injection 1200mg/20mL vial
27	01211101	Crizotinib Capsule 250mg
28	01211401	Panitumumab Injection 100mg/5mL vial
29	01212301	Carfilzomib Injection 30mg vial
30	01300602	Potassium citrate Tablet 1080mg
31	01301701	Alfuzosin Hydrochloride Tablet (extended release) 10mg
32	01302002	Oxybutynine Hydrochloride oral Solution 1mg in 5mL, 100mL bottle
33	01302002	Oxybutynine Hydrochloride oral Solution 1mg in 5mL, 100mL bottle
34	01401702	Etanercept Injection 25mg vial
35	01401702	Etanercept Injection 25mg vial
36	01402601	Colchicine Tablet 500microgram

241

Attachment 2

The list of items to inform NMRA to increase the number of registrations

No.	SR No.	Item
1	00100201	Benzyl penicillin Injection 1 million unit vial
2	00100603	Ampicillin Injection 1g vial
3	00101001	Piperacillin 4g with Tazobactam 500mg vial
4	00101101	Sulbactam sodium and Cefoperazone sodium (1:1) for Injection 1g vial
5	00101102	Sulbactam sodium and Cefoperazone sodium (1:1) for Injection 2g vial
6	00101202	Ticarcillin disodium 3g & Clavulanate potassium 200mg Injection
7	00102601	Amikacin Injection 250mg in 1mL Vial
8	00102603	Amikacin Injection 500mg in 2mL Vial
9	00103401	Sodium Fusidate Tablet 250mg
10	00103502	Vancomycin hydrochloride Injection 1g Vial
11	00103703	Co-trimoxazole paediatric oral suspension 50mL Bottle (Trimethoprim 40mg + Sulphamethoxazole 200mg in5mL)
12	00103801	Sulphadiazine Tablet 500mg
13	00103901	Trimethoprim Tablet 100mg
14	00103902	Trimethoprim Syrup 50mg in 5mL, 100mL bottle
15	00103903	Trimethoprim Tablet 200mg
16	00105204	Metronidazole oral Suspension 200mg/5mL in 100mL bottle
17	00105301	Furazolidone Tablet 100mg
18	00105503	Nalidixic oral suspension 300 mg in 5mL, 100mL bottle
19	00105903	Nitrofurantoin oral suspension 25mg/5mL in 300mL Bottle

No.	SR No.	Item
30	00111601	Caspofungin Injection 50mg vial
31	00200103	Digoxin Syrup 50microgram in 1 mL, 60mL Bottle
32	00201101	Propranolol Tablet 10 mg
33	00202001	Sodium nitroprusside Injection 50mg Vial
34	00203004	Glyceryl trinitrate sublingual spray 400microgram/MD, 200 Dose unit
35	00203701	Verapamil Hydrochloride Tablet 40mg
36	00205001	Fondaparinux sodium 2.5mg in 0.5mL solution for Injection
37	00205301	Abciximab Intravenous Infusion 10mg in 5mL
38	00205701	Alteplase(Recombinant Tissue type plasminogen activator) 20mg vial
39	00208001	Anagrelide (as Hydrochloride)Capsules, 500microgram
40	00209101	Amiloride Tablet 5mg
41	00307201	Amantadine Capsule 100mg
42	00307601	Enzyme Co Q10 Capsule 100mg
43	00400906	Sodium Bicarbonate 1.26% 500mL Collapsible bag
44	00401007	Sodium chloride for IV use, 0.45%, 500mL
45	00404101	MPG-epoetin 100microgram microgram/0.3mLInjection PFS
46	00404203	Carnitine Tablet/Capsule 500mg
47	00500505	Theophylline Syrup 25mg /5mL , 60mL bottle
48	00701501	Hydrocortisone Tablets 5mg

20	00107101	Fluconazole Capsule 50mg
21	00107102	Fluconazole Injection 200mg in 100mL Vial
22	00107501	Nystatin Tablet 500,000 IU
23	00107701	Zidovudine Tablet 300mg
24	00107901	Aciclovir Tablet 200mg
25	00109101	Lamivudine 150mg + Zidovudine 300mg + Nevirapine 200mg Tablet
26	00109501	Nevirapine Tablet 200 mg
27	00110001	Efavirenz 600 mg+ Emtricitabine 200mg+ Tenofovir disoproxil (as fumarate) 300 mg Tablet
28	00110401	Zidovudine 300mg + Lamivudine 150mg Tablet
29	00110501	Efavirenz Tab/Cap 600mg

49	00702201	Oestradiol valerate 2mg, 11 Tablets and Oestradiol valerate 2mg + Cyproterone acetate 1mg, 10 Tablets in a calendar pack
50	00801401	Iso-osmotic bowel cleansing preparation (Polyethylene glycol 58g-60g)
51	00801601	Ursodeoxycholic acid Tablets150mg
52	00801603	Ursodeoxycholic acid Tablet 300mg
53	00802201	Loperamide Hydrochloride Tablet/Capsule 2mg
54	00802301	Budesonide Capsule 3mg
55	00802401	Macrogol 3350/4000 (6.125g-6.563g of PEG) Oral Powder Sachets, with or without electrolytes
56	00802701	Hydrocortisone acetate foam enema 10%
57	01207401	Octreotide long acting Injection 20mg vial with solvent
58	01207403	Octreotide long acting Injection 30mg vial with solvent

(24)

Attachment 3

The list of items to inform NMRA to register under Orphan category

No.	SR No.	Item
1	00000810	Morphine sulphate syrup 2mg in 1mL, 100mL bottle
2	00105101	Clofazimine Capsule/Tablet 100mg
3	00105103	Clofazimine Capsule/Tablet 50mg
4	00112201	Ketoconazole Tablet 200mg
5	00112701	Tenofovir alafenamide Tablet 25mg
6	00113201	Inosine pranobex Tablet 500mg
7	00200304	Furosemide (Frusemide) Tablet 250mg
8	00201103	Propranolol Injection 1mg in 1mL ampoule
9	00202401	Phenoxybenzamine Hydrochloride Capsule 10mg
10	00202501	Phentolamine mesylate Injection 10mg in 10mL Ampoule
11	00202703	Captopril Syrup 5mg/mL, 100mL bottle
12	00204801	Tinzaparin sodium Injection 3,500 units
13	00206401	Aprotinin Injection 10,000 kallikrein inactivator units/mL in 50mL vial
14	00207402	Clonidine hydrochloride Injection (preservative free) 0.5mg/1mL, 10mL vial
15	00207403	Clonidine Hydrochloride Tablet 100microgram

No.	SR No.	Item
33	00407301	Pyridoxal phosphate Tablet 50mg
34	00502101	Caffeine Citrate oral solution 25mg in 5mL, vial
35	00502102	Caffeine Citrate Injection 40mg in 2mL,vial
36	00502601	Tobramycin Nebulizer Solution 60mg / mL in 5mL
37	00502701	Omalizumab Injection 150mg / mL, 1mL pre-filled syringe
38	00503001	Pentamidine Isetionate powder for solution for Injection 300mg
39	00600303	Hepatitis B specific Immunoglobulin (HBIG) 100IU-500IU vial
40	00603701	Influenza Vaccine 0.5mL prefilled syringe
41	00703001	Tetracosactrin Injection 250microgram/1mL
42	00705501	Diazoxide Tablet 50mg
43	00705602	Oxandrolone Tablet 10mg
44	00801002	Mesalazine suppository 500mg
45	00801702	Pancreatic enzyme Capsule (protease 1000U, lipase 25000U, amylase 40000U)
46	00905401	Perfluoropropane Intraocular 75mL container/ canister
47	01001201	Silver Nitrate Sticks for Nasal Cautering

475

(21)

16	00209201	Flecainide Acetate Tablet 50mg
17	00209202	Flecainide Acetate Injection 10mg/mL, 15mL ampoule
18	00300302	Lorazepam Injection 4mg in 1mL ampoule.
19	00304101	Paraldehyde rectal solution 10mL single dose unit
20	00304801	Vigabatrin Tablet 500mg
21	00306002	Riluzole Tablet 50mg
22	00307101	Tetrabenazine Tablet 25mg
23	00307501	Midazolam Nasal Spray 0.5mg/md,50 dose unit
24	00307701	Stiripentol Capsule 500mg
25	00307702	Stiripentol powder for oral suspension 250mg Sachet
26	00308301	Teriflunomide Tablet 14mg
27	00400906	Sodium Bicarbonate 1.26% 500mL Collapsible bag
28	00401007	Sodium chloride for IV use, 0.45%, 500mL
29	00404401	Sodium dihydrogen orthophosphate powder
30	00404501	Disodium hydrogen orthophosphate powder
31	00406301	Potassium phosphate Injection 50mL
32	00406501	Phosphate Tablet 500 mg

48	01107401	Paromomycin cream 15% w/w with or without Gentamicin 15g tube
49	01200102	Busulphan Injection 6mg/mL, 10mL vial
50	01200301	Cyclophosphamide Tablet 50mg
51	01201302	Idarubicin hydrochloride Injection 5 mg vial
52	01201501	Mitoxantrone hydrochloride Injection 20mg in 10mL vial
53	01202801	Lecucovorin Calcium (Folinic acid)Tablet 15mg
54	01203901	Procarbazine Capsule 50mg
55	01210301	BCG suspension for intravesical chemotherapy 40mg / 1mL vial
56	01212201	Miltefosine Capsule 50mg
57	01302003	Oxybutynine Hydrochloride Tablet 5mg
58	01302201	Sevelamer hydrochloride Tablet 800mg
59	01302301	Doxazosin Tablet 1mg
60	01302302	Doxazosin Tablet 4mg
61	01400501	Ustekinumab Injection 130mg/26mL vial
62	01400902	Ustekinumab Injection 45mg/0.5mL vial
63	01501901	Dantroline sodium Injection 20mg vial
64	01502601	Sugammadex Injection 100mg/mL, in 5mL vial

476

Attachement 4

List of recommended New items (Not included to the formulary since not registered)

No.	Item Name
1	Rivaroxiban Tablet 5mg
2	Rivaroxiban Tablet 15mg
3	Enoxaparin Sodium Injection 2000IU prefilled syringe
4	Deferasirox Non-dispersible Tablet 400mg
5	Cyclosporin Injection 50mg/mL
6	Treosulfan 1g Powder for solution for Infusion
7	Treosulfan 5g Powder for solution for Infusion
8	Ferric Carboxy Moltose 100mg/2mL Vial
9	Folic Acid Tablet 400microgram
10	Fosfomycin 40mg/mL Injection
11	Tenofovir 300mg+Lamivudine 300mg+Dolutegravir 50mg
12	Ceftazidime 2g +Avibactam 0.5g Powder for concentrate for solution for infusion
13	Aztreonam + Avibactam
14	Fluconazole Oral suspension 200mg/5mL
15	Prazosin Hydrochloride Extended Release Tablet 5 mg
16	Spironolactone Tablet 12.5mg, (Scored)
17	Plasma lyte A (PH 7.4) 500mL Solusion for Infusion
18	Dabigatran Capsule 110mg
19	Apixaban Tablet 2.5mg
20	Apixaban Tablet 5mg
21	Triclofos Oral solution 500mg/5mL
22	Lacosamide Tablet 200mg
23	Human Immunoglobulin IV Infusion 10g/100mL

No.	Item Name
78	Mesalazine Tablet 1.2g
79	Simethicone Oral dropper 40mg/mL
80	Ispaghula Husk Sachet
81	Cholestyramine 5mg Sachet
82	Sodium Citrate 450mg + Sodium Lauryl Sulphate 75mg and Glycerin Enema 10mL-20mL
83	Everolimus Tablet 0.5mg
84	Sunitinib Malate Capsule 25mg
85	Isavuconazole 100mg tablet
86	Pantaprazole tablet 20mg
87	Beclometazone 0.025%, Miconazole 2% and Neomycin 0.5% ointment 15g tube
88	Lubricating jelly
89	Choriogonadotropin alfa 250mcg/0.5mL
90	Tetrachlorodecaoxide solution (sterile) 100mL
91	Terbutaline 0.25mg Subcutaneous injection
92	Oral Medroxyprogesterone acetate 20 mg
93	Methotrexate Subcutaneous injection 10mg/0.4mL
94	Pilocarpine Tablet 5mg
95	Prednisolone syrup 15mg/5mL
96	Budesonide Nasal spray 50mcg-70mcg
97	Deoxyribonuclease 1mg/mL (DNAs)
98	Mepolizumab 100mg/mL
99	Nintedanib 150mg
100	Iloprost 10mcg/mL nebulizer solution

24	Methylphenidate Hydrochloride Modified Release Tablet 18mg
25	Methylphenidate Hydrochloride Modified Release Tablet 27mg
26	Methylphenidate Hydrochloride Modified Release Tablet 36mg
27	Guanfacine Modified Release Tablet 1mg
28	Guanfacine Modified Release Tablet 2mg
29	Fluoxetine Hydrochloride Tablet 10mg
30	Acamprosate Tablet 333mg
31	Paliperidone Intramuscular Injection 150mg
32	Clonidine Tablet 25microgram
33	Liraglutide Subcutaneous Injection 1.2mg
34	Liraglutide Subcutaneous Injection 1.8mg
35	Liraglutide Subcutaneous Injection 3mg
36	Metyrapone Capsule 500mg
37	Budesonide Delayed Release Capsule 3mg
38	Budesonide Delayed Release Capsule 6mg
39	Budesonide Delayed Release Capsule 9mg
40	Obetocholic Acid Tablet 5mg
41	Obetocholic Acid Tablet 10mg
42	Voxilaprevir 100mg
43	Tenofovir Alafenamide Tablet 100mg
44	Linaclotide Capsule 290mg
45	Linaclotide Capsule 145mg
46	Prucalopride Tablet 1mg

101	Tiotropium 9mcg MDI
102	Dexamethasone syrup 0.5mg/5mg
103	Carbocysteine 500mg capsules
104	Isoniazid 300mg tablet
105	Pyrazinamide 400mg tablet
106	Ethambutol 100mg tablet
107	Rifampicin 150mg+ Isoniazid 75mg tablet
108	Rifampicin 150mg+ Isoniazid 75mg+ Ethambutol 275mg tablet
109	Rifampicin 150mg+ Isoniazid 75mg+ Pyrazinamide 400mg+ Ethambutol 275mg tablet
110	Rifampicin 75mg+Isoniazid 50mg dispersible tablet
111	Rifampicin 75mg+Isoniazid 50mg+ pyrazinamide 150mg dispersible tablet
112	Rifapentine 300mg+ Isoniazid 300mg tablet
113	Rifapentin 150mg tablet
114	Riboflaxin trans epithelium 0.25 riboflexin + 0.007BCA
115	Gatifloxatin ointment
116	Voriconazole 1% Eye drop
117	Dermal filler injection. (hyaluronic acid)
118	Carboxy Methyl cellulose 0.5% + glycerine 0.9% eye drops(Unit - dose vials)
119	Cyclosporine opthalmic emulsion. 0.05% preservative free
120	Fluorescein strips
121	Hyaluronidase injection 1500 IU
122	Lignocaine transdermal patch 5%
123	Fentanyl TD Patch 12.0mcg/h-12.5mcg/h

47	Prucalopride Tablet 2mg
48	Tofacitinib Tablet 10mg
49	Carfilzamib injection 10mg/Vial,
50	Carfilzamib injection 60mg/Vial
51	Cabozantinib Tablet 40mg
52	Cabozantinib Tablet 60mg
53	Daratumumab Injection 100mg
54	Daratumumab Injection 400mg
55	Arsenic trioxide Injection 10mg
56	Obinutuzumab 100mg/40mL(25mg/mL) single use vial
57	Rasburicase for IV Infusion 1.5mg Vial
58	Rasburicase for IV Infusion 7.5mg Vial
59	Azathioprine Tablet 25mg
60	Pomalidomide Capsule 2mg
61	Mirabegron 25mg
62	Nitrofurantoin Extended release tablet 50mg
63	Octenidine
64	Acetic acid solution
65	Desmopressin Nasal spray 150microgram -300microgram
66	Deferasirox Non-dispersible Tablet 100mg
67	Zinc Sulfate Dispersible Tablet 10mg
68	Cefazolin 1g Injection
69	Aspirin Uncoated Tablet 75mg
70	Minoxidil Tablet 5mg
71	Ticargrelor Tablet 60mg
72	Zolmitriptan Tablet 2.5mg
73	Procyclidine Injection 5mg/mL
74	Procyclidine Tablet 5mg
75	Procyclidine Tablet 10mg

124	Balance crystalloid solution without lactate for Parenteral infusion in 500mL collapsible bag/bottle
125	Ketorolac for IV/IM 15mg/mL
126	Ketorolac for IV/IM 30mg/mL
127	Levobupivacaine 0.5% 10mL
128	Levobupivacaine 0.5% 30mL
129	Human fibrinogen concentrate 1 g single use bottle
130	Human fibrinogen concentrate 2 g single use bottle
131	Oxycodone Hydrochloride 5mg tablet (IR)
132	Oxycodone Hydrochloride 5mg tablet (PR)
133	Capsaicin 5% cream
134	Buprenophine transdermal patches 5mcg/hr
135	Ropivacaine 7.5mg/mL solution
136	Oxycodone 10mg with Naloxone 5mg Tablet (PR)
137	Sufentanil 0.05mg /, mL
138	Clindamycin phosphate Injection 600mg/4mL
139	Hyoscine Butylbromide S/C injection 80mg
140	Liquid paraffin+ Magneseum Hydroxide solution
141	Octreotide delayed release tablet 20mg
142	Diazepam suppository 10mg
143	Spironolactone Tablet 50mg
144	Levomepromazine Tablet 6mg
145	Levomepromazine Tablet 25mg
146	Levomepromazine Injection 25mg in 1mL ampoule
147	Hexavalent (Acellular pertussis) Vaccine
148	Hib (Heamophelus Influenza Type b) vaccine
149	Venetoclax Tablet 100mg
150	Sofosbuvir 200mg+ Valptasvir 50mg
151	Baricitinib 4mg
152	Multivitamin and Mineral Syrup 200mL bottle

76	Aripiprazole Tablet 5mg
77	Tolvaptan Tablet 30mg

153	IV Vitamin & mineral for parenteral nutrition (Multiple Micronutrients)
154	SMOF lipid emulsion (IV parenteral Nutrition) 100mL

Attachment 5

The list of items to inform NMRA about FRC decisions

No.	SR No.	Item	FRC decision
1	00100906	Co-Amoxiclav dispersible Tablet 156.25mg	Only one supplier was registered for the item and unit price is comparatively high. Therefore decided not to proceed tenders until receive the maximum retail price from NMRA, further Co-amoxyclav oral suspension is available in the formulary
2	00405301	Human Albumin Solution BP/USP/Ph Eur 20% in 50mL bottle	Decided to inform NMRA to implement the quality parameters for this item and suggested to evaluate the quality of the product at the Technical evaluation (comparing the innovator and the generics).
3	00703001	Tetracosactrin Injection 250microgram/1mL	Inform NMRA to register this item under Orphan medicines category and inform to consider the price in NOL since it available in outside market around Rs.3000.
4	01106103	Alcohol based hand rub (75%-85%) 500mL bottle	Suggest to register at NMRA as a medicinal product to the purpose of hospital use and should not as a cosmetic.
5	01210601	Nivolumab Injection 100mg/10mL vial	1. Identified as a Rarely used Special Oncology Drug. This is recommended to supply on Named patient basis only with the approval of Secretary of Health for the indication of Metastatic Melanoma if the item is registered at NMRA 2. Propose a ceiling price for the item & to issue personal use license from NMRA
6	01301901	Solifenacin Tablet 5mg	1. Keep in the formulary if the product is registered at NMRA and price is less than Rs.50.00
7	00000102	Cocaine Hydrochloride Solution 10% w/v, 2.5mL	Cocaine Powder (000000101) will be deleted (Tail off) and replace with Cocaine Hydrochloride Solution 10% w/v, 2.5mL after registered at NMRA.
8	_	Nitrofurantoin Extended release Tablet 50mg	Nitrofurantoin Tablet 50mg (00105901) will be deleted (Tail off) the item from the formulary and gradually replace with Extended release tablet of Nitrofurantoin after registered at NMRA.
9	_	Triclofos oral solution 500mg/5mL	Chloral hydrate Oral Solution, 500mg/5mL in 200mL Bottle (00300502) will be deleted (Tail off) and gradually replace with Triclofos oral solution 500mg/5mL after registered at NMRA due to low price and freely availability
10	_	Zolmitriptan 2.5mg Tablet	Sumatriptan Tablet 50mg (00303501) will be deleted (Tail off) and gradually replace with Zolmitriptan 2.5mg Tablet after registered at NMRA

11	_	Balance crystalloid solution without lactate for Parenteral infusion in 500mL collapsible bag/bottle	Parenteral infusion fluid in 500mL collapsible bag/bottle (00407101) will be deleted (Tail off) and gradually replace with Balance crystalloid solution without lactate for Parenteral infusion in 500mL collapsible bag/bottle after registered at NMRA.
12	_	Flurorescein dye impregnated strips	Fluorescein powder for Eye Drops (00902103) will be deleted (Tail off) and gradually replace with Flurorescein dye impregnated strips after registered at NMRA
13	_	Sunitinib Malate capsules 25 mg	Sunitinib Malate Capsules 50mg (01204701) will be deleted (Tail off) and gradually replace with Sunitinib Malate capsules 25 mg (normal dose is 37.5mg) after registered at NMRA and proceed on individual request and supply on Named patient basis by MSD.

දුරකථනය
தொலைபேசி
Telephone
) 0112669192 , 0112675011
) 0112698507 , 0112694033
) 0112675449 , 0112675280

ෆැක්ස්
தொலைநகல்
Fax
) 0112693866
) 0112693869
) 0112692913

විද්‍යුත් තැපෑල
மின்னஞ்சல்
e-mail
) lpostmaster@ health.gov.lk
)

වෙබ් අඩවිය
இணையத்தளம்
website
) www.health.gov.lk
)

සුවසිරිපාය
சுவசிரிபாய
SUWASIRIPAYA

මගේ අංකය
எனது இல
My No.
) MSD/QA/DRMM-2023

ඔබේ අංකය
உமது இல
Your No.
)

ඇමුණුම 70

දිනය
திகதி
Date
) 4.04.2023

සෞඛ්‍ය අමාත්‍යාංශය
சுகாதார அமைச்சு
Ministry of Health

Circular No: 01-14/2023

DDG/NHSL – Colombo
DDG/NHSL – Kandy
All Provincial Directors of Health Services
All Regional Directors of Health Services
All Directors of THs, PGHs, DGHs
All Directors of Specialized Hospitals
All Directors of Specialized Campaigns, Institutions & Programmes
Director, N.I.H.S Kaluthara
All Medical Superintends of BHs
All DMOs, MOICs

Informing Priority List for Pharmaceuticals

Considering the prevailing crisis situation in the country, it has been decided to reduce health budget expenditures by selecting the most appropriate medical supplies for patient care management in government health care institutions.

The priority list of pharmaceuticals was finalized (Total of 850 pharmaceuticals consisting of 753 Stock items and 97 Named patient items) and is attached herewith (Annexure 1). All are requested to adhere to the priority list of pharmaceuticals and **local purchase approval will be granted only for pharmaceuticals on the priority list in the future.**

All the healthcare institutions must conduct their drug and therapeutics committee meetings in a timely manner and should take the necessary actions to adjust their treatment protocols to be compatible with the priority list.

Thank you,

Dr. ASELA GUNAWARDENA
Director General of Health Services
Ministry of Health
"Suwasiripaya"
385, Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10.

Director General of Health Services,
Ministry of Health.

Copies:

1. Secretary of Health - MOH
2. Additional Secretary /State Ministry of Pharmaceutical Production, Supply & Regulation
3. DDG(MS) – I/II
4. DDG (LS)
5. DDG(DS)
6. DDG (MSD)
7. Chairman ,NMRA
8. Chairman, SPC
9. Director/MSD
10. Presidents, All Colleges of Medical Specialties

Priority List for Pharmaceutical – Total 850 items

List 1: Stock items(753)

No.	SR No.	Item
		Normal stock items (643)
1	00000301	Fentanyl Inj.100mcg in 2mLAmp.
2	00000401	Fentanyl TD Patch 50mcg/h
3	00000403	Fentanyl TD Patch25mcg/h
4	00000801	Morphine Tab. 10mg
5	00000803	Morphine Tab. 30mg
6	00000804	Morphine Sulphate CR Tab 10mg
7	00000805	Morphine Sulphate CR Tab 30mg
8	00000807	Morphine Sulphate Inj. 15mg/mLAmp.
9	00000810	Morphine Sulphate Oral solu.2mg/1mL, 100mL Bott.
10	00001101	Pethidine HCl Inj.50mg Amp.
11	00001203	Remifentanil Inj. 1mgVial/Amp./Bot.
12	00100101	Amoxicillin Cap. 250mg
13	00100102	Amoxicillin Cap. 500mg
14	00100103	Amoxicillin Tab (Solu.) 125mg
15	00100104	Amoxicillin Oral Susp.125mg/5mL,100mL Bot.
16	00100201	Benzyl Penicillin Inj.1 million units Vial
17	00100301	Benzathine Penicillin Inj. 1.2million units Vial
18	00100402	Phenoxymethylpenicillin Tab.250mg
19	00100601	Ampicillin Inj. 250mg Vial
20	00100603	Ampicillin Inj. 1g Vial
21	00100801	Flucloxacillin Cap. 500mg
22	00100802	Flucloxacillin Inj. 500mg
23	00100804	Flucloxacillin Syr. 125mg/5mL ,100mL Bot.
24	00100805	Flucloxacillin Cap. 250mg
25	00100901	Co-amoxiclav Tab. 375mg
26	00100902	Co-amoxiclav Tab. 625mg
27	00100903	Co-Amoxiclav Oral Susp.125/31mg/5mL, 100mL Bot.
28	00100904	Co-amoxiclav Inj. 500mg/100mgVial
29	00100905	Co-amoxiclav Inj. 1000mg/200mgVial
30	00101001	Piperacillin with Tazobctaminj. 4.5g, 500mg Vial
31	00101101	Sulbactam + Cefoperazone Inj.1g Vial
32	00101102	Sulbactam + Cefoperazone Inj.2g Vial
33	00101202	Ticarcillin 3g &Clavulan.200mg Inj.
34	00101301	Cefalexin (Cephalexin) Cap.250mg
35	00101302	Cefalexin (Cephalexin) Syr.125mg/5mL, 100mL Bot.
36	00101303	Cefalexin (Cephalexin)Dispersible Tab. 125mg
37	00101403	Cefuroxime Tab. 500mg
38	00101404	Cefuroxime Oral Susp.125mg/5mL, 100mL Bot.
39	00101406	Cefuroxime Inj. 750mg Vial
40	00101502	Cefotaxime for Inj. 1g Vial

41	00101503	Cefotaxime for Inj. 500mg Vial
42	00101602	Ceftazidime for Inj. 1g Vial
43	00101704	Ceftriaxone for Inj. 1g Vial
44	00101902	Cefepime for Inj. 1g Vial
45	00102001	Imipenem+Cilastatin for Inj.500mg
46	00102102	Meropenem Inj. 1g Vial
47	00102301	Doxycycline Cap. 100mg
48	00102502	Gentamicin Inj. 80mg/2mL Amp.
49	00102603	Amikacin Inj. 500mg/2mL Vial
50	00102701	Netilmicin Inj. 100mg in 2mLVial
51	00102901	Erythromycin Tab. 250mg
52	00102903	Erythromycin Oral Susp.125mg/5mL, 100mL Bott.
53	00103001	Clarithromycin Tab. 250mg
54	00103002	Clarithromycin for Infusion500mg Vial
55	00103003	Clarithromycin Oral Susp.125mg/5mL, 100mL Bott.
56	00103006	Clarithromycin Tab. 500mg
57	00103101	Azithromycin Tab.250mg
58	00103102	Azithromycin Oral Susp.200mg/5mL, 15mL Bott.
59	00103201	Clindamycin Cap. 150mg
60	00103202	Clindamycin Cap. 300mg
61	00103203	Clindamycin Inj. 300mg/2mL Amp
62	00103501	Vancomycin Inj. 500mg Vial
63	00103502	Vancomycin Inj. 1g Vial
64	00103602	Teicoplanin Inj. 400mg Vial
65	00103702	Co-Trimoxazole Tab. 480 mg
66	00103703	Co-trimoxazole Oral susp.(Paedi.) 50mL Bott.
67	00103901	Trimethoprim Tab. 100mg
68	00104801	Dapsone Tab. 50mg
69	00105201	Metronidazole Tab.200mg
70	00105202	Metronidazole Tab.400 mg
71	00105203	Metronidazole Inj. 500mg/100mL Bot.
72	00105401	Ciprofloxacin Tab. 250mg
73	00105402	Ciprofloxacin Tab. 500mg
74	00105403	Ciprofloxacin IV Inf. 200mg in100mL Vial
75	00105502	Nalidixic acid Tab.500mg
76	00105601	Norfloxacin Tab. 400 mg
77	00105701	Ofloxacin Tab. 200 mg
78	00105801	Levofloxacin Tab. 500mg
79	00105802	Levofloxacin Inj. 500mg in100mL Bott.
80	00105901	Nitrofurantoin Tab. 50mg
81	00106501	Sodium Stibogluconte Inj.10g/100mL Vial
82	00106601	Mebendazole Tab. 100mg
83	00106701	Levamisole HCl Tab. 40mg
84	00106801	Pyrentel Pamoate Tab. 125mg
85	00106901	Diethylcarbamazine Tab 50mg
86	00107101	Fluconazole Cap. 50mg
87	00107102	Fluconazole Inj. 200mg in100mL Vial
88	00107103	Fluconazole Cap. 200mg
89	00107201	Itraconazole Cap. 100mg

90	00107301	Voriconazole Tab. 200mg
91	00107302	Voriconazole Inj. 200mg in10mL Vial
92	00107401	Amphotericin Inj. 50mg Vial
93	00107501	Nystatin Tab. 500,000IU
94	00107601	Griseofulvin Tab. 500mg
95	00107901	Aciclovir Tab. 200mg
96	00107903	Aciclovir IV Infu. 250mg Vial
97	00108001	Ganciclovir Inj. 500mg in 10mLVial
98	00108101	Valganciclovir Tab. 450mg
99	00108201	Oseltamivir Cap. 30mg
100	00108202	Oseltamivir Cap. 45mg
101	00108203	Oseltamivir Cap. 75mg
102	00108302	Linezolid Tab. 600mg
103	00108801	Albendazole Tab. 400mg
104	00110901	Terbinafine Tab. 250mg
105	00112201	Ketoconazole Tab 200mg
106	00200101	Digoxin Tab 0.25 mg
107	00200102	Digoxin Inj. 500 mcg/2mL Amp.
108	00200201	Hydrochlorothiazide Tab. 25mg
109	00200301	Furosemide (Frusemide) Tab 40mg
110	00200302	Furosemide (Frusemide) Inj.20mg/2mL Amp.
111	00200401	Spironolactone Tab. 25 mg
112	00200501	Mannitol IV Infu. 20%, 250mLBott.
113	00200601	Adenosine Inj. 6mg/2mL Vial
114	00200701	Amiodarone Tab. 100mg
115	00200702	Amiodarone Inj. 150mg/3mL Amp.
116	00201001	Atenolol Tab. 50 mg
117	00201101	Propranolol Tab. 10 mg
118	00201102	Propranolol Tab. 40 mg
119	00201201	Carvedilol Tab. 6.25mg
120	00201301	Bisoprolol Fumarate Tab. 5mg
121	00201501	Labetalol Hcl Tab. 100mg
122	00201502	Labetalol Hcl Inj. 100mg/20mLAmp.
123	00201601	Metoprolol Tab. 50mg
124	00201602	Metoprolol Inj. 5mg/5mL Amp.
125	00201701	Hydralazine Tab. 50mg
126	00201702	Hydralazine Inj. 20mg/mL Amp.
127	00201901	Sildenafil Tab. 50mg
128	00202001	Sodium Nitroprusside Inj. 50mgVial
129	00202101	Bosentan Tab. 125mg
130	00202201	Methyldopa Tab. 250 mg
131	00202301	Prazosin Tab. 1mg
132	00202402	Phenoxybenzamine HCl Inj.100mg/2mL Amp.
133	00202501	Phentolamine Mesylate for inj.10mg/1mL Amp.
134	00202601	Enalapril Tab. 5mg
135	00202701	Captopril Tab. 25mg
136	00202901	Losartan Potassium Tab. 50mg
137	00203001	Glyceryl Trinitrate Tab 0.5mg
138	00203002	Glyceryl Trinitrate(Nitroglycerin) Inj. 50mg/10mL Vial or Amp.

139	00203202	Isosorbide Mononitrate PR Tab 60mg
140	00203203	Isosorbide Mononitrate PR Tab.30mg
141	00203301	Amlodipine Besylate Tab. 5mg
142	00203401	Diltiazem Tab. 30mg
143	00203402	Diltiazem Tab.60 mg
144	00203403	Diltiazem Tab. 90mg (longacting)
145	00203501	Nifedipine ER Tab.20mg
146	00203601	Nimodipine Tab. 30mg
147	00203602	Nimodipine IV Infu. 10mg/50mLVial
148	00203701	Verapamil Tab. 40mg
149	00203702	Verapamil Inj. 5mg/2mL Amp
150	00203901	Dobutamine Inj. 250mg/20mLVial
151	00204001	Dopamine HCl Inj. 200mg/5mLAmp.
152	00204101	Isoprenaline Inj. 2mg/2mL Amp.
153	00204201	Ephedrine Inj. 30mg/1mL Amp.
154	00204301	Metaraminol Inj. 10mg/1mL Amp
155	00204401	Noradrenaline Inj. 4mg/2mL Amp
156	00204501	Phenylephrine Inj. 10mg/1mLVial
157	00204601	Heparin Inj. 25,000 I.U/5mLVial
158	00204701	Enoxaparin Inj. 4000IU/0.4mLPFS/Vial
159	00204702	Enoxaparin Inj.6000IU/0.6mLPFS/Vial
160	00205101	Warfarin Sodium Tab. 0.5mg
161	00205102	Warfarin Sodium Tab. 1mg
162	00205103	Warfarin Sodium Tab. 3mg
163	00205104	Warfarin Sodium Tab.5 mg
164	00205201	Protamine Sulphate Inj.50mg/5mL
165	00205301	Abciximab IV Infu. 10mg/5mLVial
166	00205404	Aspirin Enteric-coated Tab 75mg
167	00205501	Clopidogrel Tab. 75mg
168	00205702	Alteplase 50mg Vial
169	00205801	Streptokinase Inj. 1.5M.U.
170	00205902	Tranexamic Acid Tab/Cap 500mg
171	00205903	Tranexamic acid Inj. 500mg/5mLAmp.
172	00206005	Dried factor VII fraction1000 mcg -2500 mcg Vial
173	00206101	Dried,Factor VIII fraction200-350 IU Vial
174	00206105	Factor VIII 200-350IU Vial with vW Factor
175	00206201	Dried,Factor IX fraction 500IU-600IU Vial
176	00206301	Activated Prothrombin Comp.Concen. Inj. 500IU Vial
177	00206302	Prothrombin Comp.Concen. Inj. 500IU Vial
178	00206501	Atorvastatin Tab.10mg
179	00206502	Atorvastatin Tab. 20mg
180	00206601	Fenofibrate Cap. 200mg
181	00206901	Tenecteplase Inj. 40mg Vial
182	00207002	Papaverine HCl Inj.60mg/2mL Amp.
183	00207101	Milrinone Lactate Inj.10mg/10mL Amp.
184	00207301	Alprostadil Inj. 500mcg/mLAmp/Vial
185	00207501	Cadioplegia infu. Bulb (St.Thomas Sol)
186	00300102	Diazepam Tab. 5mg
187	00300103	Diazepam Inj. 10mg/2mL Amp.

188	00300104	Diazepam Rectal Sol....
189	00300201	Chlordiazepoxide Tab. 10mg
190	00300502	Chloral hydrate Oral Solution500mg / 5ml in 200ml Bottle
191	00300602	Methylphenidate HCl Tab 10mg
192	00300801	Haloperidol Tab. 1.5mg
193	00300803	Haloperidol Inj. 5mg/1mL Amp.
194	00300902	Chlorpromazine Tab. 50mg
195	00301001	Fluphenazine Decanoate Inj.25mg/1mL Amp.
196	00301101	Flupenthixol Inj 40mg/2mL Amp.
197	00301501	Prochlorperazine Tab 5mg
198	00301701	Trifluoperazine Tab. 5mg
199	00301801	Clozapine Tab. 100mg
200	00301902	Olanzapine Tab.10mg
201	00302001	Risperidone Tab.2mg
202	00302101	Lithium Carbonate Tab. 250mg
203	00302202	Amitriptyline Tab. 25mg
204	00302301	Imipramine Tab. 25 mg
205	00302402	Clomipramine HCl Tab. 25mg
206	00302701	Fluoxetine HCl Cap.20mg
207	00302801	Sertraline Tab. 50mg
208	00302902	Venlafaxine HCl Cap. (ER) 75mg
209	00303103	Ondansetron Inj. 8mg/4mLAmp.
210	00303104	Ondansetron Tab. 4mg
211	00303201	Aspirin Tab. 300mg
212	00303301	Paracetamol Tab. 500mg
213	00303302	Paracetamol Oral solu.120mg/5mL, 60mL Bott.
214	00303304	Paracetamol Suppository 125mg
215	00303305	Paracetamol Suppository 250mg
216	00303307	Paracetamol Infu. 10mg/mL,100mL
217	00303401	Tramadol HCl Cap. 50mg
218	00303403	Tramadol HCl Inj. 100mg/2mLAmp.
219	00303602	Phenobarbital Tab. 30mg
220	00303604	Phenobarbital Inj. 200mg/1mLAmp.
221	00303703	Phenytoin Sodium Tab. 100 mg
222	00303704	Phenytoin Inj. 250mg/5mL Amp.
223	00303802	Carbamazepine Tab. 200mg
224	00303804	Carbamazepine Oral susp.100mg/5mL,100mL Bott.
225	00303901	Clonazepam Tab. 0.5mg
226	00303902	Clonazepam Tab. 2mg
227	00304001	Sodium Valproate Tab. 100mg
228	00304002	Sodium Valproate Tab. 200mg
229	00304004	Sodium Valproate Oral solu.200mg/5mL, 100ml. Bott.
230	00304202	Clobazam Tab.10mg
231	00304301	Gabapentin Cap. 300mg
232	00304302	Gabapentin Cap. 100mg
233	00304401	Lamotrigine Tab 25mg
234	00304402	Lamotrigine Tab. 50mg
235	00304502	Topiramate Tab. 50mg
236	00304601	Ethosuximide Cap 250mg

237	00304702	Flunarizine HClTab. 5mg
238	00304801	Vigabatrin Tab. 500mg
239	00304901	Benzhexol Tab. 2mg
240	00305001	Co careldopa Tab. 25mg/100mg
241	00305002	Co Careldopa Tab. 25mg/250mg
242	00305301	Botulinum Toxin 100IU Vial
243	00305402	Disulfiram Tab. 250mg
244	00305501	Atomoxetine HCl Cap/Tab 10mg
245	00305602	Betahistine Tab. 16mg
246	00305901	Levetiracetam Tab. 500 mg
247	00305902	Levetiracetam Tab. 250mg
248	00305904	Levetiracetam Inj. 500mg/5mLVial/Amp.
249	00306301	Donepezil HCl Tab.5mg
250	00306601	Pregabalin Cap. 75 mg
251	00306701	Quetiapine Tab. 25mg
252	00307201	Amantadine Cap. 100mg
253	00400101	Ferrous Sulphate Tab. 200mg(60mg of Fe ion)
254	00400303	Iron Drops 50mg/mL,in 15mL Dropper
255	00400307	Iron Syr. 50mg/5ml in100mL-150mL Bot.
256	00400401	Iron sucrose Inj. 100mg in 5mLAmp.
257	00400601	Water for Injection 10mL Vial
258	00400701	Potassium Chloride (ER) Tab.600mg
259	00400702	Potassium Chloride 2mmol/mLin 10mL Amp.
260	00400801	Oral Rehydration Powder Sachet1Liter
261	00400901	Sodium Bicarbonate Tab 600mg
262	00400904	Sodium Bicarbonate Inj 8.4%,50mL-100mL Bot.
263	00401003	Sodium Chloride for IV Infu.0.9%, 500mL Bott.
264	00401004	Sodium Chloride IV Infu.3%, 500mL Bot.
265	00401101	Dextrose Injection 5%, 500mLBot.
266	00401102	Dextrose Inj. 10%, 500mL Bott.
267	00401104	Dextrose IV Inf. 50%, 50mLVial/Amp.
268	00401202	Sodium Chloride 0.45% &Dextrose 5% IV Inf. 500mL Bot.
269	00401301	Compound Sodium Lactate IVinfusion 500mL Bot.
270	00401401	Dextran 40,10%,in NaCl 0.9%,500mL Bot.
271	00401701	Calcium Gluconate 10%, Inj.10mL Amp.
272	00401801	Calcium Carbonate Tab. 1.25g
273	00401903	Magnesium Sulphate Inj. 50%in 10mL Amp/Vial
274	00402103	Fat emulsion Inj. 20%, 100mLBot.
275	00402202	Protein Hydrolysate Inj.10% w/v in 500ml Bot. (Aminoacid sol.)
276	00402301	Peritoneal Dialysis Sol.1.5% ,1000mL Bot.
277	00402701	Vitamin B1 Tab. 10mg
278	00402702	Thiamine HCl Inj. 100mg/2mLAmp.
279	00402704	Thiamine Tab.100mg
280	00402802	Pyridoxine Tab. 25mg
281	00403001	Calcitriol Cap. 250ng(0.25mcg)
282	00403101	Alfacalcidol Cap. 0.25mcg
283	00403201	Phytomenadione Tab 5mg
284	00403202	Phytomenadione Inj.1mg/0.5mL Amp.
285	00403203	Phytomenadione Injection10mg/1ml Amp.

286	00403401	Folic Acid Tab. 1mg
287	00403501	Hydroxocobalamine Inj. 1mg/1mLAmp.
288	00403601	Multivitamin Drops 15mL Bot.
289	00404001	Epoetin Inj. 2000 IU PFS
290	00404002	Epoetin Inj. 4000IU PFS
291	00404701	Deferasirox Tab. 100mg
292	00404702	Deferasirox Tab. 400mg
293	00404801	Desferrioxamine Inj. 500mg
294	00404901	Disposable, IV giving sets
295	00405001	Administration set for P/Dsolution
296	00405101	PD Catheter Set
297	00405301	Human Albumin Sol. 20%, 50mLBot.
298	00405604	Zinc Sulfate DispersibleTab. 20mg
299	00406202	Calcium Polystyrene Sulphonate15g-17g powder Sachet
300	00406501	Phosphate Tab. 500 mg
301	00406601	Histidine-tryptophan -ketoglutarate (HTK) solution1000mL Collap. bag
302	00406702	Cholecalciferol(Colecalciferol)Cap/Tab 1000IU (25mcg)
303	00406703	Cholecalciferol(Colecalciferol)Tab. 5000 IU
304	00406901	Magnesium Glycinate Tab 400mg(200mg of elemental Magnesium)
305	00407201	Total Parenteral Nutrition in500mL-1,500mL Collap. Bag
306	00500101	Salbutamol Tab 2mg
307	00500104	Salbutamol Inj. 5mg/5mLAmp.
308	00500105	Salbutamol D.P Caps 200mcg
309	00500106	Salbutamol D.P Caps 400mcg
310	00500107	Salbutamol MDI100mcg ,200 doses
311	00500109	Salbutamol Respiratory Sol.0.5%,15mL Vial
312	00500111	Salbutamol Oral solu.2mg/5mL, 60mL Bott.
313	00500202	Salmeterol+Fluticasone DP Cap50/250mcg
314	00500203	Salmeterol+Fluticasone DPCaps 50/500mcg
315	00500204	Fluticasone+Salmeterol MDI125/25,120 dose
316	00500205	Fluticasone+Salmeterol MDI250/25,120 dose
317	00500403	Ipratropium BromideRespiratory Sol.0.25mg/1mL, 15mL-20mL Bot.
318	00500404	Ipratropium Bromide MDI20mcg, 200dose
319	00500501	Theophylline ER Tab 125mg
320	00500505	Theophylline Syr. 25mg /5mL,60mL Bot.
321	00500601	Aminophylline Inj. 250mg/10mLAmp.
322	00500702	Beclomethasone DP Caps 200mcg
323	00500703	Beclomethasone DP Caps 400mcg
324	00500705	Beclomethasone MDI100mcg, 200dose
325	00500706	Beclomethasone MDI 250mcg, 200dose
326	00500801	Budesonide Respiratory Susp.0.5mg/2mL Resp.
327	00500902	Tiotropium Bromide DP Caps, 18mcg
328	00501101	Cetirizine Tab. 10mg
329	00501301	Chlorphenamine Tab. 4mg(Chlorpheniramine)
330	00501302	Chlorpheniramine(Chlorphenamine) Oral solu.2mg/5mL, 60mL Bot.
331	00501304	Chlorpheniramine Inj.10mg/1mL(Chlorphenamine)
332	00501405	Promethazine Inj. 25mg/1mL Amp

	[illegible]	Beractant 8mL (25mg/mL) Vial
335	00501701	Breath Activated inhaler device (for dry powder caps.)
336	00501802	Spacer device for all MDIs
337	00502001	Baby mask (Plastic) tocompatible with Spacer device
338	00600101	Tetanus Toxoid Adsorbed0.5mL (SD) Amp/Vial
339	00600204	Rabies Vaccine (Human use)0.5mL/1mL-Inactivated
340	00600301	Hepatitis B Vaccine SingleDose Vial
341	00600501	Pneumococcal Vaccine SingleDose Vial (PPSV-23)
342	00601101	Varicella Vaccine 0.5mL Vial
343	00602201	Anti-tetanus HumanImmunoglobulin 250IU PFS
344	00602301	Snake Venom Antiserum 10mLVial
345	00602401	Anti Rabies Serum Inj. 1,000I.U./5mL Amp.
346	00602501	Anti Rabies HumanImmunoglobulin 300IU Vial
347	00602801	Anti D(Rho)Immunoglobulin(human) Inj. 300mcg/1.5mLAmp/Vial
348	00603201	Human Immunoglobulin IV1g Vial
349	00603205	Human Immunoglobulin IV5g-6g Vial
350	00700101	Glibenclamide Tab. 5mg
351	00700301	Gliclazide Tab. 40mg
352	00700302	Gliclazide Tab. 80mg
353	00700401	Metformin Tab. 500mg
354	00700601	Biphasic Isophane Insulin(Human) Inj. 30/70 Vial
355	00700701	InsulinIsophane (human) 1,000IU/10mLVial
356	00700801	Insulin Soluble (Human) Inj.1,000IU/10mL Vial
357	00701001	Glucagon HCl Inj. 1 IU Vial
358	00701101	Thyroxine Tab. 50mcg
359	00701102	Thyroxine Tab. 100mcg
360	00701103	Thyroxine Tab. 25mcg
361	00701201	Carbimazole Tab. 5mg
362	00701301	Propylthiouracil Tab. 50mg
363	00701401	Fludrocortisone Tab. 0.1mg
364	00701502	Hydrocortisone Tab. 10mg
365	00701503	Hydrocortisone Sodi. succinateInj. 100mg Vial
366	00701601	Dexamethasone Tab. 0.5 mg
367	00701602	Dexamethasone Inj. 8mg/2mLAmp./Vial
368	00701603	Dexamethasone Tab. 4 mg
369	00701701	Prednisolone Tab. 5mg
370	00701704	Prednisolone Oral solu.5mg/5mL ,60mL Bott.
371	00701803	Methylprednisolone Inj.40mg/1mL Vial
372	00701804	Methylprednisolone Sodi. succinateInj. 500mg Vial
373	00701805	MethylprednisoloneSodi. succinateInj. 1g Vial
374	00702401	Hydroxyprogesterone Inj.250mg/1mL Amp.
375	00702501	Norethisterone Tab. 5mg
376	00702701	Testosterone Enanthate Inj.250mg/1mL Amp.
377	00702801	Clomifene Tab. 50mg
378	00703001	Tetracosactrin Inj.250mcg/1mL Amp.
379	00703202	Somatropin for Inj. 2IU-30IU
380	00703301	Desmopresin Tab. 100mcg
381	00703304	Desmopressin acetate NasalSpray 10mcg/metered spray(50 MS)

382	00703401	Vasopressin Inj. 20 I.U. in1mL Amp.
383	00703502	Alendronate Sodiu Tab. 70mg
384	00703601	Pamidronate Disodium IV Infu.30mg/10mL Vial
385	00703701	Zoledronic acid IV Infu.4mg/5mL Vial
386	00703801	Bromocriptine Tab. 2.5mg
387	00703901	Cabergoline Tab. 500mcg
388	00704001	Danazol Cap.100mg
389	00704301	Potassium Iodide Tab. 5 mg
390	00704502	Triamcinolone Acetonide Inj (preser. free) 40mg/mLVial
391	00705501	Diazoxide Tab. 50mg
392	00706201	Dutasteride Cap. 0.5 mg
393	00706301	Finasteride Tab. 5mg
394	00706501	Sitagliptin Tab. 100mg
395	00706601	Estradiol Valerate Tab. 1mg
396	00706602	Estradiol Valerate Tab. 2mg
397	00800202	Hyoscine Butylbromide Inj.20mg/1mL Amp.
398	00800401	Domperidone Tab. 10mg
399	00800402	Domperidone Syr. 5mg/5mL,60mL Bot.
400	00800406	Domperidone Suppository 10mg
401	00800501	Metoclopramide Tab. 10mg
402	00800502	Metoclopramide Inj.10mg/2mLAmp.
403	00800601	Famotidine Tab. 20mg
404	00800701	Ranitidine Inj. 50mg/2mL Amp.
405	00800802	Omeprazole Cap/Tab. 20mg
406	00800803	Omeprazole Sodium Inj. 40mgVial
407	00800901	Sulphasalazine Tab. 500mg
408	00801001	Mesalazine tab. 400mg
409	00801201	Bisacodyl Tab. 5mg
410	00801204	Bisacodyl Suppository 5mg
411	00801304	Lactulose Syr.3.0g-3.7g/5mL 500mL Bot.
412	00801401	Iso-Os.bowel clens.prep.(PEG 58g-60g+Elect)
413	00801601	Ursodeoxycholic acid Tab.150mg
414	00801701	Pancreatic Enzyme Cap.(Protease 600U, lipase 10000U,amylase 8000U)
415	00802401	Macrogol 3350/4000(6.125g-6.563g of PEG)Oral Powder Sachet
416	00802501	Terlipressin Acetate Inj.1mg Vial/Amp.
417	00802601	Sodium Biphosphate 1.6g+Sodiumphosp. 0.6g Enema in10mL/120mLBot.
418	00900101	Ciprofloxacin Eye drop0.3%, 5mL Vial
419	00900201	Fusidic acid Eye Drop 1%(S.R.)
420	00900401	Gentamicin Eye/Ear drop 0.3%,5mL -10mL Vial
421	00900602	Acyclovir Eye Ointment 3% w/w,4.5g-5g Tube
422	00901001	Prednisolone Acetate Eye drop1%,5mL Dropper Bot.
423	00901101	Fluorometholone Eye drop0.1% , 5mL Dropper Bot.
424	00901201	Atropine Sulphate Eye drops1%, 5mL-10mL Dropper Bot.
425	00901302	Cyclopentolate Eye drop 1%,5mL-15mL Dropper Bott.
426	00901401	Tropicamide Eye Drops 1%,5mL-15mL Dropper bottle
427	00901501	Tropicamide 0.8%+Phenylephrine HCl 5% Eye drops5mL-15mL Dropper Bot.

385, සුවසිරිපාය, බදේගම විමලවංස ථේර මාවත, කොළඹ 10 385,சுவசிரிபாய, பதேகம விமலவன்ச தேரோ மாவத்தை, கொழும்பு 10.
385, Suwasiripaya Rev. Baddegama Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka.

429	00901801	Acetazolamide Tab. 250mg
430	00901903	Pilocarpin Nitrate Eye Drop4%,10mL-15mL Vial
431	00902001	Balanced Salt, Solu. 500mLPlastic Bot.
432	00902002	Balanced salt, Solu. 500mLGlass/Non collapsiblePlastic Bot.
433	00902101	Fluorescein Sodium Inj.10%, 2mL-5mL Vial
434	00902201	Hydroxypropylmethyl CelluloseOpth. Sol. for IO use 2%,3mL-5mL PFS
435	00902401	Perflurodecalin 5mL Vial
436	00902901	Bimatoprost Ophthalmic Susp.300mcg/mL,3mL Vial
437	00903001	Brinzolamide Eye drop 1%, 5mLDropper Bot.
438	00903201	Nepafenac Ophthalmic Susp.0.1%,3mL -5mL Vial
439	00903302	Ketorolac Tromethamine 0.4%Sterile Oph. Sol. 5mLDropper Bot.
440	00903601	Carbachol IntraoccularSol. 0.01%,1mL Dropper Bot.
441	00903701	Indocyanine green Inj. 25mgVial
442	00903902	Carboxymethyl Cellulose 1%10mL-15mL Vial/Bot.
443	00904003	Chloramphenicol Eye Oint..1%, 3.5g Tube
444	00904101	Moxifloxacin HCl ophthalmicsol. 0.5%,5mL Vial
445	00904102	Moxifloxacin Preservative freeOphthalmic Sol. 0.5%5mL Dropper bott.
446	00904302	Tobramycin 0.3% +Dexamethasone 0.1% Eye drops,5mL-10mLDropper Bot.
447	00904401	Trypan Blue OphthalmicSol. 0.06%-0.08%,1mLVial /PFS
448	00904501	Olopatadine HCl Eyedrops 1mg/mL, 5mL Dropper Bot.
449	00904601	Brilliant blue G0.05% in 1mL Vial
450	00904702	Cyclosporin Opthalmic emul.0.05% w/v, 5mL Dropper Bot.
451	00904801	Proparacaine HCl OphthalmicSolution 0.5% in 5mL-15mLDropper Bot.
452	00904901	Natamycin OphthalmicSusp. 5% in 5mL-15mL DropperBot.
453	00905001	Sodium Hyaluronate 1.5%-3%+ Sodium Chondroitin Sulfate 4%0.75mL -1.5mL PFS
454	00905101	Sodium Hyaluronate 1.8%1mL-1.5mL PFS
455	00905201	Lidocaine HCl(Lignocaine)Ophthalmic Gel 2% in 30g Tube
456	00905401	Perfluoropropane Intraocular gas 75 mL Container/Canister
457	00942001	Brimonidine Tartrate Eye drops 0.15%,5 mL Vial
458	00942101	Sodium Chloride Eye drops 5%,10mL-15mL Vial
459	00942201	Lidocaine (Lignocaine) inj. 2% 5mL Vial/Amp. for opthalmicuse (preser. free)
460	01000401	Clotrimazole 1%+Lidocaine 2%Ear drops 15mL-20mLDropper Bot.
461	01000601	Betamethasone Eye/Ear/Nasaldrops 0.1%,5mL-7.5mLDropper Bot.
462	01000701	Xylometazoline Nasal Drop0.1%,10mL Dropper Bot.
463	01000901	Oxytetracyclin 3% andHydrocortisone acetate 1%,15g Ointment Tube
464	01001001	Tobramycin Ear drop 0.3%,5mL Dropper Bot.
465	01001301	Beclomethasone Nasal Spray100mcg/MD,200 dose unit
466	01001601	Clotrimazole Mouth Paint1%,15mL Bot.
467	01001701	Betamethasone 0.1%+ Neomycin 0.5% Eye/Ear/Nasal drops,5mL-7.5mL Dropper Bot.
468	01001801	Miconazole Oromucosal gel 40gTube / Container
469	01002001	Chlorhexidine Mouth Wash 0.2%60mL-100mL Bot.

470	01002101	Fluoride Mouth Wash 0.05 %60ml 100 ml Bot
471	01100701	Methoxsalen Tab. 10mg
472	01101402	Hydrocortisone Ointment 1%,15g Tube
473	01101403	Hydrocortisone Cream 1%,5gTube
474	01101404	Hydrocortisone Cream 1%,15gTube
475	01101501	Hydrocort 0.5% + Clioquinol 3% Cream 15g Tube
476	01101602	Betamethasone Ointment 0.1%,15g Tube
477	01101604	Betamethasone Cream 0.1%,15gTube
478	01101702	Betamethasone Dipropionate Lotion 0.05% 30mL Bot
479	01101901	Fluocinolone Cream 0.025%,15g Tube
480	01102001	Clobetasol Ointment 0.05%,15gTube
481	01102101	Framycetin Cream 1%, 20 g Tube
482	01102201	Silver sulphadiazine Cream1%,500g
483	01102301	Fusidic acid Cream 2% , 5gTube
484	01102401	Mupirocin 2% Ointment 5g Tube
485	01102701	Clotrimazole Cream 1%,15g Tube
486	01103301	Benzyl Benzoate application25% 500ml Bot
487	01103401	Permethrin Cream 5%, 15g Tube
488	01103403	Permethrin Lotion 5%w/v, 60ml Bot
489	01103801	Chlorhexidine Sol 4% w/v, 500ml Bot
490	01104001	Hydrogen PeroxideSol 6% 400ml - 500ml Bot
491	01104601	Povidone Iodine Sol 10%, 500ml Bot
492	01104602	Povidone Iodine Sol forSurgical Scrub 7.5% w/v , 500ml Bot
493	01104606	Povidone Iodine Ointment5% w/w, 15g Tube
494	01105001	Tretinoin Cream 0.025% w/v, 15g Tube
495	01105603	Peracetic Acid
496	01106102	Ethyl alcohol 70% - 75% or Isopropyl alcohol 70% - 75%
497	01106103	Alcohol based Hand Rub(75%-85%) 500mL Bot
498	01106104	Alcohol based Hand Rub(Isopropyl alcohol/Ethanol75%-85%) 5L Container
499	01106601	Acitretin Cap. 10mg
500	01107002	Benzoyl Peroxide Gel 2.5%, 20gTube
501	01107003	Benzoyl Peroxide Gel 5%, 20gTube
502	01107501	Metronidazole Gel 0.75% -1% w/w, 30g Tube
503	01107901	Terbinafine Cream 1%,15g Tube
504	01200101	Busulphan Tab 2mg
505	01200201	Chlorambucil Tab. 2mg
506	01200301	Cyclophosphamide Tab. 50mg
507	01200303	Cyclophosphamide for Inj 200mgVial
508	01200304	Cyclophosphamide for Inj. 1 g Vial
509	01200401	Ifosfamide1g Vial+Mesna 100mgin 1mL, 3 Amps in one set
510	01200501	Melphalan Tab 2mg
511	01200502	Melphalan Inj. 50mgPowder with Solvent
512	01200801	Bleomycin sulphate for Inj 15 000 units vial
513	01200901	Dactinomycin for Injection(Actinomycin) 500mcg Vial
514	01201001	Daunorubicin HCl for Inj. 20mg Vial
515	01201101	Doxorubicin HCl Inj 10mg Vial
516	01201103	Doxorubicin HCl Inj. 2mg/mL in 25mL Vial
517	01201201	Epirubicin HCl Inj 10mg Vial

518	01201202	Epirubicin HCl Inj.50mg/25mL Vial
519	01201401	Mitomycin for Inj. 2mg Vial
520	01201601	Capecitabine Tab. 500mg
521	01201701	Cytarabine Inj. 100mg/5mL Vial(Not for Intrathecal use)
522	01201702	Cytarabine Inj. 100mg/mLVial ,Preservative free
523	01201703	Cytarabine Inj.1g in 10mL Vial (Not for Intrathecal use)
524	01201902	Fluorouraci Inj. 250mg/10mLVial
525	01201904	Fluorouracil Inj. 1g in 20mLVial
526	01202001	Gemcitabine HClInj. 200mg Vial
527	01202002	Gemcitabine Inj. 1g Vial
528	01202101	Mercaptopurine Tab. 50mg
529	01202201	Methotrexate Tab. 2.5mg
530	01202202	Methotrexate In. 50mg/2mL Vial
531	01202203	MethotrexateInj. 50mg/2mL Vial(without preser.)
532	01202204	Methotrexate Inj. 1g/10mL Vial
533	01202401	Vincristine Sulphate Inj.1mg/mL Vial
534	01202501	Vinblastine Sulphate Inj.10mg/10mL Vial
535	01202701	Etoposide Cap.100mg
536	01202703	Etoposide Cap. 50mg
537	01202702	Etoposide Inj. 100mg Vial
538	01202801	Lecucovorin Tab 15mg(Folinic acid)
539	01202804	Lecucovorin Cal.(Folinic acid) 15mg / 2mL Amp./Vial
540	01203002	Bortezomib Inj. 2mg Vial
541	01203201	Asparaginase Inj.10,000IU Vial
542	01203301	Dacarbazine Inj. 200mgVial
543	01203401	Temozolomide Cap. 100mg
544	01203402	Temozolomide Cap. 250mg
545	01203501	Hydroxyurea (Hydroxycarbamide)Cap. 500mg
546	01203601	Carboplatin inj.150mg/15mLVial with Diluent
547	01203602	Carboplatin Inj. 450mg/45mLVial
548	01203702	Cisplatin Inj. 50mg/50mL Vial
549	01203803	Oxaliplatin Inj. 100mg in 20mLVial
550	01203901	Procarbazine Cap. 50mg
551	01204201	Everolimus Tab. 0.25mg
552	01204401	Imatinib Mesilate Tab/Cap100mg
553	01204403	Imatinib mesilateCap/Tab 400mg
554	01204601	Sorafenib Tab. 200mg
555	01204801	Docetaxel Inj. 20mgin 0.5mL-2mL Vial
556	01204802	Docetaxel Inj. 80mg/2mL Vial
557	01204901	Paclitaxel Inj. 30mg/5mLVial
558	01204904	Paclitaxel Inj.260mg
559	01205002	Irinotecan Inj. 100mg/5mL Vial
560	01205201	Azathioprine Tab. 50mg
561	01205301	Mycophenolate MofetilCap/Tab 250mg
562	01205303	Mycophenolate MofetilCap/Tab 500mg
563	01205401	Cyclosporin Cap. 25mg
564	01205402	Cyclosporin Cap. 50mg
565	01205403	Cyclosporin Cap. 100mg
566	01205404	Cyclosporin Syr.100mg/mL, 50mL Bot.

567	01205601	Tacrolimus Cap. 0.5mg
568	01205602	Tacrolimus Cap. 1mg
569	01205701	Rituximab Inj 100mg in 10mL Vial
570	01205702	Rituximab Inj 500mg in 50mL Vial
571	01206101	Filgrastim Inj 300mcg in0.5mL-1mL, PFS/Vial
572	01206301	Lenalidomide Cap. 5mg
573	01206302	Lenalidomide Cap. 10mg
574	01206401	Thalidomide Cap. 100mg
575	01206402	Thalidomide Cap. 50mg
576	01206701	Anastrozole Tab. 1mg
577	01206802	Tamoxifen Tab. 20mg
578	01206901	Letrozole Tab. 2.5mg
579	01207001	Bicalutamide Tab. 50mg
580	01207101	Flutamide Tab. 250mg
581	01207301	Goserelin Acetate Implant3.6mg
582	01207402	Octreotide Inj. 50mcg in1mL Amp.
583	01207901	Exemestane Tab. 25mg
584	01208501	Abiraterone Acetate Tab.250mg
585	01210101	Mesna Inj. 200mgin 2mL Vial/Ampoule
586	01300102	Ergometrine Inj. 500mcg/1mLAmp.
587	01300202	Oxytocin Inj. 5 I.U. /1mL Amp.
588	01300301	Dinoprostone Vaginal Tab.3mg
589	01300401	Levonorgestrel 20mcg/24hDevice
590	01300602	Potassium Citrate ER Tab1080mg
591	01301201	Clotrimazole Pessaries 100mg
592	01301301	Levonorgestrel Tab. 1.5 mg
593	01301401	Misoprostol Tab.200mcg
594	01301502	Tamsulosin Cap. 0.4 mg
595	01301801	Tolterodine Tab. 1mg
596	01301802	Tolterodine SR Cap. 2mg
597	01301901	Solifenacin Tab. 5mg
598	01302001	Oxybutynine Tab. 2.5mg
599	01302201	Sevelamer HCl Tab. 800mg
600	01302401	Estrogen Vaginal Cream 0.01%, 15g Tube
601	01400201	Ibuprofen Tab. 200mg
602	01400302	Diclofenac Sodium Tab. 50 mg
603	01400303	Diclofenac Sodium Supp. 12.5mg
604	01400304	Diclofenac Sodium Supp. 25mg
605	01400306	Diclofenac Sodium Supp.100mg
606	01400401	Indomethacin Cap. 25mg
607	01400701	Penicillamine Tab/Cap. 250mg
608	01400801	Hydroxychloroquine Sulph.Tab. 200mg
609	01400901	Leflunomide Tab. 10 mg
610	01401001	Allopurinol Tab. 100mg
611	01401101	Neostigmine Tab. 15mg
612	01401201	Pyridostigmine Tablet 60mg
613	01401302	Baclofen Tab. 10mg
614	01402301	Celecoxib Cap. 100mg
615	01500101	Thiopentone Sodium Inj. 500mgVial

616	01500201	Ketamine HCl Inj. 200mg/20mLVial
617	01500202	Ketamine HCl Inj. 500mg/10mLVial
618	01500301	Propofol Inj. for IV Infu.20mL Amp/Vial
619	01500302	Propofol Inj. IV Infu. 50mL Amp./Vial
620	01500401	Etomidate Inj. 20mg/10mLVial/Amp.
621	01500602	Isoflurane 250mL Bot.
622	01500701	Sevoflurane 250mL Bot.
623	01500801	Atropine Sulphate Inj.600mcg/1mL Amp.
624	01500902	Midazolam Inj. 5mg/1mL Amp.
625	01501001	GlycopyrrolateInj. 200mcg/mL Vial
626	01501002	Glycopyrronium Bromide Tab.0.5mg
627	01501101	Atracurium Besylate Inj.25mg/2.5mL Amp.
628	01501201	Pancuronium Inj. 4mg/2mLAmp.
629	01501301	Vecuronium Bromide Inj. 10mgVial
630	01501401	Suxamethonium Chloride Inj.100mg/2mL Amp.
631	01501501	Neostigmine Inj.0.5mg/1mL Amp.
632	01501502	Neostigmine Inj.2.5mg/1mL Amp.
633	01501701	Flumazenil Inj. 500mcg/5mLVial/Amp.
634	01501801	Naloxone Inj. 400mcg/mL Amp.
635	01501901	Dantroline Sodium Inj. 20mg Vial
636	01502001	Bupivacaine Inj. 0.5%/ 10mL Amp.
637	01502003	Bupivacaine 0.5%+Glucose 8% Inj 4ml Amp.
638	01502102	Lidocaine (Lignocaine)HCl Inj. 2%, 20mL Vial
639	01502104	Lidocaine Topical aerosol10%, 50mL Bot.
640	01502105	Lidocaine HCl Gel 2%,30g Tube
641	01502201	Lidocaine 2% + Adrenalin1:80,000 Inj. 30mL Vial
642	01502301	Lidocaine 2.5% & Prilocaine2.5% Cream 5g Tube
643	01503001	Dexmedetomidine HCl Inj200mcg/2mL Vial
		Raw materials (21)
644	00404401	Sodium DihydrogenOrthophosphate Pow.
645	00404501	Disodium hydrogenorthophosphate Pow.
646	00902502	Silicone oil 10mL Bot.
647	01100101	Liquid Paraffin (Heavy)
648	01100102	Yellow Soft Paraffin
649	01100103	White Soft Paraffin
650	01100201	Emulsifying Wax
651	01100301	Urea Crystals
652	01100401	Pure Coconut oil
653	01100501	Coal Tar Solution 20%
654	01100801	Starch Powder
655	01102601	Salicylic acid powder
656	01103001	Thymol crystals
657	01103601	Cetrimide Powder 500g Tin
658	01104201	Potassium Permanganate Crystal
659	01104801	Zinc Oxide Powder
660	01104901	Precipitated Sulphur Powder
661	01106301	Glycerin
662	01106401	Purified water
663	01300601	Potassium Citrate Powder

664	01300701	Sodium Citrate Powder
		Antidotes (10)
665	01600101	Charcoal activated, 50g Bot.
666	01600201	Acetylcysteine Inj.2g/10mL Amp
667	01600301	Fulier's earth ,60g Bot.
668	01600501	Dicobalt Edetate Inj.300mg/20mL Amp.
669	01600801	Dimercaprol Inj. 100mg/2mL Amp
670	01601001	Pralidoxime Chloride Inj.1g/20mL Amp.
671	01601101	Ethanol Inj. (96.8w/w) 5mL Amp.
672	01601201	Methylene Blue Inj. 1% w/v10mL Amp.
673	01601301	Atropine Sulphate Inj.15mg/25ml Vial
674	01601401	Fomepizole IV Infusion1g/mL, 1.5mL Vial
		Items supply to special campaigns/programmes (77)
675	00400501	Ferrous Fumarate+Folic AcidTab. (182.4mg+400mcg)(Maternal & School HP)
676	00400506	Ferrous Fumarate+Folic AcidTab. (91.2mg+400mcg)(Maternal & School HP)
677	00401601	Calcium Lactate Tab. 300mg
678	00402501	Vitamin A High dose Cap.
679	00408001	Glucose sachet 75g
680	00702601	Medroxyprogesterone Inj150mg/1mL Vial
681	00106602	Mebendazole Tab. 500mg
682	01300402	Levonorgestrel 75mg(Two rod subdermal implant)
683	01300501	Etonogestrel 68mg(Single rod Subdermal Implant)
684	01300802	Levonorgestrel 0.15mg+ Ethinyloestradiol 0.03mg Tab
685	00600102	Tetanus Toxoid Adsorbedvaccine (TT), 10 dose vial
686	00600402	Meningococcal ConjugateQuadrivalent Vaccine SingleDose Vial
687	00600601	Yellow Fever Vaccine 0.5mLSingle Dose Vial/Ampoule
688	00600801	Bacillus Calmette-GuerinVaccine (BCG),20 Dose Vial
689	00600903	Human Papilloma Virus(Quardrivalent) RecombinantVaccine
690	00600904	Typhoid Vi capsular polysaccharide vaccine multidose vial
691	00601001	Live Japanese EncephalitisVaccine (LJEV), 5 Dose Vial
692	00601601	MMR Vaccine 10 Dose Vial
693	00601701	Adsorbed Adult Tetanus andDiphtheria Vaccine (aTD),10 Dose Vial
694	00601702	Adsorbed Diphtheria andTetanus Vaccine (DT),10 Dose Vial
695	00601801	Adsorbed Diphtheria Tetanusand Purtussis Vaccine(DPT), 10 Dose Vial
696	00601903	Bivalent PoliomyelitisVaccine Live 10 Dose Vial
697	00601905	Inactivated Polio VirusVaccine (IPV) 5 Dose Vial
698	00602001	Pentavalent (DPTHepBHIb)Vaccine10 Dose Vial
699	00603301	Anti-rabies Vaccine for Animal use, 10 Dose Vial
700	00603501	Japanese EncephalitisVaccine(swine) 10 Dose Vial
701	00104001	Ethambutol Tab. 400mg
702	00104002	Ethambutol Inj 100mg/mL,10mLVial
703	00104101	Ethionamide Tab.250mg
704	00104201	Isoniazid Tab. 100mg
705	00104202	Isoniazid Oral solu. 50mg/5mL, 100mL Bott.
706	00104301	Pyrazinamide Tab. 500mg
707	00104401	Rifampicin Cap. 150mg

708	00104402	Rifampicin Inj. 600mg Vial
709	00104403	Rifampicin Syr.100mg/5mL,120mL Bot.
710	00104501	Streptomycin Inj. 1g Vial
711	00603603	Tuberculin for Mantoux test5TU/0.1mL in 1mL Vial
712	00104901	MDT-MB Paediatric
713	00104902	MDT-MB Adult
714	00105001	MDT-PB Paediatric
715	00105002	MDT-PB Adult
716	00105101	Clofazimine Cap/Tab 100mg
717	00105103	Clofazimine Cap/Tab 50mg
718	00106001	Chloroquine Phosph. Tab.250mg
719	00106101	Primaquine Tab 7.5 mg
720	00106201	Quinine Sulphate Tab. 300 mg
721	00106202	Quinine Dihydrochlo Inj.600mg in 2mL Amp.
722	00106301	Mefloquine Tab. 250mg
723	00108501	Artesunate Inj. 60mg Vial
724	00108901	Artemether 20mg+Lumefantrine 120mg Tab
725	00108902	Artemether Inj. 80mg/mL Vial
726	00114001	Atovaquone 250mg +ProguanilHcl 100mg filmcoated Tab.
727	00109001	Emtricitabine 200mg +Tenofovir300mg Tab.
728	00109101	Lamivudine150mg+Zidovudine300mg+Nevirapine 200mg Tab.
729	00109102	Lamivudine 30mg +Zidovudine 60mg+ Nevirapine 50mg Tab.
730	00109201	Isoniazid 75mg+Rifampicin150mg+Ethambutol 275mg Tab.
731	00109301	Isoniazid 75mg+Rifampicin150mgTab.
732	00109401	Isoniad 75mg+Rifampicin 150mg+Ethambutol 275mg +Pyrazinamide400mg Tab.
733	00109501	Nevirapine Tab. 200 mg
734	00109503	Nevirapine Oral susp.50mg/5 mL, 100mL Bott.
735	00109601	Abacavir Tab. 300mg
736	00109701	Lopinavir 100mg+Ritonavir 25mgTab.
737	00109702	Lopinavir 200mg+Ritonavir 50mgTab.
738	00110001	Efavirenz 600 mg + Emtricitabine 200 mg +Tenofovir 300 mg Tab.
739	00110101	Darunavir (as ethanolate)300 mg Tab.
740	00110102	Darunavir (as ethanolate)600 mg Tab.
741	00110301	Raltegravir (potassium salt)400 mg Tab.
742	00110401	Zidovudine 300mg + Lamivudine150mg Tab.
743	00110402	Lamivudine 30mg + Zidovudine60mg Tab.
744	00110403	Dispersible Lamivudine 30mg +Zidovudine 60mg Tab.
745	00110501	Efavirenz Tab/Cap 600mg
746	00110502	Efavirenz Tab/Cap 200mg
747	00110601	Abacavir Sulfate 60mg +Lamivudine 30mg Tab.
748	00110701	Atazanavir (as sulphate) Cap.300 mg
749	00110702	Atazanavir 300mg + Ritonavir100mg Tab.
750	00110801	Ritonavir Tab. 100mg
751	00113101	Dolutegravir Tab. 50mg
		Misecellinous (02)
752	43400301	Tropical chlorinated lime
753	43412201	Soda lime

List 2: Named patient items (97)

No.	SR No.	Item	Supply Method by MSD
1	00102304	Tigecycline Injection 50mg vial	Keep a stock at institution and issue on NPB
2	00103704	Cotrimoxazole Injection 480 mg in 5ml ampoule	On individual request
3	00104203	Isoniazid inj. 50mg/2ml	On individual request
4	00107403	Liposomal Amphotericin B Inj. 50mg Vial	Keep a stock at MSD and issue on NPB
5	00108301	Linezolid Injection 600mg/300ml	Keep a stock at institution and issue on NPB
6	00108401	Colistimethate Injection 1,000,000 IU vial	Keep a stock at institution and issue on NPB
7	00108601	Tenofovir Tablet 300mg	On individual request
8	00108701	Anidulafungin Injection 100mgvial	On individual request
9	00109801	Ribavirin Capsule/Tablet 200mg	On individual request
10	00111101	Moxifloxacin Tablet 400 mg	On individual request
11	00111501	Posaconazole Tablet 100mg	On individual request
12	00111601	Caspofungin Injection50mg vial	On individual request
13	00111801	Flucytosine Tablet 250mg	On individual request
14	00112301	Sofosbuvir Tablet 400mg	On individual request
15	00112501	Valpatasvir 100mg + Sofosbuvir 400mg Tablet	Keep a stock at MSD and issue on NPB
16	00112701	Tenofovir Alafenamide Tablet 25mg	On individual request
17	00112801	Entecavir Tablet 0.5 mg	On individual request
18	00112901	Cidofovir 75mg/ml in 5mlvial	On individual request
19	00203004	Glyceryl trinitrate sublingual spray 400microgram/MD,200 Dose unit	Keep a stock at institution and issue on NPB
20	00207403	Clonidine Hydrochloride Tablet 100microgram	On individual request(Restricted use for paediatric)
21	00209101	Amiloride Tablet 5mg	On individual request
22	00404202	Trientine Hydrochloride Capsule 300mg	Keep a stock at MSD and issue on NPB
23	00404203	Carnitine 500mg Tablet	On individual request
24	00404301	Oxymetholone Tab. 50mg	Keep a stock at MSD and issue on NPB
25	00405801	Eltrombopag Tab. 50mg	Keep a stock at MSD and issue on NPB
26	00405802	Eltrombopag Tab 25mg	Keep a stock at MSD and issue on NPB
27	00405901	Biotin Capsule 5mg	Keep a stock at MSD and issue on NPB
28	00407401	Cinacalcet Tablet 30mg	On individual request
29	00407601	Betaine Hydrochloride Tablet 500mg	On individual request (Restricted use for paediatric)
30	00502501	Pirfenidone Tab. 200mg	Keep a stock at MSD and issue on NPB
31	00502601	Tobramycin Nebuliser Solution 60mg / ml in 5ml	On individual request
32	00502701	Omalizumab injection 150mg / ml, 1ml PFS	On individual request

33	00502901	Talc powder sterile 4g bottle	Keep a stock at institution and issue on NPB
34	00600303	Hepatitis B specific IG(HBIG) 100IU-500IU vial	On individual request
35	00600502	Pneumococcal Conjugate Vaccine	Keep a stock at MSD and issue on NPB
36	00603102	Antithymocyte Injection 250mg 5ml vial	On individual request
37	00603701	Influenza Vaccine 0.5ml prefilled syringe	Keep a stock at MSD and issue on NPB
38	00706701	Insulin Soluble (Human) 25%-30% + Protamine 70%-75%, 300IU per 3ml cartridge	Keep a stock at institution and issue on NPB
39	00706801	Insulin pen to be used with replaceable Soluble (Human) 25%-30% + Protamine 70%-75% Insulin cartridge	Keep a stock at institution and issue on NPB
40	00706802	Needle for Soluble (Human) 25%-30% + Protamine 70% -75% Insulin pen, size 30-32 Gauge, 3mm-5mm length	Keep a stock at institution and issue on NPB
41	00706803	Insulin pen to be used with Soluble Insulin cartridge	Keep a stock at institution and issue on NPB
42	00706804	Needle for Soluble Insulin pen, size 30-32G, 3mm-5mm length	Keep a stock at institution and issue on NPB
43	00706901	Insulin Soluble (Human)300IU in 3ml cartridge	Keep a stock at institution and issue on NPB
44	00707301	Metyrapone Capsule 250mg	On individual request (Restricted use for paediatric)
45	00707501	Tolvaptan Tablet 15mg	On individual request
46	00801002	Mesalazine suppository 500mg	Keep a stock at institution and issue on NPB
47	00802301	Budesonide Capsule 3mg	Keep a stock at MSD and issue on NPB
48	00802701	Hydrocortisone Acetate Foam Enema 10%	On individual request
49	00900802	Dexamethasone Intravitreal Implant 0.7mg	Keep a stock at institution and issue on NPB
50	00905901	Riboflavin TE solution 0.25%, 2ml prefilled syringe	On individual request
51	00906001	Riboflavin D solution 0.1%, 3ml prefilled syringe	On individual request
52	01106803	Ivermectin Tablet 6mg	On individual request
53	01200702	Carmustine Injection 100mg single dose Vial	On individual request
54	01202901	Bevacizumab Injection 100mg/4ml Vial	Keep a stock at MSD and issue on NPB
55	01204002	Dasatinib Tablet 50mg	On individual request
56	01204003	Dasatinib Tablet 20mg	On individual request
57	01204101	Erlotinib hydrochloride Tablet 150mg	On individual request
58	01204301	Gefitinib Tablet 250mg	On individual request
59	01204701	Sunitinib Malate Capsule 50mg	On individual request
60	01204702	Sunitinib Malate Capsule 12.5mg	On individual request
61	01205101	Trastuzumab Injection 150mg Vial	On individual request
62	01205102	Trastuzumab Injection 440mg vial	Keep a stock at institution and issue on NPB
63	01205501	Basiliximab Injection 20mg	Keep a stock at MSD and issue on NPB

64	01205902	Interferon beta 1a Injection 44microgram prifilled syringe	Keep a stock at MSD and issue on NPB
65	01205904	Interferon beta 1a Injection30 microgram prifilled syringe	Keep a stock at MSD and issue on NPB
66	01205905	Interferon beta 1a Injection 22microgram prifilled syringe	Keep a stock at MSD and issue on NPB
67	01207201	Leuprorelin acetate Injection 3.75mg Vial	Keep a stock at institution and issue on NPB
68	01207302	Goserelin Acetate Implant 10.8mg (in syringe applicator)	Keep a stock at institution and issue on NPB
69	01207401	Octreotide long acting Injection 20mg	On individual request
70	01207403	Octreotide long acting Injection 30mg vial	On individual request
71	01207701	Tocilizumab 80mg/4ml for IVinfusion	Keep a stock at MSD and issue on NPB
72	01207702	Tocilizumab 200mg/10ml for IVinfusion	Keep a stock at MSD and issue on NPB
73	01208101	Pazopanib Tablet 200mg	Keep a stock at MSD and issue on NPB
74	01208201	Decitabine Injection 50mg powder for infusion	On individual request
75	01208301	Cladribine Injection 10mg/10ml Vial	On individual request
76	01208701	Mycophenolic Acid Tablet 180mg	Keep a stock at MSD and issue on NPB
77	01208802	Mycophenolic Acid Tablet 360mg	Keep a stock at MSD and issue on NPB
78	01208901	Nilotinib Capsule 150mg	Keep a stock at MSD and issue on NPB
79	01208902	Nilotinib Capsule 200mg	Keep a stock at MSD and issue on NPB
80	01209001	Bendamustine HCl Injection 100mg/20ml	Keep a stock at MSD and issue on NPB
81	01209101	Mitotane Tablets 500mg	On individual request
82	01209201	Golimumab Injection 50mg in pre-filled syringe	On individual request
83	01209301	Ruxolitinib Tablet 20mg	Keep a stock at MSD and issue on NPB
84	01209302	Ruxolitinib Tablet 5mg	Keep a stock at MSD and issue on NPB
85	01209303	Ruxolitinib Tablet 15mg	Keep a stock at MSD and issue on NPB
86	01209401	Fingolimod Capsule 500microgram	On individual request
87	01209501	Tretinoin Capsule 10mg	On individual request
88	01210201	Azacitidine Injection100mg Vial	Keep a stock at MSD and issue on NPB
89	01210501	Fulvestrant Injection250mg/5ml PFS	Keep a stock at MSD and issue on NPB
90	01303001	Carboprost Tromethamine Injection 250mcg/ml	Keep a stock at institution and issue on NPB
91	01400501	Ustekinumab Injection 130mg/26ml vial	On individual request
92	01400502	Ustekinumab Injection 90mg/0.5ml vial	On individual request
93	01401401	Adalimumab Injection 40mg	On individual request (Restricted use for paediatric)
94	01401503	Tofacitinib Tablet 5mg	On individual request
95	01401701	Infliximab Injection 100mg	Keep a stock at institution and issue on NPB
96	01401702	Etanercept injection 25 mg vial	On individual request
97	01700001	Phenylalanine & tyrosine free medical food powder	On individual request (Restricted use for paediatric)

252

ඇමුණුම 71

දුරකථන 694113
தொலைபேசி 694114
Telephones 686528-30

විදුලි පණිවුඩ රස සෙවෙස
தந்தி மெட்ஸ்ரோர்ஸ்
Telegrams MEDSTORES

ෆැක්ස 941-697096
தொலை நகல்
Fax

කේබල් GOVTDRUG
கடல் வழித்தந்தி
Cables

මගේ අංකය MSD/FR/QA/SCO/2023-01
எனது இல.
My No.

ඔබේ අංකය
உமது இல.
Your No.

වෛද්‍ය සැපයීම් අංශය
(සෞඛ්‍ය සේවා දෙපාර්තමේන්තුව)
வைத்திய விநியோகப்பகுதி
(சுகாதார சேவைத் திணைக்களம்)
MEDICAL SUPPLIES DIVISION
(Department of Health Services)

අංක 357, බද්දේගම විමලවංස මාවත, කොළඹ 10, ශ්‍රී ලංකාව.
இல. 357, பத்தேகம விமலவங்ச மாவத்தை, கொழும்பு 10, இலங்கை.
No. 357, Baddegama Wimalawansa Mawatha, Colombo 10, Sri La

තැ. පෙ.
த.பெ.
P.O.Box 1679

දිනය/திகதி/Date : 11/.04.2023

Chairman,
National Medicine Regulatory Authority,
120, Norris Canal Road,
Colombo 10

Requesting to be considered in the "Orphan "drug category

The following list of pharmaceuticals (Annexure 1) is selected from the "priority list" mentioned in the circular No:01-14/2023 issued by DGHS.
The following reasons rendered it impractical for the selected items to be supplied continuously.

- Required in small quantities
- High prices have been quoted for SPC tenders.
- Not quoted for SPC tenders
- Not available in Osusala/private market
- Available in private market but not registered at NMRA

You are kindly requested to consider registering these items under the orphan category at NMRA or to take the necessary steps to make these items available in the country, as making these items available is critical in patient care management. .
Your cooperation in this regard is highly appreciated.

Thank you.

Dr. H. M. K. WICKRAMANAYAKE
Director
Medical Supplies Division
Rev. Baddegama Wimalawansa Thero Mw
Colombo 10

.....
Director
Medical Supplies Division

Copies:

1. Additional Secretary /State Ministry of Pharmaceutical Production, Supply & Regulation
2. Director General of Health Services
3. Deputy Director General (Medical Supplies)
4. Chairman/SPC
5. Presidents/ All colleges of Medical Specialties
6. Assistant Director (P) I,II/ MSD

(12)

Annexure I

Suggestions for "Orphan drug category"

No	SR No	Item
1	00000810	Morphine Sulphate Oral solu.2mg/1mL, 100mL Bott.
2	00103703	Co-trimoxazole Oral susp.(Paedi.) 50mL Bott.
3	00103901	Trimethoprim Tab. 100mg
4	00104801	Dapsone Tab. 50mg
5	00105101	Clofazimine Cap/Tab 100mg
6	00105103	Clofazimine Cap/Tab 50mg
7	00109001	Emtricitabine 200mg +Tenofovir300mg Tab.
8	00109101	Lamivudine150mg+Zidovudine300mg+Nevirapine 200mg Tab.
9	00109102	Lamivudine 30mg +Zidovudine 60mg+ Nevirapine 50mg Tab.
10	00109201	Isoniazid 75mg+Rifampicin150mg+Ethambutol 275mg Tab.
11	00109301	Isoniazid 75mg+Rifampicin150mgTab.
12	00109401	Isoniad 75mg+Rifampicin 150mg+Ethambutol 275mg +Pyrazinamide400mg Tab.
13	00109501	Nevirapine Tab. 200 mg
14	00109503	Nevirapine Oral susp.50mg/5 mL,100mL Bott.
15	00109601	Abacavir Tab. 300mg
16	00109701	Lopinavir 100mg+Ritonavir 25mgTab.
17	00109702	Lopinavir 200mg+Ritonavir 50mgTab.
18	00110001	Efavirenz 600 mg + Emtricitabine 200 mg +Tenofovir 300 mg Tab.
19	00110101	Darunavir (as ethanolate)300 mg Tab.
20	00110102	Darunavir (as ethanolate)600 mg Tab.
21	00110301	Raltegravir (potassium salt)400 mg Tab.
22	00110401	Zidovudine 300mg + Lamivudine150mg Tab.
23	00110402	Lamivudine 30mg + Zidovudine60mg Tab.
24	00110403	Dispersible Lamivudine 30mg +Zidovudine 60mg Tab.
25	00110501	Efavirenz Tab/Cap 600mg
26	00110502	Efavirenz Tab/Cap 200mg
27	00110601	Abacavir Sulfate 60mg +Lamivudine 30mg Tab.
28	00110701	Atazanavir (as sulphate) Cap.300 mg
29	00110702	Atazanavir 300mg + Ritonavir100mg Tab.
30	00110801	Ritonavir Tab. 100mg
31	00113101	Dolutegravir Tab. 50mg
32	00112201	Ketoconazole Tab 200mg
33	00112701	Tenofovir Alafenamide Tablet 25mg
34	00201101	Propranolol Tab. 10 mg
35	00202001	Sodium Nitroprusside Inj. 50mgVial
36	00202402	Phenoxybenzamine HCl Inj.100mg/2mL Amp.

37	00202501	Phentolamine Mesylate for inj.10mg/1mL Amp.
38	00203602	Nimodipine IV Infu. 10mg/50mLVial
39	00205801	Streptokinase Inj. 1.5M.U.
40	00207403	Clonidine Hydrochloride Tablet 100microgram
41	00300104	Diazepam Rectal Sol.5mg/2.5mL Tube
42	00300502	Chloral hydrate Oral Solution500mg / 5ml in 200ml Bottle
43	00303804	Carbamazepine Oral susp.100mg/5mL,100mL Bott.
44	00304801	Vigabatrin Tab. 500mg
45	00403201	Phytomenadione Tab 5mg
46	00404401	Sodium DihydrogenOrthophosphate Pow.
47	00404501	Disodium hydrogenorthophosphate Pow.
48	00406501	Phosphate Tab. 500 mg
49	00406703	Cholecalciferol(Colecalciferol)Tab. 5000 IU
50	00406901	Magnesium Glycinate Tab 400mg(200mg of elemental Magnesium)
51	00502601	Tobramycin Nebuliser Solution 60mg / ml in 5ml
52	00600303	Hepatitis B specific IG(HBIG) 100IU-500IU vial
53	00701301	Propylthiouracil Tab. 50mg
54	00701401	Fludrocortisone Tab. 0.1mg
55	00702701	Testosterone Enanthate Inj.250mg/1mL Amp.
56	00703001	Tetracosactrin Inj.250mcg/1mL Amp.
57	00703601	Pamidronate Disodium IV Infu.30mg/10mL Vial
58	00705501	Diazoxide Tab. 50mg
59	00904102	Moxifloxacin Preservative freeOphthalmic Sol. 0.5%5mL Dropper bott.
60	00905201	Lidocaine HCl(Lignocaine)Ophthalmic Gel 2% in 30g Tube
61	00905401	Perfluoropropane Intraocular gas 75 mL Container/Canister
62	00942201	Lidocaine (Lignocaine) inj. 2% 5mL Vial/Amp. for opthalmicuse (preser. free)
63	01104001	Hydrogen PeroxideSol. 6% 400mL- 500ml Bot.
64	01104201	Potassium Permanganate Crystal
65	01200101	Busulphan Tab 2mg
66	01200201	Chlorambucil Tab. 2mg
67	01200301	Cyclophosphamide Tab. 50mg
68	01200502	Melphalan Inj. 50mgPowder with Solvent
69	01201701	Cytarabine Inj. 100mg/5mL Vial(Not for Intrathecal use)
70	01201702	Cytarabine Inj. 100mg/mLVial ,Preservative free
71	01201902	Fluorouraci Inj. 250mg/10mLVial
72	01202203	MethotrexateInj. 50mg/2mL Vial(without preser.)
73	01202701	Etoposide Cap.100mg
74	01202703	Etoposide Cap. 50mg
75	01202702	Etoposide Inj. 100mg Vial
76	01202801	Lecucovorin Tab 15mg(Folinic acid)
77	01203901	Procarbazine Cap. 50mg

250-A

(10)

78	01205404	Cyclosporin Syr.100mg/mL, 50mL Bot.
79	01206402	Thalidomide Cap. 50mg
80	01207101	Flutamide Tab. 250mg
81	01301901	Solifenacin Tab. 5mg
82	01302201	Sevelamer HCl Tab. 800mg
83	01501002	Glycopyrronium Bromide Tab.0.5mg
84	01501901	Dantroline Sodium Inj. 20mg Vial
85	01502104	Lidocaine Topical aerosol10%, 50mL Bot.
86	01600301	Fuller's earth ,60g Bot.
87	01600501	Dicobalt Edetate Inj.300mg/20mL Amp.
88	01600801	Dimercaprol Inj. 100mg/2mL Amp
89	01601001	Pralidoxime Chloride Inj.1g/20mL Amp.
90	01601101	Ethanol Inj. (96.8w/w) 5mL Amp.
91	01601401	Fomepizole IV Infusion1g/mL, 1.5mL Vial
92	01204901	Paclitaxel Inj. 30mg/5mLVial *
93	01204904	Paclitaxel Inj.260mg *
94	00402301	Peritoneal Dialysis Sol.1.5% ,1000mL Bot. *
95	00405001	Administration set for Peritoneal Dialysis solution *
96	00405101	Peritoneal Dialysis Catheter Set *

* Specifications of these items attached- Annexure II

Annexure II

SR No	Item	Specification
01204901	Paclitaxel Inj. 30mg/5mLVial *	Paclitaxel Injection 30mg in 5ml vial Each 5ml, sterile solution to contain 30mg of Paclitaxel for intravenous infusion Note: 1.This injection should be stable for a minimum of 24 months when stored under manufacturer's conditions. 2. Each vial should be labeled accordingly. 3. One set of administration device and suitable diluent compatible with Paclitaxel injection,to be supplied with every five vials of Paclitaxel injection. Administration device sets should be 3.1.Free from Polyvinyl Chloride (PVC) and di-(2-ethylhexyl) Phthalate (DEHP) 3.2.Contain needle, in line filter with a microspores membrane not greater than 0.22 micrometer and a polyethylene- lined.
01204904	Paclitaxel Inj.260mg *	Paclitaxel Injection USP, 260mg Each vial to contain 6mg/1 ml of sterile, stabilized solution of paclitaxel USP, suitable for dilution for intravenous administration. Note: 1.This product should be stable for a minimum of 24 months when stored at a temperature below 25?C 2. Each vial should be labelled accordingly. 3. Two sets of administration device and two bottles of suitable diluent compatible with Paclitaxel injection,to be supplied with each vial of Paclitaxel injection. Administration device sets should be 3.1.Free from Polyvinyl Chloride (PVC) and di-(2-ethylhexyl) Phthalate (DEHP) 3.2.Contain needle, in line filter with a microspores membrane not greater than 0.22 micrometer and a polyethylene- lined.

00402301	Peritoneal Dialysis Sol.1.5% ,1000mL Bot. *	Peritoneal Dialysis solution BP. Each 1000ml air freight tamper evident, pyrogen free, sterile container (bottle) to contain 130-140 mmol/l of Sodium, 1.5 -2.00 mmol/l of Calcium Bicarbonate equivalent to 32 - 45 mmol/l (as Acetate or Lactate), 95 - 110 mmol/l of Chloride, 1.5% of glucose BP in water for injection BP/USP Note: 1.Bottle should be graduated to 500ml and to be medicinal grade Polyethylene or Polypropylene. PVC is not acceptable. 2. The bottle should have a device for hanging. 3. To prevent leakage of fluid with insertion or withdrawal of spike or continuous use the site of the insertion of piercing spike should be converted with a sterile rubber disk or bung should be fused to the neck of the bottle right round. 4. Each bottle should be packed individually in a protective Polyethylene cover. 5. The product should be sterile and stable for a minimum of 24 months within a temperature range 30'C - 35'C 6. The bottle should be labelled accordingly.
00405001	Administration set for Peritoneal Dialysis solution *	Administration set for Peritonial dialysis solution with two leads. Each set comprising; A. Patient line with injection port and roller clamp for connection to the catheter. B. Connection line to peritoneal dialysis solution with piercing spike, fluid chamber and roller clamp. C. Connection line to drainage bag/container with fluid chamber and roller clamp. Pack; Each sterile set to be packed individually in a peel open sachet and labelled accordingly.
00405101	Peritoneal Dialysis Catheter Set *	Peritoneal dialysis catheter set for Peritoneal dialysis and Peritoneal lavage. Each sterile catheter set to consist of 1. Catheter with a device to control penetration depth and perforated distal end. Size; 1.5x3.5x280mm 2. Stylet with triangular cutting tip. Pack; Each sterile set to be packed individually in a peel open sachet and labelled accordingly.

දුරකථන Telephones: 694113, 694114, 686528-30

විදුලි පණිවුඩ Telegrams: රස මෙඩ්ස්ටෝස් MEDSTORES

ෆැක්ස් Fax: 941-697096

කේබල් සටහන Cables: GOVTDRUG

මගේ අංකය My No.: MSD/FR/QA/SCO/2023-02

ඔබේ අංකය Your No.:

සෞඛ්‍ය සැපයීම් අංශය

(සෞඛ්‍ය සේවා අධ්‍යක්ෂ ජනරාල්)

වෛද්‍යකීය සිත්‍රාගාලාපති

(සෞඛ්‍ය සේවයේ දිසාපතිතුමා)

MEDICAL SUPPLIES DIVISION

(Department of Health Services)

අංක 357, බද්දේගම වීමලවංශ මාවත, කොළඹ 10, ශ්‍රී ලංකාව.

இல. 357, பத்தேகம விமலவங்ச மாவத்தை, கொழும்பு 10, இலங்கை.

No. 357, Baddegama Wimalawansa Mawatha, Colombo 10, Sri L

තැ. පෙ. පිටුව P.O.Box: 1679

දිනය/திகதி/Date : 11.04.2023

Chairman,
National Medicine Regulatory Authority,
120, Norris Canal Road,
Colombo 10

Request for registering following newly recommended medicines

The formulary revision committee (FRC) has recommended the following list of items to include in the medicine formulary. According to the FRC's suggestion, it was decided to hold off on creating SR numbers in MSMIS until the suggested items have been registered at NMRA.

Hence you are kindly requested to consider registering these newly recommended pharmaceuticals in order to complete the SR number creation.

Your cooperation in this regard is highly appreciated.

Thank you.

o/c Director
Medical Supplies Division

Dr. H. M. K. WICKRAMANAYAKE
Director
Medical Supplies Division
Rev. Baddegama Wimalawansa Thero Mw.
Colombo 10.

.....

Copies:

1. Additional Secretary /State Ministry of Pharmaceutical Production, Supply & Regulation
2. Director General of Health Services
3. Deputy Director General (Medical Supplies)
4. Chairman/SPC
5. Presidents/ All colleges of Medical Specialties
6. Assistant Director (P) I,II/ MSD

255-A
06

Annexure I

No	Item Name
1	Rivaroxaban Tablet 5mg
2	Enoxaparin Sodium Injection 2000IU prefilled syringe
3	Deferasirox Non-dispersible Tablet 100mg
4	Deferasirox Non-dispersible Tablet 400mg
5	Cyclosporin Injection 50mg/ml
6	Treosulfan 1g Powder for solution for Infusion
7	Treosulfan 5g Powder for solution for Infusion
8	Ferric Carboxy Moltose 100mg/2ml Vial
9	Fosfomycin 40mg/ml Injection
10	Tenofovir 300mg+Lamivudine 300mg+Dolutegravir 50mg
11	Ceftazidime 2g +Avibactam 0.5g Powder for concentrate for solution for infusion
12	Aztreonam + Avibactam
13	Fluconazole Oral suspension 200mg/5ml
14	Spironolactone Tablet 12.5mg, (Scored)
15	Plasma lyte A (PH 7.4) 500ml Solusion for Infusion
16	Dabigatran Capsule 110mg
17	Triclofos Oral solution 500mg/5ml
18	Lacosamide Tablet 200mg
19	Methylphenidate Hydrochloride Modified Release Tablet 18mg
20	Methylphenidate Hydrochloride Modified Release Tablet 27mg
21	Methylphenidate Hydrochloride Modified Release Tablet 36mg
22	Guanfacine Modified Release Tablet 1mg
23	Guanfacine Modified Release Tablet 2mg
24	Fluoxetine Hydrochloride Tablet 10mg
25	Acamprosate Tablet 333mg
26	Paliperidone Intramuscular Injection 150mg
27	Clonidine Tablet 25microgram
28	Liraglutide Subcutaneous Injection 1.2mg
29	Liraglutide Subcutaneous Injection 1.8mg
30	Liraglutide Subcutaneous Injection 3mg
31	Metyrapone Capsule 500mg
32	Budesonide Delayed Release Capsule 3mg
33	Budesonide Delayed Release Capsule 6mg
34	Budesonide Delayed Release Capsule 9mg
35	Obeticholic Acid Tablet 5mg
36	Obeticholic Acid Tablet 10mg
37	Voxilaprevir 100mg
38	Tenofovir Alafenamide Tablet 100mg
39	Linaclotide Capsule 290mg
40	Linaclotide Capsule 145mg
41	Prucalopride Tablet 1mg
42	Prucalopride Tablet 2mg
43	Tofacitinib Tablet 10mg
44	Carfilzomib Injection 10mg/Vial,
45	Carfilzomib Injection 60mg/Vial
46	Cabozantinib Tablet 40mg
47	Cabozantinib Tablet 60mg
48	Arsenic trioxide Injection 10mg
49	Obinutuzumab 100mg/40ml(25mg/ml) single use vial

50	Rasburicase for IV Infusion 1.5mg Vial
51	Rasburicase for IV Infusion 7.5mg Vial
52	Azathioprine Tablet 25mg
53	Pomalidomide Capsule 2mg
54	Mirabegron 25mg
55	Extended release tablet of Nitrofurantoin 50mg
56	Octenidine
57	Acetic acid solution
58	Desmopressin Nasal spray 150microgram -300microgram
59	Zinc Sulfate Dispersible Tablet 10mg
60	Cefazolin 1g Injection
61	Aspirin Uncoated Tablet 75mg
62	Minoxidil Tablet 5mg
63	Ticargrelor Tablet 60mg
64	Zolmitriptan Tablet 2.5mg
65	Procyclidine Injection 5mg/ml
66	Procyclidine Tablet 5mg
67	Procyclidine Tablet 10mg
68	Aripiprazole Tablet 5mg
69	Tolvaptan Tablet 30mg
70	Mesalazine Tablet 1.2g
71	Simethicone Oral dropper 40mg/ml
72	Ispaghula Husk Sachet
73	Cholestyramine 5mg Sachet
74	Sodium Citrate 450mg + Sodium Lauryl Sulphate 75mg and Glycerin Enema 10ml-20ml
75	Everolimus Tablet 0.5mg
76	Sunitinib Malate Capsule 25mg
77	Isavuconazole 100mg tablet
78	Beclomethasone 0.025%, Miconazole 2% and Neomycin 0.5% ointment 15g tube
79	Lubricating jelly
80	Choriogonadotropin alfa 250mcg/0.5ml
81	Tetrachlorodecaoxide solution (sterile) 100ml
82	Terbutaline 0.25mg Subcutaneous injection
83	Oral Medroxyprogesterone acetate 20 mg
84	Methotrexate Subcutaneous injection 10mg/0.4ml
85	Pilocarpine Tablet 5mg
86	Prednisolone syrup 15mg/5ml
87	Deoxyribonuclease 1mg/ml (DNAs)
88	Mepolizumab 100mg/ml
89	Nintedanib 150mg
90	Iloprost 10mcg/ml nebuliser solution
91	Dexamethasone syrup 0.5mg/5mg
92	Carbocisteine 500mg capsules
93	Isoniazid 300mg tab
94	Pyrazinamide 400mg tab
95	Ethambutol 100mg tab
96	Rifampicin 150mg+ Isoniazid 75mg tab
97	Rifampicin 150mg+ Isoniazid 75mg+ Ethambutol 275mg tab
98	Rifampicin 150mg+ Isoniazid 75mg+ Pyrazinamide 400mg+ Ethambutol 275mg tab
99	Rifampicin 75mg+Isoniazid 50mg dispersible tab
100	Rifampicin 75mg+Isoniazid 50mg+ pyrazinamide 150mg dispersible tab
101	Rifapentine 300mg+ Isoniazid 300mg tab
102	Rifapentin 150mg tab

254 - A

84

103	Riboflaxin trans epitheliam 0.25 riboflexin + 0.007BCA
104	Gatifloxacin ointment
105	Voriconazole 1% Eye drop
106	Dermal filler injection. (hyaluronic acid)
107	Carboxy Methyl cellulose 0.5% + glycerine 0.9% eye drops(Unit - dose vials)
108	Fluorescein strips
109	Hyaluronidase injection 1500 IU
110	Lignocaine transdermal patch 5%
111	Fentanyl TD Patch 12.0mcg/h-12.5mcg/h
112	Balance crystalloid solution without lactate for parentaral infusion in 500ml collapsible bag/bottle
113	Ketorolac for IV/IM 15mg/ml
114	Levobupivacaine 0.5% 10ml
115	Levobupivacaine 0.5% 30ml
116	Human fibrinogen concentrate 1 g single use bottle
117	Human fibrinogen concentrate 2 g single use bottle
118	Oxycodone Hydrochloride 5mg tablet (IR)
119	Oxycodone Hydrochloride 5mg tablet (PR)
120	Oxycodone 10mg with naloxone 5mg Tablet (PR)
121	Capsaicin 5% cream
122	Buprenophine transdermal patches 5mcg/hr
123	Ropivacaine 7.5mg/ml solution
124	Sufentanil 0.05mg /, ml
125	Hyoscine Butylbromide S/C injection 80mg
126	Liquid paraffin+Magneseum Hydroxide solution
127	Octreotide delayed release tablet 20mg
128	Diazepam suppository 10mg
129	Spironolactone Tablet 50mg
130	LevomepromazineTab 6mg
131	LevomepromazineTab 25mg
132	Levomepromazine Inj. 25mg in 1ml ampoule
133	Hib (Heamophelus Influenza Type b) vaccine
134	Venetoclax Tablet 100mg
135	Sofosbuvir 200mg+ Valptasvir 50mg

The Scope & Responsibilities of the NMRA in the approval of Medi

The NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015 provides the authority to the NMRA to regulate all aspects pertaining to medicines.

National Medicines Regulatory Authority (NMRA) will thereby regulate and control manufacture, importation, storage, distribution, transportation, pricing, wholesale and retail sale, advertising, and disposal of medicines to ensure that medicines made available in the country are of good quality, efficacious, safe, and affordable.

The National Medicines Regulatory Authority Act specifies that no person shall manufacture or import any medicine without registering such medicines with the NMRA.

The Medicines Evaluation Committee (MEC) formed under NMRA Act will use registration and certification procedures to carry out scientific and technical reviews, inspections and surveillance activities of the medicines forwarded for registration to ensure the quality, efficacy, safety, need and cost of such medicines. The MEC consist of experts drawn from various specialties in medical and pharmaceutical fields who meets monthly to decide on applications submitted for marketing authorization of medicines and to make policy decisions relevant to marketing authorization of medicines.

NMRA grants Priority review to following Products

- ABACAVIR SULFATE 60 MG + LAMIVUDINE 30 MG TABLETS
- ABACAVIR TABLETS 300 MG
- ABCIXIMAB INJECTION 2 MG / ML
- ACETAZOLAMIDE INJECTION 500 MG
- ACETYLSALICYLIC ACID TABLETS 300 MG
- ACICLOVIR SODIUM FOR INTRAVENOUS INFUSION 250 MG
- ACITRETIN CAPSULES / TABLETS 10 MG
- ACTINOMYCIN D INJECTION 500 MCG
- ADALIMUMAB INJECTION 40 MG / 0.8 ML
- ADENOSINE INJECTION USP 3 MG / ML
- ADRENALINE INJECTION SYRINGE AUTO INJECTION 0.15MG / 0.3 ML, 0.3 MG / 0.3 ML
- ALBENDAZOLE ORAL SOLUTION USP 200 MG / 5 ML
- ALLOPURINOL TABLETS 100 MG
- ALLYLESTRENOL TABLETS 5 MG
- ALPROSTADIL INJECTION USP 0.5 MG / ML
- ALTEPLASE (RECOMBINANT HUMAN TISSUE TYPE PLASMINOGEN ACTIVATOR INJECTION 20 MG / 50 MG
- AMANTADINE CAPSULES 100 MG
- AMIKACIN SULPHATE INJECTION BP 500 MG / 2 ML, 250 MG / 2 ML, 100 MG / 2 ML
- AMILORIDE HYDROCHLORIDE 5 MG + HYDROCHLOROTHIAZIDE 50 MG TABLETS
- AMINOPHYLLINE INJECTION 25 MG / ML
- AMISULPRIDE TABLETS 100 MG, 200 MG, 300 MG
- AMITRIPTYLINE HYDROCHLORIDE TABLETS 25 MG, 10 MG
- AMPHOTERICIN B FOR INJECTION 50 MG

(62)

- ANIDULAFUNGIN FOR INJECTION 100 MG
- ANTI HEMOPHILIC FACTOR-HUMAN INJECTION 220-2000 IU VIAL
- ANTI RABIES SERUM EQUINE 1000 IU IN 5ML
- ANTI RHO-D IMMUNOGLOBULIN INJECTION 300 MCG
- ANTI THYMOCYTE GLOBULIN EQUINE 250 MG / 5 ML
- ANTIHEMOPHILIC FACTOR VIII CONCENTRATED HUMAN INJECTION 250 IU
- ARTEMETHER 20 MG + LUMEFANTRINE 120 MG TABLETS
- ARTESUNATE FOR INJECTION 60 MG
- ATAZANAVIR CAPSULES 300 MG
- ATENOLOL INJECTION 5 MG / 10 ML
- ATOMOXETINE CAPSULES 10 MG, 25 MG
- ATRACURIUM BESYLATE INJECTION 25 MG / 2.5 ML
- ATROPINE EYE DROPS 1% W/V
- ATROPINE INJECTION BP 15 MG / 25 ML, 1 MG / 1 ML
- AZACITIDINE FOR INJECTION 100 MG / VIAL
- AZATHIOPRINE TABLETS 50 MG
- BALANCED SALT SOLUTION
- BARIUM SULPHATE FOR SUSPENSION
- BCG VACCINE
- BENDAMUSTIN HYDROCHLORIDE FOR INJECTION 100 MG VIAL
- BENZHEXOL TABLETS 2 MG
- BENZTROPINE MESYLATE INJECTION 1 MG / 1 ML
- BENZYL PENICILLIN FOR INJECTION 300 MG (500,000 U), 600 MG (1,000,000 U)
- BERACTANT INTRATRACHEAL SUSPENSION 200 MG in 8 ML
- BICALUTAMIDE TABLETS 150 MG
- BLEOMYCIN FOR INJECTION 15 UNIT
- BOTULINUM TOXIN TYPE A 100 U / 50 U
- BROMAZEPAM 1.5 MG / 3 MG
- BUPIVACAINE INJECTION 0.5%
- BUSPIRONE HYDROCHLORIDE TABLETS 20 MG
- CABAZITAXEL INJECTION 60 MG / 1.5 ML WITH SOLVENT
- CABERGOLINE TABLETS 0.5 MG
- CANAGLIFLOZIN TABLETS 100 MG
- CARBAMAZEPINE Tablets 100 mg, 200 mg / Syrup 100 MG / 5 ML
- Carbergoline Tablets BP 500 mcg
- CEFEPIME FOR INJECTION 1 G, 500 MG
- CeEFOTAXIME FOR INJECTION 1 G, 500 MG, 250 MG
- CEFPIROME FOR INJECTION 1 G
- CEFTAZIDIME FOR INJECTION 500 MG
- CEFTRIAXONE FOR INJECTION 250 MG, 500 MG
- CEFUROXIME SODIUM FOR INJECTION 1.5 G, 250 MG
- CERITINIB CAPSULES 150 MG
- CETUXIMAB SOLUTION FOR INJECTION 5 MG / ML
- CHLORAMBUCIL TABLETS 2 MG

- CHLORAMBUCIL TABLETS BP 5 MG, 2 MG
- CHLORAMPHENICOL CAPSULES 250MG
- CHLORAMPHENICOL SODIUM SUCCINATE INJECTION 1 G, 500MG
- CHLORDIAZEPOXIDE TABLETS 10 MG / 5 MG
- CHLOROQUINE PHOSPHATE TABLETS 250 MG
- CHLORPHENIRAMINE MALEATE INJECTION 10 MG / ML
- CHLORPROMAZINE HYDROCHLORIDE 25 MG / 50 MG
- CHLOTHALIDONE TABLETS 6.25 MG
- CHOLECALCIFEROL TABLETS 400IU
- CHORIOGONADOTROPIN INJECTION
- CICLOSPORIN CAPSULES 25 MG, 50 MG, 100 MG / EYE DROPS 0.1% / ORALS SOLUTION 100 MG / ML
- CILNIDIPINE TABLET 5 MG / 10 MG
- CILOSTAZOL TABLETS USP 50 MG / 100 MG
- CITALOPRAM HYDROBROMIDE TABLETS 10 MG / 20 MG
- CLOBAZAM TABLETS 5 MG
- CLOFAZIMINE TABLETS 100 MG
- COAGULATION FACTOR IX (HUMAN)
- CORTICOTROPHIN CARBOXYMETHYLCELLULOSE INJECTION 60 IU / ML
- CO-TRIMOXAZOLE ORAL SUSPENSION IP 240 MG / 5 ML
- CRISANTAPASE INJECTION 10000 U
- CYCLOPHOSPHAMIDE FOR INJECTION BP 100 MG / 200 MG / 500 MG / 1000 MG
- CYCLOPHOSPHAMIDE Tablets ALL STRENGTH
- CYCLOSERINE CAPSULES 250 MG
- CYTARABINE INJECTION BP 100
- MICONAZOLE 2% + HYDROCORTISONE 1% CREAM
- POVIDONE IODINE CREAM
- PRAZOSIN 2.5 MG/ 5MG TABLETS
- TRICLOFOX ORAL SOLUTION 500 mg/5 ml

Published: 14 October 2020

Contact Us

No 120,
Norris Canal Road,
Colombo 10
Sri lanka.

+94 11 2687743 (tel:+94 11 2687743)

Administrative Office

No 47,
W.A.D Ramanayake Mw,

(2) වෛද්‍ය වෘත්තිකයා, දන්ත වෛද්‍යවරයා හෝ පශු වෛද්‍යවරයාට අවශ්‍ය වන අවස්ථාවක දී ඔහු විසින් නිකුත් කරන ඖෂධ වට්ටෝරුවේ ඖෂධීය නාමයට අමතරව එම ඖෂධයේ විශේෂිත වෙළඳ නාමයක් ද සඳහන් කරනු ලැබිය හැකි ය.

(3) වෛද්‍ය වෘත්තිකයකු, දන්ත වෛද්‍යවරයකු හෝ පශු වෛද්‍යවරයකු විසින් නියම කරනු ලබන ඖෂධය සඳහා ඖෂධීය නාමයක් නොමැති සංයෝග ඖෂධයක් වන අවස්ථාවකදී ඔහු විසින් නිකුත් කරන ඖෂධ වට්ටෝරුවෙහි එම ඖෂධයේ වෙළඳ නාමය පමණක් සඳහන් කරනු ලැබිය හැකි ය.

මේ කොටසේ විධිවිධාන උල්ලංඝනය කිරීම වරදක් බව.

(4) ඖෂධ වට්ටෝරුවේ සඳහන් වෙළඳ නාමයෙන් දක්වා ඇති ඖෂධය එකී ඔසුසලේ නොමැති විටදී හෝ දක්වා ඇති මිලට ලබාගැනීමට පරිභෝගිකයාට නොහැකිවන අවස්ථාවේදී, පාරිභෝගිකයාගේ කැමැත්ත මත ඖෂධවේදියා විසින් වෙනත් වර්ගීය ඖෂධයක් පාරිභෝගිකයාට ලබා දිය හැක.

ඖෂධ ලියාපදිංචි කිරීම ආදිය සඳහා අවශ්‍යතා.

(5) පාරිභෝගිකයාට තමාගේ කැමැත්ත පරිදි අදාළ ඖෂධයක් මිලදී ගැනීමට හැකිවන පරිදි ඔසුසලේ ඇති, එම ඖෂධයට අදාළ විවිධ වෙළඳනාම සහිත හෝ රහිත වර්ගීය ඖෂධ සහ ඒවායේ මිල ගණන් ඖෂධවේදියා විසින් පාරිභෝගිකයාට දැනුම් දිය යුතු ය.

(6) මිලදී ගැනීම සිදුකරන අවස්ථාවේදී ඔසුසලේ ඇති අදාළ වර්ගීය ඖෂධයට අදාළ වෙළඳ නාම සහිත හෝ රහිත ඖෂධ සඳහා ඒවායේ මිල ගණන් පාරිභෝගිකයාට දැනුම්දීම පැහැර හරින යම් ඖෂධවේදියකු මේ පනත යටතේ වරදක් සිදු කරනු ලැබිය යුතු ය.

57. මේ පනතේ මේ කොටසේ නිශ්චිතව දක්වා ඇති විධිවිධාන උල්ලංඝනය කරන යම් තැනැත්තකු වරදක් සිදු කරනු ලැබිය යුතු ය.

IV වන කොටස

ඖෂධ ලියාපදිංචි කිරීම සහ බලපත්‍ර ලබාදීම

ඖෂධයක් ලියාපදිංචි කිරීම සඳහා වූ ඉල්ලීම.

සිදු තැනැත්තකු විසින් යම් ඖෂධයක් අධිකාරියේ ලියාපදිංචි නොකර සහ අධිකාරියෙන් බලපත්‍රයක් ලබා නොගෙන නිෂ්පාදනය කිරීම හෝ ආනයනය කිරීම නොකළ යුතු ය.

අලුත් කිරීම.

යුතු අවස්ථා, භාවිතා නොකළ යුතු අවස්ථා, වෙනත් රටවල නියාමන මණ්ඩල විසින් කරනු ලබන නව නිර්දේශ, සීමා කිරීම්, ලියාපදිංචිය අවලංගු කිරීමේ ආදිය ඇතුළු ඖෂධය පිළිබඳ යම් අලුත් වර්ධනයන් සම්බන්ධයෙන් අධිකාරියට කරුණු හා තොරතුරු අනාවරණය වීමෙන් පසු යම් නියමිත කාලයක් තුළ අධිකාරියට දැනුම් දෙන බවට සහතිකය දරන්නා විසින් අධිකාරිය සමග ගිවිසුමකට ඇතුළත් විය යුතු ය.

63. (1) ලියාපදිංචි කිරීමේ සහතිකය නිකුත් කිරීමෙන් පසු සහ සහතිකය දරන්නාගේ ලිඛිත ඉල්ලීමක් මත ශ්‍රී ලංකාවට එම ඖෂධය ආනයනය කිරීම සඳහා සහ එය අලෙවි කිරීම සඳහා වූ බලපත්‍රයක් අධිකාරිය විසින් සහතිකය දරන්නා වෙත නිකුත් කරනු ලැබිය හැකි ය.

(2) යම් ආනයනකරුවකු විසින් ආනයනය කරනු ලබන සෑම ඖෂධයකම තත්ත්වය, ආරක්ෂා සහිත බව සහ ප්‍රතක්ෂභාවය පිළිබඳව සහතිකවීම එම ආනයනකරුගේ වගකීම විය යුතු ය.

[redacted]ම් ලියාපදිංචියක් හෝ බලපත්‍රයක කාලය අවසන්වීමේ දිනයට මාස හයකට පෙර එම ලියාපදිංචිය හෝ බලපත්‍රය අලුත් කිරීම සඳහා සහතිකය දරන්නා විසින් අධිකාරිය වෙත ඉල්ලීමක් ඉදිරිපත් කරනු ලැබිය හැකි ය.

(2) ලියාපදිංචිය හෝ බලපත්‍රය අලුත් කිරීම සඳහා වූ ඉල්ලීමක් නියමිත ආකෘති පත්‍රය අනුව විය යුතු අතර එම ඉල්ලීම සමග නියමිත ගාස්තුව ඉදිරිපත් කරනු ලැබිය යුතු ය.

ලියාපදිංචිය සහ බලපත්‍රය අවලංගු කිරීම හෝ අත්හිටුවීම.

[redacted]අධිකාරිය වෙත ඉල්ලීමක් ලැබීමේ දී, අධිකාරිය විසින් එම ඉල්ලීම පිළිබඳ මතය දැනගැනීම සඳහා එම ඉල්ලීම එම්ඊසී වෙත ඉදිරිපත් කරනු ලැබිය යුතු ය.

(4) එම ඖෂධය ඇගයීම සඳහා ඉල්ලුම්කරුගෙන් හෝ වෙනත් යම් තැනැත්තකුගේ හෝ ආයතනයකින් අවශ්‍ය යැයි සලකනු ලබන සාම්පල, ලේඛන හෝ වෙනත් යම් සාක්ෂියක් ලබාදෙන ලෙස එම්ඊසී විසින් අධිකාරිය මගින් ඉල්ලීමක් කරනු ලැබිය හැකි ය.

(5) එම්ඊසී විසින් අවශ්‍ය යයි සලකනු ලබන අවස්ථාවල දී එම ඖෂධය පිළිබඳ ඇගයීම් වාර්තාවක් ඉදිරිපත් කරන ලෙස, එම්ඊසී

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

අංක 2145/1 - 2019 ඔක්තෝබර් මස 14 වැනි සඳුදා - 2019.10.14

(රජයේ බලයපිට ප්‍රසිද්ධ කරන ලදී)

I වැනි කොටස: (I) වැනි ඡෙදය - සාමාන්‍ය

රජයේ නිවේදන

එල්. ඩී. බී. 9/2016

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 142 වන වගන්තිය යටතේ සෞඛ්‍ය, පෝෂණ හා දේශීය වෛද්‍ය අමාත්‍යවරයා විසින් සාදනු ලබන නියෝග.

වෛද්‍ය රුජිත සේනාරත්න (පා.මි.),
සෞඛ්‍ය, පෝෂණ හා දේශීය වෛද්‍ය අමාත්‍ය

2019 ඔක්තෝබර් 11,
කොළඹ දී ය.

නියෝග

1. (1) මේ නියෝග 2019 ජාතික ඖෂධ (ඖෂධ ලියාපදිංචි කිරීමේ සහ බලපත්‍ර ලබාදීමේ) නියෝග යනුවෙන් හඳුන්වනු ලැබේ.

(2) නුදෙක්ම සත්ත්වයන් සඳහා භාවිත කරනු ලබන ඖෂධ සඳහා හැර සියලු ඖෂධ සඳහා මේ නියෝග අදාළ විය යුතු ය.

I වන කොටස

ඖෂධ ලියාපදිංචි කිරීම

2. (1) (මෙහි මින් මතු "අධිකාරිය" යනුවෙන් සඳහන් කරනු ලබන) ජාතික ඖෂධ නියාමන අධිකාරියෙහි ඖෂධයක් ලියාපදිංචි කිරීමට අදහස් කරන බලපත්‍රලාභී දේශීය නිෂ්පාදකයකු විසින් හෝ අධිකාරිය විසින් අනුමත කරනු ලැබූ විදේශීය නිෂ්පාදකයකුගේ බලයලත් ආනයනකරුවකු විසින් අධිකාරිය වෙත ඉල්ලුම් පත්‍රයක් ඉදිරිපත් කරනු ලැබිය යුතු ය.

1A - PG 4687 — 617 (2019/10)

(ඍ) ඉලක්කගත සැකසුම් කාල සීමා

පහතින් විධිවිධාන සලස්වා ඇති පරිදි ඉල්ලුම්පත්‍ර සඳහා වන ඉලක්කගත සැකසුම් කාලසීමා සපුරාලීමට අධිකාරිය විසින් ප්‍රයත්න දරනු ලැබිය යුතු ය.

ඉල්ලුම් පත්‍රයේ වර්ගය	සැකසුම් කාල සීමාව (වැඩ කරන දින ගණන)
ලියාපදිංචි ඩොසියරයක් සම්පූර්ණත්වය පිළිබඳ මූලික පරීක්ෂණය	15
ලියාපදිංචි ඩොසියරයක් ඇගයීම	300
ප්‍රමුඛතා පදනම මත ලියාපදිංචි ඩොසියරයක් ඇගයීම	180
අතිරේක දත්ත ඇගයීම	180
ස්ථානයේ ප්‍රධාන ලිපිගොනුව ඇගයීම	180
සැකැස්ම මැඩි දියුණු කිරීම සඳහා වන අනුමැතිය ලබා ගැනීම සඳහා වන ඉල්ලුම්පත්‍රය	90
ඖෂධ නිෂ්පාදනයක් සඳහා වන සහතිකය (බෘතිසවය) ලබා ගැනීම සඳහා වන ඉල්ලුම්පත්‍රය	10
විදේශීය නිෂ්පාදකයකු සඳහා අනුමැතිය ලබා ගැනීම සඳහා වන ඉල්ලුම්පත්‍රය	180
පෞද්ගලික භාවිත කරන්නකු සඳහා වන බලපත්‍රය සඳහා වන ඉල්ලුම්පත්‍රය	02
ජීඑම්පී අධීක්ෂණ වාර්තාව (අධීක්ෂණයේ දින සිට)	30
සිල්ලර ඔසුසලක් සඳහා වන බලපත්‍රය සඳහා වන ඉල්ලුම්පත්‍රය	180
සිල්ලර ඔසුසලක් සඳහා වන බලපත්‍රය අලුත් කිරීම සඳහා වන ඉල්ලුම්පත්‍රය	120
තොග වශයෙන් විකිණීම සඳහා වන බලපත්‍රය සඳහා වන ඉල්ලුම්පත්‍රය	120
තොග වශයෙන් විකිණීම සඳහා වන බලපත්‍රය අලුත් කිරීම සඳහා වන ඉල්ලුම්පත්‍රය	120
ප්‍රවාහන බලපත්‍රය සඳහා වන ඉල්ලුම්පත්‍රය	60
බලපත්‍රලත් ඖෂධ නිෂ්පාදකයකු ලෙස කටයුතු කිරීම සඳහා වන ඉල්ලුම්පත්‍රය	10
ලියාපදිංචි කළ ඖෂධයක් නිෂ්පාදනය කිරීම සඳහා වන ඉල්ලුම්පත්‍රය	10

(අ) මේ කාලරාමු

(i) වැඩකරන දින වලට පමණක් අදාළ විය යුතු අතර ඊට ප්‍රසිද්ධ නිවාඩු දින සහ අන්ත ඇතුළත් නොවිය යුතු

(ii) පෙරසැරි ගාස්තුව ගෙවීමෙන් අනතුරුව සැකසීම සඳහා ඉල්ලුම් පත්‍රයක් බාරගෙන ඇති විට දී පමණ ආරම්භ විය යුතු ය.

(ආ) අධිකාරිය විසින් අමතර දත්ත ඉල්ලා සිටිනු ලබන හෝ පරීක්ෂණයේ දී සොයා දැනගත් ඌනතා සම්පූර්ණ ලෙස නියම කරනු ලබන කවර හෝ විටක දී අවසන් කළයුතු කාල සීමාව අත්හිටුවනු ලැබේ.

(ඇ) අධිකාරිය විසින් නිශ්චිතව සඳහන් කාල රාමුව තුළ ඇගයීම අවසන් කරනු ලැබිය යුතු වුවද, ඉල්ලුම්කරුවන් ඉල්ලුම් පත්‍රයට අදාළ තීරණය පිළිබඳ පූර්වානුමතය කරනු නොලැබිය යුතු ය.

(ඈ) නිශ්චිතව සඳහන් කාලරාමුව තුළ ඉල්ලුම්පත්‍රයක් සම්බන්ධයෙන් තීරණයක් ගැනීමට අපොහොසත්වීම ඇති වන හෝ උද්ගත වන ඕනෑම ආකාරයක පාඩුවක්, හානියක් හෝ පීඩාවක් සම්බන්ධයෙන් අධිකාරිය හෝ කාර්ය මණ්ඩලය විසින් යම් තැනැත්තකුට වගකියනු නොලැබේ.

ශ්‍රී ලංකා රජයේ මුද්‍රණ දෙපාර්තමේන්තුවේ මුද්‍රණය කරන ලදී.

ලියාපදිංචිය සඳහා ඉදිරිපත් වූ නව ඖෂධ ගොනු අතුරින් 2023 ජුනි 30 දිනට පොරොත්තුව පැවති ගොනු

	ඩොසියරය ලද දිනය	ඩොසියර අංකය	ඖෂධයේ නම
1	7/1/2022	M/4385/NP/2022	Empagliflozin Tablet 25mg
2	7/1/2022	M/4387/NP/2022	Pemetrexed Powder, for Solution 500mg
3	24/01/2022	M/4399/NP/2022	Etoricoxib tablets 90mg
4	31/01/2022	M/4404/NP/2022	Rosuvastatin Tablet 5mg
5	31/01/2022	M/4408/NP/2022	0.45% Sodium Chloride & 5% Glucose Intravenous Infusion BP
6	31/01/2022	M/4409/NP/2022	Rosuvastatin 10mg
7	3/2/2022	M/4413/NP/2022	Sterile Cardioplegia Solution 20ml
8	7/2/2022	M/4416/NP/2022	Octreotide Injection 50mcg/ml
9	7/2/2022	M/4418/NP/2022	Fusidic Acid Cream BP 2%w/w
10	11/2/2022	M/4422/NP/BTP/2022	Bevacizumab 100 mg/4 ml concentrate solution for infusion
11	11/2/2022	M/4423/NP/BTP/2022	Bevacizumab 400 mg/ 16ml concentrate solution for infusion
12	11/2/2022	M/4424/NP/2022	Ascorbic Acid Chewable Tablet 500mg
13	18/02/2022	M/4430/NP/2022	Emitricitabine and Tenofovir Disoproxil Fumarate Tablets 200 mg/300mg
14	18/02/2022	M/4431/NP/PQ/VAC/2022	Rotavirus Vaccine (Live, Oral) BP
15	18/02/2022	M/4434/NP/2022	Fluoxetine Capsule BP 20mg
16	21/02/2022	M/4436/NP/2022	Aceclofenac Tablets 100mg
17	25/02/2022	M/4437/NP/2022	Sodium Hyaluronate Sterie Injection 20mg/2ml
18	25/02/2022	M/4438/NP/2022	vitamin B complex Injection
19	28/02/2022	M/4441/NP/2022	Letrozole Film Coated Tablet 2.5 mg
20	28/02/2022	M/4447/NP/2022	Rabeprazole capsules 20mg
21	4/3/2022	M/4448/NP/2022	Carbozantinib Tablets 60 mg
22	4/3/2022	M/4449/NP/2022	Cefuroxime Axetil Tablets USP 250mg
23	4/3/2022	M/4451/NP/BTP/2022	Enoxaparin Injection 60 mg
24	4/3/2022	M/4454/NP/2022	Cholecalciferol Orally Disintegrating Tablets 2000IU
25	4/3/2022	M/4456/NP/2022	Cholecalciferol Tablets 1000IU
26	4/3/2022	M/4457/NP/2022	Duloxatine Hydrochloride Delayed release capsules 20 mg
27	4/3/2022	M/4458/NP/2022	Duloxatine Hydrochloride Delayed release capsules 30 mg
28	4/3/2022	M/4459/NP/2022	Duloxatine Hydrochloride Delayed release capsules 60 mg

29	4/3/2022	M/4461/NP/2022	Olopatadine Hcl Opthalmic Solution USP 0.2% w/v
30	4/3/2022	M/4462/NP/2022	Irbesartan Tablets USP 300 mg
31	4/3/2022	M/4463/NP/2022	Moxifloxacin Tablet 400mg
32	4/3/2022	M/4464/NP/2022	Oral rehydration salt 4.3g
33	4/3/2022	M/4465/NP/2022	Methylprednisolone Sodium Succinate for Injection USP 1g
34	4/3/2022	M/4466/NP/2022	Methylprednisolone Sodium Succinate for Injection USP 500mg
35	4/3/2022	M/4467/NP/2022	Co-Amoxiclav for Injection BP 1.2g
36	7/3/2022	M/4470/NP/2022	Colecalciferol Tablets BP 2000 IU
37	7/3/2022	M/4471/NP/2022	Sodium Valproate and valproic acid controlled release Tablets 200mg
38	11/3/2022	M/4472/NP/2022	Diclofenac Potassium Tablet USP
39	11/3/2022	M/4474/NP/2022	Sodium Valproate and valproic acid controlled release Tablets 300mg
40	11/3/2022	M/4480/NP/BTP/NFDC/2022	Pertuzumab ,Trastuzumab, HyaLuronidase 1200 mg, 600mg, 30000 Units Per 15ml
41	11/3/2022	M/4481/NP/BTP/NFDC/2022	Pertuzumab ,Trastuzumab, HyaLuronidase 600 mg, 600mg, 20000 Units Per 15ml
42	11/3/2022	M/4482/NP/2022	Desloratadine syrup 2.5mg/5ml
43	14/03/2022	M/4486/NP/2022	Tacrolimus Capsules USP 0.5mg
44	14/03/2022	M/4487/NP/2022	Tacrolimus Capsules USP 1.0mg
45	14/03/2022	M/4488/NP/2022	Cyclosporine Oral Solution USP 100mg/ml
46	14/03/2022	M/4489/NP/2022	Empagliflozin Tablet 25mg
47	14/03/2022	M/4490/NP/2022	Pantroprazole sodium delayed release tablet USP 20mg
48	14/03/2022	M/4491/NP/2022	Prednisolone Acetate Opthalmic Suspension USP 1% W/V
49	14/03/2022	M/4492/NP/2022	Sodium Valporate & Acid Controlled Release Tablets 500 mg
50	14/03/2022	M/4493/NP/2022	Linagliptin Tablets film coated 5mg
51	14/03/2022	M/4494/NP/2022	Diclofenac Sodium Suppositories 100mg
52	18/3/2022	M/4498/NP/2022	Chewable Ascorbic acid Tablet BP 500 mg
53	18/03/2022	M/4499/NP/BTP/2022	Rituximab Injection(Concentrate ,solution for infusion) 10mg/ml
54	18/03/2022	M/4500/NP/2022	Celecoxib capsules BP 200 mg
55	18/03/2022	M/4501/NP/2022	Celecoxib capsules BP 100 mg
56	18/03/2022	M/4502/NP/2022	Meloxicam Tablet (uncoated) USP 7.5 mg
57	18/03/2022	M/4505/NP/2022	Memantine Hydrochloride Tablets 5mg

58	18/03/2022	M/4506/NP/2022	Ibandronic Acid Tablets 150mg
59	21/03/2022	M/4511/NP/BTP/NCE/2022	Atezolizumab Injection 1200mh/20ml
60	21/03/2022	M/4512/NP/2022	Paracetamol Solution for Intravenous Infusion 10 mg/mL
61		M/4516/NP/2022	Aspirin delayed release Capsules USP 100 mg
62	25/03/2022	M/4517/NP/2022	Lamotrigine Tablet (Uncoated) 50mg
63	25/03/2022	M/4518/NP/2022	Lamotrigine Tablet (Uncoated) 100mg
64	25/03/2022	M/4519/NP/2022	Rosuvastatin Tablet 10 mg
65	25/03/2022	M/4522/NP/2022	Pregabalin Capsules 150 mg
66	28/03/22	M/4529/NP/2022	Labetarol Hydrochloride Tablets USP 100mg
67	28/03/2022	M/4530/NP/2022	Vidagliptin Tablets 50mg
68	28/03/2022	M/4531/NP/2022	Rivaroxaban Film Coated Tablets 2.5mg
69	28/03/2022	M/4532/NP/2022	Rivaroxaban Film Coated Tablets 10mg
70	28/03/2022	M/4533/NP/2022	Rivaroxaban Film Coated Tablets 15mg
71	28/03/2022	M/4534/NP/2022	Rivaroxaban Film Coated Tablets 20mg
72	28/03/2022	M/4537/NP/2022	Amisulpride Tablets BP 200mg
73	28/03/2022	M/4538/NP/2022	Amisulpride Tablets BP 100mg
74	28/03/2022	M/4539/NP/2022	Imipenem & Cilastatin for Injection USP 500mg/vial
75	28/03/2022	M/4540/NP/2022	Zoledronic Acid for Injection 4mg
76	28/03/2022	M/4541/NP/2022	Vancomycin Hydrochloride for Injection USP 1000mg
77	1/4/2022	M/4544/NP/2022	Etoricoxib Tablets 60mg
78	1/4/2022	M/4546/NP/2022	Pantoprazole Gastro-resistant Tablet BP 20 mg
79	1/4/2022	M/4547/NP/2022	Tamsolusin Hydrochloride Capsules USP 0.4mg
80	1/4/2022	M/4548/NP/2022	Pantoprazole Gastro-resistant Tablet BP 40 mg
81	1/4/2022	M/4549/NP/2022	Vancomycin Hydrochloride for Injection USP 500 mh
82	1/4/2022	M/4550/NP/2022	Mebeverine Hydrochloride Midified Release Capsule 200 mg
83	1/4/2022	M/4552/NP/2022	Lamotrigine Tablets USP 100 mg
84	1/4/2022	M/4554/NP/BTP/NCE/2022	Trastuzumab emtansine Injection 100 mg
85	1/4/2022	M/4555/NP/BTP/NCE/2022	Trastuzumab emtansine Injection 160 mg
86	4/4/2022	M/4557/NP/2022	Diazepam Injection 5mg/ml
87	4/4/2022	M/4558/NP/2022	Topiramate Tablets USP 25 mg

88	4/4/2022	M/4563/NP/NCE/2022	Lulicanazole Cream 1.0 % w/w
89	6/4/2022	M/4565/NP/2022	Baclofen Tablets BP 10 mg
90	8/4/2022	M/4566/NP/2022	Danazol xcapsules USP 200MG
91	8/4/2022	M/4568/NP/2022	Terbinafine Tablet USP 250 mg
92	8/4/2022	M/4570/NP/BTP/2022	Somatropin Injection 5mg/1.5ml
93	8/4/2022	M/4572/NP/NCE/2022	Halobetasol propionate ointment 0.05%w/w
94	8/4/2022	M/4573/NP/2022	Rivaroxaban Tablets 10mg
95	8/4/2022	M/4574/NP/2022	Rivaroxaban Tablets 20mg
96	8/4/2022	M/4575/NP/2022	Escitalopram Tablets USP 20mg
97	8/4/2022	M/4576/NP/2022	Escitalopram Tablets USP 5mg
98	8/4/2022	M/4579/NP/2022	Finasteride Tablets USP 5mg
99	8/4/2022	M/4581/NP/2022	Etoricoxib Tablets 90mg
100	8/4/2022	M/4583/NP/2022	Prednisolone Tablets BP20mg
101	18/04/2022	M/4584/NP/NFDC/LMP/2022	Empagliflozin and Metformin Hydrochloride Tablets 5 mg/500 mg
102	22/04/2022	M/4590/NP/2022	Clopidogrel Tablets USP 75 mg
103	22/04/2022	M/4594/NP/2022	Amisulpride Tablets IP 300mg
104	22/04/2022	M/4595/NP/2022	Escitalopram Tablets USP 20mg
105	22/04/2022	M/4597/NP/2022	Vitamin C 500mg chewable tablets
106	22/04/2022	M/4598/NP/2022	Sodium Valproate & Valproic Acid Controlled release tablets 500mg
107	22/04/2022	M/4600/NP/2022	Clopidogrel Tablets USP 75 mg
108	22/04/2022	M/4603/NP/2022	Colecaalciferol (Vitamin D3) Chewable tablets 400 IU
109	25/04/2022	M/4605/NP/2022	Imiquimod 5% w/w Cream
110	25/04/2022	M/4607/NP/BTP/2022	Rituximab Injection 100mg/10ml, 500mg/50ml
111	25/04/2022	M/4609/NP/2022	Meloxicam Tablets BP 7.5mg
112	25/04/2022	M/4612/NP/NCE/2022	Apixaban Tablet 5mg
113	25/04/2022	M/4613/NP/NCE/2022	Dabigatran Etexilate Capsules 110mg
114	25/04/2022	M/4616/NP/2022	Azithromycin capsules USP 250mg
115	25/04/2022	M/4618/NP/2022	Metformin Hudrochloride Extended Release Tablet USP 500mg
116	29/04/2022	M/4622/NP/2022	Olmesartan Medoxomil 20mg Tablets
117	29/04/2022	M/4623/NP/2022	Mometasone Furoate Lotion 0.1% w/v
118	29/04/2022	M/4624/NP/2022	Choline Salicylate 9% W/V and Benzalkonium Chloride 0.02% W/V Gel
119	29/04/2022	M/4625/NP/2022	Cilnidipine Tablets 5mg
120	29/04/2022	M/4627/NP/2023	Etoricoxib Tablets 120 mg
121	29/04/2022	M/4630/NP/2022	Clobetasol Propionate Cream USP 0.05% W/W
122	29/04/2022	M/4631/NP/2022	Giefitinib Tablets 250mg

123	29/04/2022	M/4632/NP/2022	Vinorelbine injection USP 10MG/1M;L
124	29/04/2022	M/4633/NP/2022	Colistemethate Sodium (USP) Injection 1 million / (100000 IU) Vial
125	29/04/2022	M/4634/NP/BTP/2022	Insulin Aspart Solution for Injection 100U/ml
126	6/5/2022	M/4637/NP/2022	Azithromycin Tablets 500 mg
127	6/5/2022	M/4638/NP/2022	Enalapril malate Tablets USP 10 mg
128	6/5/2022	M/4640/NP/BTP/2022	Insulin Determir (r DNA) solution for injection 100 IU/ml
129	9/5/2022	M/4642/NP (Site change)	Empagliflozin Tablets 10mg
130	13/05/2022	M/4645/NP/2022	Gemcitabine for injection USP 1G
131	19/5/2022	M/4651/NP/2022	Glycopyrronium 12.5 mcg and Furmeterol Fumarate 12 mcg
132	19/5/2022	M/4652/NP/2022	Gemcitabine For Injection USP 200mg
133	19/5/2022	M/4653/NP/2022	Empagliflozin Tablets 25 mg
134	19/05/2022	M/4654/NP/2022	Betahistine Hydrocholride Tablets BP 24mg
135	20/05/2022	M/4659/NP/2022/EX	Vitamin C 500mg chewable tablets
136	20/05/2022	M/4661/NP/2022/EX	Urea Cream 12% w/w
137	23/05/2022	M/4664/NP/EX	Adrenaline Injection Bp 1 mg/1 mL
138	23/05/2022	M/4667/NP/2022	Losartan Potassium tablets USP 50mg
139	23/05/2022	M/4668/NP/2022/EX	Epirubicin Hydrochloride for Injection 10 mg/ml
140	23/05/2022	M/4672/NP/2022/EX	Escitalopram Tablets USP 5 mg
141	27/05/2022	M/4673/NP/2022	Dapagliflozin 5mg INN Tablets
142	27/05/2022	M/4674/NP/2022/EX	Cefixime for oral Suspension USP 100mg/5ml
143	27/05/2022	M/4678/NP/BTP/NCE/2022	Atezolizumab Concentrate Solution for Infusion 840mg/14ml
144	27/05/2022	M/4679/NP/2022/EX	Nicorandil Tablets bp 10mg
145	27/05/2022	M/4680/NP/NFDC/2022	Brinzolamide 1% and Brimonidine Tartrate 0.2 % Opthalmic Suspension
146	27/05/2022	M/4681/NP/2022	Glucose Intravenous Infusion BP 5% W/V
147	30/05/2022	M/4686/NP/2022/EX	Amlodipine Besylate Tablets USP 5mg
148	30/05/2022	M/4687/NP/2022/EX	Vitamin C Chewable Tablets 500 mg
149	30/05/2022	M/4688/NP/2022/EX	Pemetrexed injection IP 500mg/vial
150	30/05/2022	M/4689/NP/2022	Levetiracetam tablet 250mg
151	30/05/2022	M/4690/NP/2022/EX	Celecoxib capsules 100 mg
152	30/05/2022	M/4691/NP/2022	Solifenacin Succinate Tablets 5 mg
153	30/05/2022	M/4695/NP/2022/EX	Epirubicin Hydrochloride for Injection 50mg/vial

154	3/6/2022	M/4698/NP/2022/Ex	Fluoxetine Capsules USP
155	6/6/2022	M/4705/NP/NFDC/LMP/2022	Empagliflozin and Metformin Hydrochloride Tablets 12.5 mg/500 mg
156	6/6/2022	M/4706/NP/LMP/2022	Propranolol Hydrochloride Tablets USP 10mg
157	6/6/2022	M/4714/NP/2022/EX	Pantoprazole Enteric Coated Tablets 40mg
158	6/6/2022	M/4716/NP/2022/EX	Pantoprazol sodium Delayed Release Tablets USP 40 mg
159	6/6/2022	M/4717/NP/2022/EX	Loratadine Tablets USP 10mg
160	6/6/2022	M/4718/NP/2022/EX	Aceclofenac Tablets 100mg
161	6/6/2022	M/4720/NP/2022/EX	Levofloxacin Tablets 250mg
162	6/6/2022	M/4721/NP/BTP/2022/EX	Somatropin 15mg/1.5ml solution for injection (Human growth Hormone)
163	6/6/2022	M/4722/NP/2022	Letrozole Tablets 2.5 mg
164	6/6/2022	M/4724/NP/2022	Celecoxib Capsules 100 mg
165	10.06.2022	M/4725/NP/2022	Lamotrigine Extended Release Tablets 100mg
166	10.06.2022	M/4727/NP/2022	Paclitaxel Injection USP 6 mg/mL
167	10.06.2022	M/4731/NP/2022	Rivaroxaban Tablets 10 mg
168	16/06/2022	M/4736/NP/2022	congugated estrogen tablets USP 1.25mg
169	16/06/2022	M/4737/NP/2022	Rosuvastatin Tablets IP 10mg
170	16/06/2022	M/4738/NP/2022	Gliclazide Modified-Release Tablets 60mg
171	16/06/2022	M/4739/NP/2022	Lamotrigine Extended Release Tablets 50mg
172	16/06/2022	M/4740/NP/2022	Methyl Prednisolone Aceponate Cream 0.1% w/w
173	16/06/2022	M/4742/NP/2022/EX	esomeprazole Tablets 40mg
174	16/06/2022	M/4743/NP/2022	Losartan Pottasium Tablets USP 25mg
175	17/06/2022	M/4744/NP/2022	Solifenacin Succinate Tablets 10 mg
176	17/06/2022	M/4746/NP/2022	Levodopa 200 mg+Carbidopa 50 mg Controlled release tablets
177	17/06/2022	M/4751/NP/2022	Etoposide Injection USP 100mg/5ml
178	17/06/2022	M/4753/NP/2022/EX	Azythromycin Tablets 250 mg
179	20/06/2022	M/4756/NP/2022	Mycophenolic acid delayed release tablet 180mg
180	20/06/2022	M/4757/NP/2022	Gliclazide MR Tablets 30 mg
181	20/06/2022	M/4759/NP/2022	Methyl Prednisolone Aceponate Ointment 0.1% w/w
182	20/06/2022	M/4760/NP/2022	Zolendronic Acid Injection 4mg/5ml
183	20/06/2022	M/4761/NP/2022/EX	Enalapril malate Tablets USP 5 mg
184	24/06/2022	M/4764/NP/2022	Prednisolone Tablets BP 5 mg
185	24/06/2022	M/4766/NP/2022	Donepezil Hydrochloride Tablets USP 5mg

186	24/06/2022	M/4767/NP/2022	Sodium valporate and valporic acid Controlled release tablets 200mg
187	27/06/2022	M/4776/NP/2022	Daclatasvir Tablets 30mg
188	27/06/2022	M/4777/NP/2022/EX	Sodium Valproate oral solution BP 200mg/5ml
189	27/06/2022	M/4778/NP/2022	:Leveteracetam Tablets 1000mg
190	27/06/2022	M/4779/NP/2022	Clindamycin Phosphate 1.2% w/w+ Tretinoin 0.025% w/w gel
191	27/06/2022	M/4780/NP/2022	Cefuroxime for Injection USP 250mg
192	1/7/2022	M/4781/NP/NCE/2022	Ceftazidime 2g and Avibactam 0.5g powder for concentrate for solution for infusion
193	1/7/2022	M/4782/NP/2022/EX	Nifedipine Prolonged Release Tablets 30 mg
194	1/7/2022	M/4784/NP/2022	Levetiracetam Tablet 1000mg
195	1/7/2022	M/4785/NP/2022	Clarithromycin Tablets USP 250 mg
196	1/7/2022	M/4786/NP/NCE/2022	Teriparatide Injection IP 750mcg/3mL (Recombinant Human Parathyroid Hormone)
197	01/072022	M/4787/NP/2022/EX	Linezolid Tablets 600mg
198	1/7/2022	M/4788/NP/2022/EX	Tamsulosin Hydrochloride Capsules USP 0.4mg
199	1/7/2022	M/4789/NP/2022	Donepezil Hydrochloride Tablets USP 10mg
200	4/7/2022	M/4792/NP/NFDC/2022	Amlodipine 5mg + Valsartan 80mg Tablets USP
201	4/7/2022	M/4793/NP/2022	Levofloxacin Tablets USP 500mg
202	08.07.2022	M/4799/NP/2022	Vildagliptin Tablets 50mg
203	11/7/2022	M/4805/NP/2022	Vildagliptin Tablets 50 mg
204	11/7/2022	M/4806/NP/2022	Dapagliflozin 10mg INN Tablets
205	15/07/2022	M/4809/NP/2022/Ex	Mometasone Furoate Lotion 0.1% w/v
206	15/07/2022	M/4814/NP/NFDC/2022	Amlodipine 5 mg + Valsartan 160 mg Tablets USP
207	15/07/2022	M/4816/NP/2022	Gabapentin Capsules BP 300mg
208	15/07/2022	M/4818/NP/2022/EX	Simvastatin Tablets 20 mg
209	15.07.2022	M/4821/NP/2022/Ex	Clotrimazole cream BP 1% w/w
210	18/07/2022	M/4822/NP/BTP/2022	Bevacizumab Injection for Intravenous Infusion, 100mg/4ml
211	18/07/2022	M/4823/NP/2022	Celecoxib Capsules 200 mg
212	18/07/2022	M/4824/NP/2022	Mycophenolic acid delayed release tablet USP 360mg
213	18/07/2022	M/4825/NP/EX/2022	Meropenem for Injection USP 1g/vial
214	18/07/2022	M/4826/NP/EX/2022	Meropenem for Injection USP 500 mg/vial

215	18/07/2022	M/4827/NP/NFDC/2022	Amlodipine 10 mg+ Valsartan 160 mg Film coated Tablets USP
216	18/07/2022	M/4829/NP/EX/2022	Atorvastatin Tablets 20mg
217	22/07/2022	M/4830/NP/2022	Mesalamine Delayed Release Tablet USP 400mg
218	22/07/2022	M/4831/NP/2022	Alprazolam Tablets USP 0.5mg
219	22/07/2022	M/4832/NP/2022	Memantine Hydrochloride Tablet 10mg
220	22/07/2022	M/4834/NP/2022	Venlafaxine Prolonged Release Capsules BP 150mg
221	22/07/2022	M/4835/NP/2022	Venlafaxine Prolonged Release Capsules BP 37.5 mg
222	22/07/2022	M/4836/NP/2022	Venlafaxine Prolonged Release Capsules BP 75 mg
223	22/07/2022	M/4837/NP/2022	Vincristine Sulfate Injection USP 1mg/ml
224	22/07/2022	M/4839/NP/2022/EX	Esomeprazole Delayed Release Capsules USP 20mg
225	22/07/2022	M/4840/NP/2022	Clonazepam Tablet USP 2mg
226	22/07/2022	M/4841/NP/2022	Betahistine Hydrocholride Tablets BP 16mg
227	22/07/2022	M/4842/NP/2022	Fexofenadine Hydrochloride Tablets USP 180 mg
228	22/07/2022	M/4843/NP/2022	Losartan Potassium 50 mg and Hydrochlorothiazide 12.5 mg Tablets USP
229	25/07/2022	M/4845/NP/2022	Fosaprepitant Dimeglumine for Injection 150mg
230	25/07/2022	M/4846/NP/2022	Ursodeoxycholic acid 250mg capsules
231	25/07/2022	M/4849/NP/2022	Ribocicilib Tablets 200mg
232	25/07/2022	M/4850/NP/2022	Etoposide Capsules USP 50mg
233	25/07/2022	M/4852/NP/2022/EX	Ketotifen Tablets 1mg
234	29/07/2022	M/4853/NP/2022	Vitamin D3 USP Film Coated Tablets 1000 IU
235	29/07.2022	M/4854/NP/2022	Tofacitinib 11mg Tablet
236	29/07/2022	M/4855/NP/2022/EX	Metformin Hydrochloride Tablets USP 500mg
237	29.07.2022	M/4856/NP/2022	Mesna Injection 400mg/ml
238	29.07.2022	M/4857/NP/2022	Lamotrigine Dispersiable Tablets 50mg
239	29.07.2022	M/4858/NP/2022/EX	Cisplatin Injection BP 10mg/10ml
240	29.07.2022	M/4859/NP/2022	Tizanidine 4 mg
241	29.07.2022	M/4861/NP/2022	Tranexamic Acid Tablets BP 500mg
242	29.07.2022	M/4862/NP/LMP/2022	Formeterol Fumarate 6 mcg and budenoside 400 mcg pressurized inhalation, suspension
243	29/07/2022	M/4865/NP/2022	Etoricoxib Tablets 120 mg

244	1/8/2022	M/4871/NP/2022/EX	Etoricoxib Tablets 60 mg
245	1/8/2022	M/4874/NP/2022	Diclofenac Gel BP 1%
246	1/8/2022	M/4875/NP/2022	Afatinib Tablets 40 mg
247	5/8/2022	M/4882/NP/2022	Losartan Potassium Tablets USP 25 mg
248	5/8/2022	M/4884/NP/2022	Losartan Potassium Tablets USP 50 mg
249	5/8/2022	M/4885/NP/2022	Gliclazide Prolonged Release Tablets 60mg
250	5/8/2022	M/4886/NP/2022	Rosuvastatin Tablets 20 mg
251	5/8/2022	M/4889/NP/2022	Teicoplanin Injection IP 400mg
252	5/8/2022	M/4891/NP/2022/EX	Pregabalin Capsules 75mg
253	5/8/2022	M/4892/NP/2022/EX	Pregabalin Capsules 50mg
254	5/8/2022	M/4893/NP/2022	Erlotinib Tablets 100mg
255	8/8/2022	M/4895/NP/2022	Hydralazine Hydrochloride Injection USP 20 mg/1ml
256	8/8/2022	M/4899/NP/2022	Febuxostat Tablets 40 mg
257	8/8/2022	M/4900/NP/2022	Etoposide Capsules USP 100mg
258	8/8/2022	M/4901/NP/2022/EX	Olanzapine Tablets USP 5 mg
259	8/8/2022	M/4902/NP/2022/EX	Olanzapine Tablets USP 10 mg
260	8/8/2022	M/4904/NP/2022/EX	Levofloxacin Tablets 500 mg
261	12/8/2022	M/4906/NP/2022	Salbutamol Pressurized Inhalation Suspension BP 100mcg /dose
262	12/8/2022	M/4909/NP/2022	Buproprione Hydrochloride extended release tablets 150mg
263	12/8/2022	M/4911/NP/2022	Candesartan Cilexetil Tablets USP 8 mg
264	12/8/2022	M/4913/NP/2022/EX	Levetitacetam Injection USP 500mg/5ml
265	15/08/2022	M/4914/NP/2022	Olopatadine HCl Ophthalmic Solution USP 0.1% w/v
266	15/08/2022	M/4915/NP/2022	Nepafenac Ophthalmic Suspension 1mg/ml
267	15/08/2022	M/4916/NP/LMP/2022	Vitamin E Capsules USP 400 mg
268	15/08/2022	M/4917/NP/2022	Polyethylene Glycol 0.4% w/v & Propylene Glycol 0.3% w/v Eye Drops
269	15/08/2022	M/4918/NP/2022	Febuxostat Tablets 80 mg
270	15/08/2022	M/4919/NP/2022/EX	Loperamide Capsules BP 2 mg
271	15/08/2022	M/4921/NP/2022/EX	Candesartan Cilexetil Tablets USP 16mg
272	15/08/2022	M/4922/NP/2022/EX	Azithromycin Capsules USP 250mg
273	19/08/2022	M/4924/NP/2022	Betamethasone 0.5mg/g and Gentamicin 1.0mg/g Cream
274	19/08/2022	M/4925/NP/2022	Ticagrelor Tablets 90mg
275	19/08/2022	M/4926/NP/2022	Teicoplanin Injection IP 200mg
276	19/08/2022	M/4927/NP/2022/EX	Hyoscine Butylbromide Tablets BP

			10mg
277	19/08/2022	M/4928/NP/2022/EX	Cefotaxime for Injection USP 1g/vial
278	19/08/2022	M/4929/NP/2022	Salbutamol 100mcg and Ipratropium Bromide 20mcg Inhaler
279	22/08/2022	M/4931/NP/2022	Ofloxacin Ophthalmic Solution USP 0.3% w/v
280	22/08/2022	M/4932/NP/2022	Suxamethonium Chloride Injection 50 mg/mL
281	22/08/2022	M/4935/NP/2022	Vildagliptin Tablets 50 mg
282	22/08/2022	M/4936/NP/2022	Brinzolamide Ophthalmic Suspension 1% w/v
283	22/08/2022	M/4937/NP/2022	Olapatadine Hydrochloride Ophthalmic Solution 1% w/v
284	22/08/2022	M/4943/NP/2022	Metformin Tablets BP 850 mg
285	26/08/2022	M/4944/NP/2022/EX	Chloramphenicol Capsules 250mg
286	26/08/2022	M/4945/NP/2022	Tamsulosin Hydrochloride and Dutasteride capsules 0.4mg/0.5mg
287	26/08/2022	M/4946/NP/2022	Ketoconazole Shampoo USP 2%
288	26/08/2022	M/4948/NP/2022	Esomeprazole Gastro-Resistant Tablet I.P 20mg
289	26/08/2022	M/4949/NP/2022/EX	Celecoxib Capsules 200 mg
290	26/08/2022	M/4950/NP/2022/EX	Beclomethasone Dipropionate DP caps 200 mg
291	29/08/2022	M/4955/NP/2022	Rosuvastatin Tablets USP 20mg
292	29/08/2022	M/4958/NP/2022	Aceclofenac Tablets 100mg
293	29/08/2022	M/4960/NP/NFDC/2022	Solution for Peritonial Dialysis
294	29/08/2022	M/4961/NP/2022	Sitagliptin tablets USP 25mg
295	29/08/2022	M/4962/NP/2022/EX	Bisoprolol Fumarate Tablets USP 5mg
296	29/08/2022	M/4965/NP/2022/EX	Cephalexin Capsules USP 250mg
297	29/08/2022	M/4966/NP/2022	Rivaroxaban Tablets Ph Eur 2.5 mg
298	2/9/2022	M/4968/NP/2022/EX	Glibenclamide Tablet BP 5mg
299	2/9/2022	M/4969/NP/2022/EX	Azithromycin Capsules USP 500mg
300	2/9/2022	M/4970/NP/2022	Glycopyrronium 12.5mcg, Formeterol Fumarate 12mcg & Fluticasone Propionate 250mcg powder for Inhalation
301	2/9/2022	M/4971/NP/2022/EX	Clarithromycin for oral suspension USP 125mg/5mg
302	2/9/2022	M/4972/NP/2022/EX	Levodopa 250mg+ Carbidopa 25mg Tablets BP
303	2/9/2022	M/4973/NP/2022	Paopanib Tablets 200mg
304	2/9/2022	M/4976/NP/2022	Lamotrigine Dispersiable Tablets 100mg
305	2/9/2022	M/4978/NP/2022/EX	Zinc Sulphate Dispersible Tablets USP 20mg

306	5/9/2022	M/4981/NP/EX/2022	Moxifloxacin Ophthalmic Solution USP 5mg/ml
307	5/9/2022	M/4983/NP/2022	Sitagliptin Tablets USP 5mg
308	5/9/2022	M/4985/NP/EX/2022	Telmisartan Tablets USP 80mg
309	5/9/2022	M/4986/NP/2022	Lamotrigine Tablet 25mg
310	09.09.2022	M/4990/NP/2022/EX	Bisacodyl Tablets BP 5mg
311	09.09.2022	M/4991/NP/2022/EX	Montelukast Sodium Tablet 10mg
312	09.09.2022	M/4992/NP/2022/EX	Oxaliplatin Injection 100mg
313	09.09.2022	M/4993/NP/2022	Drospirenone Ethinylestradiol Tablet with Inert Tablets 3mg/0.02mg
314	09.09.2022	M/4996/NP/2022	Quetiapine Tablet 100mg
315	09.09.2022	M/4997/NP/2022	Cilnidipine Tablets 10mg
316	12/9/2022	M/4999/NP/2022/EX	Betamethasone Sodium Phosphate Drops for Eye, Ear and Nose 0.1% w/v
317	12/9/2022	M/5000/NP/2022/Ex	Irinotecan Hydrochloride Injection 20mg/ml
318	12/9/2022	M/5003/NP/2022	Linezolid Tablets 400mg
319	16/09/2022	M/5007/NP/2022	Formeterol Fumarate BP 10mcg + Fluticasone Propionate BP 250mcg MDI
320	16/09/2022	M/5009/NP/2022/Ex	Ceftriaxone for Injection USP 1g
321	22/09/2022	M/5011/NP/LMP/2022	Carbidopa and Levodopa Tablets USP 25mg/100mg
322	22/09/2022	M/5015/NP/2022	Glucose (Dextrose) Intravenous Infusion BP 10% w/v
323	23/09/2022	M/5018/NP/NCE/2022	Plerixafor Injection 24mg/1.2ml
324	23/09/2022	M/5022/NP/BTP/2022	Recombinant Human Beta 1a Interferon 22mcg
325	23/09/2022	M/5023/NP/2022	Telmisartan 80mg Hydrochlorothiazide 25mg Tablets
326	26/09/2022	M/5039/NP/2022	Mannitol Intravenous Infusion BP 20% w/v
327	26/09/2022	M/5041/NP/LMP/2022	Dextromethorphan Hydrobromide BP 10mg+ Chlopheniramine Maleate BP 3mg+ Menthol USP 4mg/10ml
328	26/09/2022	M/5043/NP/2022/EX	Fexofenadine Hydrochloride Tablets USP 180 mg
329	26/09/2022	M/5046/NP/2022/EX	Fexofenadine Hydrochloride Tablets USP 120 mg
330	26/09/2022	M/5047/NP/2022	Dapagliflozin Tablets 5mg
331	30/09/2022	M/5051/NP/2022	Pregabalin Capsules 50 mg
332	30/09/2022	M/5053/NP/2022/EX	Aluminium Hydroxide Tablets BP 500 mg
333	30/09/2022	M/5054/NP/NFDC/2022	Amlodipine 5mg and Valsartan 160mg Tablets USP
334	30.09.2022	M/5055/NP/2022/EX	Oxaliplatin for Injection 50mg

335	30.09.2022	M/5056/NP/LMP/2022	Lidocaine Injection BP 2% w/v
336	30/09/2022	M/5057/NP2022	Levetitracetam 250 mg Tablets
337	30/09/2022	M/5061/NP/2022	Pantaprazole Injection for BP 40 mg
338	30/09/2022	M/5063/NP/2022/EX	Clomefene Tablets BP 50 mg
339	30.09.2022	M/5065/NP/2022	Sodium Chloride Intravenous Infusion IP 0.9% w/v
340	30.09.2022	M/5066/NP/2022/EX	Esomeprazole Capsules 40mg
341	3/10/2022	M/5068/NP/2022	Levofloxacin Tablets USP 250 mg
342	3/10/2022	M/5070/NP/2022	Vancomycin Hydrochloride for Injection USP 500 mg
343	3/10/2022	M/5071/NP/2022	Telmisartan and Hydrochlorothiazide Tablets USP 80 mg and 12.5 mg
344	3/10/2022	M/5072/NP/2022/EX	Chloramphenicol Sodium Succinate for Injection BP 1 mg
345	3/10/2022	M/5073/NP/2022/EX	Flucloxacillin Powder for Injection BP 500 mg
346	3/10/2022	M/5074/NP/2022/EX	Hydrocortisone Acetate Cream BP 1%
347	3/10/2022	M/5075/NP/2022	Ciprofloxacin Eye Drops IP 0.3% w/v
348	3/10/2022	M/5076/NP/2022	Erlotinib Tablets 150mg
349	7/10/2022	M/5078/NP/2022/EX	Lansoprazole capsules 30mg + Tinidazole tablets 500mg + Clarithromycin tablets USP 250mg
350	7/10/2022	M/5079/NP/2022/EX	Azithromycin tablets USP 250mg
351	7/10/2022	M/5080/NP/2022/EX	Azithromycin tablets USP 500mg
352	7/10/2022	M/5082/NP/2022	Pyrantel Pamoate Oral Suspension USP 50mg/ml
353	7/10/2022	M/5083/NP/2022/EX	Losartan Potassium Tablets USP 25 mg
354	7/10/2022	M/5084/NP/2022/EX	Losartan Potassium Tablets USP 50mg
355	7/10/2022	M/5085/NP/2022	Rosuvastatin Tablets 5mg
356	7/10/2022	M/5086/NP/2022	Diclofenac Sodium Gel 1%w/w
357	7/10/2022	M/5089/NP/NFDC/2022	Amlodipine 10 mg and Valsartan 160 mg Tablets USP
358	7/10/2022	M/5090/NP/LMP/2022	Levetiracetam ER Tablets USP 500 mg
359	7/10/2022	M/5091/NP/LMP/2022	Levetiracetam ER Tablets USP 750 mg
360	10/10/2022	M/5095/NP/2022	Colistimethate Sodium for injection USP 1,000.000 MIU (Million I.U)
361	10/10/2022	M/5099/NP/2022	Ketotifen Fumarate Syrup 1 mg/5 mL
362	10/10/2022	M/5100/NP/2022	Moxifloxacin Tablets USP 400 mg
363	14/10/2022	M/5102/NP/2022/EX	Rivastigmine capsules 3mg
364	14/10/2022	M/5106/NP/2022/EX	Carbimazole Tablets IP 5mg

365	14/10/2022	M/5113/NP/2022/EX	Adrenaline Injection syringe auto-injector 0.15mg/0.3ml
366	14/10/2022	M/5116/NP/BTP/2022	Trastuzumab Lyophilized powder for solution for Infusion 440mg
367	14/10/2022	M/5117/NP/2022/EX	Cetirizine Dihydrochloride Tablets 10mg
368	14/10/2022	M/5118/NP/2022	Vincristine Sulphate Injection USP 2mg
369	14/10/2022	M/5121/NP/2022	Quetiapine FumarateTablet 200mg
370	14/10/2022	M/5125/NP/2022	Mometasone furoate monohydrate nasal spray 50mcg
371	17/10/2022	M/5126/NP/2022	Cilnidipine Tablets 10mg
372	17/10/2022	M/5127/NP/2022	Bromohexine Hydrochloride Tablets 8mg
373	17/10/2022	M/5128/NP/2022	Linezolid Tablets 600mg
374	17/10/2022	M/5129/NP/2022/EX	Pantoprazole Sodium Delayed Release Tablets USP 40mg
375	17/10/2022	M/5130/NP/2022	Vildagliptin Tablets 50 mg
376	17/10/2022	M/5134/NP/BTP/2022	30% Soluble and 70% Isophane Insulin Injection 100IU/ml (rDNA Origin)
377	21.10.2022	M/5140/NP/LMP/2022	Propranolol Injection BP 1mg/ml
378	21.10.2022	M/5145/NP/2022	Solifenacin Succinate Tablets 5mg
379	21.10.2022	M/5146/NP/2022/EX	Levothyroxine Tablets BP 0.05mg
380	28.10.2022	M/5149/NP/LMP/2022/EX	Neostigmine Tablets USP 15mg
381	28/10/2022	M/5150/NP/2022/EX	Empagliflozin INN 25 mg
382	28/10/2022	M/5151/NP/2022	Empagliflozin INN 10 mg
383	28/10/2022	M/5152/NP/LMP/2022	Pantoprazole Gastro-resitant Tablets BP 40mg
384	28/10/2022	M/5154/NP/2022/EX	Tacrolimus Capsules USP 1.0mg
385	28/10/2022	M/5155/NP/2022	Letrozole Tablet USP 2.5 mg
386	28/10/2022	M/5158/NP/2022/EX	Ranitidine Tablets USP 300mg
387	28/10/2022	M/5163/NP/2022/EX	Topiramate Tablets USP 25 mg
388	28/10/2022	M/5165/NP/2022	Bicalutamide Tablets 50mg
389	28/10/2022	M/5166/NP/2022	Telmisartan and Hydrochlorothiazide Tablets USP 40 mg and 12.5 mg
390	28/10/2022	M/5167/NP/2022	Cholecalciferol Chwable Tablets 60.000 IU
391	28/10/2022	M/5168/NP/2022/EX	Topiramate Tablets USP 50 mg
392	28/10/2022	M/5169/NP/2022	Tofacitinib 5mg Tablets
393	28/10/2022	M/5171/NP/LMP/2022	Terazosin Tablets USP 1mg
394	28/10/2022	M/5172/NP/NFDC/2022	Solution for Peritoneal Dialysis
395	28/10/2022	M/5173/NP/2022/EX	Flucloxacillin Powder for Injection BP 500 mg
396	28/10/2022	M/5174/NP/2022/EX	Levothyroxine Tablets BP 0.1mg
397	28/10/2022	M/5176/NP/2022	Tigecycline for injection USP 50 mg

398	31.10.2022	M/5177/NP/2022	Diflucortolone valerate 1mg + Isoconazole nitrate 10mg cream
399	31.10.2022	M/5180/NP/2022	Formeterol Fumarate Dihydrate BP 5 mcg + Fluticasone Propionate BP 125 mcg MDI
400	31.10.2022	M/5181/NP/2022/EX	Danazol Capsules USP 200mg
401	31.10.2022	M/5184/NP/2022	Levetiracetam Tablets USP 500 mg
402	31.10.2022	M/5185/NP/2022	Levofloxacin Tablets USP 500mg
403	31.10.2022	M/5187/NP/2022/EX	Azithromycin Capsules USP 250 mg
404	04.11.2022	M/5189/NP/2022/EX	Glimepiride Tablets USP 2mg
405	04.11.2022	M/5190/NP/2022	Vitamin D3 1000IU/10ml Syrup
406	04.11.2022	M/5191/NP/2022/EX	Aceclofenac SR Capsules 200mg
407	04.11.2022	M/5192/NP/2022/EX	Rosuvastatin Tablets 10mg
408	04.11.2022	M/5193/NP/2022	Dapagliflozin Tablets 10mg
409	04.11.2022	M/5194/NP/2022/EX	Finasteride Tablets 5mg
410	04.11.2022	M/5195/NP/2022	Colistimethate Sodium for injection USP 2 million IU
411	04.11.2022	M/5199/NP/2022	Bicalutamide Tablets 150mg
412	04.11.2022	M/5203/NP/LMP/2022	Oseltamivir Phosphate Capsules USP 30mg
413	11.11.2022	M/5207/NP/2022	Ticagrelor Tablets 60mg
414	11.11.2022	M/5208/NP/2022	Valsartan 50mg + Hydrochlorothiazide 12.5mg Tablets USP
415	11.11.2022	M/5209/NP/2022	Mometasone furoate 0.1% w/w
416	11.11.2022	M/5212/NP/2022	Clotrimazole dusting powder 1% w/w
417	11.11.2022	M/5214/NP/2022	Anastrozole Tablets 1mg
418	11.11.2022	M/5215/NP/2022/EX	Sildenafil Tablets 50mg
419	11.11.2022	M/5216/NP/2022/EX	Tramadol Hydrochloride Capsules BP 50mg
420	11.11.2022	M/5217/NP/2022/EX	Aceclofenac Tablets 100mg
421	14/11/2022	M/5218/NP/LMP/2022	Atorvastatin Calcium Tablets USP 10mg
422	14/11/2022	M/5219/NP/LMP/2022	Atorvastatin Calcium Tablets USP 20mg
423	14/11/2022	M/5220/NP/2022	Colecalciferol (Vitamin D) Tablets BP 1000IU
424	14/11/2022	M/5221/NP/2022/EX	Cetrizine Hydrochloride Tablets 5mg
425	14/11/2022	M/5222/NP/2022	Ticagrelol Tablets 90 mg
426	14/11/2022	M/5223/NP/NDF/2022	Bromohexine Hydrochloride Tablets 8mg
427	14/11/2022	M/5225/NP/LMP/2022	Quinine dihydrochloride Sterile Concentrate BP 600mg/2ml
428	14/11//2022	M/5227/NP/2022/EX	Ceftazidime For Injection USP 1g
429	18/11/2022	M/5236/NP/2022	Terbutaline Syrup 1.5mg/5ml
430	18/11/2022	M/5237/NP/2022	Tranexamic Acid Capsules 500mg

431	18/11/2022	M/5238/NP/2022	Valsartan 160mg + Hydrochlorothiazide 12.5mg Tablets USP
432	18/11/2022	M/5241/NP/LMP/2022	Cilnidipine Tablets 10mg
433	18/11/2022	M/5242/NP/2022	Duloxetine Hydrochloride Capsules 60mg
434	18/11/2022	M/5243/NP/2022	Ropirinol Hydrochloride Tablet USP 0.25 mg
435	18/11/2022	M/5245/NP/2022	Cefixime capsules 200 mg
436	18/11/2022	M/5248/NP/2022	Flunarazine Tablet BP 5 mg
437	18/11/2022	M/5251/NP/2022	Flunarizine Tabvlets BP 10 mg
438	18/11/2022	M/5252/NP/2022	Beclomethasone Dipropionate Aqueous Nasal Spray 0.1% w/v
439	21/11/2022	M/5255/NP/LMP/2022	Formoterol Fumarate Dihydrate 6 mcg and Budesonide 100 mcg Pressurized Inhaler
440	21/11/2022	M/5256/NP/LMP/2022	Formoterol Fumarate Dihydrate 6 mcg and Budesonide 200 mcg Pressurized Inhaler
441	21/11/2022	M/5257/NP/LMP/2022	Formoterol Fumarate Dihydrate 6 mcg and Budesonide 400 mcg Pressurized Inhaler
442	21/11/2022	M/5265/NP/2022	Linezolid Tablets 600mg
443	21/11/2022	M/5268/NP/2022	Capecitabine Tablets USP 500 mg
444	21/11/2022	M/5269/NP/2022	Colecalciferol (Vitamin D) Tablets BP 5 000 IU
445	25/11/2022	M/5270/NP/2022	Mirtazapine Orodispersible Tablets USP 15 mg
446	25/11/2022	M/5273/NP/2022/EX	Carvedilol Tablets 6.25 mg
447	25/11/2022	M/5274/NP/2022/EX	Amoxicillin and Clavulanate Pottasium Tablets USP 625 mg
448	25/11/2022	M/5275/NP/2022/EX	Amoxicillin and Clavulanate Pottasium Tablets USP 375 mg
449	25/11/2022	M/5278/NP/NFDC/2022	Dapagliflozin 5 mg + Metformin 850 mg Tablets
450	25/11/2022	M/5279/NP/LMP/2022	Pregabalin Capsules 75mg
451	25/11/2022	M/5280/NP/LMP/2022	Pregabalin Capsules 150 mg
452	25/11/2022	M/5281/NP/2022	Blossom Pharmaceuticals, India
453	28/11/2022	M/5286/NP/LMP/2022	Fenofibrate Capsules USP 200mg
454	28/11/2022	M/5287/NP/LMP/2022	Fluoxatine Capsules USP 20mg
455	28/11/2022	M/5288/NP/LMP/2022	Carbimazole Tablets BP 5mg
456	28/11/2022	M/5292/NP/2022	Nilotinib Capsules 150mg
457	28/11/2022	M/5293/NP/2022	Mirtazapine Orodispersible Tablets USP 30 mg
458	2/12/2022	M/5294/NP/2022	Colecalciferol (Vitamin D) Tablets BP 2 000 IU
459	2/12/2022	M/5299/NP/LMP/2022	Loratadine Tablets USP 10 mg
460	2/12/2022	M/5301/NP/2022	Esomeprazole Tablets USP 20 mg

461	2/12/2022	M/5304/NP/2022	Miconazole Nitrate Cream USP 2% w/w
462	2/12/2022	M/5305/NP/NCE/2022	Darunavir Tablets 600mg
463	2/12/2022	M/5306/NP/2022	Clindamycin Capsules USP 300mg
464	05.12.2022	M/5307/NP/LMP/2022	Silodosin Capsules 4mg
465	05.12.2022	M/5311/NP/LMP/2022	Glimepiride Tablets USP 4mg
466	05.12.2022	M/5312/NP/LMP/2022	Paracetamol Tablets BP 500mg
467	05.12.2022	M/5313/NP/LMP/2022	Paracetamol Tablets BP 500mg
468	05.12.2022	M/5314/NP/LMP/2022	Esomeprazole delayed release capsule USP 40mg
469	05.12.2022	M/5315/NP/2022	Cefixime for Oral Suspension USP 100mg/5ml
470	05.12.2022	M/5317/NP/2022	Cefixime Capsules 400 mg
471	9/12/2022	M/5318/NP/2022	Vitamin D Tablets BP 60,000 IU
472	9/12/2022	M/5319/NP/2022	Levodopa and Carbidopa Tablets BP (250mg/25mg)
473	9/12/2022	M/5320/NP/2022	Fluticasone Propionate Aqueous Nasal Spray 50mcg/dose
474	9/12/2022	M/5321/NP/2022	Dapagliflozin Tablets 5mg
475	9/12/2022	M/5322/NP/2022	Budesonide Inhaler 200mcg Metered dose Inhaler
476	9/12/2022	M/5323/NP/2022	Desogestrel 150mcg and Ethinylestradiol 30mcg Tablets
477	9/12/2022	M/5324/NP/2022	Salmeterol 50 mcg+Fluticasone Propionate 250mcg Capsules (Powder for inhalation IP)
478	9/12/2022	M/5325/NP/2022	Carbamazepine Oral Suspension USP 100mg/5ml
479	9/12/2022	M/5326/NP/2022	Pivmecillinam Hydrochloride Tablet 200 mg
480	9/12/2022	M/5327/NP/2022	Sildenafil Tablets USP 20mg
481	9/12/2022	M/5328/NP/LMP/2022	Dobutamine Injection USP 250mg/20ml
482	12/12/2022	M/5330/NP/2022	Levodopa and Carbidopa Tablets BP (100 mg/25 mg)
483	12/12/2022	M/5331/NP/BTP/NCE/2022	Pembrolizumab Injection 100 mg/4 mL
484	12/12/2022	M/5334/NP/LMP/NDF/2022	Ritonavir Tablets USP 100 mg
485	12/12/2022	M/5339/NP/2022	Tranexamic Acid Capsules 250 mg
486	12/12/2022	M/5340/NP/2022	Salmeterol 50 mcg+Fluticasone Propionate 500 mcg Capsules (Powder for inhalation IP)
487	16/12/2022	M/5341/NP/2022	Sulfasalazine Tablets BP 500mg
488	16/12/2022	M/5343/NP/2022	Dapagliflozin Tablet 10mg
489	16/12/2022	M/5344/NP/2022	Clotrimazole 1% w/w + Hydrocortisone 1% w/w cream
490	16/12/2022	M/5345/NP/2022	Clobetasol Propionate BP 0.05%

			W/W
491	19/12/2022	M/5346/NP/2022	Solifenacin succinate Tablets 5mg
492	19/12/2022	M/5347/NP/2022	Levodopa & Carbidopa Controlled Release Tablets (200mg/50mg)
493	19/12/2022	M/5348/NP/LMP/2022	Tamsulosin hydrochloride Capsule USP 0.4mg
494	19/12/2022	M/5350/NP/2022	Moxifloxacin Ophthalmic solution USP 5mg/ml
495	19/12/2022	M/5351/NP/2022	Adapalene cream BP 0.1% w/w
496	23/12/2022	M/5353/NP/2022	Budesonide Inhalation Suspension 0.25mg/2ml
497	23/12/2022	M/5354/NP/LMP/2022	Sitaglipting Tablets USP 50 mg
498	23/12/2022	M/5355/NP/LMP/2022	Sitaglipting Tablets USP 100 mg
499	23/12/2022	M/5356/NP/LMP/2022	Folic Acid Tablets USP 1 mg
500	23/12/2022	M/5357/NP/LMP/2022	Eltrombopag tablets 50mg
501	23/12/2022	M/5358/NP/2022	Naproxen Tablets BP 500 mg
502	23/12/2022	M/5359/NP/2022	Amoxicillin and Clavulanate Pottasium powder for oral suspension USP 156.25mg/5ml
503	23/12/2022	M/5360/NP/2022	Oxymetazoline Hydrochloride Nasal solution USP 0.05%
504	23/12/2022	M/5361/NP/2022	Fexofenadine Hydrochloride Tablets USP 180mg
505	23/12/2022	M/5362/NP/2022	Clobetasol Propionate lotion 0.05% W/V
506	23/12/2022	M/5363/NP/2022	Cholecalciferol (Vitamin D3) Tablets 5000IU
507	23/12/2022	M/5364/NP/2022	Resperidone Tablets 2mg
508	30/12/2022	M/5365/NP/LMP/2022	Phenytoin Injection BP 250mg/5ml
509	30/12/2022	M/5366/NP/LMP/2022	Hydralazine Hydrochloride Injection USP 20mg/ml
510	30/12/2022	M/5367/NP/2022	Paracetamol Tablets BP 500mg
511	30/12/2022	M/5368/NP/LMP/2022	Rivaroxaban Tablets 2.5 mg
512	30/12/2022	M/5369/NP/LMP/2022	Rivaroxaban Tablets 10 mg
513	30/12/2022	M/5370/NP/LMP/2022	Ibuprofen Tablets BP 200 mg
514	30/12/2022	M/5372/NP/LMP/2022	Lamivudine and Zidovudine Tablets USP 150mg/300mg
515	30/12/2022	M/5373/NP/BTP/2022	Insulin Glargine Injection IP.(rDNA) 100IU/ml
516	30/12/2022	M/5374/NP/LMP/2022	Prasugel Tablets USP 10mg
517	30/12/2022	M/5375/NP/BTP/2022	Trastuzumab Liophilized power for concentrate for solution for infusion 440mg
518	30/12/2022	M/5376/NP/BTP/2022	Human Chorionic Gonadotropin Injection 5000 IU
519	30/12/2022	M/5377/NP/2022	Ketorolac Tromethamine IM/IV Infusion 30mg/ml

520	30/12/2022	M/5378/NP/2022	Beclomthasone Dipropionate BP 0.025% & Clotrimazole BP 1%
521	30/12/2022	M/5379/NP/LMP/2022	Itraconazole Capsules USP 100 mg
522	30/12/2022	M/5380/NP/LMP/2022	Metformin Hydrochloride Tablets USP 500 mg
523	30/12/2022	M/5381/NP/LMP/2022	Metformin Hydrochloride Tablets USP 850 mg
524	2/1/2023	M/5382/NP/2023	Solifenacin succinate Tablets 10mg
525	02.01.2023	M/5383/NP/2023	Metformin Tablets BP 500mg
526	9/1/2023	M/5385/NP/2023	Budesonide Nebuliser Suspension BP 0.5 mg/ 2ml
527	9/1/2023	M/5386/NP/NCE/2023	Eflornithine Cream 13.9% w/w
528	9/1/2023	M/5392/NP/BTP/2023	Trastuzumab Liophilized powder for solution for infusion 440mg
529	13/01/2023	M/5393/NP/2023	Folic Acid Tablet BP 1 mg
530	13/01/2023	M/5394/NP/2023	Chlorhexidine Gluconate Mouthwash BP
531	13/01/2023	M/5395/NP/2023	Divalproex Sodium Extended Release Tablets USP 500 mg
532	13/01/2023	M/5396/NP/LMP/2023	Levofloxacin Infusion 0.5% (w/v)
533	13/01/2023	M/5397/NP/NFDC/2023	Sitagliptin 50 mg+Metformin 500 mg
534	13/01/2023	M/5399/NP/LMP/2023	Montelukast Sodium Tablets USP 5 mg
535	13/01/2023	M/5400/NP/2023	Carbegoline Tablets BP 0.5mg
536	13/01/2023	M/5401/NP/LMP/2023	Montelukast Sodium Tablets USP 10 mg
537	13/01/2023	M/5403/NP/BTP/2023	Follitropin Alfa (r - hFSH) 300 IU/ 0.48 ml Injection
538	16/01/2023	M/5404/NP/NFDC/2023	Sitagliptin 50 mg+Metformin 850 mg Tablets
539	20/01/2023	M/5405/NP/BTP/2023	Recombinant Human Follicle Stimulating Hormone (Follitropin alfa or rHu FSH) Solution for Injection 75 IU/0.12 mL
540	20/01/2023	M/5409/NP/LMP/2023	Telmisartan Tablets USP 40mg
541	20/01/2023	M/5410/NP/LMP/2023	Telmisartan Tablets USP 20mg
542	20/01/2023	M/5411/NP/LMP/2023	Neostigmine Injection BP 2.5 mg/mL
543	20/01/2023	M/5412/NP/LMP/2023	Chewable Ascorbic Acid Tablets BP 500mg(pineapple flavoured)
544	20/01/2023	M/5413/NP/LMP/2023	Neostigmine Injection BP 0.5 mg/mL
545	20/01/2023	M/5414/NP/LMP/2023	Chewable Ascorbic Acid Tablets BP 500mg(Orange flavoured)
546	20/01/2023	M/5415/NP/2023	Tofacitinib Tablets 5mg
547	23.01.2023	M/5417/NP/2023	Cyclosphosphamide for Injection USP 1g

548	23.01.2023	M/5419/NP/2023	Tranexamic Acid Tablets BP 250mg
549	23.01.2023	M/5420/NP/LMP/2023	Pregabalin Capsules IP 50mg
550	23.01.2023	M/5421/NP/LMP/2023	Pregabalin Capsules IP 150mg
551	27.01.2023	M/5422/NP/2023	Azacitidine for Injection 100mg/vial
552	27.01.2023	M/5423/NP/2023	Fluconazole Capsules BP 150mg
553	27.01.2023	M/5424/NP/LMP/2023	Ropinirole Tablets USP 0.5 mg
554	27.01.2023	M/5425/NP/2023	Dapagliflozin Tablets 5mg
555	27.01.2023	M/5428/NP/2023	Bezoyl Peroxide Gel BP 2.5% w/w
556	27/01/2023	M/5429/NP/2023	Escitalopram Oxalate Tablets USP 10 mg
557	27/01/2023	M/5430/NP/2023	Zinc Sulphate Syrup 10mg/5ml
558	27/01/2023	M/5431/NP/2023	Clobetasol Cream BP 0.05% w/w
559	27/01/2023	M/5432/NP/LMP/2023	Rosuvastatin Calcium Tablets USP 5 mg
560	27/01/2023	M/5433/NP/LMP/2023	Rosuvastatin Calcium Tablets USP 10mg
561	27/01/2023	M/5434/NP/LMP/2022	Rosuvastatin Calcium Tablets USP 20mg
562	30/01/2023	M/5435/NP/2023	Budesonide Inhalation Suspension 1.0mg/2ml
563	30.01.2023	M/5436/NP/2023	Pramipexole Dihydrochloride Tablets 0.25mg
564	30.01.2023	M/5437/NP/LMP/2023	Bupivacaine Hydrochloride in Dextrose Injection USP 20mg/4ml
565	30.01.2023	M/5438/NP/LMP/2023	Bupivacaine Hydrochloride Injection USP 50mg/10ml
566	30.01.2023	M/5439/NP/LMP/2023	Paracetamol Infusion IP 10mg/ml
567	30.01.2023	M/5440/NP/LMP/2023	Esmolol Hydrochloride Injection 100mg/10ml
568	30.01.2023	M/5442/NP/2023	Vitamin C Chewable Tablets 500mg
569	3/2/2023	M/5443/NP/BTP/2023	Insulin Injection IP Soluble Human (rDNA) origin) 100 IU/ml
570	3/2/2023	M/5444/NP/LMP/2023	Ascorbic Acid Tablets BP 100 mg
571	3/2/2023	M/5445/NP/2023	Rivaroxaban 15 mg Tablets
572	3/2/2023	M/5447/NP/LMP/2023	Tranexamic Acid Injection USP 500mg/5ml
573	3/2/2023	M/5448/NP/2023	Rivaroxaban 10 mg Tablets
574	3/2/2023	M/5449/NP/2023	Rivaroxaban 20 mg Tablets
575	3/2/2023	M/5451/NP/LMP/2023	Prednisolone Oral Solution USP 5mg/5ml
576	3/2/2023	M/5452/NP/2023	Rivaroxaban Tablets Ph. Eur 15 mg
577	3/2/2023	M/5453/NP/LMP/2023	Pediatric Paracetamol Oral Solution BP 120mg/5ml
578	3/2/2023	M/5454/NP/LMP/2023	Paracetamol Tablets BP 500mg
579	3/2/2023	M/5455/NP/LMP/2023	Vildagliptin Tablets 100mg
580	6/2/2023	M/5456/NP/LMP/2023	Vildagliptin Tablets 50 mg
581	6/2/2023	M/5457/NP/2023	Levetiracetam Tablets USP 500 mg

582	06.02.2023	M/5458/NP/LMP/2023	Ursodeoxycholic Acid tablets BP 300mg
583	6/2/2023	M/5459/NP/2023	Benzoyl Peroxide Gel BP 5% w/w
584	06.02.2023	M/5461/NP/2023	Donepezil hydrochloride Orally Disintegrating Tablets USP 10mg
585	6/2/2023	M/5462/NP/2023	Empagliflozin Tablets 10 mg
586	06.02.2023	M/5463/NP/LMP/2023	Calamine Lotion BP
587	10.02.2023	M/5465/NP/2023	Levetiracetam Tablets USP 250 mg
588	10.02.2023	M/5466/NP/2023	Sofosbuvir tablets 400mg
589	10.02.2023	M/5467/NP/2023	Bosentan tablets 62.5mg
590	10/2/2023	M/5468/NP/2023	Pirfenidone Tablets IP 200mg
591	10.02.2023	M/5469/NP/2023	Capecitabine tablets 500mg
592	13.02.2023	M/5470/NP/2023	Leflunomide tablets USP 20mg
593	13.02.2023	M/5471/NP/2023	Bosentan tablets 62.5mg
594	13.02.2023	M/5472/NP/LMP/2023	Clindamycin Injection USP 300mg/2ml
595	13.02.2023	M/5474/NP/2023	Dexamethasone oral solution 0.5mg/5ml
596	13.02.2023	M/5477/NP/2023	Tacrolimus Ointment 0.03% w/w
597	13.02.2023	M/5478/NP/2023	Gliclazide Modified Release tablets 60mg
598	13.02.2023	M/5479/NP/LMP/2023	Abacavir and Lamivudine Tablets USP 600mg/300mg
599	13.02.2023	M/5480/NP/LMP/2023	Pyridoxine Tablets BP 25mg
600	13.02.2023	M/5481/NP/LMP/NDF/2023	Ritonavir Tablets USP 100 mg
601	13.02.2023	M/5482/NP/LMP/2023	Lopinavir and Ritonavir tablets USP 100/25mg
602	13.02.2023	M/5484/NP/2023	Rivaroxaban Tablets Ph. Eur 2.5 mg
603	17.02.2023	M/5487/NP/2023	Escitalopram Tablets USP 6 mg
604	17.02.2023	M/5489/NP/LMP/2023	Desloratadine Tablets USP 5mg
605	17.02.2023	M/5490/NP/LMP/2023	Tolbutamide Tablets USP 500mg
606	17/02/2023	M/5491/NP/2023	Ondansetron Orally Disintegrating Tablet USP 4mg
607	20.02.2023	M/5492/NP/2023	Amlodipine Tablets USP 10mg
608	20.02.2023	M/5493/NP/2023	Escitalopram Tablets USP 20 mg
609	20.02.2023	M/5494/NP/LMP/2023	Atropine Sulphate Injection USP 600 mcg/ml
610	20.02.2023	M/5495/NP/LMP/2023	Mefloquine Hydrochloride Tablets USP 250 mg
611	20/02/2023	M/5496/NP/LMP/2023	Chlorphenamine Injection BP 10mg/ml
612	20/02/2023	M/5497/NP/2023	Danazol Capsules USP 50mg
613	20/02/2023	M/5498/NP/2023	Caspofungin acetate 50mg powder for concentrate for solution
614	20/02/2023	M/5499/NP/LMP/2023	
615	20.02.2023	M/5501/NP/2023	Rivaroxaban Tablets Ph.Eur 10 mg
616	20/02/2023	M/5502/NP/LMP/2023	

617	20.02.2023	M/5503/NP/LMP/2023	[illegible]
618	24.02.2023	M/5504/NP/2023	Tranexamic Acid Injection BP 500 mg
619	24.02.2023	M/5505/NP/2023	Framycetin Sulfate Cream BP 1% w/w
620	24/02/2023	M/5506/NP/NCE/LMP/2023	Rizatriptan Benzoate Tablets USP 5 mg
621	24/02/2023	M/5507/NP/LMP/2023	Carbidopa and Levodopa Tablets USP 10 mg/100 mg
622	24/02/2023	M/5508/NP/2023	Gliclazide Tablets BP 80mg
623	24/02/2023	M/5510/NP/LMP/2023	Fexofenadine Hydrochloride Tablets USP 120mg
624	27/02/2023	M/5511/NP/2023	Rivaroxaban Tablets Ph. Eur 20mg
625	27/02/2023	M/5512/NP/2023	Tizanidine Hydrochloride USP equivalent to Tizanidine 2mg
626	27/02/2023	M/5513/NP/2023	Dapagliflozin tablets 10mg
627	27/02/2023	M/5514/NP/2023	Prednisolone Tablets BP 20mg
628	27/02/2023	M/5515/NP/LMP/2023	Ascorbic Acid Tablets BP 500 mg
629	27/02/2023	M/5516/NP/2023	Budesonide Nebuliser Suspension BP 0.5 mg/ 2ml
630	27/02/2023	M/5517/NP/2023	Aripiprazole Tablet 15mg
631	27/02/2023	M/5518/NP/2023	Doxycycline Hyclate Tablets USP 100mg
632	27/02/2023	M/5519/NP/2023	Liposomal Amphotericin B Dispersion for Infusion 50mg
633	03.03.2023	M/5522/NP/LMP/2023	Stagliptin Tablets USP 100mg
634	03.03.2023	M/5523/NP/2023	Betahistine Tablets IP 8 mg
635	03.03.2023	M/5524/NP/2023	Betahistine Tablets IP 16 mg
636	03.03.2023	M/5525/NP/2023	Betahistine Tablets IP 24 mg
637	03.03.2023	M/5526/NP/2023	Caspofungin acetate 70mg powder for concentrate for solution I.V.
638	03.03.2023	M/5527/NP/2023	Paracetamol Suppositories BP 125mg
639	10.03.2023	M/5528/NP/LMP/2023	Aqueous Cream B.P. With Glycerin B.P.
640	10.03.2023	M/5529/NP/2023	Everolimus Tablet 10 mg
641	10.03.2023	M/5530/NP/LMP/2023	Atomoxetine Capsules USP 10mg
642	10.03.2023	M/5531/NP/2023	Leflunomide tablets USP 10mg
643	10.03.2023	M/5532/NP/2023	Dapagliflozin tablets 10mg
644	10.03.2023	M/5533/NP/2023	Paracetamol Suppositories BP 250mg
645	10.03.2023	M/5534/NP/LMP/2023	Hydroxocobalamine Injection BP 1mg/ml
646	10.03.2023	M/5535/NP/LMP/2023	Thiamine Hydrochloride Tablet USP 10mg
647	10.03.2023	M/5536/NP/LMP/2023	Propylthiouracil Tablets BP 50 mg
648	10.03.2023	M/5537/NP/LMP/2023	Flumazenil Injection USP

			0.5mg/5ml
649	10.03.2023	M/5538/NP/LMP/2023	Leucovorin Calcium Tablets USP 15 mg
650	10.03.2023	M/5539/NP/2023	Linezolid Injection 600 mg/ 300 ml
651	10.03.2023	M/5540/NP/LMP/2023	Gliclazide Modified Release tablets 30mg
652	10.03.2023	M/5541/NP/LMP/2023	Telmisartan Tablets USP 40mg
653	10.03.2023	M/5542/NP/2023	Aripiprazole Tablet 10 mg
654	10.03.2023	M/5543/NP/LMP/2023	Prednisolone Oral Solution USP 5mg/5ml
655	10.03.2023	M/5544/NP/LMP/2023	Cetirizine Oral Solution USP 5mg/5ml
656	10.03.2023	M/5545/NP/LMP/2023	Gliclazide Modified Release Tablets 60mg
657	13.03.2023	M/5546/NP/2023	Dapagliflozin Tablets 5mg
658	13/03/2023	M/5547/NP/2023	Paracetamol suppository 500mg
659	13/03/2023	M/5548/NP/2023	Ringer's lactate solution intravenous infusion (Compound sodium lactate infusion BP)
660	13/03/2023	M/5549/NP/2023	Ivabradine Tablets 5mg
661	13/03/2023	M/5550/NP/2023	Oxytocin Injection BP 5IU/1ml
662	17/03/2023	M/5551/NP/LMP/2023	Fexofenadine Hydrochloride Tablets USP 180mg
663	17/03/2023	M/5552/NP/LMP/2023	Fexofenadine Hydrochloride Tablets USP 120mg
664	17/03/2023	M/5553/NP/2023	Aripiprizol Tablets 5 mg
665	17/03/2023	M/5555/NP/LMP/2023	Gentamyci Injection USP 80mg/2ml
666	17/03/2023	M/5556/NP/2023	Tranexamic Acid Injection USP 500mg/5ml
667	17/03/2023	M/5558/NP/2023	Cilnidipine Tablet 10 mg
668	17.03.2023	M/5559/NP/LMP/2023	
669	17/03/2023	M/5560/NP/2023	Palonosetron for Injection 0.075mg/1.5ml(0.05mg/ml)
670	17/03/2023	M/5561/NP/2023	Everolimus Tablet 5mg
671	20/03/2023	M/5564/NP/2023	Betahistine Dihydrochloride Tablets BP 8mg
672	20/03/2023	M/5566/NP/2023	Tenofovir Disoproxil Fumarate 300mg and emtricitabine 200mg Tablet
673	20/03/2023	M/5567/NP/2023	Cilnidipine Tablet 5 mg
674	20/03/2023	M/5568/NP/2023	Everolimus Tablet 10mg
675	24/03/2023	M/5569/NP/NCE/LMP/2023	Lurasidone Hydrochloride Tablets 40mg
676	24/03/2023	M/5570/NP/2023	Betahistine Dihydrochloride Tablets BP 16 mg
677	24/03/2023	M/5571/NP/LMP/2023	Rispedidone Tablets USP 1mg
678	24/03/2023	M/5572/NP/LMP/2023	Famotidine Tablets USP 20mg
679	24/03/2023	M/5573/NP/LMP/2023	Ondansetron Injection USP 8mg/4ml

680	24/03/2023	M/5574/NP/2023	Budesonide Nebuliser Suspension BP 0.5 mg/ 2ml
681	24/03/2023	M/5575/NP/LMP/2023	Metformin Tablets BP 850mg
682	24/03/2023	M/5576/NP/2023	Sacubitiril 24 mg & Valsartan 26 mg Tablets
683	24/03/2023	M/5577/NP/LMP/2023	Rosuvastatin Tablets USP 10 mg
684	24/03/2023	M/5579/NP/LMP/2023	Lactulose Solution USP 3.33g/5ml
685	24/03/2023	M/5580/NP/2023	Empagliflozin Tablets 10mg
686	24/03/2023	M/5581/NP/2023	Sitagliptin Tablets 50 mg
687	24/03/2023	M/5582/NP/2023	Atorvastatin Tablets 10 mg
688	24/03/2023	M/5583/NP/2023	Atorvastatin Tablets 20 mg
689	24/03/2023	M/5584/NP/2023	Dapagliflozin tablets 10mg
690	27/03/2023	M/5585/NP/2023	Bicalutamide Tablets USP 50 mg
691	27/03/2023	M/5586/NP/LMP/2023	Aqueous Cream B.P.
692	27/03/2023	M/5587/NP/LMP/2023	Linagliptin Tablets 5 mg
693	27/03/2023	M/5588/NP/LMP/2023	Oxybutynin Tablets BP 2.5 mg
694	27/03/2023	M/5589/NP/2023	Sacubitiril 49 mg & Valsartan 51 mg Tablets
695	27.03.2023	M/5590/NP/2023	Methylprednisolone Sodium Succinate Injection USP 1g/vial
696	27.03.2023	M/5591/NP/2023	Isotretinoin Capsules USP 20mg
697	27/03/2023	M/5592/NP/LMP/2023	Metformin Tablets BP 850 mg
698	27/03/2023	M/5593/NP/2023	Empagliflozin Tablets 25 mg
699	31/03/2023	M/5595/NP/2023	Leflunomide Tablets USP 10mg
700	31/03/2023	M/5596/NP/LMP/2023	Phenylephrine Injection BP 10mg/ml
701	31/03/2023	M/5597/NP/VAC/BTP/2023	Inactivated Influenza Vaccine (Surface Antigen) Quadrivalent 15 mcg/0.5ml prefilled syringe (SH)
702	31/03/2023	M/5598/NP/LMP/2023	Amikacin Sulfate Injection IP 250mg/ml
703	31/03/2023	M/5599/NP/LMP/2023	Efavirenz Tablets USP 600 mg
704	31/03/2023	M/5600/NP/2023	Lapatinib Tablet 250 mg
705	31/03/2023	M/5601/NP/2023	Zinc Oxide Ointment BP 400mg/g
706	31/03/2023	M/5602/NP/LMP/2023	Folic Acid Tablets USP 1mg
707	31/03/2023	M/5603/NP/LMP/2023	Gabapentin Capsules USP 100mg
708	31/03/2023	M/5604/NP/2023	[illegible]
709	31/03/2023	M/5605/NP/2023	[illegible]
710	3/4/2023	M/5606/NP/LMP/2023	Fexofenadine Hydrochloride Suspension 30 mg/ 5 mL
711	03.04.2023	M/5607/NP/2023	Levothyroxine Sodium Tablets USP 25mcg
712	03.04.2023	M/5608/NP/LMP/2023	Folic Acid Tablets BP 1mg
713	3/4/2023	M/5609/NP/2023	Vitamin E Capsules USP 400 mg
714	03.04.2023	M/5610/NP/BTP/2023	Enoxaparin Sodium Injection USP 40mg

715	3/4/2023	M/5611/NP/LMP/2023	Apixaban Tablets 2.5 mg
716	03.04.2023	M/5612/NP/2023	Methylprednisolone Sodium Succinate for IM/IV Injection USP 500mg
717	3/4/2023	M/5613/NP/LMP/2023	Apixaban Tablets 5 mg
718	10/4/2023	M/5614/NP/2023	Orlistat capsules 120mg
719	10/4/2023	M/5615/NP/2023	Betahistine Dihydrochloride Tablets BP 24mg
720	10.04.2023	M/5616/NP/LMP/2023	Hydrochlorothiazide Tablets USP 25mg
721	10.04.2023	M/5617/NP/2023	Ketoprofen Gel BP 2.5% w/w
722	10.04.2023	M/5618/NP/BTP/NCE/2023	Denosumab Solution for injection 60mg/ml
723	10.04.2023	M/5620/NP/2023	Telmisartan Tablets USP 40mg
724	17.04.2023	M/5621/NP/LMP/2023	Venlafaxine Hydrochloride Extended Relaese Capsule USP 75mg
725	17.04.2023	M/5622/NP/2023	Prednisolone Tablets BP 5mg
726	21.04.2023	M/5623/NP/2023	Phenytoin Tablets BP 50mg
727	21.04.2023	M/5624/NP/2023	Cholecalciferol Chewable Tablet 1000IU
728	21.04.2023	M/5625/NP/2023	Levothyroxine Sodium Tablets USP 75mg
729	21.04.2023	M/5626/NP/NFDC/2023	Sodium Sulfate, Potassium Sulfate, Magnesium Sulfate Oral Solution
730	21.04.2023	M/5627/NP/2023	Sacubitril 97mg + Valsartan 103mg Tablets
731	21.04.2023	M/5628/NP/LMP/2023	Venlafaxine Hydrochloride Extended Relaese Capsule USP 37.5 mg
732	21.04.2023	M/5629/NP/LMP/2023	Sitagliptin Tablets USP 50mg
733	21.04.2023	M/5630/NP/LMP/2023	Metoclopramide Injection BP 10mg/2ml
734	21.04.2023	M/5631/NP/2023	Pantoprazole for IV Injection 40mg
735	21.04.2023	M/5632/NP/LMP/2023	Sodium Alginate 500mg, Sodium Bicarbonate 267mg, Calcium Carbonate 160mg /10ml oral suspension
736	21.04.2023	M/5633/NP/LMP/2023	Chlorphenamine Maleate oral Solution USP 2mg/5ml
737	21.04.2023	M/5634/NP/2023	Mosapride Citrate Tablet 2.5mg
738	24.04.2023	M/5635/NP/2023	Cholecalciferol Chewable Tablet 2000 IU
739	24/04/2023	M/5636/NP/2023	Sacubitril 49mg+ Valsartan 51mg Tablets
740	24/04/2023	M/5637/NP/2023	Isotretinoin Capsules USP 10mg
741	24.04.2023	M/5638/NP/LMP/2023	Levetiracetam Tablets USP 500mg
742	24/04/2023	M/5639/NP/LMP/2023	Gastro-resistant Diclofenac Tablets BP 100mg
743	24.04.2023	M/5640/NP/LMP/2023	Levetiracetam Tablets USP 250 mg
744	24.04.2023	M/5641/NP/2023	Ondansetron Tablets 8mg

745	28/04/2023	M/5642/NP/LMP/2023	Beclometasone propionate Dry powder inhalation capsules BP 400mcg
746	28/04/2023	M/5643/NP/LMP/2023	Beclometasone propionate Dry powder inhalation capsules BP 200mcg
747	28/04/2023	M/5644/NP/LMP/2023	Fluticasone propionate 500mcg and salmetarol 50mcg dry powder inhalation capsules BP
748	28/04/2023	M/5645/NP/2023	Sevelamear Carbonate Tablets 800mg
749	28/04/2023	M/5646/NP/2023	Glucagon for injection USP 1mg
750	28/04/2023	M/5647/NP/2023	Beclomethasone Metered Dose Nasal Spray BP 50 mcg
751	28/04/2023	M/5648/NP/2023	Clopidogrel Bisulfate Tablets 75 mg
752	28/04/2023	M/5649/NP/2023	Metoprolol Tartrate Tablets BP 50mg
753	28/04/2023	M/5650/NP/2023	Levothyroxine Tablets BP 100mcg
754	28/04/2023	M/5651/NP/2023	Levothyroxine Tablets BP 50mcg
755	28/04/2023	M/5652/NP/2023	Clopidogrel Tablets USP 75mg
756	28/04/2023	M/5653/NP/2023	Nebivolol Tablets 5mg
757	28/04/2023	M/5654/NP/LMP/2023	Emtricitabine and tenofovir disoproxil fumarate tablets 200mg/300mg
758	28/04/2023	M/5655/NP/2023	Cefepime Hydrochloride for injection USP 500mg
759	28/04/2023	M/5656/NP/2023	Cefepime Hydrochloride for injection USP 1g
760	28/04/2023	M/5657/NP/LMP/2023	loratadine oral solution USP 5mg/5ml
761	28/04/2023	M/5658/NP/2023	Prednisolone Oral Solution USP 5mg/5ml
762	28.04.2023	M/5659/NP/LMP/2023	Losartan Potassium Tablets IP 25mg
763	28.04.2023	M/5660/NP/2023	Telmisartan Tablets 80mg
764	4/5/2023	M/5661/NP/2023	Sacubitril 24mg + Valsartan 26mg Tablets
765	4/5/2023	M/5662/NP/LMP/2023	Ketoconazole Cream BP 2% w/w
766	4/5/2023	M/5663/NP/LMP/2023	Sevelamer Hydrochloride Tablets 400mg
767	4/5/2023	M/5664/NP/LMP/2023	Phytomenadione Injection BP 10mg/1ml
768	4/5/2023	M/5665/NP/LMP/2023	Sertraline Hydrochloride Tablets USP 25mg
769	4/5/2023	M/5666/NP/2023	Lamotrigine Dispersible Tablets BP 25mg
770	4/5/2023	M/5667/NP/2023	Cefalexin Dispersible 125mg Tablets
771	4/5/2023	M/5668/NP/2023	Pegaspargase Injection 3750IU/5ml
772	8/5/2023	M/5669/NP/2023	Fusikdic Acid Eye Drops BP 1% w/w

773	8/5/2023	M/5670/NP/2023	Tranexamic Acid Tablet BP 500mg
774	8/5/2023	M/5671/NP/BTP/NCE/2023	Anti-Human T-Lymphocyte Immunoglobulin (Rabbit) concentrate for solution for infusion 20mg/ml
775	8/5/2023	M/5672/NP/LMP/2023	Empagliflozin Tablets 25 mg
776	8/5/2023	M/5673/NP/LMP/2023	Empagliflozin Tablets 10 mg
777	8/5/2023	M/5674/NP/2023	Oral Rehydration Salt BP 21.8 g
778	12/5/2023	M/5675/NP/2023	Ondansetron Orally Disintegrating Tablet USP 4mg
779	12/5/2023	M/5676/NP/2023	Amoxicillin Capsules BP 500 mg
780	12/5/2023	M/5677/NP/LMP/2023	Salbutamol Inhalation Powder Pre Dispensed Capsules BP 400 mcg
781	12/5/2023	M/5678/NP/LMP/2023	Salbutamol Dry Powder Inhalation Capsules BP 200 mcg
782	12/5/2023	M/5679/NP/LMP/2023	Fluticasone propionate 250 mcg and Salmetarol 50 mcg Dry Powder Inhalation Capsules
783	12/5/2023	M/5680/NP/LMP/2023	Norepinephrine Bitartrate Injection USP 4 mg/ 2 mL
784	12/5/2023	M/5681/NP/LMP/2023	Furosemide Injection BP 20 mg/2 mL
785	12/5/2023	M/5682/NP/2023	Itraconazole Capsules 100 mg
786	12/5/2023	M/5683/NP/2023	Clotrimazole Cream BP 10 mg/g
787	12/5/2023	M/5684/NP/2023	Glyceryl Suppository BP 1.15 g
788	12/5/2023	M/5685/NP/2023	Glyceryl Suppository BP 2.3 g
789	12/5/2023	M/5686/NP/BTP/2023	Human Albumin Solution For Infusion 200 g/L
790	12/5/2023	M/5687/NP/2023	Pegaspargase Injection 3750IU/5ml
791	12.05.2023	M/5688/NP/2023	Apixaban Tablets 5mg
792	15.05.2023	M/5689/NP/LMP/2023	Tolterodine Tablets BP 1mg
793	15.05.2023	M/5690/NP/2023	Salmeterol 25mcg and Fluticasone Propionate BP 250mcg metered dose inhalation
794	15.05.2023	M/5691/NP/2023	Sacubitril 24mg and Valsartan 26mg Tablet
795	15/05/2023	M/5692/NP/2023	Amoxicillin Capsules BP 250 mg
796	15/05/2023	M/5693/NP/LMP/2023	Celecoxib Capsules 200 mg
797	15/05/2023	M/5694/NP/2023	Lamotrigine Dispersible Tablets BP 50mg
798	19/05/2023	M/5695/NP/2023	Atorvastatin Calcium Tablets USP 40mg
799	19/05/2023	M/5696/NP/2023	Cefuroxime Axetil Tablets BP 500mg
800	19/05/2023	M/5697/NP/LMP/2023	Atorvastatin Tablets IP 10 mg
801	19/05/2023	M/5698/NP/LMP/2023	phytomenadione Injection BP 1mg/05 ml

802	19/05/2023	M/5699/NP/LMP	Povidone iodine cleansing solution USP 7.5% w/v
803	19/05/2023	M/5700/NP/2023	Mupirocin Ointment BP 2% w/w
804	19/05/2023	M/5701/NP/2023	Lactulose Solution USP 3.35g/5ml
805	19/05/2023	M/5702/NP/LMP/2023	Betahistine Dihyrochloride Tablets BP 16mg
806	19/05/2023	M/5703/NP/2023	Olmesartan Medoxomil USP 20mg & Hydrochlorothiazide USP 12.5mg Tablets
807	19/05/2023	M/5704/NP/2023	Dorzolamide 20mg and Timolol 5mg BP eye drops in 1ml
808	19/05/2023	M/5705/NP/LMP/2023	Terbutaline Sulphate Syrup 1.5mg/5ml
809	22/05/2023	M/5706/NP/2023	Lenalidomide Capsules 5mg
810	22/05/2023	M/5707/NP/2023	Cefuroxim\e Sodium Powder for injection USP 750mg
811	22/05/2023	M/5708/NP/LMP/2023	Lamivudine Tablets USP 150mg
812	22/05/2023	M/5709/NP/LMP/2023	Lopinavir and Rotinavir Tablets USP 100mg/25mg
813	22/05/2023	M/5710/NP/LMP/2023	Tenofovir Disoproxil Fumarate and emtricitabine 300mg/ 200mg Tablet
814	22/05/2023	M/5711/NP/2023	Vildagliptin Tablets 50mg
815	22/05/2023	M/5712/NP/2023	Adapalene 0.1% w/w + Clindamycin Phosphate 1% w/w Gel
816	22/05/2023	M/5713/NP/2023	Tacrolimus Ointment 0.1% w/w
817	22/05/2023	M/5714/NP/NFDC/2023	Vildagliptin 50mg + Metformin 850mg Tablet
818	22/05/2023	M/5715/NP/LMP/2023	Gliclazide Modified Release Tablets 60mg
819	22/05/2023	M/5716/NP/2023	Cefuroxime Tablets BP 250mg
820	26.05.2023	M/5717/NP/LMP/2023	Furosemide Injection BP 100mg/10ml
821	26.05.2023	M/5718/NP/LMP/2023	Lopinavir and Rotinavir Tablets USP 200mg/50mg
822	26.05.2023	M/5719/NP/LMP/2023	Sodium Chloride Intavenous Infusion BP 0.9% W/V
823	26.05.2023	M/5720/NP/2023	Amoxicillin oral suspension BP 125mg/ml
824	26.05.2023	M/5721/NP/2023	Leuprolide Injection 3.75mg
825	26.05.2023	M/5722/NP/2023	Deferasirox Dispersible Tablets 500mg
826	26.05.2023	M/5723/NP/LMP/2023	Pregabalin Capsules 150mg
827	26.05.2023	M/5724/NP/LMP/2023	Prednisolone Tablets USP 5mg
828	26.05.2023	M/5725/NP/LMP/2023	Fluticasone Furoate nasal spray 27.5mcg
829	26.05.2023	M/5726/NP/2023	Oral Rehydration Salt BP
830	26.05.2023	M/5727/NP/2023	Vildagliptin Tablets 50mg

831	26.05.2023	M/5728/NP/2023	Ceftriaxone for Injection USP 1g
832	26.05.2023	M/5729/NP/2023	Clotrimazole Cream BP 1% w/w
833	29.05.2023	M/5730/NP/2023	Baclofen Tablets USP 10mg
834	29/05/2023	M/5731/NP/2023	Ezetimibe Tablets 10 mg
835	29/05/2023	M/5732/NP/2023	Paracetamol IV Infusion 1g
836	29/05/2023	M/5733/NP/2023	Deferasirox Tablets 250mg
837	29/05/2023	M/5734/NP/2023	Azithromycin for Oral Suspension USP 200 mg/5 mL
838	29/05/2023	M/5735/NP/2023	Ursodeoxycholic Acid Capsules BP 250 mg
839	29/05/2023	M/5736/NP/LMP/2023	Tolterodine Tartrate Sustained Release Capsules 2 mg
840	29/05/2023	M/5737/NP/BTP/2023	Menotrophin For injection BP, 75IU/Vial
841	29/05/2023	M/5738/NP/LMP/2023	Famotidine Tablets USP 40 mg
842	29/05/2023	M/5739/NP/LMP/2023	Betahistine Dihydrochloride Tablets BP 16 mg
843	29/05/2023	M/5740/NP/LMP/2023	Betahistine Dihydrochloride Tablets BP 8 mg
844	29/05/2023	M/5741/NP/LMP/2023	Betahistine Dihydrochloride Tablets BP 24 mg
845	29/05/2023	M/5742/NP/LMP/2023	Promethazine Oral Solution BP 5 mg/ 5 mL
846	29/05/2023	M/5743/NP/LMP/2023	Gliclazide Modified Release Tablets 30mg
847	29/05/2023	M/5744/NP/LMP/2023	Ketotifen Fumarate Syrup 1 mg/ 5mL
848	29/05/2023	M/5745/NP/LMP/2023	Gliclazide Modified Release Tablets 30mg
849	2/6/2023	M/5746/NP/LMP/2023	Salbutamol Inhalation Powder Pre Dispensed Capsules BP 400 mcg
850	2/6/2023	M/5747/NP/LMP/2023	Salbutamol Dry Powder Inhalation Capsules BP 200 mcg
851	02.06.2023	M/5748/NP/2023	Pemetrexed Powder for Concentrate for solution for infusion 100mg
852	02.06.2023	M/5749/NP/2023	Ranolazine Extended-Release Tablets 500mg
853	02.06.2023	M/5750/NP/2023	Linagliptin 5 mg+ empagliflozin 10mg Tablet
854	02.06.2023	M/5751/NP/LMP/2023	Hyoscine Butylbromide Injection BP 20mg/ml
855	02.06.2023	M/5752/NP/2023	Leflunomide Tablets USP 20mg
856	02.06.2023	M/5753/NP/2023	Ciprofloxacin Injection USP 2mg/ml
857	02.06.2023	M/5754/NP/2023	Betahistine Dihydrochloride Tablets BP 8mg
858	02.06.2023	M/5755/NP/LMP/2023	Ascorbic acid chewable tablets 500mg
859	02.06.2023	M/5756/NP/LMP/2023	Gliclazide tablets BP 80mg
860	02.06.2023	M/5757/NP/LMP/2023	Glicalazide modified relaese tablets

			60mg
861	05.06.2023	M/5758/NP/2023	Sodium Valproate and Valproic Acid Controlled Release Tablets 200mg
862	5/6/2023	M/5759/NP/LMP/2023	Atenolol Tablets BP 50mg
863	5/6/2023	M/5760/NP/2023	Risperidone Tablets USP 2mg
864	5/6/2023	M/5761/NP/2023	Rosuvastatin Calcium 20mg Film coated tablet
865	5/6/2023	M/5762/NP/2023	Esomeprazole powder for Injection 40mg
866	5/6/2023	M/5763/NP/LMP/2023	Tamsulosin Hydrohloride Capsules USP 0.4mg
867	5/6/2023	M/5764/NP/LMP/2023	Pregabalin Capsules 75mg
868	5/6/2023	M/5765/NP/LMP/2023	Salbutamol Oral Solution BP 2mg/5ml
869	5/6/2023	M/5766/NP/2023	Linagliptin 5 mg+ empagliflozin 25mg Tablet
870	5/6/2023	M/5767/NP/2023	Esomeprazole Tablet 40mg
871	5/6/2023	M/5768/NP/LMP/2023	Montelukast Tablets IP 10mg
872	5/6/2023	M/5769/NP/LMP/2023	Montelukast Tablets IP 5mg
873	9/6/2023	M/5770/NP/NDF/2023	Terbinafine Hydrochloride Gel 1.112% w/w
874	9/6/2023	M/5771/NP/2023	Metronidazole Intravenous Infusion BP 500 mg/100 mL
875	9/6/2023	M/5772/NP/2023	Deferasirox Dispersible Tablets 100 mg
876	9/6/2023	M/5773/NP/2023	Deferasirox Dispersible Tablets 400 mg
877	9/6/2023	M/5774/NP/LMP/2023	Sodium Valproate Tablets BP 100 mg
878	9/6/2023	M/5775/NP/LMP/2023	Rosuvastatin Tablets USP 5 mg
879	9/6/2023	M/5776/NP/LMP/2023	Eltrombopag Olamine tablets 50 mg
880	9/6/2023	M/5777/NP/2023	Ursodeoxycholic Acid Capsules BP 500 mg
881	9/6/2023	M/5778/NP/LMP/2023	Irbesartan Tablets USP 300 mg
882	9/6/2023	M/5779/NP/LMP/2023	Irbesartan Tablets USP 150 mg
883	9/6/2023	M/5780/NP/LMP/2023	Irbesartan Tablets USP 75mg
884	9/6/2023	M/5781/NP/2023	Ambroxol Hydrochloride Expectorant BP 6 mg (Paediactric Drops)
885	9/6/2023	M/5782/NP/2023	Empagliflozin 5 mg and Metformin 850 mg Tablets
886	9/6/2023	M/5783/NP/2023	Empagliflozin 12.5 mg and Metformin 850 mg Tablets
887	9/6/2023	M/5784/NP/2023	Metformin Hydrochloride Sustained Release Tablets 1 000 mg
888	9/6/2023	M/5785/NP/2023	Esomeprazole GR Tablets IP 20 mg
889	12.06.2023	M/5786/NP/2023	Empagliflozin Tablets 25mg

890	12.06.2023	M/5787/NP/LMP/2023	Metformin Hydrochloride Sustained Release Tablets IP 500 mg
891	12.06.2023	M/5788/NP/2023	Cilnidipine Tablets 5mg
892	12.06.2023	M/5789/NP/2023	Telmisartan Tablets 40mg
893	12.06.2023	M/5790/NP/2023	Brinzolamide Ophthalmic Suspension IP 1% w/w
894	12.06.2023	M/5791/NP/NDF/2023	Melphalan for injection 50mg
895	12.06.2023	M/5792/NP/LMP/2023	Cefotaxime for injection USP 500mg
896	12.06.2023	M/5793/NP/LMP/2023	Glycopyrrolate Injection USP 200mcg/1ml
897	12.06.2023	M/5794/NP/LMP/2023	Lamivudine & Zidovudine Dispersible Tablets 30mg/60mg
898	12.06.2023	M/5796/NP/LMP/2023	Ceftazidime for injection USP 500mg
899	12.06.2023	M/5797/NP/LMP/2023	Gastro-resistant Aspirin Tablets BP 75mg
900	12.06.2023	M/5798/NP/LMP/2023	Efavirenz Tablets USP 600 mg
901	12.06.2023	M/5799/NP/LMP/2023	Ceftriaxone for Injection USP 500mg
902	12.06.2023	M/5801/NP/LMP/2023	Efavirenz Tablets USP 200 mg
903	12.06.2023	M/5802/NP/2023	Cefixime Dispersible Tablets 100mg
904	12.06.2023	M/5803/NP/2023	Clindermycin Lotion BP 10mg/ml
905	12.06.2023	M/5804/NP/2023	Paclitaxel Injection USP 6mg/ml
906	16/06/2023	M/5805/NP/LMP/2023	Cefuroxime Axetil Tablets BP 250mg
907	16/06/2023	M/5806/NP/LMP/2023	Cefuroxime Axetil Tablets BP 125mg
908	16/06/2023	M/5807/NP/LMP/2023	Cefuroxime Axetil Tablets BP 500mg
909	16/06/2023	M/5808/NP/LMP/2023	Ceftriaxone for Injection USP 1000mg
910	16/06/2023	M/5809/NP/LMP/2023	Cefotaxime for Injection USP 250mg
911	16/06/2023	M/5810/NP/LMP/2023	Cefuroxime for Injection USP 250mg
912	16/06/2023	M/5811/NP/LMP/2023	Aspirin Delayed Release Tablets USP 75 mg
913	16/06/2023	M/5812/NP/LMP/2023	Papaverine Injection BP 60mg/2ml
914	16/06/2023	M/5813/NP/LMP/2023	Leucovorin Calcium Injection USP 15mg/2ml
915	16/06/2023	M/5814/NP/LMP/2023	Pancuronium Injection BP 4mg/2ml
916	16/06/2023	M/5815/NP/2023	Clindamycin Capsules BP 300 mg
917	16/06/2-23	M/5816/NP/BTP/2023	Human Normal Immunoglobulin for IV 5% w/v
918	16/06/2023	M/5817/NP/LMP/2023	Aspirin Delayed Release Tablets USP 75 mg
919	16/06/2023	M/5818/NP/LMP/2023	Telmisartan Tablets IP 40 mg
920	16/06/2023	M/5819/NP/LMP/2023	Telmisartan Tablets IP 20 mg
921	16/06/2023	M/5820/NP/LMP/2023	Rosuvastatin Tablets USP 20mg

922	16/06/2023	M/5821/NP/2023	Sacubitril 49mg + Valsartan 51mg Tablets
923	16/06/2023	M/5822/NP/2023	Diclofenac Sodium Suppository 25mg
924	16/06/2023	M/5823/NP/2023	Permethrin Cream 5%
925	16/06/2023	M/5824/NP/2023	Levothyroxine Sodium Tablets USP 75mg
926	19/06/2023	M/5825/NP/2023	Cefepime for Injection USP 1 g
927	19/06/2023	M/5826/NP/2023	Telmisartan Tablets USP20 mgq
928	19/06/2023	M/5827/NP/LMP/2023	Potassium citrate tablets usp 1080mg (mEq)
929	19/06/2023	M/5828/NP/LMP/NFDC/2023	Iron, Minerals & vitamins soft gelatin capsules
930	19/06/2023	M/5829/NP/LMP/2023	Fluconazole Capsules BP 50mg
931	19/06/2023	M/5830/NP/LMP/2023	Desloratadine Syrup 0.5mg/1ml
932	19/06/2023	M/5831/NP/2023	Solifenacin Succinate Tablets 10 mg
933	19/06/2023	M/5832/NP/LMP/2023	Diclofenac Gel BP 1% w/w
934	19/06/2023	M/5833/NP/2023	Dopamine Hydrochloride Injection USP 200mg/5ml
935	23.06.2023	M/5834/NP/LMP/2023	Ceftazidime for injection USP 1000mg
936	23.06.2023	M/5835/NP/LMP/2023	Cefotaxime For Injection USP 1000mg
937	23.06.2023	M/5836/NP/LMP/2023	Cefepime for Injection USP 1000mg
938	23.06.2023	M/5837/NP/LMP/2023	Cefepime for Injection USP 500mg
939	23.06.2023	M/5838/NP/LMP/2023	Rosuvastatin Tablets BP 5mg
940	23.06.2023	M/5839/NP/LMP/2023	Rosuvastatin Tablets BP 10mg
941	23.06.2023	M/5840/NP/LMP/2023	Rosuvastatin Tablets BP 20mg
942	23.06.2023	M/5841/NP/2023	Tacrolimus Ointment 0.03% w/w
943	23.06.2023	M/5842/NP/LMP/2023	Gastro-resistant Sodium Valproate Tablets BP 100mg
944	23/06/2023	M/5843/NP/LMP/2023	Abacavir and Lamivudine Tablets bUSP 60mg/30mg
945	23.06.2023	M/5844/NP/LMP/2023	Montelikast Sodium Tablets USP 5mg
946	23.06.2023	M/5845/NP/LMP/2023	Montelikast Sodium Tablets USP 10mg
947	23/06/2023	M/5846/NP/2023	Cholecalciferol Capsules USP 60000 IU
948	23/06/2023	M/5847/NP/LMP/2023	Etoricoxib Tablets 60mg
949	23/06/2023	M/5848/NP/LMP/2023	Etoricoxib Tablets 60mg
950	23/06/2023	M/5849/NP/LMP/2023	Diclofenac Gastro Resistant Tablets BP 50mg
951	23/06/2023	M/5850/NP/LMP/2023	Metformin Hydrochloride ER Tablet USP 500mg
952	23/06/2023	M/5851/NP/LMP/2023	Paediatric Paracetamol oral solution BP 120mg/5ml

953	23/06/2024	M/5852/NP/2023	Prolonged Release Diclofenac sodium Tablets BP 100mg
954	23/06/2023	M/5853/NP/LMP/2023	Paediatric Paracetamol oral solution BP 120mg/5ml
955	23/06/2023	M/5854/NP/2023	Diclofenac sodium Suppository 12.5mg
956	23/06/2023	M/5855/NP/2023	Aceclofenac Tablet 100mg
957	23/06/2023	M/5856/NP/2023	Hydroquinone 2% w/w & Tretinoin 0.025% w/w
958	23/06/2023	M/5857/NP/2023	Cyclophosphamide for injecton USP 200mg
959	26/06/2023	M/5858/NP/2023	Rosuvastatin Tablets USP 10 mg
960	26/06/2023	M/5859/NP/2023	Bortezomib for Injection 2mg/Vial
961	26/06/2023	M/5860/NP/2023	Finasteride Tablets USP 5 mg
962	26/06/2023	M/5861/NP/VAC/2023	Purified Diptheria toxoid, Purified Teatnus toxoid, Whole Cell Pertussis, Polymelitis, Recombinant Hepaitis B ,Haemophillus influenza type B conjugate and Inactivated Poliomyelitis Trivalent Vaccine (Adsorbed)
963	26/06/2023	M/5862/NP/2023	Fusidic Acid BP 2% w/w & Betamethasone Valerate BP 0.1% w/w Cream
964	26/06/2023	M/5863/NP/PQ/VAC/2023	Diptheria , Teatnus , Pertussis (Whole Cell) , Hepaitis B (rDNA) and Haemophillus influenza type B conjugated Vaccine (Adsorbed) IP
965	26/06/2023	M/5864/NP/2023	Eltrombopag Film Coated tablets 50 mg
966	26/06/2023	M/5865/NP/2023	Empagliflozin INN 10 mg
967	30/06/2023	M/5866/NP/LMP/2023	Formetarol Fumarate 6mcg and Budesonide 200mcg dry powder inhalation capsules
968	30/06/2023	M/5867/NP/LMP/2023	Formetarol Fumarate 6mcg and Budesonide 400mcg dry powder inhalation capsules
969	30/06/2023	M/5868/NP/LMP/2023	Enalapril Maleate Tablets USP 5mg
970	30/06/2023	M/5869/NP/BTP/2023	Human Normal Immunoglobulin Solution for Infusion 50g/l
971	30/06/2023	M/5870/NP/PQ/VAC/2023	Diptheria, Teatnus, Pertussis (whole cell), Hepaitis B (rDNA) and Haemophilus Influenza type B conjugated vaccine (absorbed) IP
972	30/06/2023	M/5871/NP/LMP/2023	Risperidone Tablets BP 1mg
973	30/06/2023	M/5872/NP/2023	Fluconazole Powder for Suspension USP 50mg/5ml
974	30/06/2023	M/5873/NP/2023	Linagliptin Tablets 5mg
975	30/06/2023	M/5874/NP/LMP/2023	Levetiraceztam Tablets USP 250 mg

976	30/06/2023	M/5875/NP/2023	Cefuroxime Axetil for oral suspension USP 125mg/5ml
977	30/06/2023	M/5876/NP/2023	Clobetasol Propionate Ointment IP 0.05% w/w
978	30/06/2023	M/5877/NP/LMP/2023	Carbamazepine Tablets BP 100mg
979	30/06/2023	M/5878/NP/LMP/2023	Carbamazepine Tablets BP 200mg
980	22/04/2022	MEDERG/2021/00621	Betahistine Dihydrochloride Tablest 24mg
981	18/02/2022	MEDGEG/2020/00460	Muitocin ointment USP 2 % w/w
982	19/05/2023	MEDREG//2020/00182	Mycophenolic Acid delayed Release Tablet USP 360 mg
983	12.09.2022	MEDREG//2021/01493	Cefuroxime Axetil Tablets USP 500mg
984	24/01/2022	MEDREG/2019/01159	Degarelix for injection 80mg
985	28.02.2020	MEDREG/2020/00045	Mefenamic Acid Tablets BP 500mg
986	17/03/2023	MEDREG/2020/00089	Sildenafil Tablets 100mg
987	24/01/2022	MEDREG/2020/00093	BenzethoniumChloride 0.2% w/w Lidnocaine Hydrochloride 3.0% w/w Aerosol spray
988	19/05/2022	MEDREG/2020/00103	Fluticasone Nasal Spray BP 50mcg
989	07.01.2022	MEDREG/2020/00104	Povidone-Iodine Aerosol, spray USP 5% w/w
990	3/6/2022	MEDREG/2020/00118	Salmeterol 50 mg Fluticasone Propionate 100 mg Dry Powder Inhalation Capsule
991	6/5/2022	MEDREG/2020/00131	Amorolfine Hydrochloride Nail Lacquer 5% w/v
992	28/01/2022	MEDREG/2020/00136	Paracetamol Injection (Solutioon for infusion) BP 1g/100 ml
993	27/05/2022	MEDREG/2020/00148	Cefuroxime Oral Suspension USP 125mg/5ml
994	17/06/2022	MEDREG/2020/00159	Valsartan 80mg + Amlodipine 5mg tablet (Film coated) USP
995	10.06.2022	MEDREG/2020/00164	Valsartan 160mg+Amlodipine 10mg tablet USP
996	22.09.2022	MEDREG/2020/00183	Cefixime Dispersible Tablets 200mg
997	19/05/2023	MEDREG/2020/00216	Azathioprine Tablets USP 50 mg
998	07.02.2022	MEDREG/2020/00255	Vitamin B Complex Tablets
999	8/4/2022	MEDREG/2020/00277	Amoxicillin Capsules USP 250 mg
1000	22/04/2022	MEDREG/2020/00293	Lidocaine Hydrochloride Jelly 2%
1001	25/04/2022	MEDREG/2020/00311	Febuxostat Tablet 80mg
1002	31/01/2022	MEDREG/2020/00355	Ranitidine Tablets USP 150 mg
1003	3/6/2022	MEDREG/2020/00361	Aciclovir Tablets BP 200mg
1004	10.01.2022	MEDREG/2020/00392	Telmisartan Tablets USP 40 mg
1005	26/08/2022	MEDREG/2020/00394	Fenofibrate Capsules 200mg
1006	19/06/2023	MEDREG/2020/00411	Bisoprolol Fumarate Tablets USP 5mg

1007	25/03/2022	MEDREG/2020/00418	Amoxicillin and Clavulanate Pottasium Tablets USP (500mg & 125mg)
1008	12/5/2023	MEDREG/2020/00426	Atorvastatin Tablets 10 mg
1009	27/06/2022	MEDREG/2020/00437	Pethidine Injection BP 50mg/ml
1010	22/07/2022	MEDREG/2020/00443	Esomeprazole Tablets 20mg
1011	21/01/2022	MEDREG/2020/00452	Cyclosporin Capsules USP 50 mg
1012	24/01/2022	MEDREG/2020/00452	Cyclosporine Capsules USP 50mg
1013	1/4/2022	MEDREG/2020/00453	Clarithromycin for Infusion BP 500 mg/vial
1014	28/04/2023	MEDREG/2020/00499	Nifedipine Sustained relaese tablets 20mg
1015	19/05/2022	MEDREG/2020/00503	Cholecalciferol Drops 400 IU
1016	31/01/2022	MEDREG/2020/00517	Fexofenadine hydrochloride Suspension 30 mg/5 ml
1017	24/01/2022	MEDREG/2020/00547	Cetrimide BP 0.10% w/w Lidnocaine Hydrochloride USP 1.0% w/w Aerosol spray
1018	25/03/2022	MEDREG/2020/00559	Piracetam Tablets 800mg
1019	23/12/2022	MEDREG/2020/00586	Mycophenolate Mofetil Capsules 250mg
1020	28/07/2023	MEDREG/2020/00590	Amoxicillin Capsules BP 500mg
1021	4/7/2022	MEDREG/2020/006563	2-Propanol 45g + 1-Propanol 30g + Mecetronium Ethylsuphate 0.2g
1022	27/05/2022	MEDREG/2020/00693	Calcium Vitamin D3 Cewable Tablets 500mg/400IU
1023	07.02.2022	MEDREG/2020/008807	Bortezomib for injection 3.5mg
1024	1/4/2022	MEDREG/2021/00596	Meropenem for injection USP 1000MG
1025	29/08/2022	MEDREG/2021/00632	Azithromycin TabletsUSP 500 mg
1026	29/04/2022	MEDREG/2021/00675	Orlistat Capsules 120mg
1027	31/01/2022	MEDREG/2021/00680	Bromhexine Hydrochloride Syrup 4 mg/5 ml
1028	10.06.2022	MEDREG/2021/00689	Motelukast Chewable Tablets 40 mg
1029	25/02/2022	MEDREG/2021/00690	Hydroxyurea capsules USP 500mg
1030	19/05/2022	MEDREG/2021/00698	Gemcitabine 38 mg/ml concentrate for solution for infusion 5.26 ml
1031	30/09/2022	MEDREG/2021/00716	Ibuprofen Gel BP 10% w/w
1032	07.01.2022	MEDREG/2021/00727	Triamcinolone Acetonide Injectable Suspension USP 40 mg
1033		MEDREG/2021/00734	Metformin Hydrochloride ER Tablets 500mg
1034	30/09/2022	MEDREG/2021/00737	Fluoxetine Capsules USP 20 mg
1035	5/8/2022	MEDREG/2021/00743	Prolonged Release Morphine Tablet BP 30mg
1036	21/01/2022	MEDREG/2021/00748	Pomalidomide Capsule 1 mg
1037	21/01/2022	MEDREG/2021/00749	Pomalidomide Capsule 2 mg
1038	21/01/2022	MEDREG/2021/00750	Pomalidomide Capsule 3 mg

1039	21/01/2022	MEDREG/2021/00751	Pomalidomide Capsule 4 mg
1040	20/05/2022	MEDREG/2021/00752	Proparacaine Hydrochloride sterile ophthalmic solution 0.5% w/v
1041	07.01.2022	MEDREG/2021/00759	Cinnarazine tablet IP 25mg
1042	07.01.2022	MEDREG/2021/00764	Mycophenolate Mofetil Tablets USP500mg
1043	07.01.2022	MEDREG/2021/00766	Mycophenolate Acid Delayed Release Tablets USP 180mg
1044	07.01.2022	MEDREG/2021/00768	Mycophenolate Acid Delayed Release Tablets USP 360mg
1045	8/4/2022	MEDREG/2021/00801	Salmeterol 25mcg & Fluticasone propionate 50mg (Powder for Inhalation Metered Dose Inhaler
1046	13/01/2023	MEDREG/2021/00802	Amoxicillin Capsules BP 500 mg
1047	17/06/2022	MEDREG/2021/00803	Risperidone Tablet USP 1 mg
1048	22/04/2022	MEDREG/2021/00805	Tenofovir Disoproxil Fumarate Tablets 300mg
1049	5/8/2022	MEDREG/2021/00813	Atorvastatin Tablets 20 mg
1050	7/3/2022	MEDREG/2021/00814	Gatifloxacin Ophthalmic Solution 0.3%
1051	17/06/2022	MEDREG/2021/00815	Mefanamic acid and dicyclovmine hydrochloride tablet IP
1052	9/5/2022	MEDREG/2021/00816	Salmeterol 25mcg+ Fluticasone Propionate 250mcg Powder for inhalation
1053	24/03/2023	MEDREG/2021/00819	Emulsion for Intravenous Infusion N9-840E
1054	19/05/2022	MEDREG/2021/00831	Pantoprazole Sodium Delayed Release Tablets
1055	02.01.2023	MEDREG/2021/00834	Allopurinol Tablets BP 100mg
1056	08.07.2022	MEDREG/2021/00841	Dinoprostone Tablet USP 3 mg
1057	08/.04/2022	MEDREG/2021/00844	Vidagliptin Tablets 50 mg
1058	28/02/2022	MEDREG/2021/00862	Testosterone Injection (solution) 250mg/1ml
1059	3/6/2022	MEDREG/2021/00867	Medroxyprogesterone Acetate Injection 150 mg/1 ml
1060	1/7/2022	MEDREG/2021/00868	Amlodipine Besylate & Atorvastatin Calcium Tablets 5mg/20mg
1061	1/8/2022	MEDREG/2021/00870	Itraconazole Capsules 100 mg
1062	28/01/2022	MEDREG/2021/00874	Sulfasalazine Delayed released tablet USP 1000MG
1063	18/04/2022	MEDREG/2021/00904	Montelukast Chewable Tablets 5mg
1064	21/03/2022	MEDREG/2021/00931	Losartan Potassium Tablets USP 50 mg
1065	29/04/2022	MEDREG/2021/00940	Ceftazidime for injection USP 1g
1066	08.07.2022	MEDREG/2021/00942	Meropenem for injection USP 500mg

1067	19/05/2022	MEDREG/2021/00956	Desonide Cream 0.05% w/w
1068	7/3/2022	MEDREG/2021/00961	Fluconazole Tablets 150mg
1069	27/01/2023	MEDREG/2021/00971	Fexofenadine Hydrochloride USP Tablet 60mg
1070	02.01.2023	MEDREG/2021/00972	Dorzolamide Hydrocholride 2% & Timolol Maleate 0.5% Eye drop solution
1071	18/04/2022	MEDREG/2021/00978	Labetalol Injection BP 100 mg/20 mL
1072	21/01/2022	MEDREG/2021/00983	Clavulanic acid 125mg + Amoxicillin 875 mg tablet
1073	22/04/2022	MEDREG/2021/00990	Methylprednisolone Sodium Succinate for injection USP 1g
1074	24/01/2022	MEDREG/2021/01005	Nilotinib Capsule 150 mg
1075	18/02/2022	MEDREG/2021/01011	Hydrocortisone Sodium Succinate USP 100mg
1076	11/3/2022	MEDREG/2021/01023	Clonodine Tablets BP 25mcg
1077	28/01/2022	MEDREG/2021/01042	Betamethasone Eye/Ear Drops 0.% W/V
1078	11.02.2022	MEDREG/2021/01052	Doxycycline capsules BP 100MG
1079	24/06/2022	MEDREG/2021/01053	Ipratropium Bromide 500mcg and salbutamol 2.5mg/2.5ml respirator solution
1080	11.02.2022	MEDREG/2021/01054	Dapoxetine Tablets 60mg
1081	25/02/2022	MEDREG/2021/01055	Mitomycin for Injection USP 2mg (Lyphilized)
1082	7/1/2022	MEDREG/2021/01060	Fludrocortisone Tablets IP 100mcg
1083	23/12/2022	MEDREG/2021/01067	Irbesartan Tablets USP 150mg
1084	16/12/2022	MEDREG/2021/01068	Suxamethonium Chloride 50mg/ml solution for injection
1085	22/04/2022	MEDREG/2021/01074	Methylprednisolone Sodium Succinate for injection USP 500mg
1086	21/01/2022	MEDREG/2021/01083	Nilotinib Capsule 150 mg
1087	13/05/2022	MEDREG/2021/01098	Dextromethorphan Hydrobromide Phenylephrine Hydroch;oride and Chlopheniramine Maleate syrup
1088	18/02/2022	MEDREG/2021/01102	Gentamicin Injection BP 40 mg/ml
1089	14/02/2022	MEDREG/2021/01124	Mebeverine Hydrochloride Capsules 200 mg
1090		MEDREG/2021/01126	Levothyroxine Sodium Tablets 88mcg
1091	21/02/2022	MEDREG/2021/01127	Levothroxine Sodium tablets 112mcg
1092	20/02/2023	MEDREG/2021/01129	Ferrous fumarate plus folic acid & Cyanocobalamin
1093	25/02/2022	MEDREG/2021/01132	Levothyroxine Sodium Tablets 137mcg
1094	2/9/2022	MEDREG/2021/01133	Dapagliflozin tablets 10mg

1095	9/5/2022	MEDREG/2021/01153	Beclometasone Pressurized Inhalation BP 200mcg/Actuation
1096	25/04/2022	MEDREG/2021/01157	Salmeterol 25mcg & Fluticasone Propionate 50mcg /Actuation Pressurised Inhalation
1097	25/02/2022	MEDREG/2021/01166	Amoxicillin and Clavulanate Potassium Tablets USP 625 mg
1098	3/2/2022	MEDREG/2021/01167	Moxifloxacin Tablets 400mg
1099	19/08/2022	MEDREG/2021/01178	Linagliptin Tablets 5mg
1100	18/03/2022	MEDREG/2021/01181	Bupropion Hydrochloride Extended Release Tablets USP 150 mg
1101	18/02/2022	MEDREG/2021/01185	Gabapentin Capsules BP 100mg
1102	18/02/2022	MEDREG/2021/01186	Amoxicillin for ORal Suspension USP 125mg/5ml
1103	22/04/2022	MEDREG/2021/01190	Amoxicillin Tablets for Oral Suspension USP 125 mg
1104	1/7/2022	MEDREG/2021/01191	Amoxicillin Tablets for Oral Suspension USP250 mg
1105	17/06/2022	MEDREG/2021/01195	Cefixime Oral Suspension USP 100mg/5ml
1106	28/04/2023	MEDREG/2021/01197	B complex Forte capsules with Vitamin C, E & zinc
1107	3/6/2022	MEDREG/2021/01203	Minoxidil Topical Solution BP 5% W/V
1108	29/08/2022	MEDREG/2021/01206	Lamotrigine Dispersible Tablet 50mg
1109	23/12/2022	MEDREG/2021/01207	Empagliflozin Tablets 10 mg
1110	11.11.2022	MEDREG/2021/01208	Empagliflozin Tablets 25 mg
1111	20/05/2022	MEDREG/2021/01209	CefiximeTablets USP 200 mg
1112	24/06/2022	MEDREG/2021/01210	Minoxidil Topical Solution BP 2% W/V
1113	1/8/2022	MEDREG/2021/01214	Azithromycin Capsules USP 250 mg
1114	11.11.2022	MEDREG/2021/01215	Fuldic Acid cream BP 2% w/w
1115	17/06/2022	MEDREG/2021/01221	Adapalene Cream BP 0.1% W/W
1116	14/03/2022	MEDREG/2021/01227	Glucose Intravenous Infusion BP 5%
1117	25/02/2022	MEDREG/2021/01231	Lidocain 60mg+Hydrocortisone Acetate 5mg suppository
1118	21/03/2022	MEDREG/2021/01232	Duloxetine Capsule Delayed release USP 60mg
1119	22/04/2022	MEDREG/2021/01235	Levetiracetam Tablets USP 750mg
1120	1/7/2022	MEDREG/2021/01249	Medroxyprogesterone Acetate Injectable Suspension USP 150 mg/1 ml
1121	1/7/2022	MEDREG/2021/01250	Carbamazepine Tablet BP 200mcg
1122	29/04/2022	MEDREG/2021/01260	Ceftazidime for injection USP 500mg

1123	23.01.2023	MEDREG/2021/01276	Olopatadine ophthalmic solution USP 0.2% w/v
1124	21/02/2022	MEDREG/2021/01277	Hydrocortisone acetate opthalmic ointment USP 1%
1125	29/05/2023	MEDREG/2021/01278	Testosterone Injection (solution) USP 250 mg/ml
1126	24/01/2022	MEDREG/2021/01279	Moxifloxacin Hydrochloride Film Coated Tablets 400mg
1127	18/02/2022	MEDREG/2021/01283	Itraconazole Tablet BP100 mg
1128	4/4/2022	MEDREG/2021/01284	Lactulose Solution USP 3.35g/5ml
1129	30/09/2022	MEDREG/2021/01285	Tranexamic Acid Capsules 500 mg
1130	14/03/2022	MEDREG/2021/01297	Multivitamin and mineral syrup
1131	18/02/2022	MEDREG/2021/01302	Gabapentin Capsules BP 300mg
1132	23.01.2023	MEDREG/2021/01304	Cefoperazone and Salbactum for Injection USP 1000mg
1133	29/04/2022	MEDREG/2021/01308	Trurbutalin Sul[hate Oral Solution 1.5mg/5ml
1134	28/03/2022	MEDREG/2021/01312	Lactulose Syrup USP3.35 in 5ml
1135	11/3/2022	MEDREG/2021/01314	Rosuvastatin TabletsIP 10 mg
1136	28/03/2022	MEDREG/2021/01319	Daclatasvir tablets 60kmg
1137	7/3/2022	MEDREG/2021/01320	Nepafenac Ophthalmic Suspension 0.1%
1138	18/02/2022	MEDREG/2021/01322	Fusidic Acid Eye Drops BP 1% W/V
1139	8/4/2022	MEDREG/2021/01328	Atorvastatin Tablets 10mg
1140	28/02/2022	MEDREG/2021/01330	Bortezomib for injection 3.5mg
1141	30/05/2022	MEDREG/2021/01359	Fluticasone Furoate Nasal Spray 27.5 mcg/spray
1142		MEDREG/2021/01362	Loperamide capsues BP 2mg
1143	14/02/2022	MEDREG/2021/01377	Pethidine Injection BP 50mg/ml
1144	28/02/2022	MEDREG/2021/01378	Salbutamol Pressurized Inhalation BP 100 mcg/ Actuation
1145	4/3/2022	MEDREG/2021/01387	Bisoprolol Fumarate Tablets USP 5mg
1146	8/7/2022	MEDREG/2021/01398	Glycopyrronium Bromide Dry powder for capsules for inhalation 50 mcg
1147	25/03/2022	MEDREG/2021/01401	Voriconazole Tablets 200mg
1148	28/02/2022	MEDREG/2021/01410	Donepezil Hydrochloride Tablets USP 5 mg
1149	5/8/2022	MEDREG/2021/01424	Doxycycline Capsule BP 100mg
1150	28/01/2022	MEDREG/2021/01426	Dexamethasone Tablets BP 0.5 mg
1151	12/8/2022	MEDREG/2021/01439	Gliclazide Tablets BP 80mg
1152	30/12/2022	MEDREG/2021/01442	Cefalexin Oral suspension BP 125mg/5ml
1153	20/01/2023	MEDREG/2021/01443	Metoclopramide Injection USP 5 mg/mL
1154	08/.04/2022	MEDREG/2021/01445	Cefuroxime Axetil Tab let USP

			250MG
1155	18/03/2022	MEDREG/2021/01449	Pregabalin Capsules 25mg
1156	18/03/2022	MEDREG/2021/01452	Pregabalin Capsules 100mg
1157	20/06/2022	MEDREG/2021/01453	Salmeterol 25 mcg & Fluticasone Propionate 250 mcg Inhaler
1158	7/3/2022	MEDREG/2021/01459	Mefenamic Acid Tablets BP 500mg
1159	26.09.2022	MEDREG/2021/01466	Diltiazem Hydrochloride Tablets USP 30mg
1160	1/4/2022	MEDREG/2021/01470	Thiamine(B1) 100mg + Pyridoxine (B6) 200mg + Cyanocobalamine (B12) 200mg film coated tablet
1161	29/05/2023	MEDREG/2021/01473	Latanoprost Eye Drops 50 mcg/mL
1162	28/02/2022	MEDREG/2021/01476	Cisplatin Injection 50 mg/50 ml
1163	9/6/2023	MEDREG/2021/01477	Moxifloxacin Opthalmic Solution USP 0.5%
1164	20/05/2022	MEDREG/2021/01478	Ranitidine Injection USP 50mg/2ml
1165	18/07/2022	MEDREG/2021/01484	Pramipexole Dihydrochloride Tablets 1 mg
1166	16/06/2022	MEDREG/2021/01495	Abiraterone Acetate Tablets USP 250mg
1167	10/1/2022	MEDREG/2021/1220	Glycopyrrolate Tablets USP 1 mg
1168	3/6/2022	MEDREG/2021?00809	Salmeterol 25mcg and Flutioasone Propionate 125mcg (Powder for Inhalation) metered dose inhaler
1169	16/06/2022	MEDREG/2022/00534	Streptokinase for Injection BP 1500000 IU

ලියාපදිංචිය අලුත් කිරීම සඳහා ඉදිරිපත් වූ ඖෂධ පොරොත්තු ගොනු

	ඩොසියරය ලද දිනය	ඩොසියර අංකය	ඖෂධයේ නම
1	28/04/2023	M//4374/RR/2023	Levonogestrel Tablets 1.5mg
2	7/1/2022	M/3632/RR/2022	Rosuvastatin Tablets 5mg
3	21/01/2022	M/3676/RR/2022	Metolazone Tablets USP 2.5mg
4	31/01/202	M/3694/RR/2022	Paracetamol Tablets BP 500 mg
5	31/01/2022	M/3699/RR/2022	Furosemide Injection BP 10mg/ml
6	3/2/2022	M/3702/RR/2022	Aceclofenac Tablets BP 100mg
7	3/2/2022	M/3703/RR/LMP//2022	Vitamin B Complex, Vitamin C, Folic Acid with 20mg Elemental Zinc Capsules
8	11/2/2022	M/3717/RR/VAC/2022	Diptheria, Teatnus, Pertussis, Polymelitis, Haemophillus influenza type B conjugate vaccine
9	11/2/2022	M/3720/RR/LMP/2022	Hydrochlorothiazide Tablets BP 50 mg
10	18/02/2022	M/3729/RR/LMP/2022	Vitamin B Complex with Vitamin C & Zinc Capsules
11	21/02/2022	M/3733/RR/2022	Erythromycin Stearate Tablests USP

			500mg
12	28/02/2022	M/3744/RR/LMP/2022	Not Provided
13	14/03/2022	M/3767/RR/2022	Metronidazole Tablets USP 200mg
14	25/03/2022	M/3786/RR/2022	Latanoprost Eye Drop 0.005% w/v
15	25/03/2022	M/3788/RR/VAC/2022	Hepatitis B Vaccine (rDNA) (Paediatric) 5ml - 10 dose
16	28/03/2022	M/3789/RR/LMP/2022	Water soluble Vitamins with minerals capsules USP
17	4/4/2022	M/3796/RR/2022	Isoconazole Nitrate Cream 1% w/w
18	4/4/2022	M/3799/RR/2022	Ferrous Fumarate 350mg, Cyanocobalamin 5mcg, Folic acid 1mg, Ascorbic acid 75mg, Pyridoxine HCL 1.5mg , Zinc Sulfate 55mg capsules
19	8/4/2022	M/3804/RR/BTP/2022	Heparin Sodium Injection BP 5000 IU/ml
20	8/4/2022	M/3809/RR/BTP/2022	Human Albumin 20% solution for intravenous infusion
21	25/04/2022	M/3832/RR/2022	Danazol capsules USP 200mg
22	25/04/2022	M/3833/RR/2022	Multivitamins with Minerals Capsules
23	29/04/2022	M/3839/RR/2022	Clindamycin Phospate 1.2% w/w
24	9/5/2022	M/3850/RR/2022	Esomeprazole for Injection 40 mg
25	13/05/2022	M/3857/RR/2022	Calcium & Colecalciferol TabletsbBP (400mg+400IU)
26		M/3862/RR/2022	Sterile Medroxyprogesterone Acetate Suspesion USP 150 mg/ml
27	20/05/2022	M/3873/RR/2022	Olanzapine Tablet USP 10mg
28	20/05/2022	M/3879/RR/2022	Telmisartan Tablets USP 80mg
29	23/05/2022	M/3882/RR/2022	Rabeprazole Sodium for Injection 20 mg
30	23/05/2022	M/3883/RR/2022	Flucanazole Capsules BP 150 mg
31	23/05/2022	M/3884/RR/2022	Fusidic Acid 2% w/w + Beclamethasone Dipropionate 0.025% w/w Cream
32	30/5/2022	M/3900/RR/2022	Mannitol Solution 20 % w/v for intravenous infusion
33	3/6/2022	M/3909/RR/BTP/2022	Recombinant Interferon Beta 1a Injection 30mcg
34	6/6/2022	M/3913/RR/2022	Hepatitis B (rDNA) Vaccine 20 mcg/ml (Adult-single dose)
35	10/6/2022	M/3917/RR/2022	Metformin Tablets BP 500 mg
36	10.06.2022	M/3921/RR/2022	Amiodarone Hydrochloride Tablet 200mg
37	16/06/2022	M/3924/RR/2022	Vitamin E capsules USP 600mg
38	17/06/2022	M/3932/RR/2022	Levofloxacin Intravenous Infusion 500mg/ 100ml

39	2022.06.20	M/3936/RR/2022	Clonazepam Tablets 0.5 mg
40	24.06.2022	M/3938/RR/LMP/2022	Tiotropium Dry Powder Inhalation Capsules 18 mcg
41	24/06/2022	M/3939/RR/2022	Ibuprofen Tablets BP 200mg
42	24/06/2022	M/3943/RR/2022	Clonazepam Tablets 2mg
43	27/06/2022	M/3948/RR/2022	Esomeprazole Magnesium Tablets 20mg
44	1/7/2022	M/3950/RR/BTP/2022	Human Albumin Solution 20% EUP
45	4/7/2022	M/3952/RR/2022	Roxithromycin Tablets 150mg
46	8/7/2022	M/3958/RR/2022	Esomeprazole Tablets 20mg
47	8/7/2022	M/3959/RR/2022	Gemcitabine for Injection USP 1000 mg
48	8/7/2022	M/3960/RR/2022	Piroxicam Orodispersible Tablets 20 mg
49	15/07/2022	M/3964/RR/2022	Amoxicillin with Potassium Clavulanate Tablets USP 375 mg
50	15.07.2022	M/3971/RR/2022	Betahistine Dihydrochloride Tablets BP 16mg
51	15.07.2022	M/3972/RR/2022	Glimepiride Tablets USP 1mg
52	18/07/2022	M/3973/RR/2022	Rosuvastatin Tablets USP 10 mg
53	22/07/2022	M/3975/RR/2022	Metformin Tablets BP 500 mg
54	22/07/2022	M/3977/RR/2022	Celecoxib Tablets 200mg
55	22/07/2022	M/3980/RR/2022	Sitagliptin Phosphate Tablets USP 50mg
56	22/07/2022	M/3981/RR/2022	Baclofen Tablets USP 10mg
57	29.07.2022	M/3991/RR/2022	Ketoprofen Gel 2.5% w/w
58	5/8/2022	M/3997/RR/2022	Dutasteride Capsules 0.5 mg
59	12/8/2022	M/4004/RR/2022	Meropenem for injection 500mg USP
60	15/08/2022	M/4005/RR/2022	Benzalkonium 0.1% w/w & Zinc oxide 8.5% cream
61	19/08/2022	M/4006/RR/2022	Tobramycin 3mg + Dexamethasone 1mg ophthalmic suspension
62	19/08/2022	M/4008/RR/2022	Clotrimazole 1% w/v and Lidocaine Hydrochloride 2% w/v Ear drops
63	22/08/2022	M/4011/RR/2022	Lidocaine 25 mg + Prilocaine 25 mg in 1 g Cream
64	26/08/2022	M/4014/RR/2022	Celecoxib Capsules 200 mg
65	26/08/2022	M/4017/RR/2022	Irinotecan Hydrochloride Injection 100mg/5ml
66	29/08/2022	M/4019/RR/2022	Telmisartan Tablets USP 20mg
67	29/08/2022	M/4020/RR/2022	Levocetrizine Dihydrochloride oral solution 2.5mg/5ml
68	2/9/2022	M/4024/RR/2022	Mefanamic acid Tablets BP 500mg
69	2/9/2022	M/4025/RR/2022	Mefenamic acid tablets BP 250mg
70	2/9/2022	M/4029/RR/2022	Quetiapine Tablets USP 200mg

71	9/9/2022	M/4032/RR/BTP/2022	Follitropin alfa (r hFSH) 150IU + Lutropin alfa (r- hLH) 75IU powder and solvent for solution for injection
72	9/9/2022	M/4033/RR/2022	Pimecrolimus cream 1%
73	9/9/2022	M/4034/RR/2022	Brinzolamide 10mg + Timolol 5mg Eye Drops
74	12/9/2022	M/4037/RR/2022	Sulmeterol 25mcg+Fluticasone Propionate 250mcg Inhalation IP
75	16/09/2022	M/4038/RR/BTP/2022	Heparin Sodium Injection 5000 IU/ml
76	16/09/2022	M/4041/RR/2022	Sitagliptin Tablet USP 50mg
77	16/09/2022	M/4042/RR/2022	Sitagliptin Tablet USP 100 mg
78	22/09/2022	M/4045/RR/2022	Levonogestrel Tablets BP 1.5mg
79	22/09/2022	M/4046/RR/2022	Povidone Iodine Topical solution USP 10% w/v
80	22/09/2022	M/4047/RR/2022	Losartan Potassium Tablets USP 50mg
81	22/09/2022	M/4048/RR/2022	Metformin Hydrochloride Tablets USP 500mg
82	23/09/2022	M/4049/RR/2022	Vitamin B complex Syrup
83	26.09.2022	M/4050/RR/2022	Clarithromycin Tablets USP 500mg
84	30/09/2022	M/4053/RR/LMP/2022	Povidone Iodine Cleansing Solution USP 7.5% w/v
85	30/09/2022	M/4054/RR/2022	Nabumetone Tablets BP 500mg
86	30/09/2022	M/4055/RR/LMP/2022	Povidone Iodine Solution BP 10% w/v(1% available iodine)
87	30/09/2022	M/4056/RR/LMP/2022	Calamine 4%+ Witch Hazel 5%+Phenol 0.2%+Sodium Benzoate 0.1% Lotion
88	30/09/2022	M/4057/RR/2022	Irbesartan Tablets USP 150mg
89	3/10/2022	M/4060/RR/2022	Amoxicillin Powder for Oral Suspension 125 mg/ 5 mL
90	3/10/2022	M/4061/RR/VAC/2022	Hepatitis A Virus (Inactivated) Vaccine 720 ELISA units/0.5 mL
91	7/10/2022	M/4065/RR/2022	Cefixime for oral suspension USP 100mg/5ml
92	14/10/2022	M/4071/RR/2022	Ondansetron Injection BP 8mg/4ml
93	17/10/2022	M/4075/RR/2022	Oxymetazoline Hydrochloride Nasal Drops USP 0.025% v/v
94	17/10/2022	M/4076/RR/2022	Budesonide 200 mcg+Formoterol Fumarate Dihydrate 6mcgDry powder inhalation Capsules
95	17/10/2022	M/4078/RR/2022	Acetaminophen Suppositories USP 125mg
96	17/10/2022	M/4079/RR/2022	Glimepiride Tablets USP 2mg
97	17/10/2022	M/4080/RR/2022	Telmisartan Tablets USP 40mg
98	21.10.2022	M/4081/RR/BTP/2022	Human Albumin 20% Solution for infusion 200g/l

99	21.10.2022	M/4082/RR/2022	Escitalopram Tablets USP 10mg
100	21.10.2022	M/4083/RR/2022	Gabapentine tablets USP 100 mg
101	28/10/2022	M/4084/RR/2022	Mometasone Furoate Monohydrate Nasal Spray 50 mcg
102	28/10/2022	M/4085/RR/2022	Meropenem for injection 500mg USP
103	28/10/2022	M/4086/RR/2022	Diclofenac Potassium Tablets USP 50mg
104	28/10/2022	M/4087/RR/2022	Betamethasone Valreate Ointment BP 0.1% w/w
105	31.10.2022	M/4090/RR/2022	Dorzolamide 2% w/v + Timolol 0.5% w/v USP Ophthalmic solution
106	04.11.2022	M/4091/RR/2022	Aripiprazole Tablets USP 15mg
107	04.11.2022	M/4096/RR/2022	Zoledronic Acid for Injection 4mg
108	4/11/2022	M/4098/RR/2022	Domperidone Suspension 5 mg/5ml
109	04.11.2022	M/4099/RR/2022	Esomeprazole Tablets 20mg
110	04.11.2022	M/4100/RR/2022	Ciprofloxacillin Ophthalmic Solution 0.3% w/v
111	04.11.2022	M/4101/RR/2022	Alumina, Magnesia & Simethicone chewable Tabletys USP
112	11.11.2022	M/4103/RR/2022	Tranexamic Acid Tablets BP 500mg
113	11.11.2022	M/4104/RR/2022	Amoxicillin Oral Suspension BP 125mg/5ml
114	11.11.2022	M/4105/RR/2022	Zinc sulphate oral solution USP 10mg/5ml
115	14.11.2022	M/4107/RR/2022	Amoxicillin 500mg+Clavilanic Acid 125 mg Oral Suspension
116	18/11/2022	M/4109/RR/2022	Gastro resistant Diclofenac Sodium Tablets BP 50mg
117	18/11/2022	M/4110/RR/2022	Paliperidone prolonged relaese suspension for injection
118	18/11/2022	M/4111/RR-D/2022	Prednisolone Tablets BP 5mg
119	18/11/2022	M/4114/RR-D/BTP/2022	Human recombinant granulocytes colony stimulating factor Injection 300mcg/ml
120	18/11/2022	M/4115/RR/2022	Citaloplram Tablets USP 10mg
121	18/11/2022	M/4116/RR/BTP/2022	Interferon Beta- 1a Solution for Injection 44 mcg (12 MIU)/0.5ml
122	18/11/2022	M/4118/RR/2022	Tadalafil Tablets USP 10 mg
123	21/11/2022	M/4123/RR/2022	Pregabalin Capsule 75mg
124	21/11/2022	M/4125/RR/2022	Donepezil Hydrochloride Tablets USP 5mg
125	25/11/2022	M/4128/RR/2022	Esomeprazole Capsules USP 20 mg
126	25/11/2022	M/4129/RR-D/2022	Desloratadine tablets 5mg
127	25/11/2022	M/4131/RR/2022	Levonorgesytral 0.15 mg and Ethinylestradiol 0.03 mg Tablets BP with Ferrous Fumarate Tablets BP 75 mg

128	25/11/2022	M/4134/RR-D/2022	Pregabalin Capsules 75mg
129	25/11/2022	M/4135/RR-D/2022	Pregabalin Capsules 100mg
130	25/11/2022	M/4136/RR/2022	Salmeterol BP 25 mcg and Fluticasone Propionate BP 250 mcg Pressurized Inhalation
131	25/11/2022	M/4137/RR/2022	Sitagliptin Tablets 50mg
132	25/11/2022	M/4138/RR/2022	Pantoprazole Powder for Injection 40 mg
133	25/11/2022	M/4139/RR/2022	Ondansetron orally disintegrating strip 4mg
134	25/11/2022	M/4141/RR/2022	Ondansetron orally disintegrating strip 8mg
135	25/11/2022	M/4142/RR/2022	Vildagliptin Tablets 50mg
136	25/11/2022	M/4143/RR/BTP/2022	Recombinant Human Erythropoietin Injection 2000 IU
137	28/11/2022	M/4144/RR-D/2022	Tranexamic Acid Capsules 500mg
138	28/11/2022	M/4145/RR-D/2022	Tizanidine Tablets USP 2mg
139	28/11/2022	M/4149/RR-D/2022	Atenalol Tablets 50 mg
140	2/12/2022	M/4151/RR/2022	Dibasic Calcium Phosphate 430mg+Cholecalciferol 200 I.U. (Vitamin D3) + Ascorbic Acid (Vitamin C) 40 mg Chewable Tablets.
141	2/12/2022	M/4152/RR/2022	Multivitamin Drops
142	02.12.2022	M/4156/RR-D/2022	Metformin Hydrochloride Sustained Release Tablets 500mg
143	02.12.2022	M/4157/RR/2022	Moxonidine Tablets 0.2mg
144	02.12.2022	M/4160/RR/2022	Diclofenac Sodium Suppsitories 50mg
145	05.12.2022	M/4161/RR/2022	Rispoeridone Tablets USP 2mg
146	05.12.2022	M/4162/RR/2022	Vitamin C Tablet 500mg
147	05.12.2022	M/4163/RR/BTP/2022	Erythropoietin Injection BP 4000iu/0.4ml
148	09.12.2022	M/4167/RR-D/2022	Calcitriol Capsules BP 0.25 mg
149	09.12.2022	M/4168/RR-D/2022	Erlotinib Hydrochloride Tablets 150 mg
150	9/12/2022	M/4169/RR/BTP/2022	Factor VIII inhibitor bypassing fraction powder for solution for infusion 500U/vial
151	9/12/2022	M/4170/RR/2022	Montelukast Sodium Chewable tablets 4mg
152	9/12/2022	M/4171/RR/2022	Montelukast Sodium Chewable tablets 5mg
153	9/12/2022	M/4173/RR-D/2022	Oxymetazoline Hydrochloride Nasal Solution USP 0.025%
154	12/12/2022	M/4177/RR/2022	Pregabalin Capsules IP 75 mg
155	16/12/2022	M/4179/RR-D/2022	Miconazole cream BP 2%w/w
156	16/12/2022	M/4180/RR/2022	Rosuvastatin Calcium Tablets 20mg
157	16/12/2022	M/4182/RR-D/2022	Simvastatin Tablets USP 20mg

158	16/12/2022	M/4183/RR-D/2022	Dinoprostone Vaginal Tablets 3mg
159	16/12/2022	M/4184/RR/2022	Acetaminophen Suppositories USP 250mg
160	16.12.2022	M/4186/RR-D/2022	Fexofenadine Hydrochloride Suspension 30mg/5ml
161	19.12.2022	M/4187/RR-D/2022	Progesterone soft gelatin capsules 200mg
162	19.12.2022	M/4188/RR-D/2022	Metformin Hydrochloride Tablets USP 850mg
163	19.12.2022	M/4189/RR-D/2022	Sitagliptin Phosphate Tablets 100mg
164	19.12.2022	M/4190/RR/2022	Levonogestrel 52mg Intrauterine System 20mcg/24h
165	19.12.2022	M/4191/RR-D/2022	Losartan Potassium Tablets USP 50mg
166	19.12.2022	M/4192/RR-D/2022	Losartan Potassium Tablets USP 25mg
167	19.12.2022	M/4194/RR-D/2022	Cefuroxime for injection USP 750mg
168	19.12.2022	M/4195/RR-D/2022	Magnesium Hydrochloride 400mg, Aluminium Hydrochloride 400mg & Simehicone 40mg in 5ml oral suspension (Alumina, Magnisia & Simethicone oral suspension USP)
169	23/12/2022	M/4198/RR-D/2022	Amoxacillin & Clavulanate Potassium for Oral Suspension USP 156.25 mg/5 ml
170	23/12/2022	M/4200/RR-D/2022	Metformin Hydrochloride Tablets USP 500mg
171	23/12/2022	M/4201/RR/2022	Etoricoxib Tablets 60mg
172	23/12/2022	M/4202/RR/2022	Fusidic acid cream 2%w/w
173	23/12/2022	M/4203/RR/2022	Etoricoxib Tablets 90mg
174	23/12/2022	M/4204/RR/2022	Adapalene Gel Microspheres 0.1% w/w
175	23/12/2022	M/4205/RR/BTP/2022	Interferon Beta- 1a Solution for Injection 44 mcg (12 MIU)/0.5ml
176	23/12/2022	M/4206/RR/2022	Amocillin and Pottasium clavulanate powder for oral suspension USP 156.25mg/5ml
177	23/12/2022	M/4208/RR/2022	Iron Polymaltose complex 235mg+ Folic acid 0.35mg capsules
178	23/12/2022	M/4209/RR-D/2022	Morphine Sulphate Prolonged Release Tablets BP 60mg
179	23/12/2022	M/4210/RR-D/2022	Morphine Sulphate Prolonged Release Tablets BP 10mg
180	23.12.2022	M/4211/RR-D/2022	Prednisolone Acetate Ophthalmic Susupension USP 10mg/ml
181	30/12/2022	M/4212/RR/2022	Gliclazide modified release tablets 30mg
182	30/12/2022	M/4213/RR/2022	Urofollitropin For Injection BP/75IU

183	30/12/2022	M/4214/RR-D/2022	Amoxicillin and clavulanate Pottasium Tablets 625mg
184	30/12/2022	M/4215/RR/2022	Amoxicillin 500mg and clavulanate Pottasium 125 mgTablets
185	30/12/2022	M/4216/RR-D/2022	Metronidazole tablets BP 200mg
186	30/12/2022	M/4217/RR/2022	Etonogestrel Implant 68mg
187	30/12/2022	M/4218/RR-D/2022	Magnesium Hydroxide 185mg+simethicone 50mg+Aluminium hydroxide 830mg+ Carboxymethyl cellulose 100mg in 10ml oral liquid
188	30/12/2022	M/4219/RR/2022	Mebeverine Hydrochloride BP 135 mg and Ispaghula Husk BP 3.5g Scahets
189	30/12/2022	M/4220/RR/2022	Clopidogrel tablets USP 75mg
190	30/12/2022	M/4221/RR/2022	Tadalafil Tablets USP 10 mg
191	02.01.2023	M/4226/RR/2023	Haloperidol Tablets BP 1.5mg
192	02.01.2023	M/4228/RR-D/2023	Rispoeridone Tablets USP 1mg
193	2/1/2023	M/4229/RR-D/2023	Oxaliplatin for Injection USP 50mg
194	02.01.2023	M/4230/RR/2023	Sitagliptin Tablets USP 100mg
195	2/1/2023	M/4231/RR-D/2023	Oxaliplatin for Injection USP 100mg
196	02.01.2023	M/4232/RR-D/2023	Dexamethasone Tablets BP 0.5mg
197	02.01.2023	M/4233/RR-D/2023	Chlorphenamine Tablets BP 5mg
198	02.01.2023	M/4234/RR/2023	Clopidogrel tablets USP 75mg
199	9/1/2023	M/4236/RR/2023	Tadalafil tablets USP 10mg
200	9/1/2023	M/4237/RR-D/2023	Ondansetron oral solution USP 4mg/5ml
201	9/1/2023	M/4238/RR-D/BTP/2023	Recombinant human follicle stimulating hormone powder for injection 75 IU
202	9/1/2023	M/4239/RR-D/2023	Glibencamide Tablets BP 5mg
203	9/1/2023	M/4240/RR-D/2023	Losartan Pottasium Tablets USP 50mg
204	9/1/2023	M/4241/RR-D/BTP/2023	Recombinant human follicle stimulating hormone powder for injection 150 IU
205	9/1/2023	M/4242/RR-D/2023	Fexofenadine Hydrochloride Tablet USP 120mg
206	13/01/2023	M/4243/RR/2023	Anastrozole Tablet 1mg
207	13/01/2023	M/4246/RR-D/2023	Diclofenac Sodium Suppsitory 100mg
208	13/01/2023	M/4247/RR-D/VAC/2023	Adsorbed Tetanus Vaccine BP
209	13/01/2023	M/4249/RR/2023	Dinoprostone Vaginal Gel 2mg/3g with Disposable Plastic Applicator
210	20/01/2023	M/4250/RR/2023	Gliclazide Tablets BP 80mg
211	20/01/2023	M/4251/RR-D/2023	Dequalinium Chloride Lozenges 0.25 mg
212	23.01.2023	M/4252/RR-D/2023	Olanzapine Tablets USP 10mg

213	23.01.2023	M/4253/RR/2023	Ketoprofen Gel BP 2.5% w/w
214	27/01/2023	M/4254/RR-D/2023	Chlorhexidine Mouthwash BP 0.2% w/v
215	27/01/2023	M/4255/RR-D/2023	Ruxolitinib Tablets 15mg
216	27/01/2022	M/4256/RR/2023	Bimatoprost Eye Drop 0.03%
217	30.01.2023	M/4257/RR/2023	Etoricoxib tablets 90mg
218	30.01.2023	M/4258/RR-D/2023	Methylprednisolone Tablets IP 8mg
219	3/2/2023	M/4260/RR/2023	Gabapentine tablets USP 100 mg
220	3/2/2023	M/4261/RR/2023	Gabapentine tablets USP 300 mg
221	3/2/2023	M/4262/RR-D/2023	Fexofenadine Hydrochloride Tablets USP 120mg
222	3/2/2023	M/4264/RR-D/2023	Phytomenadione Injection BP 1mg/0.5ml
223	2-Mar /2023	M/4265/RR-D/2023	Furosemide Injection BP 10mg/ml
224	3/2/2023	M/4266/RR-D/LMP/2023	Sulbutamol Tablets BP 2 mg
225	06.02.2023	M/4267/RR-D/2023	Methylprednisolone Tablets IP 4mg
226	06.02.2023	M/4268/RR-D/2023	Glipizide tablets BP 5mg
227	6/2/2023	M/4269/RR-D/2023	Brinzolamide 10 mg & Brimonidine Tartrate 2 mg Per 1 mL Suspension
228	6/2/2023	M/4270/RR/2023	Rosuvastatin Calcium Tablets 10 mg
229	10/2/2023	M/4271/RR/2023	Clotrimazole 1% BP Hydrocortisone 1% BP cream
230	10/2/2023	M/4272/RR-D/2023	Enalapril Maleate tablets USP 5mg
231	10/2/2023	M/4273/RR/2023	Candesartan Cilexetil Tablets 8mg
232	10/2/2023	M/4274/RR/2023	Candesartan Cilexetil Tablets 16mg
233	10/2/2023	M/4275/RR/2023	Betahistine Dihydrochloride tablets BP 8mg
234	10/2/2023	M/4276/RR/2023	Flucloxacillin capsules BP 500mg
235	10/2/2023	M/4277/RR/2023	Flucloxacillin capsules BP 250mg
236	10/2/2023	M/4278/RR-D/2023	Oxaliplatin Injection USP 50mg/25ml
237	10.02.2023	M/4279/RR/2023	Clopidogrel tablets USP 75mg
238	10.02.2023	M/4282/RR/2023	Rosuvastatin Calcium Tablets 20mg
239	10.02.2023	M/4283/RR-D/2023	Esomeprazole capsules BP 20 mg
240	13.02.2023	M/4284/RR-D/2023	Metformin HCl Tablets 500mg
241	13.02.2023	M/4285/RR-D/2023	Metformin HCl Tablets 850mg
242	13.02.2023	M/4286/RR/2023	Betamethasone Valreate Ointment BP 0.1% w/w
243	17.02.2023	M/4287/RR/2023	Candesartan Cilexatil Tablets 4mg
244	17.02.2023	M/4288/RR/2023	Cefuroxime Axetil Tablets USP 125 mg
245	17.02.2023	M/4289/RR-D/2023	Topiramate Tablets USP 50mg
246	17.02.2023	M/4290/RR/BTP/2023	Erythropoietin Injection BP (Recombinant Human Erythropoietin Alfa Injection)10000IU/1ml
247	20.02.2023	M/4291/RR-D/2023	Phenobarbital Injection BP

			200mg/ml
248	20.02.2023	M/4293/RR/2023	Prednisolone Acetate Ophthalmic Susupension USP 10mg/ml
249	20.02.2023	M/4294/RR/2023	Metoprolol Succinate Extended release Tablets USP 50 mg
250	20/02/2023	M/4295/RR-D/2023	Fluorouracil Injection IP 250mg/5ml
251	20.02.2023	M/4296/RR-D/2023	Multivitamin & Mineral
252	20.02.2023	M/4297/RR-D/2023	Ketotifen Syrup 1mg/5ml
253	20/02/2023	M/4298/RR-D/2023	Salicylic Acid 40% Medicated Plaster
254	24/02/2023	M/4299/RR/LMP/2023	Codeine Phosphate Syrup BP 25 mg/5 mL
255	24/02/2023	M/4300/RR-D/LMP2023	Cloxacillin Capsules USP 250 mg
256	24/02/2023	M/4301/RR-D/2023	Ferrous Glycine Sulphate Equivalent to 60 mg of Iron+Niacinamide BP 50 mg+Pyridoxine Hydrochloride BP 3mg+Cyanocobalamine BP 15 mg+Folic Acid BP 1mg+Zinc Sulphate BP Equivalent to Zinc 5mg
257	24/02/2023	M/4302/RR/2023	Betamethasone Dipropionate Solution USP 0.064%w/v
258	24/02/2023	M/4303/RR-D/2023	Esomeprazole Enteric Coated Tablets 20 mg
259	24/02/2023	M/4304/RR-D/2023	Aceclofenac Sodium Tablet 100mg
260	24/02/2023	M/4305/RR-D/2023	Vinorelbine Injection IP 10 mg/mL
261	24/02/2023	M/4306/RR-D/2023	Levocetirizine Dihydrochloride Tablets USP 5 mg
262	24/02/2023	M/4307/RR-D/2023	Clopidogrel tablets USP 75mg
263	24/02/2023	M/4308/RR-D/2023	Miconazole Oromucosal Gel BP 2% w/w
264	27/02/2023	M/4309/RR-D/2023	Frusemide tablets 40mg
265	27/02/2023	M/4310/RR-D/BTP/2023	Tuberculin purified protein derivative for human use 5IU/0.1ml
266	27/02/2023	M/4311/RR-D/2023	Clopidogrel tablets USP 75mg
267	27/02/2023	M/4312/RR-D/2023	Glimepiride Tablets USP 4mg
268	27/02/2023	M/4313/RR-D/2023	Glyceryl Trinitrate Tablets BP 0.5mg
269	27/02/2023	M/4314/RR-D/2023	Metolazone Tablets USP 5mg
270	3/3/2023	M/4315/RR-D/2023	Flupentixol Injection 20mg/ ml
271	3/3/2023	M/4316/RR-D/2023	Clobetasol Ointment BP 0.05% w/w
272	3/3/2023	M/4317/RR/2023	Basiliximab powder for solution for injection or infusion 20mg
273	3/3/2023	M/4318/RR-D/2023	Hydroxyapatite (Milk Calcium) 600mg + Vitamin D3 50IU Tablets
274	03.03.2023	M/4319/RR-D/2023	Sodium Bicarbonate Tablets USP 600m
275	10.03.2023	M/4320/RR/2023	Goserelin Injection 3.6 mg
276	10.03.2023	M/4321/RR/2023	Diltiazem Hydrochloride Capsules

			90 mg
277	10.03.2023	M/4322/RR-D/2023	Loratidine Tablets USP 10 mg
278	10.03.2023	M/4323/RR-D/2023	Betamethasone Valreate Ointment USP 0.1%
279	10.03.2023	M/4324/RR-D/2023	Ivabradine Tablets 5 mg
280	10.03.2023	M/4325/RR/2023	Esomeprazole Tablets 40 mg
281	10.03.2023	M/4326/RR/2023	Atorvastatin Tablets 10 mg
282	13.03.2023	M/4327/RR-D/2023	Povidone Iodine Ointment USP 5% w/w
283	13/03/2023	M/4328/RR-D/2023	Octreotide Acetate LAR Powder and solvent for suspension for injection 30mg
284	13/03/2023	M/4329/RR-D/2023	Chlorphenamine Tablets BP 4mg
285	13/03/2023	M/4330/RR-D/2023	Saline Nasal Solution 0.74% w/v
286	13/03/2023	M/4331/RR-D/BTP/VAC/2023	Diphtheria Tetanus Pertussis (Whole cell) Hepatitis B (r DNA) and Heamophillus type b conjugate vaccine (adsorbed) (Liquid pentavalent vaccine)
287	17/03/2023	M/4332/RR/2023	Budesonide 200mcg+ Formoterol fumarate dihydrate 6mcg metered dose inhaler
288	17/03/2023	M/4333/RR/2023	Levocvetrizine Dihydrochloride Tablets 5mg
289	17/03/2023	M/4334/RR-D/2023	Docetaxel Concentrate IP 80mg/2ml with solvent
290	17/03/2023	M/4335/RR-D/2023	Moxifloxacinj Hydrochloride Tablets 400mg
291	17/03/2023	M/4336/RR/2023	Mosapride citrate tablets 5mg
292	17/03/2023	M/4337/RR-D/2023	Atorvastatin Tablets IP 10mg
293	20/03/2023	M/4339/RR/2023	Bupivacaine HCl 5mg/ml solution for injection
294	20/03/2023	M/4341/RR-D/2023	Clarithromycin Tablets 500mg
295	20/03/2023	M/4343/RR-D/2023	Salbutamol Sulphate Dry Powder Inhalation Capsules 200mcg
296	24/03/2023	M/4344/RR-D/2023	Cefuroxime Axetil Tablets USP 500mg
297	24/03/2023	M/4345/RR/BTP/2023	Antihaemophilic factor (Human) Injection (220-2000) I.U./Vial Method M, Monoclonal Purified, Nano filtered 300 IU/Vial
298	24/03/2023	M/4346/RR/2023	Metformin Hydrochloride Prolonged Release Tablets 500 mg
299	24/03/2023	M/4347/RR-D/BTP/2023	Streptokinase for Injection BP 1500000IU
300	31/03/2023	M/4350/RR/2023	Salbutamol Sulphate Respirator Solution 5mg/ml
301	31/03/2023	M/4351/RR-D/2023	Montelukast Sodium Tablets 5mg
302	31/03/2023	M/4352/RR-D/2023	Cefuroxime Axetil Tablets BP 250

			mg
303	31/03/2023	M/4353/RR-D/2023	Desonide Lotion 0.05% w/w
304	31/03/2023	M/4354/RR-D/2023	Betamethasone Valerate Cream BP 0.1% w/w
305	31/03/2023	M/4355/RR-D/2023	Gentamicin Eye/Ear Drops 0.3% w/v
306	31/03/2023	M/4356/RR/2023	Clarithromycin Oral Suspension USP 125mg/5ml
307	3/4/2023	M/4357/RR/2023	Bimatoprost 0.3 mg/mL + Timolol 5 mg/mL Eye Drops Solution
308	03.04.2023	M/4358/RR-D/2023	Haloperidol Tablets BP 5mg
309	03.04.2023	M/4359/RR-D/2023	Acyclovir Ointment USP 5% W/W
310	03.04.2023	M/4361/RR-D/2023	Neostigmine Injection BP 2.5mg/ml
311	10.04.2023	M/4362/RR-D/2023	Compound Methyl Salicylate Ointment
312	10.04.2023	M/4363/RR-D/2023	Rosuvastatin Tablet 5mg
313	10.04.2023	M/4364/RR/2023	Rosuvastatin Tablet 10mg
314	10.04.2023	M/4365/RR/2023	Ceforoxime Axetil Tablet IP 250mg
315	21.04.2023	M/4366/RR-D/2023	Labetalol Hydrochloride Tablets USP 100mg
316	21.04.2023	M/4367/RR-D/2023	Calcium with Vitamin D Tablets USP (500mg/200IU)
317	21.04.2023	M/4368/RR-D/2023	Losartan Pottasium Tablets USP 50mg
318	21.04.2023	M/4369/RR-D/2023	Fusidic acid cream BP 2%
319	21.04.2023	M/4370/RR-D/2023	Clobetasone Cream BP 0.05% w/w
320	24/04/2023	M/4371/RR-D/2023	Topiramate Tablets IP 50mg
321	24/04/2023	M/4372/RR-D/2023	Clobetasol Propionate Cream USP 0.05% w/w
322	28/04/2023	M/4373/RR/2023	Salmeterol 25mcg + Fluticasone propionate 125mcg Inhaler
323	28/04/2023	M/4375/RR-D/2023	Lenalidomide Capsules 5 mg
324	28/04/2023	M/4376/RR-D/2023	Lenalidomide Capsules 10 mg
325	28/04/2023	M/4377/RR-D/2023	Bortezomib for Injection 2mg/vial
326	28/04/2023	M/4378/RR/2023	Domperidone Suspension 5mg/5ml
327	4/5/2023	M/4379/RR-D/2023	Amlodipine Besylate Tablets USP 5mg
328	4/5/2023	M/4380/RR-D/2023	Amlodipine Besylate Tablets USP 10mg
329	8/5/2023	M/4381/RR-D/2023	Etoposide Injection USP 100mg/5ml
330	8/5/2023	M/4383/RR-D/2023	Loratidine Tablets USP 10 mg
331	8/5/2023	M/4384/RR-D/2023	Amiodarone Tablet BP 200mg
332	8/5/2023	M/4385/RR-D/2023	Fexofenadine Hydrochloride Tablets USP 120mg
333	8/5/2023	M/4386/RR/2023	Hydrocortisone Cream USP 1% w/w
334	8/5/2023	M/4387/RR/2023	Desmopressin Acetate Tablets 0.1 mg
335	12/5/2023	M/4388/RR-D/LMP/2023	Vitamin & Mineral Supplement

			Capsules
336	12/5/2023	M/4389/RR-D/2023	Azithromycin Tablets USP 500mg
337	12/5/2023	M/4390/RR-D/2023	Azithromycin Tablets USP 250mg
338	12/5/2023	M/4391/RR-D/2023	Tranexamic Acid Capsules 500mg
339	12/5/2023	M/4392/RR-D/2023	Clarithromycin Tablets USP 500 mg
340	12/5/2023	M/4393/RR-D/2023	Dapoxetine Mouth Dissolving Tablets 30 mg
341	12/5/2023	M/4394/RR/2023	Ciprofloxacin Eye/Ear Drops 0.3% w/v
342	12/5/2023	M/4395/RR/2023	Clindamycin Injection 150 mg in 1ml
343	12/5/2023	M/4396/RR-D/2023	Azithromycin for Oral Suspension USP 200mg/5ml
344	19/05/2023	M/4397/RR/2023	Cilnidipine Tablets 10mg
345	19/05/2023	M/4398/RR-D/2023	Metformin Hydrochloride extented release tablets USP 500mg
346	19/05/2023	M/4399/RR/2023	Amoxicillin and clavulanate Pottasium Tablets 375mg
347	19/05/2023	M/4400/RR/2023	Amoxicillin and clavulanate Pottasium Tablets 625mg
348	19/05/2023	M/4401/RR-D/2023	Montelukast Sodium Tablets 4mg
349	19/05/2023	M/4402/RR/2023	Etoricoxib tablets 60mg
350	22/05/2023	M/4403/RR-D/2023	Beclometasone Pressurised Inhalation BP 100mcg/ Actuation
351	26.05.2023	M/4404/RR-D/2023	Levothyroxine sodium Tablets 50mcg
352	26/05/2023	M/4405/RR-D/2023	Rosuvastatin Tablets 20 mg
353	26.05.2023	M/4406/RR/2023	Atenolol Tablet BP 25mg
354	26.05.2023	M/4407/RR-D/2023	Donepezil Hydrochloride Tablet USP 5mg
355	26.05.2023	M/4408/RR/2023	Sitagliptin Phosphate Tablets 100mg
356	26.05.2023	M/4409/RR-D/2023	Flunarizine Dihydrochloride Tablets 5mg
357	29/05/2023	M/4410/RR/BTP/2023	Infliximab Powder for Injection 100 mg
358	29/05/2023	M/4411/RR/2023	Pregabalin Capsules BP 100mg
359	29/05/2023	M/4412/RR-D/2023	Amoxicillin and Potassium Clavulanate Tablets BP 625 mg
360	2/6/2023	M/4413/RR/2023	Rabeprazole Sodium Delayed Release Tablets 20 mg
361	02.06.2023	M/4414/RR/2023	Metronidazole tablets BP 200mg
362	02.06.2023	M/4415/RR/2023	Fusidic acid cream BP 2%
363	02.06.2023	M/4416/RR-D/2023	Meloxicam Tablets BP 7.5mg
364	05.06.2023	M/4417/RR-D/2023	Methylprednisolone Sodium Succinate for Injection USP 1g
365	5/6/2023	M/4418/RR-D/2023	Carboxymethylcellulose sodium opthalmic solution 0.5% w/v

366	05.06.2023	M/4419/RR/2023	Azithromycin Tablets USP 250mg
367	05.06.2023	M/4420/RR/2023	Alumina(918mg), Magnesia(300mg) and Simethicone(60mg) Oral Suspension USP
368	9/6/2023	M/4421/RR-D/2023	Polyethylene Glycol 0.4% and Propylene Glycol 0.3% Eye Drops
369	12.06.2023	M/4422/RR/LMP/2023	Chlorphenamine Tablet BP 4mg
370	12.06.2023	M/4423/RR/VAC/2023	Yellow fever vaccine (Live) Sigle dose
371	12.06.2023	M/4424/RR/2023	Econazole Nitrate 1% w/w + Triamcinolone acetonide 0.1% w/w cream
372	12.06.2023	M/4425/RR-D/2023	Fexofenadine Hydrochloride Tablets USP 180mg
373	16.06.2023	M/4426/RR/LMP/2023	Amoxicillin Capsules USP 500 mg
374	16.06.2023	M/4427/RR/2023	Metoprolol Tablets 25mg
375	16,06.2023	M/4428/RR-D/2023	Cetririzine Dihydrochloride Tablets BP 10mg
376	16.06.2023	M/4429/RR-D/2023	Orlistat Capsules USP 120mg
377	19.06.2023	M/4430/RR/2023	Cetririzine Dihydrochloride USP 5mg/5ml Syrup
378	19.06.2023	M/4431/RR/2023	Metoprolol Succinate Prolonged Release Tablets 100mg
379	19.06.2023	M/4432/RR/2023	Metoprolol Succinate Prolonged Release Tablets 50mg
380	19/06/2023	M/4433/RR-D/2023	Celecoxib Capsules 200 mg
381	19/06/2023	M/4434/RR/2023	Levetiracetam Tablets USP 500 mg
382	19/06/2023	M/4435/RR-D/2023	Ketotifen Fumarate Tablets 1mg
383	19/06/2023	M/4436/RR-D/2023	ciprofloxacin Eye/Ear Drops .0.3% w/v
384	23/06/2023	M/4437/RR/BTP/2023	Alteplase for injection EP with the solvent
385	23/06/2023	M/4438/RR/2023	Dried Aluminium Hydroxide BP 250mg+Magnesium Trisilicate BP 250mg+Dimeticone BP 125mg/ 15m; suspension
386	23/06/2023	M/4439/RR/2023	Metthylprednisolone Tablets 16mg
387	23/06/2023	M/4440/RR-D/2023	Norethisterone Tablets BP 5mg
388	23/06/2023	M/4441/RR-D/2023	Rosuvastatin Tablets IP 20 mg
389	23/06/2023	M/4442/RR-D/2023	Dried Aluminium Hydroxide gel 240mg+Magnesium Hydroxide 100mg+ Light Magnesiun carbonate 60mg+ Activated Dimeticone 25mg Tablet
390	26/06/2023	M/4443/RR/2023	Clotrimazole Cream USP 1% w/w
391	26/06/2023	M/4444/RR-D/2023	Metoprolol Injection BP 1mg/ml
392	26/06/2023	M/4445/RR-D/2023	Sildenafil Tablets USP 50 mg

393	30/06/2023	M/4446/RR-D/2023	Phytomenadione Injection BP 2mg/1ml
394	30/06/2023	M/4447/RR/LMP/2023	Formoterol Fumarate BP 12mcg + Budesonide BP 400mcg dry powder inhalation capsules
395	30/06/2023	M/4448/RR/2023	Salmeterol 50mcg and Fluticasone Propionate 250mcg dry powder capsules
396	30/06/2023	M/4449/RR-D/2023	Clarithromycin Tablets USP 500mg

අමුණුම 77

28

Senior Prof Rohini Fernandopulle MBBS, PhD (Colombo) FCGP (Hon)
No.33, Police Park Avenue,
Colombo 05
Phone: +94112501217 +94772987707 +94710219244
Email: rohinifernandopulle@hotmail.com

12/12/2020

Asita de Silva | MBBS DPhil (Oxon) FRCP (Lond)
Senior Professor of Pharmacology
Chairman NMRA
Sri Lanka

Re: Opinion on dossiers evaluated by four pharmacists under investigation.

Prof Asita de Silva,

Thank you for inviting me to give an expert opinion on the files evaluated by four pharmacists Mr Sandaruwan, Mr Pathum, Ms Gayathri and Ms Dinuda attached to the NMRA. I have scrutinized 25 dossiers and my observations are given below.

1. All the files are for either new chemical entities (NCEs) which are generics or from new manufacturers for a Single Market Authorisation holder named Tabrane pharmaceuticals Ltd, Tabrane Health Care and Soft Care International Ltd.

2. The policy decision of the Medicines Evaluation committee for NCEs is that it should be presented to the MEC to make a decision under the "NEED" clause of the NMRA Act of 2015. However such files have by passed MEC and gone directly to the pharmacists under investigation for evaluation and have been granted registration.

3. The policy decision by MEC in accordance to the NMRA Act of 2015 for new manufacturers is that the manufactured medicines should be given PROVISIONAL registration (PR) for 2 years in order to monitor for quality issue and adverse reactions. This policy has been clearly violated by all 4 pharmacists: PR has been given for 2years ending in 2022 but within 2 – 4 months of PR in 2020 the files have been re-evaluated by the 4 pharmacists and granted FULL registration (FR) form 2022 – 2027) with statements such as additional data is satisfactory although there is no evidence of inclusion of such additional documents in the file. Even if there was they cannot change PR to FR until the 2 year PR period lapses in 2022. This has also been done by the 4 pharmacists for files given PR following evaluation by other pharmacists.

4. Overall the majority of files evaluated by the four pharmacists under investigation have been done superficially in a hurried manner and some critical documents such as bioequivalence studies and the product information sheets have not been perused ay all or indicated as satisfactory when such a document has not been included.

5. In some files the price of the medicine has been quoted low and got priority for provisional registration giving tender quotation as the justification but at the time of FR they have indicated that they are unable to supply at that price and quoted a price higher by 2 – 3 hundred rupees.

Recommendation.

The files that have been evaluated by a few other pharmacists at the NMRA could be granted PR after cancellation of FR as the evaluation is satisfactory.

All files evaluated by the four pharmacists under evaluation should undergo a full dossier evaluation in the CTD format and be given PR only if found to be satisfactory. Most of

Detail comments on each of the 25 dossiers are annexed.

Fdopulle.

Snr Prof Rohini Fernandopulle MBBS, PhD, FCGP(SL)
President Sri Lanka College of Clinical Pharmacology and Therapeutics
WHO National Consultant on Regulatory Functions to NMRA Sri Lanka
Professor, Clinical Pharmacology and Therapeutics
General Sir John Kotelawala Defence University
Kandawala Estate
Ratmalana
Sri Lanka

Serial No	Genaric Name	Brand Name	Manufacturer	Importer	Sample licence issuing date	Submittion Date	Dossier No	Dossier Evaluated by	Checked by	Period of validity of PR	FR Reg No	FR Issued Date	Period of validity of FR	Price per unit	Additional - Renewal evaluated (2nd Time) by	Checked by	Comments/Recommendation of Reviewing officer (Prof.Fernandofulle)
1	Vitamin E (Tocopherol) Capsules USP 400mg	E-400 Natural	Gelnova Laboratories (India) Private Limited	Tabrane Pharmaceuticals (Pvt) Ltd	2/24/2020	2020.02.24	M/3813/NP	P29 on 06/03/2020	P5,P23,P12	16/03/2020- 15/03/2020	M-008352-FR	2020.06.13	2022.03.16- 2027.03.15	Rs 60.00	P29 on 02/06/2020	P5, P2, P23	Brand name **"Natural"** cannot be allowed,MRP-very high. Decision of MEC sought if this product should be rejected as there are fundamental issues in the dossier.
2	Dasatinib Tablets 50mg	Dasatin 50	Julphar Bangladesh Ltd	Tabrane Healthcare (Pvt)Ltd	2/28/2020	2020.02.28	M/3823/NP	P29 on 12/03/2020	P5,P6,P12	16/03/2020- 15/03/2020	M-008336-FR	2020.06.12	2022.03.16- 2027.03.15	Rs.2800.00	P29 on 08/06/2020	P5, P2,P10	Explanation needed on following statements in stabilility study reports, i.Real time satbility data has been given as accerlated stability studies. ii. Stating that type of batch as "Exibhit" and Market as "Export". **Full evaluation of Dossier is recommended,**
3	Mycophenoiate Mofetil Tablets USP 500mg	Mycolate 500	Concent Pharmaceuticals Ltd- India	Softcare International (Pvt) Ltd	Not available in the dossier.	2020.04.03	M/3880/NP	P 29 on 06/04/2020	P5,P23,P10	22/04/2020 - 21/04/2022	M-008329-FR	2020.06.11	2022.04.21- 2027.04.20	Rs. 45.00	P29 on 28 /05/2020	P5, P10,P23	Document for Processing with pharmacist signature is not in the dossier, but a receipt is attached for processing fee which contained different application no. - A sample licence is not availabe in the dossier. BE check list has not been completed. **Dossier need full evaluation includin BE Report.**
4	Vitamin E (Tocopherol) Capsules USP 200mg	E-200 Natural	Gelnova Laboratories (India) Private Limited	Tabrane Pharmaceuticals (Pvt) Ltd	2020.02.24	2020.02.24	M/3812/NP	P29 on 06/03/2020	P5,P23,P12	16/03/2020- 15/03/2020	M-008277-FR	2020.06.01	2022.03.16- 2027.03.15	Rs.30.00	P29	P5, P2, P4	Brand name **"Natural"** cannot be allowed,MRP-very high. Decision of MEC sought if this product should be rejected as there are fundamental issues in the dossier.
5	Lenvatinib Capsules 10mg	Levat 10	Julphar Bangladesh Ltd	Tabrane Healthcare (Pvt)Ltd	3/11/2020	2020.03.11	M/3856/NP	P29 on 11/03/2020	P5,P4,P12	12/03/2020- 11/03/2022	M-008337-FR	2020.06.12	2022.03.11- 2027.03.10	Rs 5900.00	P29	P5, P2, P10	All parameteres have not been done/tested in COA.Need full evaluation of the dossier.
6	Empagliflozin Tablets 10mg	Sucozin 10	Globe pharmaceuticals ltd-Bangladesh	Tabrane Healthcare (Pvt)Ltd	3/10/2020	2020.03.13	M/3874/NP	P10 on 17/03/2020	P5,P23,P22	17/03/2020- 16/03/2020	M-008207-FR	2020.05.27	2022.03.17- 2027.03.16	Rs 98.00	P29	P6, P10, P23	The Evaluation has been done in a superficial manner within 24 hours for a product which is not categorised as aan essential medicine. Need a full evaluation according to WHO guidelines.
7	Rifaximin Tablets 550mg	Rifaliv 550	Atra Pharmaceuticals Ltd- India	Tabrane Healthcare (Pvt)Ltd		2019.11.18	MEDREG/2019/00019	Initialy evaluated by P36 through automated system date is not appeared in auto generated evaluation sheet.Then additinasl evaluted by 36 manually on 13/02/2020	P5,P23,P10	17/02/2020- 16/02/2020	M-007954-FR	2020.04.09	2022.02.17- 2027.02.16	Rs 684.00	P29 on 30/03/2020	P2, P10, P23	submission of the dossier and first evaluation had been done on automated system . The evaluation report issued by the system doesnot contained any date(Date of evalution/issuing date). only additional documents submitted manually were avalable for review. FR is cancelled .Recommend to maintained PR given initially for two years.

8	Hydroxyurea Capsules USP 100mg	Joxdramide 100	Jodas Expoim (Pvt) Ltd-India	Softcare International (Pvt) Ltd	Not available. enclosed SL is for a different product	2020.04.08	M/3901/NP	P5 on 09/04/2020	P4,P6,P30	09/04/2020- 08/04/2020	M-008359-FR	2020.06.13	2022.04.09- 2027.04.08	Rs 195.00	P29	P5, P10, P23	Following defeciencies need to be addressed, -Brand name to be checked as it may prone to medication errors. -Sample licence (althogh it indicate same brand name) and the PIL attached with dossier are for totally different products. **Dossier need full evaluation.**
9	Rifaximin Tablets 200mg	Rifaliv 200	Atra Pharmaceuticals Ltd- India	Tabrane Healthcare (Pvt)Ltd	Not available in the additional file	2020.01.0820 20.01.03 through automation system	MEDREG/2020/00044	Initialy evaluated by P36 through automated system date is not appeared in auto generated evaluation sheet.Then additinasl evaluted by 36 manually on 13/02/2020	P5,P23,P10	17/02/2020- 16/02/2020	M-007956-FR	2020.04.09	2022.02.17- 2027.02.16	Rs 270.00	P29 on 30/03/2020	P5, P10, P23	submission of the dossier and first evaluation had been done on automated system . The evaluation report issued by the system doesnot contained any date(Date of evalution/issuing date). only additional documnts submitted manually were avalable for review. FR is cancelled .Recommend to maintained PR given initially for two years.
576 10	Vitamin E Capsules USP 200mg	E-200 Natural	Gelnova Laboratories (India) Private Limited	Tabrane Pharmaceuticals (Pvt) Ltd	1/24/2020	2020.01.24	M/3722/NP	Evaluated byP32 on 08/02/2020 and has requested additional documentation then additional doc.evaluated by P29 on 12/02/2020	1st Evaluation checked by P5,P10,P23 2 nd Evaluation checked by P5,P10,P23	13/02/2020- 12/02/2020	M-007948-FR	2020.04.09	2022.02.13- 2027.02.12	Rs 7.00	P29	P5, P10, P23	In both files (200 mg & 400 mg) the batch size is 3000.(as per batch formula and other documentation) according to manufacturing records 2500 are defective. When asked for clarification they have informed that the batch size is 300,000 Decision of MEC sought if this product should be rejected as there are fundamental issues in the dossier.Dossier has been given priorityand evaluated in one day saying it is for a tender,However the letter sent on 3/11/2020 indicates it is for the open market
11	Tenofovir Disoproxil Fumarate 300mg +Emtricitabine	Tenoliv EM	Atra Pharmaceuticals Ltd- India	Tabrane Healthcare (Pvt)Ltd	13/08/2019	2019.12.09	M/3479/NP	P35 on 04/01/2020	P5,P10,P23	08/01/2020- 07/01/2020	M-007940-FR	2020.04.08	2022.01.08- 2027.01.07	Rs 600.00	P29	P5, P10, P23	After reviewindg documentation given provisional registration at the first time is recommended.
12	Eltrombopag Tablets 50mg	Eltrom 50	Julphar Bangladesh Ltd	Tabrane Healthcare (Pvt)Ltd	12/2/2019	2020.01.13	M/3706/NP	P38 on13/01/2020		17/01/2020- 16/01/2020	M-007953-FR	2020.04.09	2022.01.17- 2027.01.16	Rs 3500.00	P29 on 30/03/2020	P5, P10, P23	As per first evaluator (P38) has commented as "Pharmaceutical Documentation satisfactory" but at the 2nd time the evaluator (P29) has stated as "Additional Documents satisfactory". But any docementation was not there for evaluation. **Need Full Evaluation for reneawl of PR.**
13	Deferiprone Capsules 500mg	Novator 500	Atra Pharmaceuticals Ltd- India	Tabrane Healthcare (Pvt)Ltd	8/13/2019	2019.12.09	M/3480/NP	P35 on 04/01/2020	P5,P10,P23	08/01/2020 - 07/01/2020	M-007952-FR	2020.04.09	2022.01.08- 2027.01.07	Rs 300.00	P29	P5, P10, P23	**Dossier need full evaluation.**

14	Vitamln E Capsules USP 400mg	E-400	Gelnova Laboratories (India) Private Limited	Tabrane Pharmaceuticals (Pvt) Ltd	1/24/2020	2020.01.24	M/3721/NP	Evaluated by P32 on 08/02/2020 and has requested additional documentation then additional doc.evaluated by P29 on 12/02/2020	1st Evaluation checked by P5,P10,P23 2 nd Evaluation checked by P5,P10,P23	13/02/2020-12/02/2020	M-007949-FR	2020.04.09	2022.02.13-2027.02.12	Rs 14.00	P29	P5, P10, P23	In both files (200 mg & 400 mg) the batch size is 3000.(as per batch formula and other documentation) according to manufacturing records 2500 are defective. When asked for clarification they have informed that the batch size is 300,000 Decision of MEC sought if this product should be rejected as there are fundamental issues in the dossier.Dossier has been given priorityand evaluated in one day saying it is for a tender,However the letter sent on 3/11/2020 indicates it is for the open market.
15	Tamsulosin Hydrochloride Capsules USP 0.2mg	Tamurin 0.2	Globe pharmaceuticals Ltd-Bangladesh	Tabrane Healthcare (Pvt)Ltd	4/6/2020	2020.04.03	M/3885/NP	P29 on 06/04/2020		2020.04.06-202.04.05	M-008369-FR	2020.06.16	2022.04.06-2027.04.05	Rs 20.00	P29	P6, P10,P12	Evaluation sheet is not complete,Indicate PIL is Satisfactory, but the packet containing the PIL has not been opened,**Dossier needs full evaluation.**
16	Lenvatinib Capsules 4mg	Levat 4	Julphar Bangladesh Ltd	Tabrane Healthcare (Pvt) Ltd	3/11/2020	2020.03.11	M/3855/NP	P29 on 11/03/2020	P5,P4,P12	12/03/2020-11/02/2022	M-008357-FR	2020.06.13	2022.03.11-2027.03.10	Rs 2600.00	P29	P6, P5, P2	All parameteres have not been done/tested in COA.**Need full evaluation of the dossier.**
17	Gastro-Resistant Omeprazole Tablets BP 10mg	OP 10	Globe pharmaceuticals Ltd-Bangladesh	Tabrane Healthcare (Pvt) Ltd	6/4/2020	2020.04.03	M/3886/NP	6/4/2020	P5,P10,P23	06/04/2020-05/04/2020	M-008361-FR	2020.06.13	2022.04.06-2027.04.05	Rs 10.00	P29	P5, P10, P23	Recomend to get **opinion of MEC on the need** for 10 mg gastro-resistant tablets
18	Prolonged Release Tamsulosin Tablets BP 0.4mg	Tamflow 0.4	Concept Pharmaceuticals Ltd- India	Softcare International (Pvt) Ltd	20/04/202	2020.04.22	M/3932/NP	P 29 on 22/04/2020	P5,P10,P23	23/04/2020-22/04/2022	M-008358-FR	2020.06.13	2022.04.23-2027.04.22	Rs 24.00	P29	P5, P10, P23	Evaluation indicates that BE report is satisfactory.But there is no BE report available with the dossier. Also Brand name "Tamflow" could be mistaken for Tamiflu. Need full evaluation of the dossier.
19	Lapatinib Tablets 250mg	Alkenib 250	Julphar Bangladesh Ltd	Tabrane Healthcare (Pvt)Ltd	27/01/2020	2020.02.26	M/3815/NP	P35 by on 27/02/2020	P5,P6P,23	27/02/2020-26/02/2020	M-007935-FR	2020.04.08	2022.02.27-2027.02.26	Rs.1490.00	P29	P5,P10,P23	MAH has requested priority registration and been granted. There is no requirement for priority registration as there are 3 registered product with valid registration including a product from same local agent..Need full evaluation of the dossier.

(3) එකී තොරතුරු ඉදිරිපත් කිරීම සඳහා ගෙවිය යුතු ගාස්තුව, ගාස්තු නියෝගයේ නිශ්චිතව සඳහන් ආකාරයට විය යුතු ය.

7. ඖෂධයක් ලියාපදිංචි කිරීම සඳහා වන සියලු අවශ්‍යතාවන් සපුරා ඇති බවට අධිකාරිය සෑහීමකට පත්වීමේ දී,

(අ) (i) නව රසායනික සංයුතීන් ;
(ii) දැනට ලියාපදිංචි රසායනිකයන්ගේ නව මාත්‍රා ස්වභාවයන් ;
(iii) දැනට ලියාපදිංචි රසායනිකයන්ගේ නව සංයෝජනයන් ;
(iv) නව රසායනික සංයුතීන් ඇතුළු ජීව ව්‍යාත්මක සම්භවකයකින් යුත් නව නිෂ්පාදන ;
(v) දැනට ලියාපදිංචි ඖෂධයක (ඖෂධීය නාමය හෝ වෙළඳ නාමයක් සහිත) නව ඖෂධ නිෂ්පාදන ; සහ
(vi) පවතින තොග අවසන් කිරීම සඳහා, අවශ්‍ය කාලය ලබා දීම සඳහා හෝ සුදුසු විකල්ප ඖෂධයකට මාරු වීම සඳහා රෝගීන්ට ඉඩ ලබා දීම සඳහා අධිකාරිය විසින් භාවිතා කිරීම අත්හිටුවීම සඳහා යෝජනා කර ඇති ඖෂධ,

සම්බන්ධයෙන් වසර දෙකක කාල සීමාවක් සඳහා තාවකාලික ලියාපදිංචියක් නිකුත් කළ යුතු ය:

එසේ වුවද, ඇගයීම් වාර්තා මත පදනම්ව තාවකාලික ලියාපදිංචිය ප්‍රදානය කරනු ලැබිය යුතු වන්නේ වසරක් සඳහා ද නැතහොත් වසර දෙකක් සඳහා ද යන්න පිළිබඳව තීරණය කිරීම සඳහා අභිමතය ඖෂධ ඇගයීම් කමිටුව සතු විය යුතු ය ;

(ආ) (i) නිශ්චිත කාල සීමාවක් සඳහා ලියාපදිංචිය අත්හිටවූ යම් ඖෂධයක්, එම අත්හිටුවීම අහෝසි කිරීමෙන් පසුව එකී ඖෂධයේ නව ලියාපදිංචිය සඳහා ඉල්ලීම් කරන විට දී; සහ
(ii) යම් ඖෂධයක නිෂ්පාදකයකු සඳහා වන තහනමක් අහෝසි කිරීමෙන් පසු එකී ඖෂධ ලියාපදිංචි කිරීම සඳහා ඉල්ලුම් කරන විට දී,

වසරක කාලසීමාවක් සඳහා තාවකාලික ලියාපදිංචියක් නිකුත් කළ යුතු ය.

8. ඖෂධයක තාවකාලික ලියාපදිංචිය සඳහා වන කාලසීමාව, අවසන්වීමෙන් පසුව ඖෂධයක් සඳහා අධිකාරිය විසින් නිශ්චය කරනු ලැබිය හැකි කාල සීමාවක් සඳහා සම්පූර්ණ ලියාපදිංචියක් ප්‍රදානය කරනු ලැබිය හැකි ය.

9. ඖෂධය ලියාපදිංචි කිරීමෙන් පසු අධිකාරිය විසින් මෙහි III වන උපලේඛනයේ දක්වා ඇති ආකෘතියේ පරිදි ලියාපදිංචි සහතිකයක් නිකුත් කරනු ලැබිය යුතු ය.

10. (1) ලියාපදිංචි කරන අවස්ථාවේ දී, අධිකාරිය විසින් පහත දැක්වෙන වර්ග යටතේ එකී ඖෂධ වර්ගීකරණය කිරීම සහ ලියාපදිංචි කිරීම කළ යුතු ය:-

(අ) I වන උපලේඛනයේ නිශ්චිතව සඳහන් ඖෂධ -

(i) විකිණීම සඳහා ඖෂධ වට්ටෝරුවක් සහ එකී ඖෂධ ගබඩා කර ඇති පරිශ්‍රයන් සඳහා අධිකාරියෙන් ලබා දෙන බලපත්‍රයක් නොමැතිව විකුණනු ලැබිය හැකි ඖෂධ ;

(ii) මේ ඖෂධ නිෂ්පාදකයාගේ විවෘත නොකළ මුල් බදුන් හෝ ඇසුරුම්වල පමණක් විකුණනු ලැබිය යුතු ඖෂධ;

(iii) ශ්‍රී ලංකාවේ සාමාන්‍ය ගබඩා තත්ත්වයන් යටතේ ස්ථායී බව සනාථ වී ඇති අතර විශේෂ ගබඩා තත්ත්වයන් අවශ්‍ය නොවන ඖෂධ;

(ආ) II වන උපලේඛනයේ අ කාණ්ඩයේ නිශ්චිතව සඳහන් ඖෂධ - අධිකාරිය විසින් බලපත්‍ර ලබා දුන් සිල්ලර ඔසුසලක සේවය කරනු ලබන ඖෂධවේදියකු හැර වෙනත් කැනැත්තකු විසින් විකුණනු නොලැබිය යුතු ඖෂධ මෙම කාණ්ඩයට අයත් වේ, ඒවා ඖෂධ වට්ටෝරුවක් නොමැතිව විකුණනු ලැබිය හැකි ය.

(ඇ) II වන උපලේඛනයේ ආ කාණ්ඩයේ හෝ ඇ කාණ්ඩයේ සහ III වන උපලේඛනයේ නිශ්චිතව සඳහන් ඖෂධ -

(i) වෛද්‍ය ආඥා පනත (105 වන අධිකාරය) යටතේ ලියාපදිංචි වෛද්‍ය වෘත්තිකයකුගෙන් හෝ දන්ත වෛද්‍යවරයකුගෙන්; හෝ

ඇමුණුම 79

Exten-

දුරකථන
தொலைபேசி
Telephone : 0112696896/7
0112695173

ෆැක්ස්
பெக்ஸ்
Fax : 0112689704

වෙබ් අඩවිය
இணையத்தளம்
Website : nmra.gov.lk

ජාතික ඖෂධ නියාමන අධිකාරිය

தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை

National Medicines Regulatory Authority

මගේ අංකය
எனது இல
My No. : NMRA/SP/CEO/020/2020

ඔබේ අංකය
உமது இல
Your No. :

දිනය
திகதி
Date : 17-11-2020

Director General of Customs,
Sri Lanka Customs.

Extension of Validity of Certificates of Registration, Manufacturing and Import Licences pertaining to Medicines, Medical devices, Borderline products and cosmetics

This is further to my letter dated 06- 08-2020 on above matter.

After reassessing the prevailing situation in the country due to COVID 19 pandemic, the National Medicines Regulatory Authority has decided to extend the validity of certificates of registration, manufacturing and import licenses pertaining to Medicines, Medical Devices, Borderline Products and Cosmetics up to 30 th June 2021. The extension is applicable for certificates and licenses expiring after 30th of June 2019 or would be expired up to 30 th June of 2021.

The decision was taken in order to minimise the movement of people considering the prevailing situation in the country due to Covid 19 pandemic. The decision would be reassessed again on or before 30 th June 2021.

As such there is no requirements for the NMRA to consider individual requests in this regards. Please note this letter supersedes our previous communication letters on above subject matters.

Your kind corporation on the matter is very much appreciated.

Thank you.

Dr. Kamal Jayasinghe
Director General/Chief Executive Officer
National Medicines Regulatory Authority

Copies: 1. Controller General, Department of Import and Export Control
2. Director General of Health Service
3. Chairman, State Pharmaceutical Corporation of Sri Lanka
4. Director, Medical Supplies Division
5. Chief Food & Drug Inspector
6. President, SLCPL

Established under the National Medicines Regulatory Authority Act no 5 of 2015 and came into operation by gazette bearing no. 1920/28 dated 25.06.2015

Final Accounts and Auditor General's Reports (/index.php?option=com_content&view=article&id=630&Itemid=360&lang=en)

Guideline (http://nmra.gov.lk/index.php?option=com_content&view=article&id=441:general-guideline-topics&catid=42&Itemid=331&lang=en)

Lab Services (/index.php?option=com_content&view=article&id=89&Itemid=228&lang=en)

Legislation (/index.php?option=com_content&view=article&id=263&Itemid=190&lang=en)

Medical Product Alert (/index.php?option=com_content&view=article&id=115&Itemid=246&lang=en)

Pharmacovigilance (/index.php?option=com_content&view=article&id=75&Itemid=284&lang=en)

Price Controls (/index.php?option=com_content&view=article&id=74&Itemid=184&lang=en)

Public Consultation (https://nmra.gov.lk/index.php?option=com_content&view=category&id=31&Itemid=250&lang=en)

Retail & Wholesale Pharmacy (/index.php?option=com_pharmacy&view=pharmacies&Itemid=328&lang=en)

Report Adverse Events (/index.php?option=com_contact&view=reporting&Itemid=293&lang=en)

Vacancies (/index.php?option=com_content&view=article&id=575&Itemid=359&lang=en)

Extension of certificates of registration, import licenses & manufacturing licenses

-certificates-of-registration-import-licenses-manufacturing-licenses&catid=30&tmpl=component&print=1&layout=default&Itemid=309&lang=en)

To all marketing authorization holders of medicines and medical devices

Extension of certificates of registration, import licences and manufacturing licences

Revised Closing Date for applying for extension of certificates of registration, import licenses and manufacturing licenses for medicines

This is to bring to your notice that at the meeting held with the Sri Lanka Chamber of Pharmaceutical Industry and Hon. State Minister of Pharmaceutical Production, Supplies and Regulation which was held on 15th July 2021, a decision was taken to bring forward the closing date for applications for extension of registration certificates and licenses for medicines, by one month.

As such, the applications which are entertained through the email exm.nmra@gmail.com (mailto:exm.nmra@gmail.com) will be closed on **31st July 2021 at 12 a.m.**

You are hereby informed that after reassessing the prevailing situation in the country due to COVID 19 pandemic, the National Medicines Regulatory Authority has decided to extend the validity of certificates of registration, manufacturing and import licenses pertaining to Medicines and Medical Devices for a period of one year. This extension can be considered for the certificates of registration and licences expired after 30th of June 2019 and would be expired up to 31st December 2021.

1. Following conditions shall be applied.

පැවති ලියාපදිංචිය වසර 5 කින් දීර්ඝ කිරීම

2022 වර්ෂය	
70 වන ඖෂධ ඇගයීම් කමිටුවේ සභාගත කරන ලද ලියාපදිංචිය දීර්ඝ කරන ලද ඖෂධ ගණන	139
71 වන ඖෂධ ඇගයීම් කමිටුවේ සභාගත කරන ලද ලියාපදිංචිය දීර්ඝ කරන ලද ඖෂධ ගණන	211
72 වන ඖෂධ ඇගයීම් කමිටුවේ සභාගත කරන ලද ලියාපදිංචිය දීර්ඝ කරන ලද ඖෂධ ගණන	140
73 වන ඖෂධ ඇගයීම් කමිටුවේ සභාගත කරන ලද ලියාපදිංචිය දීර්ඝ කරන ලද ඖෂධ ගණන	128
	618
2023 වර්ෂය	
74 වන ඖෂධ ඇගයීම් කමිටුවේ සභාගත කරන ලද ලියාපදිංචිය දීර්ඝ කරන ලද ඖෂධ ගණන	69
75 වන ඖෂධ ඇගයීම් කමිටුවේ සභාගත කරන ලද ලියාපදිංචිය දීර්ඝ කරන ලද ඖෂධ ගණන	62
76 වන ඖෂධ ඇගයීම් කමිටුවේ සභාගත කරන ලද ලියාපදිංචිය දීර්ඝ කරන ලද ඖෂධ ගණන	62
77 වන ඖෂධ ඇගයීම් කමිටුවේ සභාගත කරන ලද ලියාපදිංචිය දීර්ඝ කරන ලද ඖෂධ ගණන	56
	249

වලංගු කාලය වසරකින් දීර්ඝ කරන ලද තාවකාලික ලියාපදිංචි සහතික පිළිබඳ විස්තර

අනු අංකය	දේශීය නියෝජිතගේ නම	ඖෂධයේ නම	පවත්නා ලියාපදිංචි සහතිකයේ අංකය	පවත්නා ලියාපදිංචි සහතිකයේ වලංගු කාලය	දීර්ඝ කිරීම වලංගු දිනය
1	Morison PLC	Promethazine Hydrochloride Tablets BP 25 mg	M-007994-PR	20.02.2020-19.02.2022	19.02.2023
2	Morison PLC	Levothyroxine Tablets BP 100mcg	M-009136-PR	02.03.2020-01.03.2022	01.03.2023
3	Morison PLC	Prochloroperazine Tablets BP 5mg	M-007580-PR	24.01.2020-23.01.2022	23.01.2023
4	Morison PLC	Paracetamol Oral Solution (Paediatric)BP 120mg/5ml	M-005655-PR	08.02.2018-07.02.2020	07.02.2023
5	Morison PLC	Prednisolone Tablets BP 5mg	M-007892-PR	19.02.2020-18.02.2022	18.02.2023
6	Morison PLC	Diazepam Tablets BP 2mg	M-005579-PR	2019.04.05-04.04.2021	04.04.2023
7	Morison PLC	Empagliflozin Tablets 25mg	M-009064-PR	03.05.2021-02.05.2022	02.05.2023
8	Morison PLC	Imipramine Tablets BP 25 mg	M-008040-PR	19.02.2020-18.02.2022	18.02.2023
9	Morison PLC	Clonazepam Tablets USP 2mg	M-008219-PR	20.02.2020-19.02.2022	19.02.2023
10	Morison PLC	Sulfasalazine Tablets USP 500 mg	M-007506-PR	13.01.2020-12.01.2022	12.01.2023
11	Morison PLC	Salbutamol Oral Solution BP 2mg/5ml	M-001888-PR	01.01.2018-31.12.2019 (Previous extension upto 31.12.2021)	31.12.2022 31.12.2023
12	Emergen Life Scienses	Budesonide Nasal Spray BP 64mcg	M-005534-PR	10.04.2019-09.04.2021 (Previous extension upto 09.04.2022)	09.04.2023
13	Emergen Life Scienses	Esomeprazole Capsules 20mg	M-002626-PR	22.03.2018-21.03.2020(Previous extension upto 21.03.2022)	21.03.2023
14	Morison PLC	Metformin Tablets BP 500mg	M-007911-PR	13.02.2020-12.02.2022	12.02.2023
15	Celogen Lanka	Pyrimethamine tablets BP 25 mg	M-005590-PR	10.04.2019-09.04.2021 (Previous extension upto 09.04.2023)	09.04.2023
16	Celogen Lanka	Mycophenolate Mofetil Tablets USP 500 mg	M-005680-PR	29.04.2019-28.04.2021(Previous extension upto 28.04.2022)	28.04.2023
17	Celogen Lanka	Colecalciferol Tablet BP 400IU	M-008140-PR	28.04.2020-27.04.2022	27.04.2023
18	Celogen Lanka	Metformin Tablets 500mg	M-005161-PR	06.02.2019-05.02.2021(Previous extension upto 05.02.2022)	05.02.2023
19	Celogen Lanka	Pyridostigmine Tablets BP 60 mg	M-008037-PR	09.05.2020-08.05.2022	08.05.2023
20	Celogen Lanka	Prolonged Release Isosorbide Mononitrate Tablets BP 30mg	M-008458-PR	10.06.2020-09.06.2022	09.06.2023

21	Celogen Lanka	Carvedilol Tablets USP 3.125mg	M-008159-PR	28.04.2020-27.04.2022	27.04.2022
22	Celogen Lanka	Doxepin Capsules BP 50 mg	M-005545-PR	10.04.2019-09.04.2021(Previous extension upto 09.04.2022)	09.04.2023
23	Celogen Lanka	Clopidogrel Tablets USP 75 mg	M-007992-PR	13.02.2020- 12.02.2022	12.02.2023
24	Celogen Lanka	Hydroxychloroquine Sulfate Tablets USP 200 mg	M-007736-PR	10.02.2020-09.02.2022	09.02.2023
25	Emergen Life Scienses	Pantoprazole Delayed Release Capsules 40mg	M-006324-PR	11.07.2019-10.07.2021(Previous extension upto 10.07.2022)	10.07.2023
26	Lina Manufacturing	Captopril Tablets BP 25 mg	M-006394-PR	05.06.2019-04.06.2021(Previous extension upto 04.06.2022)	04.06.2023
27	Lina Manufacturing	Gastro Resistant Aspirin Tablets BP 75 mg	M-009165-PR	07.06.2021-06.06.2022	06.06.2023
28	Lina Manufacturing	Salbutamol Inhalation Powder-Pre-Dispensed BP Capsules 400 mcg	M-006723-PR	31.07.2019 - 30.07.2021(Previous extension upto 30.07.2022)	30.07.2023
29	Navesta Pharmaceuticals	Ampicillin for injection BP 1g	M-006490-PR	19.06.2019-18.06.2021(Previous extension upto 18.06.2022)	18.06.2023
30	Navesta Pharmaceuticals	Benzylpenicillin for Injection BP 1 MIU (600mg)	M-007386-PR	15.12.2019-14.12.2021	14.12.2022
31	Navesta Pharmaceuticals	Ticarcillin and Clavulanic Acid for Injection USP 3.2g	M-007758-PR	01.02.2020-31.01.2022	31.01.2023
32	Navesta Pharmaceuticals	Piperacillin and Tazobactam for Injection USP 4.5g	M-008868-PR	18.07.2020-17.07.2022	17.07.2023
33	Navesta Pharmaceuticals	Flucloxacillin sodium for Injection BP 500mg	M-008874-PR	10.07.2020-09.07.2022	09.07.2023
34	Navesta Pharmaceuticals	Penicillin G Benzathine for Injection 1.2 MIU	M-006501-PR	06.07.2019-05.07.2021(Previous extension upto 05.07.2022)	05.07.2023
35	Navesta Pharmaceuticals	Co-amoxiclav for Injection BP 1.2g	M-009198-PR	11.08.2020-10.08.2022	10.08.2023
36	Navesta Pharmaceuticals	Co-amoxiclav for Injection BP 600mg	M-009197-PR	14.08.2020-13.08.2022	13.08.2023
37	Diyatha pharmaceuticals	Salbutamol Oral Solution 2 mg / 5 ml	M/006425-PR	05.08.2019-04.08.2021(Previous extension upto 04.08.2022)	04.08.2023
38	SmithKline Beecham	Paracetamol BP 500mg & Codeine Phosphate USP 8mg Tablets	M-008184-PR	19.03.2020-18.03.2022	18.03.2023
39	SmithKline Beecham	Paracetamol Tablets 500mg	M-006315-PR	17.07.2019-16.07.2020(Previous	16.07.2023

				extension upto 16.07.2022)	
40	Celogen Lanka	Sodium Bicarbonate Tablets USP 600mg	M-007451-PR	17.01.2020-16.01.2022	16.01.2023
41	Celogen Lanka	Vitamin E Capsules 400 IU	M-009060-PR	31.05.2021-30.05.2022	30.05.2023
42	Celogen Lanka	Gastro Resistant Omeprazole Tablets 10mg	M-008634-PR	01.07.2020-30.06.2022	30.06.2023
43	Celogen Lanka	Voriconazole Tablets 200mg	M-008398-PR	28.03.2020-27.03.2022	27.03.2023
44	Celogen Lanka	Warfarin Sodium Tablets USP 5mg	M-007698-PR	19.02.2020-18.02.2022	18.02.2023
45	Celogen Lanka	Valganciclovir Tablets USP 450mg	M-005136-PR	22.02.2019-21.02.2021(Previous extension upto 21.02.2022)	21.02.2023
46	Celogen Lanka	Metoprolol Tartrate Tablets USP 50mg	M-008474-PR	15.06.2020-14.06.2022	14.06.2023
47	Celogen Lanka	Prolonged Release Diltiazem Tablets BP 90mg	M-008540-PR	19.06.2020-18.06.2022	18.06.2023
48	CIC	Metformin Hydrochloride Extended Release Tablets USP 500 mg	M-005317-PR	25.02.2019-24.02.2020(Previous extension upto 24.02.2022)	24.02.2023
49	Celogen Lanka	Gastro Resistant Aspirin Tablets BP 75 mg	M-009253-PR	12.11.2021-11.11.2022	11.11.2023
50	Celogen Lanka	Vigabatrin Tablets BP 500 mg	M-009144-PR	23.08.2021-22.08.2022	22.08.2023
51	Celogen Lanka	Zinc Sulfate Tablets USP 10 mg	M-006991-PR	17.10.2019-16.10.2020(Previous extension upto 16.10.2022)	16.10.2023
52	Celogen Lanka	Zinc Sulfate Tablets USP 20mg	M-007007-PR	17.10.2019-16.10.2020(Previous extension upto 16.10.2022)	16.10.2023
53	Celogen Lanka	Amisulpride Tablets BP 200 mg	M-009254-PR	12.11.2021-11.11.2022	11.11.2023
54	Celogen Lanka	Ferrous Sulphate Tablets BP 200mg	M-007522-PR	16.07.2020-15.07.2022	15.07.2023
55	Celogen Lanka	Domperidone Tablets BP 10mg	M-006805-PR	10.09.2019-09.09.2021(Previous extension upto 09.09.2022)	09.09.2023
56	Celogen Lanka	Oseltamivir Phosphate Capsules USP 75mg	M-009186-PR	24.09.2021-23.09.2022	23.09.2023
57	Celogen Lanka	Glicalazide Modified Releases Tablets 30mg	M-009193-PR	14.10.2021-13.10.2022	13.10.2023
58	Celogen Lanka	Nalidixic Acid Tablets BP 250 mg	M-006956-PR	12.09.2019-11.09.2021(Previous extension upto 11.09.2022)	11.09.2023
59	Celogen Lanka	Mycophenolate Mofetil Tablet USP 250 mg	M-009204-PR	14.10.2021-13.10.2022	13.10.2023
60	Celogen Lanka	Mupirocin Ointment USP 2% W/W	M-009176-PR	21.09.2021-20.09.2022	20.09.2023

61	Celogen Lanka	Labetalol Tablets BP 100 mg	M-008058-PR	11.07.2020-10.07.2022	10.07.2023
62	Celogen Lanka	Levamisole Hydrochloride Tablets USP 40 mg	M-008038-PR	10.07.2020-09.07.2022	09.07.2023
63	Celogen Lanka	Clindamycin Capsules BP 300mg	M-009106-PR	09.07.2021-08.07.2022	08.07.2023
64	Lina Spiro	Salbutamol Pressurized Inhalation BP 100 mcg/Dose	M-009196-PR	14.10.2021-13.10.2022	13.10.2023
65	Lina Manufacturing	Beclomethasone Inhalation Powder, Pre - Dispensed BP 200mcg	M-009209-PR	14.10.2021-13.10.2022	13.10.2023
66	Interpharm	Rosuvastatin Tablet IP 10mg	M-009154-PR	06.09.2021-05.09.2022	05.09.2023
67	Medicom (Pvt) Ltd	Povidone Iodine Solution USP 10% w/v	M-006872-PR	27.09.2019-26.09.2021(Previous extension upto 26.09.2022)	26.09.2023
68	Kelun Lifesciense	Sodium Chloride Intravenous Infusion BP 0.9% W/V	M-009143-PR	03.09.2021-02.09.2022	02.09.2023
69	Astron	Framycetin Skin Cream 1% w/w	M-008800-PR	17.07.2020-16.07.2022	16.07.2023
70	Astron	Losartan Potassium Tablets USP 50mg	M-009320-PR	06.08.2020-05.08.2022	05.08.2023
71	Astron	Mebendazole Tablets USP 500 mg	M-009294-PR	11.08.2020-10.08.2022	10.08.2023
72	Astron	Azithromycin Powder for Oral suspension USP 200 mg/5 ml	M-008257-PR	25.07.2020-24.07.2022	24.07.2023
73	CIC	Sitagliptin Tablets BP 100mg	M-008725-PR	10.08.2020-09.08.2022	09.08.2023
74	Morison PLC	Paracetamol Tablets BP 500 mg	M-003910-PR	16.08.2018-15.08.2020(Previous extension upto 15.08.2022)	15.08.2023
75	Celogen Lanka	Calcium Lactate Tablets BP 300 mg	M-006640-PR	05.09.2019-04.09.2021(Previous extension upto 04.09.2022)	04.09.2023
76	Celogen Lanka	Sulfadiazine Tablets USP 500mg	M-006369-PR	25.07.2019-24.07.2021 (Previous extension upto 24.07.2022)	24.07.2023
77	Celogen Lanka	Atorvastatin Tablets IP 20 mg	M-007624-PR	29.08.2021-28.08.2021(Previous extension upto 28.08.2022)	28.08.2023
78	Celogen Lanka	Hydralazine Tablets BP 50mg	M-006617-PR	28.08.2019-27.08.2021(Previous extension upto 27.08.2022)	27.08.2023
79	Celogen Lanka	Ursodeoxycholic Acid Tablet BP 150mg	M-009235-PR	12.11.2021-11.11.2022	11.11.2023
80	Celogen Lanka	Pancreatin Capsules 150mg (Amylase-8,000 U, Lipase-10,000 U & Protease-600 U)	M-008859-PR	17.11.2020-16.11.2021(Previous extension upto 16.11.2022)	16.11.2023

81	Celogen Lanka	Baclofen Tablets BP 10mg	M-006700-PR	10.09.2021-09.09.2021(Previous extension upto 09.09.2022)	09.09.2023
82	Lina Spiro	Fluticasone 125 mcg / dose and Salmeterol 25 mcg / dose pressurized Inhalation, Suspension BP	M-009271-PR	03.12.2021-02.12.2022	02.12.2023
83	Lina Spiro	Beclomethasone Pressurised Inhalation BP 250 mcg/dose	M-009322-PR	06.12.2021-05.12.2022	05.12.2023
84	Lina Spiro	Beclomethasone Pressurised Inhalation BP 100mg / Dose	M-009255-PR	22.11.2021-21.11.2022	21.11.2023
85	Lina Spiro	Beclomethasone Pressurised Inhalation BP 50mcg/dose	M-009276-PR	03.12.2021-02.12.2022	02.12.2023
86	Lina Spiro	Fluticasone 50mcg/dose and Salmeterol 25mcg/dose Pressurized Inhalation, Suspensin BP	M-009240-PR	12.11.2021-11.11.2022	11.11.2023
87	Lina Spiro	Fluticasone 250 mcg/dose and Salmeterol 25 mcg/dose Presurerissed Inhalation, Suspension BP	M-009238-PR	12.11.2021-11.11.2022	11.11.2023
88	Astron	Amoxycillin Capsules USP 250mg	M-007358-PR	02.12.2018-01.12.2020(Previous extension upto 01.12.2022)	01.12.2023
89	Morison PLC	Vitamin B Compound Tablets (Each Tablet Contains Thiamine HCL 1mg + Riboflavin 1mg + Nicotinamide 10mg)	M-008626-PR	01.01.2020-31.12.2021(Previous extension upto 31.12.2022)	31.12.2023
90	Morison PLC	Amitriptyline Tablets BP 25 mg	M-004349-PR	11.12.2018-10.12.2020(previous extension upto 10.12.2022)	10.12.2023
91	Morison PLC	Diazepam Tablets BP 5mg	M-007272-PR	11.12.2018-10.12.2020(previous extension upto 10.12.2022)	10.12.2023
92	Emergen	Budesonide Nasal Spray BP 64mcg	M-005534-PR	09.04.2021(Pervious extension up to 09.04.2023)	09.04.2024
93	Emergen	Pantoprazole delayed release capsules 20 mg	M-007402-PR	25.12.2021 (Previous extension up to 25.12.2022)	25.12.2023
94	Celogen	Warfarin Sodium Tablets USP 0.50 mg	M-007768-PR	04.12.2020(Previous extension up to 04.12.2022)	04.12.2023
95	Celogen	Losartan Potassium Tablets USP 50mg	M-004724-PR	25.12.2020 (Previous extension up to 25.12.2022)	25.12.2023

96	Celogen	Penicillamine Capsules USP 250mg	M-007151-PR	27.11.2020(Previous extension up to 27.11.2022)	27.11.2023
97	Celogen	Warfarin Sodium Tablets USP 3 mg	M-007771-PR	04.12.2020 (Previous extension up to 04.12.2022)	04.12.2023
98	Celogen	Dapsone Tablets BP 25mg	M-007281-PR	22.12.2021 (Previous extension up to 22.12.2022)	22.12.2023
99	Celogen	Warfarin Sodium Tablets USP 1 mg	M-007769-PR	04.12.2020 (Previous extension up to 04.12.2022)	04.12.2023
100	Celogen	Sitagliptin Tablets USP 100mg	M-008893-PR	02.12.2022	02.12.2023
101	Celogen	Sitagliptin Tablets USP 50mg	M-010422-PR	14.01.2023	14.01.2024
102	Astron	Amoxycillin Capsules USP 250mg	M-007358-PR	01.12.2020 (Previous extension up to 01.12.2022)	01.12.2023
103	Astron	Clarithromycin Tablets USP 250mg	M-009297-PR	22.03.2023	22.03.2024
104	Astron	Calcium with Vitamin C & D Tablets	M-009353-PR	13.12.2022	13.12.2023
105	Morison PLC	Vitamin B Compound Tablets (Each Tablet Contains Thiamine HCL 1mg + Riboflavin 1mg + Nicotinamide 10mg)	M-008626-PR	31.12.2021(Previous extension upto 31.12.2022)	31.12.2023
106	Morison PLC	Amitriptyline Tablets BP 25 mg	M-004349-PR	10.12.2020(previous extension upto 10.12.2022)	10.12.2023
107	Morison PLC	Diazepam Tablets BP 5mg	M-007272-PR	10.12.2020(previous extension upto 10.12.2022)	10.12.2023
108	Morison PLC	Salbutamol Oral Solution BP 2mg/5ml	M-001888-PR	01.01.2018-31.12.2019 (Previous extension upto 31.12.2022)	31.12.2023
109	Morison PLC	Chlorphenamine Oral Solution BP 2mg/5ml	M-009553-PR	01.01.2019-31.12.2020 (Previous extension upto31.12.2022)	31.12.2023
110	Navesta	Cloxacillin for Injection 500 mg	M-004610-PR	15.12.2018-14.12.2020 (Previous extension upto 14.12.2022)	14.12.2023
111	Kelun L/S	Sterilized Water for Injection BP	M-009530-PR	28.03.2022-27.03.2023	27.03.2024
112	Kelun L/S	Sodium Chloride Injection BP 0.9% w/v	M-009365-PR	15.02.2022-14.02.2023	14.02.2024
113	Kelun L/S	Glucose Intravenous Infusion BP 5% W/V	M-009531-PR	28.03.2022-27.03.2023	27.03.2024
114	Kelun L/S	Dextran 40 Intravenous Infusion BP 10% w/v	M-009370-PR	15.02.2022-14.02.2023	14.02.2024
115	SPMC	Trifluoperazine Tablets BP 5 mg	M-004381-PR	12.11.2018-11.11.2020 (Previous extension upto11.11.2022)	11.11.2023

116	SPMC	Nimodipine Tablets BP 30mg	M-008733-PR	08.07.2020-07.07.2022	07.07.2023
117	CIC	Sitagliptin Tablets BP 50mg	M-008726-PR	10.08.2020-09.08.2022	09.08.2023
118	Lina Manufacturing	Gastro Resistant Aspirin Tablets BP 75 mg	M-009165-PR	07.06.2021-06.06.2022	06.06.2023
119	Morison PLC	Clonazepam Tablets USP 2mg	M-008219-PR	20.02.2020-19.02.2022 (Previous extension upto 19.02.2023)	19.02.2024
120	Celogen	Prolonged Release Diltiazem Tablets BP 90mg	M-008540-PR	19.06.2020-18.06.2022 (Previous extension up to 18.06.2023)	18.06.2024
121	Celogen	Pyridostigmine Tablets BP 60 mg	M-008037-PR	09.05.2020-08.05.2022(Previous extension upto 08.05.2023)	08.05.2024
122	Celogen	Metoprolol Tartrate Tablets USP 50mg	M-008474-PR	16.06.2020-14.06.2022(Previous extension upto 14.06.2023)	14.06.2024
123	Celogen	Warfarin Sodium Tablets USP 5mg	M-007698-PR	19.02.2020-18.02.2022(Previous extension upto 18.02.2023)	18.02.2024
124	Celogen	Sodium Bicarbonate Tablets USP 600mg	M-007451-PR	17.01.2020-16.01.2022(Previous extension up to 16.01.2023)	16.01.2024

ලියාපදිංචි වලංගු කාලය වසර 2 ත් 4 ත් අතර කාලයකින් දීර්ඝ කර තිබුණු අවස්ථා

අනු අංකය	දේශීය නියෝජිතගේ නම	ඖෂධයේ නම	පවත්නා ලියාපදිංචි සහතිකයේ අංකය	පවත්නා ලියාපදිංචි සහතිකයේ වලංගු කාලය	දීර්ඝ කිරීම වලංගු දිනය
1	Morison PLC	Salbutamol Oral Solution BP 2mg/5ml	M-001888-PR	01.01.2018-31.12.2019 (Previous extension upto 31.12.2021)	31.12.2022 31.12.2023
2	Morison PLC	Salbutamol Tablets BP 2 mg	M-005654-FR	23.04.2016-22.04.2021 (Previous extension upto 22.04.2022)	22.04.2023
3	Morison PLC	Promethazine Hydrochloride Tablets BP 10mg	FR-061598	08.02.2016-07.02.2021(Previous extension upto 07.02.2022)	07.02.2023
4	Emergen Life Scienses	Budesonide Nasal Spray BP 64mcg	M-005534-PR	10.04.2019-09.04.2021 (Previous extension upto 09.04.2022)	09.04.2023
5	Emergen Life Scienses	Esomeprazole Capsules 20mg	M-002626-PR	22.03.2018-21.03.2020(Previous extension upto 21.03.2022)	21.03.2023
6	Celogen Lanka	Pyrimethamine tablets BP 25 mg	M-005590-PR	10.04.2019-09.04.2021 (Previous extension upto 09.04.2023)	09.04.2023
7	Celogen Lanka	Mycophenolate Mofetil Tablets USP 500 mg	M-005680-PR	29.04.2019-28.04.2021(Previous extension upto 28.04.2022)	28.04.2023
8	Celogen Lanka	Metformin Tablets 500mg	M-005161-PR	06.02.2019-05.02.2021(Previous extension upto 05.02.2022)	05.02.2023
9	Celogen Lanka	Doxepin Capsules BP 50 mg	M-005545-PR	10.04.2019-09.04.2021(Previous extension upto 09.04.2022)	09.04.2023
10	Emergen Life Scienses	Formoterol Fumarate BP 6mcg+ Budesonide BP 200mcg Dry Powder Inhalation Capsules	FR-062904	09.07.2016-08.07.2021(Previous extension upto 08.07.2022)	08.07.2023
11	Emergen Life Scienses	Salmeterol 50mcg & Fluticasone Propionate BP 500mcg Dry Powder Inhalation Capsule	FR-062000	09.07.2016-08.07.2021(Previous extension upto 08.07.2022)	08.07.2023
12	Emergen Life Scienses	Pantoprazole Delayed Release Capsules 40mg	M-006324-PR	11.07.2019-10.07.2021(Previous extension upto 10.07.2022)	10.07.2023

13	Lina Manufacturing	Captopril Tablets BP 25 mg	M-006394-PR	05.06.2019-04.06.2021(Previous extension upto 04.06.2022)	04.06.2023
14	Lina Manufacturing	Salbutamol Inhalation Powder-Pre-Dispensed BP Capsules 400 mcg	M-006723-PR	31.07.2019 - 30.07.2021(Previous extension upto 30.07.2022)	30.07.2023
15	Lina Manufacturing	Beclametasone Dipropionate 400mcg Dry Powder Inhalation Capsule	FR-064643	31.07.2016 - 30.07.2021(Previous extension upto 30.07.2022)	30.07.2023
16	Lina Manufacturing	Salmeterol 50mcg & Fluticasone Propionate 250mcg Dry Powder Inhalation Capsules	M-003744-FR	17.08.2016-16.08.2021(Previous extension upto 16.08.2022)	16.08.2023
17	Navesta Pharmaceuticals	Ampicillin for Injection BP 1g	M-006490-PR	19.06.2019-18.06.2021(Previous extension upto 18.06.2022)	18.06.2023
18	Navesta Pharmaceuticals	Penicillin G Benzathine for Injection 1.2 MIU	M-006501-PR	06.07.2019-05.07.2021(Previous extension upto 05.07.2022)	05.07.2023
19	Diyatha pharmaceuticals	Salbutamol Oral Solution 2 mg / 5 ml	M/006425-PR	05.08.2019-04.08.2021(Previous extension upto 04.08.2022)	04.08.2023
20	SmithKline Beecham	Paracetamol Tablets 500mg	M-006315-PR	17.07.2019-16.07.2020(Previous extension upto 16.07.2022)	16.07.2023
21	Celogen Lanka	Valganciclovir Tablets USP 450mg	M-005136-PR	22.02.2019-21.02.2021(Previous extension upto 21.02.2022)	21.02.2023
22	CIC	Metformin Hydrochloride Extended Release Tablets USP 500 mg	M-005317-PR	25.02.2019-24.02.2020(Previous extension upto 24.02.2022)	24.02.2023
23	Celogen Lanka	Zinc Sulfate Tablets USP 10 mg	M-006991-PR	17.10.2019-16.10.2020(Previous extension upto 16.10.2022)	16.10.2023
24	Celogen Lanka	Zinc Sulfate Tablets USP 20mg	M-007007-PR	17.10.2019-16.10.2020(Previous extension upto 16.10.2022)	16.10.2023
25	Celogen Lanka	Domperidone Tablets BP 10mg	M-006805-PR	10.09.2019-09.09.2021(Previous extension upto 09.09.2022)	09.09.2023
26	Celogen Lanka	Nalidixic Acid Tablets BP 250 mg	M-006956-PR	12.09.2019-11.09.2021(Previous extension upto 11.09.2022)	11.09.2023

27	Medicom (Pvt) Ltd	Povidone Iodine Solution USP 10% w/v	M-006872-PR	27.09.2019-26.09.2021(Previous extension upto 26.09.2022)	26.09.2023
28	Emergen Life Scienses	Salmeterol 50mcg & Fluticasone Propionate 100mcg Dry Powder Inhalation Capsule	FR-065699	13.11.2015-12.11.2020(Previous extension upto 12.11.2022)	12.11.2023
29	Astron	Multivitamin & Mineral Capsule	FR-061872	07.08.2015-06.08.2020 (Previous extension upto 06.08.2022)	06.08.2023
30	Astron	Iron, Vitamin B Complex, Vitamin C & Folic Acid Capsules	FR-064726	24.09.2016-23.09.2021 (Previous extension upto 23.09.2022)	23.09.2023
31	Morison PLC	Paracetamol Tablets BP 500 mg	M-003910-PR	16.08.2018-15.08.2020(Previous extension upto 15.08.2022)	15.08.2023
32	Morison PLC	Tolbutamide Tablets BP 500mg	M-005631-FR	14.06.2015-13.06.2020(Previous extension upto 13.06.2022)	13.06.2023
33	SmithKline Beecham	Paracetamol Tablets 500mg	FR-064850	17.10.2016-16.10.2021(Previous extension upto 16.10.2022)	16.10.2023
34	Celogen Lanka	Calcium Lactate Tablets BP 300 mg	M-006640-PR	05.09.2019-04.09.2021(Previous extension upto 04.09.2022)	04.09.2023
35	Celogen Lanka	Sulfadiazine Tablets USP 500mg	M-006369-PR	25.07.2019-24.07.2021 (Previous extension upto 24.07.2022)	24.07.2023
36	Celogen Lanka	Atorvastatin Tablets IP 20 mg	M-007624-PR	29.08.2021-28.08.2021(Previous extension upto 28.08.2022)	28.08.2023
37	Celogen Lanka	Hydralazine Tablets BP 50mg	M-006617-PR	28.08.2019-27.08.2021(Previous extension upto 27.08.2022)	27.08.2023
38	Celogen Lanka	Pancreatin Capsules 150mg (Amylase-8,000 U, Lipase-10,000 U & Protease-600 U)	M-008859-PR	17.11.2020-16.11.2021(Previous extension upto 16.11.2022)	16.11.2023
39	Celogen Lanka	Baclofen Tablets BP 10mg	M-006700-PR	10.09.2021-09.09.2021(Previous extension upto 09.09.2022)	09.09.2023
40	Astron	Amoxycillin Capsules USP 250mg	M-007358-PR	02.12.2018-01.12.2020(Previous extension upto 01.12.2022)	01.12.2023

41	Morison PLC	Vitamin B Compound Tablets (Each Tablet Contains Thiamine HCL 1mg + Riboflavin 1mg + Nicotinamide 10mg)	M-008626-PR	01.01.2020-31.12.2021(Previous extension upto 31.12.2022)	31.12.2023
42	Morison PLC	Amitriptyline Tablets BP 25 mg	M-004349-PR	11.12.2018-10.12.2020(previous extension upto 10.12.2022)	10.12.2023
43	Morison PLC	Diazepam Tablets BP 5mg	M-007272-PR	11.12.2018-10.12.2020(previous extension upto 10.12.2022)	10.12.2023
44	Morison PLC	Hyoscine Butylbromide Tablets BP 10mg	M-005656-FR	19.12.2016-18.12.2021(Previous extension upto 18.12.2022)	18.12.2023
45	Morison PLC	Haloperidol Tablets BP 1.5mg	M-004838-FR	01.01.2015-31.12.2019(Previous extension upto 31.12.2022)	31.12.2023
46	Emergen	Budesonide Nasal Spray BP 64mcg	M-005534-PR	09.04.2021(Pervious extension up to 09.04.2023)	09.04.2024
47	Emergen	Pantoprazole delayed release capsules 20 mg	M-007402-PR	25.12.2021 (Previous extension up to 25.12.2022)	25.12.2023
48	Celogen	Warfarin Sodium Tablets USP 0.50 mg	M-007768-PR	04.12.2020(Previous extension up to 04.12.2022)	04.12.2023
49	Celogen	Losartan Potassium Tablets USP 50mg	M-004724-PR	25.12.2020 (Previous extension up to 25.12.2022)	25.12.2023
50	Celogen	Penicillamine Capsules USP 250mg	M-007151-PR	27.11.2020(Previous extension up to 27.11.2022)	27.11.2023
51	Celogen	Warfarin Sodium Tablets USP 3 mg	M-007771-PR	04.12.2020 (Previous extension up to 04.12.2022)	04.12.2023
52	Celogen	Dapsone Tablets BP 25mg	M-007281-PR	22.12.2021 (Previous extension up to 22.12.2022)	22.12.2023
53	Celogen	Warfarin Sodium Tablets USP 1 mg	M-007769-PR	04.12.2020 (Previous extension up to 04.12.2022)	04.12.2023
54	Astron	Amoxycillin Capsules USP 250mg	M-007358-PR	01.12.2020 (Previous extension up to 01.12.2022)	01.12.2023
55	Morison PLC	Vitamin B Compound Tablets (Each Tablet Contains Thiamine HCL 1mg + Riboflavin 1mg + Nicotinamide 10mg)	M-008626-PR	31.12.2021(Previous extension upto 31.12.2022)	31.12.2023
56	Morison PLC	Amitriptyline Tablets BP 25 mg	M-004349-PR	10.12.2020(previous extension upto 10.12.2022)	10.12.2023

57	Morison PLC	Diazepam Tablets BP 5mg	M-007272-PR	10.12.2020(previous extension upto 10.12.2022)	10.12.2023
58	Morison PLC	Hyoscine Butylbromide Tablets BP 10mg	M-005656-FR	18.12.2021(Previous extension upto 18.12.2022)	18.12.2023
59	Morison PLC	Haloperidol Tablets BP 1.5mg	M-004838-FR	31.12.2019(Previous extension upto 31.12.2022)	31.12.2023
60	Morison PLC	Salbutamol Oral Solution BP 2mg/5ml	M-001888-PR	01.01.2018-31.12.2019 (Previous extension upto 31.12.2022)	31.12.2023
61	Morison PLC	Hydrochlorothiazide Tablets BP 50mg	M-005653-FR	17.01.2017-16.01.2022 (Previous extension upto 16.01.2023)	16.01.2024
62	Morison PLC	Chlorphenamine Oral Solution BP 2mg/5ml	M-009553-PR	01.01.2019-31.12.2020 (Previous extension upto31.12.2022)	31.12.2023
63	Navesta	Cloxacillin for Injection 500 mg	M-004610-PR	15.12.2018-14.12.2020 (Previous extension upto 14.12.2022)	14.12.2023
64	SPMC	Trifluoperazine Tablets BP 5 mg	M-004381-PR	12.11.2018-11.11.2020 (Previous extension upto11.11.2022)	11.11.2023
65	Morison PLC	Clonazepam Tablets USP 2mg	M-008219-PR	20.02.2020-19.02.2022 (Previous extension upto 19.02.2023)	19.02.2024
66	Celogen	Prolonged Release Diltiazem Tablets BP 90mg	M-008540-PR	19.06.2020-18.06.2022 (Previous extension up to 18.06.2023)	18.06.2024
67	Celogen	Pyridostigmine Tablets BP 60 mg	M-008037-PR	09.05.2020-08.05.2022(Previous extension upto 08.05.2023)	08.05.2024
68	Celogen	Metoprolol Tartrate Tablets USP 50mg	M-008474-PR	16.06.2020-14.06.2022(Previous extension upto 14.06.2023)	14.06.2024
69	Celogen	Warfarin Sodium Tablets USP 5mg	M-007698-PR	19.02.2020-18.02.2022(Previous extension upto 18.02.2023)	18.02.2024
70	Celogen	Sodium Bicarbonate Tablets USP 600mg	M-007451-PR	17.01.2020-16.01.2022(Previous extension up to 16.01.2023)	16.01.2024

ඇමුණුම 84

193

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

දිනය திகதி Date: 02.02.2022

මගේ අංකය எனது இல. My No.: NMRA/LO/745/2020

To : Pharmacist – P18

From : Chief Executive Officer

Copies : Director-NMQAL / Legal Officer/Assistant Director (ICT)/Accountant
Administrative Officer/Chief -F&DI/ Chief Pharmacist

Subject : To get approval to issue consignment clearance -Medicines Regulatory Division

Reference No : NMRA/LO/745/2020 (275)

Board Paper No: 76.4.14

Date : 2022.01.21

Decision: -

The Board approved to grant approval for consignment clearance for importation of medicine after assessing each individual application only for this time until 30.04.2022.

Dr.Saveen Semage.
Chief Executive Officer,
National Medicines Regulatory Authority.

Dr. Saveen Semage
MBBS, MSc, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

(192)

Board Paper- National Medicines Regulatory Authority -2022 January

A. Board Paper : No...76.4.14.... Year: 2022 Month: January Date :...21...

B. Subject : To get approval to issue consignment clearance

C. Title of the Board Paper: To get approval to issue consignment clearance

D. Reference to Previous Board Papers (If any):

E. Department/Division/Unit: Medicines Regulatory Division

1. Brief Introduction :

Considered the present situation associated with covid - 19 pandemic, the period of validity of registration and import license expired after 30th of June 2019 and would be expired up to 31st December 2021 were extended.

With reference to letter (NMRA/LO/536/2019) dated on 18.02.2021 (Annexure 1). Renewal of registration could be processed before three months of expiry of previous registration certificate.

At present there is an unmanageable backlog accumulated relevant to evaluation of new, re-registration, additional dossiers and variation applications due to transfer of four pharmacists, deficiencies in documentation, e-NMRA system breakdown, multitasking of pharmacist and lack of staff.

2. Background:

The meeting was chaired by CEO –NMRA with the participation of regulatory pharmacist of MRD and representative of the Sri Lanka Chamber of Pharmaceutical Industries (SLCPI) on 12th January 2022. Representative of the SLCPI informed difficulties of consignment release due to the following reasons.

1. NMRA registration is under processing
2. NMRA registration has expired
3. NMRA Certificate of registration has short period of remaining validity
4. Products registered and residual shelf life of the product is 66 %.
5. Products registered and import license is under processing
6. Products registered and amendment of certificate of registration is under processing.
7. Break down of e- nmra system and acceptance of those dossiers manually
8. Restriction imposed for accepting dossiers which are already submitted through e-nmra system. (Annexure 2 –notice for accepting manual applications)

191

SLCPI requested quick interim action to clear consignments.

With reference to the medicines regulation 2145/1 -2019 made under the NMRA Act no 05 of 2015, there is no legal provision to issuance of consignment clearance. Ensure availability of quality safety efficacious medicines is one of objectives of NMRA. Hence considering above reasons to assure accessibility for quality safety efficacious medicines need to consider issuance of consignment clearance for products which have above issue/s.

3. Expected Outcomes: To get approval to issue consignment clearance up to 30th April 2022 after assessment of each application which have above mentioned issue/s.

4. Financial Implications: Payment for clarification letter 10 USD is applicable

5. Risk Analysis

Identified Risk	Risk Likelihood (H, M, L)	Impact (H, M, L)	Strategy to Manage Risk
-	-	-	-

6. Corporate Governance and Compliance

7. Certification and Recommendation

"This is to certify that the proposal herein before described in this board paper has been prepared having considered all the relevant provisions in the governing Act, regulations, circulars, procurement procedures etc and as such I recommend the aforesaid proposal to **obtain approval to issue consignment clearance to ensure availability of quality, safe efficacious medicines** to the members of the Board of NMRA for consideration and approval"

Amil 18

Name and Signature of HOD/name of Division/Unit/Dpt.

(Ms. Amila Ekanayake- Focal point- Medicines Regulatory Division)

(150)

8. Submission to Board Approval

"I recommend the aforesaid proposal submitted by Head of **Medicines Regulatory Division** with ~~his~~/her recommendations to **obtain approval to issue consignment clearance to availability of quality, safe efficacious medicines in the market** the members of the Board of NMRA for consideration/determination and approval"

Name and Signature of CEO

Dr. Saveen Semage
MBBS, MSc, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

(ඇ) විශේෂඥයන්ට ඡන්දය පාවිච්චි කිරීමේ අයිතියක් නොමැති විය යුතු ය.

අධිකාරියේ රැස්වීම් සඳහා සහභාගීවීම වෙනුවෙන් වූ පාරිශ්‍රමික.

13. අධිකාරියේ සාමාජිකයන් සහ විශේෂඥයන් විසින් අධිකාරියේ රැස්වීම් සඳහා සහභාගීවීම වෙනුවෙන් මුදල් විෂයය භාර අමාත්‍යවරයාගේ එකඟත්වය ඇතිව අමාත්‍යවරයා විසින් තීරණය කරනු ලැබිය හැකි යම් පාරිශ්‍රමික ගෙවනු ලැබිය හැකි ය.

අධිකාරියේ බලතල සහ කර්තව්‍ය.

14. අධිකාරියේ බලතල සහ කර්තව්‍ය වනුයේ:-

(අ) යම් නිෂ්පාදනයක්, ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ වෙනත් යම් නිෂ්පාදනයක් ද යන්න වර්ගීකරණය මත තීරණය කිරීම;

(ආ) මේ පනතේ නියම ප්‍රකාරව ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන සහ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන ලියාපදිංචි කිරීම සහ බලපත්‍ර ලබා දීම අනුමත කිරීම හෝ එවැනි යම් ලියාපදිංචි කිරීමක් හෝ බලපත්‍ර ලබාදීමක් අවලංගු කිරීම හෝ අත්හිටුවීම;

(ඇ) ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන, විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන, ලියාපදිංචි කිරීම, බලපත්‍ර ලබාදීම, නිෂ්පාදනය කිරීම, ආනයනය කිරීම, ගබඩා කිරීම, නැවත ඇසුරුම් කිරීම, ප්‍රවාහනය කිරීම, බෙදාහැරීම, විකිණීම, ප්‍රචාරණය කිරීම, ප්‍රවර්ධනය කිරීම, ආපසු කැඳවීම සහ බැහැර කිරීම නියාමනය කිරීම;

(ඈ) ඔසුසල් හා ඖෂධ ගබඩා ලියාපදිංචි කිරීම සහ නියාමනය කිරීම සඳහා බලය ලබාදීම;

(ඉ) ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන, නිෂ්පාදනය කිරීම, ආනයනය කිරීම, ගබඩා කිරීම, බෙදා හැරීම, ප්‍රවාහනය කිරීම සහ විකිණීම සඳහා බලපත්‍ර නිකුත් කිරීම සහ මේ පනතේ නියම ප්‍රකාරව එකී බලපත්‍ර අවලංගු කිරීම;

(ඊ) අධිකාරියේ කර්තව්‍ය ඵලදායී ලෙස ඉටුකිරීම සඳහා අවශ්‍යවන අනු කමිටු පත්කිරීම;

(උ) මේ පනතේ සහ වෙනත් යම් ලිඛිත නීතියක විධිවිධානවලට යටත්ව ඖෂධ, වෛද්‍ය උපකරණ,

සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන දේශීය වශයෙන් නිෂ්පාදනය කිරීම සඳහා අවශ්‍යවන ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන, අමුද්‍රව්‍ය, ඇසුරුම් ද්‍රව්‍ය, යන්ත්‍රෝපකරණ හෝ රසායනාගාර ද්‍රව්‍ය තොග රේගුවෙන් නිදහස් කර ගැනීම සඳහා අනුමතය ලබා දීම;

(උ) ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදන පිළිබඳ දැනුවත් කිරීමේ වැඩසටහන් පැවැත්වීම සහ මේ පනත යටතේ ලියාපදිංචි කර ඇති සහ බලපත්‍ර ලබාදී ඇති ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදනවල තත්ත්වය සහ ආරක්ෂාව පිළිබඳ පශ්චාත් අලෙවි සමීක්ෂණ පැවැත්වීම;

(ඌ) ලියාපදිංචි කිරීමේ සහ බලපත්‍ර ලබාදීමේ ක්‍රියාවලිය සහ මේ පනත යටතේ ලියාපදිංචි කර ඇති සහ බලපත්‍ර ලබා දී ඇති ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන භාවිතා කිරීම තුළින් ඇතිවන අහිතකර ප්‍රතික්‍රියා අධීක්ෂණය කිරීම සහ එවැනි අවස්ථාවලදී ඍණික සහ අවශ්‍ය පියවර ගැනීම;

(එ) බලපත්‍ර යටතේ ආනයනය කරන ලද ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදනවල ප්‍රමාණය පිළිබඳ දත්ත රැස් කිරීම;

(ඒ) ප්‍රවර්ධනය කිරීමේ ක්‍රියාකාරකම්වලට අදාළ කර්මාන්ත සහ වෙළඳ වියදම් පිළිබඳ දත්ත ඇතුළුව, ශ්‍රී ලංකාවේ ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදනවල භාවිතය පිළිබඳ දත්ත රැස්කිරීම;

(ඓ) නියම කරනු ලැබිය යුතු බවට නිර්දේශිත කරුණු පිළිබඳ අමාත්‍යවරයා වෙත උපදෙස් ලබා දීම;

(ක) යම් චංචල හෝ නිශ්චල දේපළ අත්කරගැනීම, දැරීම, කුළියට හෝ බද්දට ලබා ගැනීම හෝ ලබා දීම, උකස් කිරීම, ඔඩපනය කිරීම, විකිණීම හෝ අන්‍යාකාරයකින් බැහැර කිරීම;

(ඛ) එහි කර්තව්‍ය ඉටුකිරීමේ දී අවශ්‍ය වන සහ සුදුසු ගාස්තු අයකිරීම;

ඇමුණුම 86

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

දිනය திகதி Date: 30.05.2022

මගේ අංකය எனது இல My No.: NMRA/LO/745/2020

To : Pharmacist (P-18)

From : Chief Executive Officer

Copies : Director-NMQAL /Accountant/ Legal Officer./ Assistant. Director-(ICT) Chief -F&DI / Administrative Officer/ Chief Pharmacist

Subject : To obtain approval to issue consignment clearance to ensure the availability of quality, safe efficacious medicines in the market

Reference No : NMRA/LO/745/2020 (භාෂ)

Board Paper No : 80.4.6

Date of the Board Meeting : 2022.05.20

Decision: -

The Board approved issuing consignment clearance for products which have the following issues:

1. NMRA registration has expired and submitted renewal or re-registration application is under process
2. Products registered and residual shelf life of the product is sixty-six (66) percent (legal provision in the NMRA Act Section 107 (1))
3. Products with valid registration and renewal of import licence is under process
4. Products registered and amendment of certificate of registration is under process
5. Breakdown of e-NMRA system and acceptance of those dossiers manually
6. Restriction imposed for accepting dossiers which are already submitted through e-NMRA system
7. New application submitted for previously registered products due to site change

Dr. Saveen Semage
MBBS, MSc, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

Dr.Saveen Semage
Chief Executive Officer
National Medicines Regulatory Authority.

(188)

A. **Board Paper** : No. 80.4.6 Year: 2022 Month: May Date : 20

B. **Subject** : To obtain approval to issue consignment clearance to ensure availability of quality, safe efficacious medicines in the market

C. **Title of the Board Paper:** To obtain approval to issue consignment clearance to ensure availability of quality, safe efficacious medicines in the market

D. **Reference to Previous Board Papers (If any): 76.4.14**

E. **Department/Division/Unit:** Medicines Regulatory Division

1. Brief Introduction :

There is an unmanageable backlog accumulated relevant to evaluation of new, re-registration, additional and variation applications due to various reasons.

As per the board paper 76.4.14, the board approved grant approval for issue consignment clearance for importation of medicine after assessing the each individual application until 30.04.2022.

2. Background:

The board held on 21.01.2022, has approved grant approval for consignment release due to the following reasons.

1. NMRA registration has expired and submitted renewal/re-registration application is under processing
2. Products registered and residual shelf life of the product is 66 %. (legal provision in the NMRA Act 107 (1))
3. Products has valid registration and renewal of import license is under processing
4. Products registered and amendment of certificate of registration is under processing.
5. Break down of e- nmra system and acceptance of those dossiers manually
6. Restriction imposed for accepting dossiers which are already submitted through e-nmra system.
7. New application submitted for previously registered products due to site change.

With reference NMRA Act no 05 of 2015, 14) (g), the authority has power to grant approval for custom clearance of consignments. Ensure availability of quality safety efficacious medicines is one of objectives of NMRA. Hence considering above reasons to assure accessibility for quality safety efficacious medicines need to consider issuance of consignment clearance for products which have above issue/s.

3. **Expected Outcomes:** To get approval for issue consignment clearance after assessment of each application which have above mentioned issue/s.

4. **Financial Implications:** Payment for clarification letter 10 USD is applicable

5. **Risk Analysis**

Identified Risk	Risk Likelihood (H, M, L)	Impact (H, M, L)	Strategy to Manage Risk
-	-	-	-

6. **Corporate Governance and Compliance**

7. **Certification and Recommendation**

"This is to certify that the proposal herein before described in this board paper has been prepared having considered all the relevant provisions in the governing Act, regulations, circulars, procurement procedures etc and as such I recommend the aforesaid proposal to **obtain approval to issue consignment clearance to ensure availability of quality, safe efficacious medicines in the market to** the members of the Board of NMRA for consideration and approval"

Amila P18 17/05/2022

Ms. Amila Ekanayake- Focal point- Medicines Regulatory Division

(186)

8. Submission to Board Approval

"I recommend the aforesaid proposal submitted by Head of **Medicines Regulatory Division** with ~~his~~/her recommendations to **obtain approval to issue consignment clearance to ensure availability of quality, safe efficacious medicines in the market** the members of the Board of NMRA for consideration/determination and approval"

Name and Signature of CEO

Total Number of shipment clearance.

කරුණු 87

Gmail

audit msub <auditmsub@gmail.com>

Fwd: Payment notice Issuance_2022

1 message

Nishani Lanka <p35@nmra.gov.lk> Sun, Nov 19, 2023 at 11:56 PM
To: audit msub <auditmsub@gmail.com>

Dear Ms. Ayesha,

Please find the below email as per your request.

BR
K. Nishani Lanka
Regulatory Pharmacist
National Medicines Regulatory Authority
Sri Lanka
Email: p35@nmra.gov.lk
Telephone: +94 112698896/7 Ext: 308

NMRA
NATIONAL MEDICINES REGULATORY AUTHORITY

---------- Forwarded message ---------
From: **Chandika Kumarie** <mrdma1@nmra.gov.lk>
Date: Mon, Nov 20, 2023 at 11:31 AM
Subject: Payment notice Issuance_2022
To: Nishani Lanka <p35@nmra.gov.lk>

Dear Ms,
All issued - = 3523
WOR & Export approval = 321 -

Shipment clearance (CC) = 3202

--
Kumarie M.A.C. (MA)
Medicines Regulatory Division
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.
Tel: 011 2 698896/7 (Ext 320)

NMRA
NATIONAL MEDICINES REGULATORY AUTHORITY

ලබා දී තිබුණු තොග නිෂ්කාශන අනුමැතීන් අතුරින් කිහිපයක්

ඖෂධයේ නම	ආනයනකරුගේ නම	පැවති ලියාපදිංචි සහතිකයේ අංකය	පැවති ලියාපදිංචි සහතිකයේ වලංගු කාලය	තොග නිෂ්කාශන අනුමැතීන් දී තිබුණු අවස්ථා ගණන	ඉන්වොයිස් දිනය	ආනයනය කළ ප්‍රමාණය
Globetasol Propionate Ointment USP 1.05%	Ceyoka (Pvt) Ltd	M-008786-PR	2020.08.07-2022.08.06	6	2022.04.11 2022.04.26 2022.08.23 2022.09.15 2022.10.21 2023.10.06	30240 Packs 69600 Packs 42000 Packs 14252 Packs 20160 Packs 43200 Packs
Travoprost Ophthalmic Solution USP 0.004%	Heamas Pharmaceuticals (Pvt) Ltd	M-006590-PR	2019.03.13-2020.03.12	6	2022.03.07 2022.04.04 2022.05.15 2022.06.07 2022.07.12 2022.08.07	349 Packs 3640 Packs 6240 Packs 3380 Packs 3536 Packs 7150 Packs
Azithromycin Capsules USP 250mg	Heamas Pharmaceuticals (Pvt) Ltd	M-005121-PR	2018.12.17-2020.12.16	4	2022.10.20 2022.11.22 2023.01.18 2023.03.14	4161 Packs 846 Packs 2816 Packs 602 Packs
Miconazole Nitrate Cream IP 2%	Pharma Associates (Pvt) Ltd.	M-008019-PR	2020.04.22-2022.04.21	8	2021.07.09 2021.08.17 2022.06.08 2022.10.10 2022.12.20 2023.04.12 2023.07.07 2023.10.19	70000 Tablets 73090 Tablets 50000 Tablets 80000 Tablets 80000 Tablets 40000 Tablets 80000 Tablets 150000 Tablets
Finasteride Tablets 5mg	Emerchemie NB (Ceylon) Ltd.	M-002418-FR	2018.02.15-2023.02.14	7	2023.01.04 2023.02.27 2023.03.20 2023.03.20 2023.05.10 2023.06.06 2023.09.04	13750 Packs 16500 Packs 16500 Packs 14300 Packs 16500 Packs 11000 Packs 13200 Packs
Montelukast Tablets 10mg	Morison Son & Jones	FR-067003	2017.04.10-2022.04.09	10	2022.02.28 2022.03.08 2022.03.24 2022.06.30	14271 Packs 10120 Packs 11224 Packs 11400 Packs

					2022.08.03	12681	Packs
					2022.08.04	8119	Packs
					2022.08.05	17848	Packs
					2022.09.18	24840	Packs
					2022.09.18	24840	Packs
					2022.12.27	8004	Packs

තොග නිෂ්කාශන අනුමැතීන් යටතේ ආනයනය කළ ඖෂධ භාවිතයෙන් ඉවත් කළ අවස්ථා

	භාවිතයෙන් ඉවත් කිරීම සිදු කළ දිනය	ඖෂධයේ නම	නිෂ්පාදක	දේශීය නියෝජිත	ලියාපදිංචි තත්ත්වය
1.	15-Feb-2022	Dobutamine injection USP 250mg/20ml	Mercury Laboratories Ltd, Unit No 1,2/13-14, Gorwa Industrial Estate, Gorwa, Gujarat, India	Yaden International	Two years reg. from 20.02.2019-expired
2.	28-Mar-2022	Furosemide injection BP 10mg/ml	Daffodills Pharmaceuticals Ltd, Jawahar Nagar, rohta road, Meerut-250001, Uttar Pradesh, India	Nation Pharma Pvt Ltd	One year reg. from 12.05.2021-expired
3.	17-May-2022	Dobutamine injection USP 250mg/20ml	Mercury Laboratories Ltd, Unit No 1,2/13-14, Gorwa Industrial Estate, Gorwa, Gujarat, India	Yaden International	Two years reg. from 20.02.2019-expired
4.	19-May-2022	Glucose Intravenous Infusion BP 25% w/v	AMN Lifesciences Pvt Ltd,150, Sahajanand Estate, Sarkej,Tal.City, Ahmedabad, Gujarat, India	pharma Associates	One year reg. from 28.08.2018-expired
5.	15-Jun-2022	Ceftriaxone for Injection USP 500mg	inject Care Parenterals Pvt Ltd, Plot No 130, Silvassa Road, GIDC, Vapi 396195, India	Yaden International (Pvt) Ltd	Two years reg. from 21.05.2017-expired
6.	15-Jun-2022	Furosemide injection BP 10mg/ml	Daffodills Pharmaceuticals Ltd, Jawahar Nagar, rohta road, Meerut-250001, Uttar Pradesh, India	Nation Pharma Pvt Ltd	One year reg. from 12.05.2021-expired
7.	8-Jul-2022	Furosemide injection BP 10mg/ml	Daffodills Pharmaceuticals Ltd, Jawahar Nagar, rohta road, Meerut-250001, Uttar Pradesh, India	Nation Pharma Pvt Ltd	One year reg. from 12.05.2021-expired
8.	3-Aug-2022	Verapamil Injection BP 5mg/2ml	Samarth Life sciences Pvt Ltd, unit-II, Plot No.2, Indusrial area, Lodhimajra Baddi, himachal Pradesh-173205, India, HO:Ram Mandir Road, Goregaon (W), Mumbai-400104, India	Pharma associates	Full reg. from 22.07.2017-expired
9.	3-Aug-2022	Furosemide injection BP 10mg/ml	Daffodills Pharmaceuticals Ltd, Jawahar Nagar, rohta road, Meerut-250001, Uttar Pradesh, India	Nation Pharma Pvt Ltd	One year reg. from 12.05.2021-expired
10.	19-Aug-2022	Omeprazole Sodium for injection 40mg (Lyophilized)	Scott-Edil Pharmacia Ltd, 56, E.P.I.P, Phase I, Jharmajri, Baddi-173205, Dist.Salon, Himachal Pradesh, India	PTC Medical Pvt Ltd	Full reg. from 19.09.2017-expired

11.	29-Aug-2022	Levothyroxine Sodium Tablets USP 25mcg	Centurion remedies Pvt Ltd, Plot No P-2, Bio-tech park, manjusar, Savil, dist,Vadodara, India	Yaden International Pvt Ltd	Two years reg. from 19.06.2020-expired
12.	13-Oct-2022	Levothyroxine Sodium Tablets USP 25mcg	Centurion remedies Pvt Ltd, Plot No P-2, Bio-tech park, manjusar, Savil, dist,Vadodara, India	Yaden International Pvt Ltd	Two years reg. from 19.06.2020-expired
13.	13-Oct-2022	Levothyroxine Sodium Tablets USP 50mcg	Centurion remedies Pvt Ltd, Plot No P-2, Bio-tech park, manjusar, Savil, dist,Vadodara, India	Yaden Internationai Pvt Ltd	Two years reg. from 19.06.2020-expired
14.	13-Oct-2022	Cefuroxime for injection USP 750mg	Swiss Parenterals Pvt Ltd, 809, Kerala, GIDC, Nr.Bavla, Gujarat, India	PTC Medical Pvt Ltd	Two years reg. from 19.06.2020-expired
15.	20-Jan-2023	Ceftazidime for Injection USP 1000mg	Scott-Edil Advance Resarch Laboratories & Education Ltd, Hill Top Ind Area, Bhatoli Kalan, Baddi, Distt.Solan 173205, Himachal Pradesh, India	PTC Medical Pvt Ltd	Two years reg. from 11.07.2018-expired
16.	2-Feb-2023	Cefuroxime for injection USP 750mg	Swiss Parenterals Pvt Ltd, 809, Kerala, GIDC, Nr.Bavla, Gujarat, India	PTC Medical Pvt Ltd	Two years reg. from 19.06.2020-expired
17.	3-Mar-2023	Flucloxacillin Capsules BP 500mg	Navana Pharmaceuticals Ltd, Rupshi, Narayanganj, Bangladesh	Darly butler Co Ltd	Full reg. from 03.02.2018-expired
18.	30-Jun-2023	Amoxicillin and Potassium Clavulanate for Injection BP 1.2g	Navesta Pharmaceuticals Pvt Ltd, 107A, Nakandala Road, Kindelpitiya, Millewa, Horana, Sri Lanka		Two years reg. from 11.08.2020-expired
19.	20-Jul-2023	Mucolytics Bronchodialator Expectorant (Ambroxol HCL 15mg+Turbutaline sulph 1.5mg+ guaphenesin 50mg/5ml syrup-ELTUSS-A)	Stallion Laboratories Pvt Ltd, C-1B, 305/2,3,4 &5, GIDC, Kerala (Bavla), Dist: Ahmedabad-382220, Gujarat, India	Siba Healthcare Pvt ltd	Full reg. from 26.06.2015-expired
20.	20-Jul-2023	Bupivacaine HCl in Dextrose Inj USP 4ml	Divine Laboratories Pvt Ltd, Block No 471, Dabhasa, Tal-Padra, Dist-Vadodara-391440, India	Slim Pharmaceuticals	One year reg. from 31.08.2018-expired

		(5mg/80mg/ml)			
21.	9-Aug-2023	Amoxicillin and Potassium Clavulanate for Injection BP 1.2g	Navesta Pharmaceuticals Pvt Ltd, 107A, Nakandala Road, Kindelpitiya, Millewa, Horana, Sri Lanka		Two years reg. from 11.08.2020-expired
22.	22-Aug-2023	Hydroxyurea Capsules USP 500mg	Jodas Expoim Pvt Ltd, Plot No 55, Boitech Park, Phase III, Karkapatla (V), Markook (M), Siddipet (D), Telangana, Pin-502279, India	Softcare International (Pvt) Ltd	Two years reg. from 25.04.2019-expired
23.	4-Sep-2023	Co- Amoxiclav for Injection BP 1.2g	Navesta Pharmaceuticals Pvt Ltd, 107A, Nakandala Road, Kindelpitiya, Millewa, Horana, Sri Lanka	NA	Two years reg. from 11.08.2020-expired
24.	25-Sep-2023	Co- Amoxiclav for Injection BP 1.2g	Navesta Pharmaceuticals Pvt Ltd, 107A, Nakandala Road, Kindelpitiya, Millewa, Horana, Sri Lanka	NA	Two years reg. from 11.08.2020-expired
25.	10-Oct-2023	Co- Amoxiclav for Injection BP 1.2g	Navesta Pharmaceuticals Pvt Ltd, 107A, Nakandala Road, Kindelpitiya, Millewa, Horana, Sri Lanka	NA	Two years reg. from 11.08.2020-expired
26.	12-Oct-2023	Co- Amoxiclav for Injection BP 1.2g	Navesta Pharmaceuticals Pvt Ltd, 107A, Nakandala Road, Kindelpitiya, Millewa, Horana, Sri Lanka	NA	Two years reg. from 11.08.2020-expired
27.	12-Oct-23	Co- Amoxiclav for Injection BP 1.2g	Navesta Pharmaceuticals Pvt Ltd, 107A, Nakandala Road, Kindelpitiya, Millewa, Horana, Sri Lanka	NA	Two years reg. from 11.08.2020-expired
28.	12-Oct-23	Co- Amoxiclav for Injection BP 1.2g	Navesta Pharmaceuticals Pvt Ltd, 107A, Nakandala Road, Kindelpitiya, Millewa, Horana, Sri Lanka	NA	Two years reg. from 11.08.2020-expired

තොග නිෂ්කාශන අනුමැතීන් යටතේ ආනයනය කළ ඖෂධවල භාවිතය තාවකාලිකව අත්හිට වූ අවස්ථා

	භාවිතය තාවකාලිකව අත්හිට වූ දිනය	ඖෂධයේ නම	නිෂ්පාදක	දේශීය නියෝජිත	ලියාපදිංචි තත්ත්වය
1.	19-Aug-2022	Levothyroxine Sodium Tablets USP 50mcg	The ACME Laboratories Ltd, Dhaka, Bangladesh	Mega Pharma Pvt Ltd	Two years reg. from 01.10.2020-expired

2.	29-Aug-2022	Flucloxacillin Capsules BP 500mg	Navana Pharmaceuticals Ltd, Rupshi, Narayanganj, Bangladesh	Darly butler Co Ltd	Full reg. from 03.02.2018-expired
3.	23-Sep-2022	Levothyroxine Sodium Tablets USP 50mcg	Centurion remedies Pvt Ltd, Plot No P-2, Bio-tech park, manjusar, Savil, dist,Vadodara, India	Yaden International Pvt Ltd	Two years reg. from 19.06.2020-expired
4.	23-Sep-2022	Levothyroxine Sodium Tablets USP 25mcg	Centurion remedies Pvt Ltd, Plot No P-2, Bio-tech park, manjusar, Savil, dist,Vadodara, India	Yaden International Pvt Ltd	Two years reg. from 19.06.2020-expired
5.	2-Nov-2022	Ceftazidime for Injection USP 1000mg	Scott-Edil Advance Resarch Laboratories & Education Ltd, Hill Top Ind Area, Bhatoli Kalan, Baddi, Distt.Solan 173205, Himachal Pradesh, India	PTC Medical Pvt Ltd	Two years reg. from 11.07.2018-expired
6.	20-Dec-2022	Miconazole Oromucosal Gel BP	Galentic Pharma (India) Pvt Ltd, R-673, MIDC, TTC, Rabale, Thane-Belapur Road, Navi Mumbai, India	Ceyoka Pvt Ltd	Valid reg. Full reg. from 21.09.2021
7.	10-Jan-2023	Dexamethasone Sodium Phophate Injection USP 4mg/ml	Alvita Pharma Pvt Ltd, 136/B, Motinagar, No 02 Susen Tarsall Road, Vadodara 390010, Gujarat, India	Chamee Chemist	Full reg. from 07.09.2017-expired
8.	10-Jan-2023	Hydroxyurea Capsules USP 500mg	Jodas Expoim Pvt Ltd, Plot No 55, Boitech Park, Phase III, Karkapatla (V), Markook (M), Siddipet (D), Telangana, Pin-502279, India	Softcare International (Pvt) Ltd	Two years reg. from 25.04.2019-expired
9.	24-Mar-2023	Metoprolol Tartrate Tablets BP 50mg	Centurion remedies Pvt Ltd, G/5 and G/6, Industrial Estate Gorwa, Vadodara-390016, Gujarat, India	Yaden International Pvt Ltd	Full reg. from 27.03.2016-expired
10.	25-May-2023	Bupivacaine HCl in Dextrose Inj USP 4ml (5mg/80mg/ml)	Divine Laboratories Pvt Ltd, Block No 471, Dabhasa, Tal-Padra, Dist-Vadodara-391440, India	Slim Pharmaceuticals	One year reg. from 31.08.2018-expired
11.	30-Jun-2023	Povidone - Iodine Solution BP 10% w/v	Himata (Pvt) Ltd, No.535/2, Sasanawardhanarama Mw, Homagama, Sri Lanka		One year reg. from 17.09.2018-expired
12.	30-Jun-2023	Amoxicillin and Potassium Clavulanate for Injection BP 1.2g	Navesta Pharmaceuticals Pvt Ltd, 107A, Nakandala Road, Kindelpitiya, Millewa, Horana, Sri Lanka		Two years reg. from 11.08.2020-expired

13.	11-Sep-2023	Gliclazide Tablets BP 80 mg	AMN Life Sciences Pvt Ltd, 150, Sahajanand Estate, Sarkhej, Tal.City, Ahmedabad, Gujarat, India	Pharma Associates	Full reg. from 29.11.2018- expired

තොග නිෂ්කාශන අනුමැතීන් යටතේ ආනයනය කළ ඖෂධවල භාවිතය අඛණ්ඩව පවත්වා නොගත් අවස්ථා

	අඛණ්ඩව පවත්වා නොගැනීමේ තීරණය ගත් දිනය	ඖෂධයේ නම	නිෂ්පාදක	දේශීය නියෝජිත	ලියාපදිංචි තත්ත්වය
1.	12-Aug-2022	Cyclophosphamide for injection USP 1g	Getwell Pharmaceuticals, 474. Udyong Vihar, Phase V, Gurgaon-122016, Haryana, India	The Esses Pharmacy (Pvt) Ltd	One year Reg. from 03.03.2021 - expired
2.	9-Feb-2023	Hydroxyurea Capsules USP 500mg	Jodas Expoim Pvt Ltd, Plot No 55, Boitech Park, Phase III, Karkapatla (V), Markook (M), Siddipet (D), Telangana, Pin-502279, India	Softcare International (Pvt) Ltd	Two years reg. from 25.04.2019- expired

(i) ඖෂධ ලියාපදිංචිය සඳහා ඉදිරිපත් කරනු ලබන ඉල්ලීම් සහ එම ලියාපදිංචිය නැවත අලුත් කිරීම සඳහා වන ඉල්ලීම් සම්බන්ධීකරණය කිරීම;

(ii) ඖෂධ ලියාපදිංචිය අවලංගු කිරීම හෝ අත්හිටුවීමට අදාළ කරුණු සම්බන්ධීකරණය කිරීම;

(iii) ඖෂධ ආනයනකරුවන් සහ බෙදාහරින්නන් ලියාපදිංචි කිරීමට අදාළ කරුණු සම්බන්ධීකරණය කිරීම;

(iv) මෙම වගන්තිය යටතේ බලපත්‍ර නිකුත් කිරීම සම්බන්ධීකරණය කිරීම; සහ

(v) මේ පනතේ 43 වන වගන්තිය යටතේ පත්කරන ලද ඖෂධ ඇගයීම් කමිටුව වෙත පරිපාලන සහාය ලබාදීම. ඖෂධ ඇගයීම් කමිටුව.

II වන කොටස

ඖෂධ ඇගයීම්

43. (1) මෙම පනතේ කාර්ය සඳහා (මෙහි මින්මතු "එම්ඊසී" යනුවෙන් සඳහන් කරනු ලබන) ඖෂධ ඇගයීම් කමිටුව යනුවෙන් හඳුන්වනු ලබන කමිටුවක් පත්කරනු ලැබිය යුතු ය.

[redacted]යාපදිංචිය සඳහා ඉදිරිපත් කරනු ලබන ඖෂධ, තාක්ෂණික ඇගයීම සිදුකිරීම සහ ඒ පිළිබඳ වාර්තාවක් අධිකාරිය වෙත ඉදිරිපත් කිරීම එම්ඊසී හි ප්‍රධාන කර්තව්‍ය වේ. එම්ඊසී හි සංයුතිය.

(අ) එම වාර්තාවේ, ජාතික ඖෂධ ප්‍රතිපත්තිය ප්‍රකාරව ඖෂධවලට අදාළ ප්‍රතිලාභ, අවදානම්, එම ඖෂධවල තත්ත්වය, ප්‍රත්‍යක්ෂභාවය, ආරක්ෂාකාරී බව, අවශ්‍යතාවය, මිල සහ අවශ්‍ය අවස්ථාවල දී එම ඖෂධවල ඖෂධ ආර්ථික විශ්ලේෂණ පිළිබඳව නිශ්චිතව දැක්විය යුතු ය.

44. (1) අධිකාරිය විසින් පත්කරනු ලබන පහත දැක්වෙන තැනැත්තන්ගෙන් එම්ඊසී සමන්විත විය යුතු ය:—

(අ) නිලබලයෙන් පත්වන සාමාජිකයන් එනම්—

(i) කමිටුවේ සභාපති විය යුතු එම්ආර් අංශයේ ප්‍රධානියා;

(2) කිසිදු තැනැත්තකු විසින් අධිකාරියෙන් බලපත්‍රයක් ලබා නොගෙන යම් ඖෂධයක් ගබඩා කිරීම, එකලස් කිරීම, නැවත ඇසුරුම් කිරීම, බෙදාහැරීම, ප්‍රවාහනය කිරීම හෝ විකිණීම නොකළ යුතු ය.

(3) (1) වන හෝ (2) වන උපවගන්තිවල නිශ්චිතව දක්වා ඇති විධිවිධාන උල්ලංඝනය කරන යම් තැනැත්තකු වරදක් සිදු කරනු ලැබිය යුතු ය.

59. (1) යම් ඖෂධයක් නිෂ්පාදනය කිරීමට හෝ ආනයනය කිරීමට අදහස් කරන යම් තැනැත්තකු විසින් එම ඖෂධය ලියාපදිංචි කිරීම සඳහා වූ ඉල්ලීමක් නියමිත ආකෘති පත්‍රය අනුව අධිකාරිය වෙත ඉදිරිපත් කළ යුතු ය.

(2) එම ඉල්ලීම සමග එම ඖෂධයේ නියමිත විස්තර, සාම්පල සහ නියමිත ලියාපදිංචි ගාස්තුව ද ඉදිරිපත් කරනු ලැබිය යුතු ය.

(3) (අ) යම් ඖෂධයක් ලියාපදිංචි කිරීම සඳහා ලැබෙන සෑම ඉල්ලීමක්ම ලේඛනගත කළ යුතු ලේඛනයක් අධිකාරිය විසින් පවත්වාගෙන යා යුතු ය.

(ආ) එම ලේඛනයේ ඇතුළත් කළ යුතු විස්තර නියමිත පරිදි විය යුතු ය.

(4) ඉල්ලීමක් ලැබීමේ දී අධිකාරිය විසින් එම ඉල්ලීම සමග ඖෂධයේ සාම්පල සහ සියලු විස්තර -

(අ) සාධාරණ මිලකට පුරවැසියන්ගේ සෞඛ්‍ය ආරක්ෂණ අවශ්‍යතාවලට අදාළ ප්‍රත්‍යක්ෂ, ආරක්ෂාසහිත සහ නිවැරදි තත්ත්වයේ ඖෂධ ලබා දෙන බවට සහතිකවීම සඳහා ඇති අවශ්‍යතාවය සැලකිල්ලට ගනිමින් එකී ඉල්ලීම සහ ඖෂධය ඇගයීම සඳහා එම්ඊසී වෙත ඉදිරිපත් කරනු ලැබිය යුතුය; සහ

(ආ) ඖෂධයේ තත්ත්වය පරීක්ෂා කිරීම සඳහා එන්එම්කිව්ඒල් වෙත ඉදිරිපත් කරනු ලැබිය යුතු ය.

(ඇ) විශේෂඥයන්ට ශබ්දය පාවිච්චි කිරීමේ අයිතියක් නොමැති විය යුතු ය.

අධිකාරියේ රැස්වීම් සඳහා සහභාගීවීම වෙනුවෙන් වූ පාරිශ්‍රමික.

13. අධිකාරියේ සාමාජිකයන් සහ විශේෂඥයන් විසින් අධිකාරියේ රැස්වීම් සඳහා සහභාගීවීම වෙනුවෙන් මුදල් විෂයය භාර අමාත්‍යවරයාගේ එකඟත්වය ඇතිව අමාත්‍යවරයා විසින් නිරණය කරනු ලැබිය හැකි යම් පාරිශ්‍රමික ගෙවනු ලැබිය හැකි ය.

අධිකාරියේ බලතල සහ කර්තව්‍ය.

14. අධිකාරියේ බලතල සහ කර්තව්‍ය වනුයේ:-

(අ) යම් නිෂ්පාදනයක්, ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ වෙනත් යම් නිෂ්පාදනයක් ද යන්න වර්ගීකරණය මත නිරණය කිරීම;

(ආ) මේ පනතේ නියම ප්‍රකාරව ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන සහ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන ලියාපදිංචි කිරීම සහ බලපත්‍ර ලබා දීම අනුමත කිරීම හෝ එවැනි යම් ලියාපදිංචි කිරීමක් හෝ බලපත්‍ර ලබාදීමක් අවලංගු කිරීම හෝ අත්හිටුවීම;

(ඇ) ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන, විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන, ලියාපදිංචි කිරීම, බලපත්‍ර ලබාදීම, නිෂ්පාදනය කිරීම, ආනයනය කිරීම, ගබඩා කිරීම, නැවත ඇසුරුම් කිරීම, ප්‍රවාහනය කිරීම, බෙදාහැරීම, විකිණීම, ප්‍රචාරණය කිරීම, ප්‍රවර්ධනය කිරීම, ආපසු කැඳවීම සහ බැහැර කිරීම නියාමනය කිරීම;

(ඈ) ඔසුසල් හා ඖෂධ ගබඩා ලියාපදිංචි කිරීම සහ නියාමනය කිරීම් සඳහා බලය ලබාදීම්;

(ඉ) ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන, නිෂ්පාදනය කිරීම, ආනයනය කිරීම, ගබඩා කිරීම, බෙදා හැරීම, ප්‍රවාහනය කිරීම සහ විකිණීම සඳහා බලපත්‍ර නිකුත් කිරීම සහ මේ පනතේ නියම ප්‍රකාරව එකී බලපත්‍ර අවලංගු කිරීම;

(ඊ) අධිකාරියේ කර්තව්‍ය ඵලදායී ලෙස ඉටුකිරීම් සඳහා අවශ්‍යවන අනු කමිටු පත්කිරීම;

(උ) මේ පනතේ සහ වෙනත් යම් ලිඛිත නීතියක විධිවිධානවලට යටත්ව ඖෂධ, වෛද්‍ය උපකරණ,

සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන දේශීය වශයෙන් නිෂ්පාදනය කිරීම සඳහා අවශ්‍යවන ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන, අමුද්‍රව්‍ය, ඇසුරුම් ද්‍රව්‍ය, යන්ත්‍රෝපකරණ හෝ රසායනාගාර ද්‍රව්‍ය තොග පරිශ්‍රවෙන් නිදහස් කර ගැනීම සඳහා අනුමතය ලබා දීම;

(උ) ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදන පිළිබඳ දැනුවත් කිරීමේ වැඩසටහන් පැවැත්වීම සහ මේ පනත යටතේ ලියාපදිංචි කර ඇති සහ බලපත්‍ර ලබාදී ඇති ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදනවල තත්ත්වය සහ ආරක්ෂාව පිළිබඳ පශ්චාත් අලෙවි සමීක්ෂණ පැවැත්වීම;

(ඵ) ලියාපදිංචි කිරීමේ සහ බලපත්‍ර ලබාදීමේ ක්‍රියාවලිය සහ මේ පනත යටතේ ලියාපදිංචි කර ඇති සහ බලපත්‍ර ලබා දී ඇති ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන භාවිතා කිරීම තුළින් ඇතිවන අහිතකර ප්‍රතික්‍රියා අධීක්ෂණය කිරීම සහ එවැනි අවස්ථාවලදී ක්ෂණික සහ අවශ්‍ය පියවර ගැනීම;

(ඔ) බලපත්‍ර යටතේ ආනයනය කරන ලද ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදනවල ප්‍රමාණය පිළිබඳ දත්ත රැස් කිරීම;

(ක) ප්‍රවර්ධනය කිරීමේ ක්‍රියාකාරකම්වලට අදාළ කර්මාන්ත සහ වෙළඳ වියදම් පිළිබඳ දත්ත ඇතුළුව, ශ්‍රී ලංකාවේ ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදනවල භාවිතය පිළිබඳ දත්ත රැස්කිරීම;

(ඕ) නියම කරනු ලැබිය යුතු බවට නිර්දේශිත කරුණු පිළිබඳ අමාත්‍යවරයා වෙත උපදෙස් ලබා දීම;

(ක) යම් චංචල හෝ නිශ්චල දේපළ අත්කරගැනීම, දැරීම, කුළියට හෝ බද්දට ලබා ගැනීම හෝ ලබා දීම, උකස් කිරීම, ඔඩපනය කිරීම, විකිණීම හෝ අන්‍යාකාරයකින් බැහැර කිරීම;

(ග) එහි කර්තව්‍ය ඉටුකිරීමේ දී අවශ්‍ය වන සහ සුදුසු ගාස්තු අයකිරීම;

GUIDELINE ON SUBMITTING REGISTRATION SAMPLE TO NMQAL

Registration Sample of Medicines, Medical Devices and Borderline Products to National Medicines Quality Assurance Laboratory (NMQAL)

OCTOBER 15, 2019
NATIONAL MEDICINE REGULATORY AUTHORITY
No.120, Norris Canal Rd, Colombo 01000, Sri Lanka

(139)

SUBMITTING REGISTRATION SAMPLE TO NMQAL GUIDELINE

CONTENTS

1. INTRODUCTION

As per the NMRA Act No o5 of 2015 main role of the NMQAL is the testing of the quality of medicines, medical devices or borderline products submitted by the Authority including the articles which are submitted with the application for registration.
The guideline is directed primarily at laboratory personnel, although regulatory pharmacist and the local agent/ manufactures need to be aware of the steps involved in sample receipt.
Effective communications between regulatory divisions and the laboratory not only facilitates problem resolution but also prevents unnecessary delays in the analytical process.
Sample receipt activities need to be done in a timely manner to allow the laboratory and NMRA to resolve any problems on quality testing of registration samples.

2. SCOPE

This chapter provides guidance on laboratory samples receiving for registration purposes.

3. PROCEDURES

3.1 Requirement for quality testing

Before the samples are received laboratory should aware the conformity of sample with registration dossier and the requirement of quality testing.

NMQAL may receive the registration samples for quality testing upon following criteria;

I. Request for sample testing to be mentioned in Dossier Evaluation sheet.
II. Samples for analysis should be submitted for the following products at the time of submitting dossiers for registration

- Meropenam for injection
- Erythromycin (all dosage forms)
- Thyroxin (all dosage forms)

Local agent should submit the request for quotation for Quality testing to the Technical unit/NMQAL with following documents.

- The Evaluation sheet / The Acknowledgement of the registration dossier.
- The product label which is attached to the dossier. (Need to be certified by the NMRA)
- The analytical method for in-house specifications. (Need to be certified by the NMRA whether it is the same copy which is attached to the registration dossier)

NMRA should provide any other special instructions regarding the decision taken for samples to the laboratory on case by case basis.

3.2. Review of competency of sample testing

Laboratory should review of competency for sample testing, the types of analyses that are expected for the samples, before receiving the sample.
Request for sample analysis submitted by the local agent should distribute to the sectional heads of the relevant division at NMQAL.
Sectional heads should review the request with the relevant testing monograph and to be send information on tests which can be carried out by the division depending on the availability of

chemicals and reference standard to the Technical unit. (Referred pharmacopeia monograph need to be attached).
Turn over time for this will be two weeks.

3.3. Payment voucher arrangement.

Cost for the quality testing should be finalized based on the number of tests which can be carried out in the laboratory.
Senior Pharmacist at Technical unit should prepare the payment voucher based on the number of tests to be carried out and the fee for analysis

Payment vouchers to be checked by the chief pharmacist/NMQAL and approved by the D/NMQAL, and then handed over to the local agent.
Prior to payment for quality testing, local agent need to discuss with regulatory division on adequacy of number of tests which can be carried out for the product is satisfied or not for the registration.

3.4. Receipt of Sample.

Then Minimum number of the samples required for quality testing to be submitted with the yellow receipt (issued by the Accounts Branch/NMRA) to the Technical Unit/NMQAL.
Laboratory sample receipt occurs when a package containing samples is accepted
Senior Pharmacist at the Technical unit/ NMQAL should receive Samples and distributed to the relevant laboratory divisions.

4. STANDARD OPERATING PROCEDURES

A laboratory should have standard operating procedures (SOPs) for activities related to registration sample receipt and distribution.
Laboratory SOPs should describe sample management system including chain-of-custody procedures giving a comprehensive list of the elements in the program such as signing the appropriate custody forms, storing samples in a secure area.

5. REGISTER LOGS

The laboratory should keep a register (log) of all quotation requests, payment vouchers and payment receipt on registration samples.

6. REFERENCES

- WHO Handbook on laboratory quality management system

7. FEEDBACK

7.1 Staff and customers may provide feedback about this document by emailing info@nmra.gov.lk

ඇමුණුම 94

2022 ජනවාරි සිට 2023 අගෝස්තු දක්වා කාලපරිච්ඡේදය තුළ ජාතික ඖෂධ තත්ත්ව ආරක්ෂණ පර්යේෂණාගාරය විසින් විශ්ලේෂණය කර නිබුණු ලියාපදිංචි අවස්ථාවේ දී අධිකාරියට ඉදිරිපත් කරන ලද ඖෂධ සාම්පල පිළිබඳ විස්තර

විශ්ලේෂණය සඳහා ඉදිරිපත් කරන ලද සාම්පල් පිළිබඳ විස්තර		2022	2023 අගෝස්තු දක්වා	එකතුව
විශ්ලේෂණය සඳහා ඉදිරිපත් කරන ලද සාම්පල් ගණන	දේශීය වශයෙන් නිපදවන ලද ඖෂධ	27	12	76
	ආනයනය කරන ලද ඖෂධ	18	19	
තත්ත්වයෙන් අසමත් වූ සාම්පල් ගණන	දේශීය වශයෙන් නිපදවන ලද ඖෂධ	2	2	16
	ආනයනය කරන ලද ඖෂධ	7	5	
තත්ත්වයෙන් අසමත් වූ සාම්පල් ගණන ප්‍රතිශතයක් ලෙස	දේශීය වශයෙන් නිපදවන ලද ඖෂධ	7%	17%	21%
	ආනයනය කරන ලද ඖෂධ	39%	26%	

Summery of Sample Analyzed by NMQAL

Month	Registration			
	Local Products		Imported Products	
	Pass	Fail	Pass	Fail
2022				
January	3	0	1	0
Fubruary	5	0	1	0
March	1	0	2	0
April	1	1	0	0
May	7	1	2	2
June	2	0	0	0
July	1	0	0	0
August	2	0	3	0
September	0	0	1	2
October	1	0	0	2
November	2	0	1	0
December	0	0	0	1
	25	[redacted]	11	[redacted]
	27	45		18
2023				
January	0	1	0	1
Fubruary	2	0	2	1
March	5	0	5	1
April	1	0	0	0
May	2	0	3	0
June	0	0	3	0
July	0	0	1	1
August	0	1	0	1
September				
	10	[redacted]	14	[redacted]
	12	31		19

විශ්ලේෂණය කරා ලද සාම්පල් ගණන.

2022 - 45.

2023 - 31

[redacted].

සාර්ථකව අසමත් වූ සාම්පල් ගණන.

2022 - 9 → local - 2, Import - 7.

2023 - 7 → local - 2, Import 5.

[redacted]

$\frac{16}{76} \times 100 =$ [redacted] 21%.

සාර්ථකව අසමත් (Import)

2022 - 7

2023 - 5

[redacted].

(5) ඉල්ලීම ලැබී ඇති බවත් එය ඇගයීම සහ පරීක්ෂා කිරීම සඳහා ඉදිරිපත් කර ඇති බවටත් අධිකාරිය විසින් ඉල්ලුම්කරුට ලිඛිතව දැනුම් දිය යුතු ය.

(6) අමාත්‍යවරයා විසින් -

(අ) එම්ඊසී සහ එන්එම්කිව්ඒඑල් විසින් තම පරීක්ෂා කිරීමේ සහ ඇගයීමේ ක්‍රියාවලියේ දී අනුගමනය කළ යුතු කාර්ය පටිපාටි සඳහන් කරමින්;

(ආ) (i) එම පරීක්ෂා කිරීම් හෝ ඇගයීම් ක්‍රියාවලියේ කාලසීමාවන්;

(ii) එම්ඊසී විසින් ස්වකීය රැස්වීම් පැවැත්විය යුතු ආකාරය සහ එම රැස්වීම්වල දී අනුගමනය කළ යුතු කාර්ය පටිපාටිය; සහ

ඖෂධ ලියාපදිංචි කිරීම.

(iii) ඉදිරිපත් කළ යුතු වාර්තාවල ඇතුළත් කළ යුතු කාරණා,

නිශ්චිතව දක්වමින් නියෝග සාදනු ලැබිය හැකි ය.

(7) (අ) ජාතික සෞඛ්‍ය සඳහා එම ඖෂධයේ ඇති හදිසි අවශ්‍යතාවය සැලකිල්ලට ගනිමින් නිශ්චිත කාලසීමාවක් ඇතුළත පරීක්ෂණ කටයුතු හෝ ඇගයීම් කටයුතු අවසන් කරන ලෙස අධිකාරිය විසින් එම්ඊසී සහ එන්එම්කිව්ඒඑල් වෙත නියම කරනු ලැබිය හැකි ය.

(ආ) යම් ප්‍රමාද වීමක් සඳහා සාධාරණ හේතු ඇත්නම් මිස, එම්ඊසී සහ එන්එම්කිව්ඒඑල් විසින් අධිකාරිය වෙත නිශ්චිත කාල සීමාව තුළ වාර්තා ඉදිරිපත් කරනු ලැබිය යුතු ය.

60. (1) (අ) එම්ඊසී සහ එන්එම්කිව්ඒඑල් විසින් ඉදිරිපත් කරන ලද වාර්තා සම්බන්ධයෙන් අධිකාරිය විසින් අවශ්‍ය අවස්ථාවල දී එම්ඊසී සහ එන්එම්කිව්ඒඑල් වෙතින් හෝ යම් වෙනත් විශේෂඥයකුගෙන් පැහැදිලි කිරීම් ලබා දෙන ලෙස ඉල්ලා සිටිය හැකි ය.

ලියාපදිංචිය ප්‍රතික්ෂේප කිරීම.

Summary of Medicines registered under the authority gazetted by the extra ordinary gazette number 2144/20 dated October 9th 2019.

Schedule to be listed	Number of Medicines
Schedule I	23
Schedule II – Group A	166
Schedule II – Group B	7,171
Schedule III	18
Total	7,378

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය
අති විශෙෂ
The Gazette of the Democratic Socialist Republic of Sri Lanka
EXTRAORDINARY

අංක 2144/20 - 2019 ඔක්තෝබර් මස 09 වැනි බදාදා - 2019.10.09
No. 2144/20 - WEDNESDAY, OCTOBER 9, 2019

(Published by Authority)

PART I : SECTION (I) — GENERAL
Government Notifications

Order No. 01

NATIONAL MEDICINES REGULATORY AUTHORITY ACT, NO. 5 OF 2015

Order under section 60 (2)

BY VIRTUE of the powers vested in me by section 60 (2) of the National Medicines Regulatory Authority Act, No. 5 of 2015, I, Prof. Asita De Silva, Chairman of the National Medicines Regulatory Authority, do by this Order, inform the public that the medicines specified in the Schedules here to have been registered with the National Medicines Regulatory Authority.

Prof. Asita De Silva
Chairman,
(For and on behalf of)
National Medicines Regulatory Authority

Colombo
August 8, 2019

1A—PG 4679 - 257 (10/2019)
This Gazette Extraordinary can be downloaded from www.documents.gov.lk

SCHEDULE - I

11	METHYL SALICYLATE 10.2% + MENTHOL 5.44% + EUGENOL 1.36%	FLANIL	CREAM	George Steuart Health (Pvt) Ltd	Biolab Co Ltd	THAILAND	24-May-14	Full
12	METHYL SALICYLATE 6.3% ,MENTHOL 5.7% ,CAMPHAOR 1. 2% & TOCOPHEROL ACETATE	SALONPAS	PATCH	Akbar Pharmaceuticals (Pvt) Ltd	Hisamitsu Pharmaceuticals Co Inc	JAPAN	06-Apr-15	Full
13	METHYL SALICYLATE 6.3% ,MENTHOL 5.7% ,CAMPHAOR 1. 2% & TOCOPHEROL ACETATE	SALONPAS	PATCH	Akbar Pharmaceuticals (Pvt) Ltd	Hisamitsu Pharmaceuticals Co Inc	JAPAN	06-Apr-15	Full
14	METHYL SALICYLATE COMPOUND GEL	WINTERPAN	GEL	N/A	Akbar Pharmaceuticals (Pvt) Ltd	SRI LANKA	11-Apr-14	Full
15	ORAL REHYDRATION SALTS BP 21.5G	MINERVA	ORAL POWDER	Emar Pharma (Pvt) Ltd	Unicure Ramadies (Pvt) Ltd	INDIA	04-Jun-16	Full
16	PARACETAMOL (PAEDIATIC) ORAL SOLUTION B.P 120MG/5ML	PARACETOL	LIQUID	N/A	Gamma Pharmaceuticals Pvt Ltd	SRI LANKA	22-Oct-14	Full
17	PARACETAMOL (PAEDRIATIC) ORAL SOLUTION B.P 120MG/5ML	PANADOL SYRUP	SYRUP	N/A	Glaxo Wellcome (Ceylon) Ltd	SRI LANKA	16-Jun-18	Full
18	PARACETAMOL (PAEDRIATIC) ORAL SUSPENSION B.P 120MG/5ML-Elixir	*****	ORAL SOLUTION	N/A	M S J Industries (Ceylon) (Pvt) Ltd	SRI LANKA	08-Feb-18	Two Years
19	PARACETAMOL TABLETS 500MG	PANADOL	TABLETS	N/A	Smithkline Beecham (Pvt) Ltd	SRI LANKA	17-Oct-16	Full
20	PARACETAMOL TABLETS BP 500MG	ACETAMIN	TABLETS	Citihealth Imports (Pvt) Ltd	Incepta Pharmaceuticals Ltd		15-Aug-17	Two Years
21	PARACETAMOL TABLETS BP 500MG	MAXMOL	TABLETS	George Steuart Health (Pvt) Ltd	Shefa Healthcare (Pvt) ltd	INDIA	18-Jan-14	Full
22	PARACETAMOL TABLETS BP 500MG	RAPISOL	TABLETS	N/A	Astron (Pvt) Ltd	SRI LANKA	13-Nov-15	Full
	PEDIATRIC PARACETAMOL ORAL SOLUTION B.P 120MG/5ML	MAXMOL	ORAL SUSPENSION	George Steuart Health (Pvt) Ltd	Shefa Healthcare (Pvt) ltd	INDIA	10-Jun-15	Full

SCHEDULE - II (GROUP A) *(Contd.)*

157	VITAMIN B COMPLEX AND IRON & ZINC SYRUP	BIZ SYRUP	SYRUP	Tabrane Healthcare (Pvt) Ltd	Globe Pharmaceuticals Ltd		02-Aug-14	Full
158	VITAMIN B COMPLEX FORTE+VITAMIN C+ZINC	BECOZINC	CAPSULES	Emerchemie NB (Ceylon) Ltd	Dr Reddy's Laboratories Ltd	INDIA	19-Nov-17	Two Years
159	VITAMIN B COMPLEX SYRUP	POLYBION	SYRUP	Emerchemie NB (Ceylon) Ltd	Merck Limited	INDIA	09-Mar-14	Full
160	VITAMIN B COMPLEX TABLETS (VIT. B1 1MG,B2 1MG & NICOTINAMIDE 10MG)	*	TABLETS	Sunshine Healthcare lanka Ltd	Axon Drugs (Pvt) Ltd	INDIA	29-Jun-18	Full
161	VITAMIN B COMPLEX WITH VITAMIN C	ENERVON C FILMCAP	TABLETS	George Steuart Health (Pvt) Ltd	United Laboratories	PHILIP-PINES	13-Oct-16	Full
162	VITAMIN B COMPLEX, VITAMIN B12 AND FOLIC ACID SYRUP	BECOSULES	SYRUP	Astron (Pvt) Ltd	Astron (Pvt) Ltd	SRI LANKA	29-Sep-15	Full
163	VITAMIN B COMPOUND TABLETS (THIAMIN HCL 1MG+RIBOFLAVIN 1MG NICOTINAMIDE 10MG)	*	TABLETS	Morison PLC	Morison PLC	SRI LANKA	01-Jan-18	Provisional
164	VITAMIN C SUSTAINED RELEASE TABLETS 500MG	VITACEE	TABLETS	Alaris Lanka (Pvt) Ltd	Contract Manufacuring & Packging Services pty Ltd	AUSTRA-LIA	29-Oct-14	Full
165	VITAMIN MINERAL &TRACE ELEMENTS CAPSULES	AVITONE	CAPSULES	Avenier Pharma (Pvt) Ltd	Triveni Formulations Ltd	INDIA	14-Mar-15	Full
	WATER FOR INJECTION STERILISE	SWFI	INJECTION	Chamee Chemist	Axa Parenterals Ltd	INDIA	02-Apr-15	Full

SCHEDULE - H (GROUP B) *(Contd.)*

7162	ZOLMITRIPTAN NASAL SPRAY 5% W/V	ZOLMINAP	NASAL SPRAY	Emerchemie NB (Ceylon) Ltd	Sava Healtheare Ltd	INDIA	23-Jan-18	Provisional
7163	ZOLMITRIPTAN TABLETS 2.5MG	NOMI 2.5	TABLETS	PharmAce (Pvt) Ltd	Square Pharmaceuticals Ltd	BANGLADESH	14-Nov-15	Full
7164	ZOLMITRIPTAN TABLETS 2.5MG	ZOLAN	TABLETS	Hemas Pharmaceuticals (Pvt) Ltd	Cadila Healthcare Ltd	INDIA	29-Jan-15	Full
7165	ZOLPIDEM TARTRATE 10MG	ZOLPIREX	TABLETS	George Steuart Health (Pvt) Ltd	Centaur Pharmaceutical (Pvt) Ltd	INDIA	31-Jan-18	Provisional
7166	ZOLPIDEM TARTRATE 5MG TABLETS	ZOLFRESH 5	TABLETS	Sunshine Healthcare lanka Ltd	Acme Formulation (Pvt) Ltd-india for Abbott India Ltd	INDIA	03-Dec-16	Full
7167	ZOLPIDEM TARTRATE 5MG TABLETS	SOVE 5	TABLETS	Emar Pharma (Pvt) Ltd	IPCA Laboratories	INDIA	01-Sep-16	Full
7168	ZOLPIDEM TARTRATE TABLETS 10MG	NOCTE	TABLETS	Emerchemie NB (Ceylon) Ltd	Laboratoires Bago S. A	ARGENTINA	28-Jan-15	Full
7169	ZOLPIDEM TARTRATE TABLETS 10MG	NITREST	FILM COA TABLETS	Emerchemie NB (Ceylon) Ltd	Sun Pharmaceutical industries	INDIA	29-Apr-16	Full
7170	ZUCLOPENTHIXOL ACETATE INJECTION 100MG/2ML	CLOPIXOL-ACUPHASE	INJECTION	Sunshine Healthcare lanka Ltd	H Lundbeck A S	DENMARK	12-Oct-18	Full
	ZUCLOPENTHIXOL DECANOATE 200MG/ML(1ML)	CLOPIXOL DEPOT	INJECTION	Sunshine Healthcare lanka Ltd	H Lundbeck A S	DENMARK	30-Jun-14	Full

SCHEDULE - III *(Contd.)*

10	MORPHINE SULPHATE INJECTION BP 2MG /2ML	***	INJECTABLE SOLUTION	Yaden International (Pvt) Ltd	Kwality Pharmaceuticals Pvt Ltd	INDIA	04-May-18	Provisional
11	MORPHINE SULPHATE PROLONGED RELEASE TABLETS BP 10MG	VERMOR SR 10	TABLETS	Leader Pharma Agency Pvt Ltd	Verve Human Care Laboratories	INDIA	04-May-18	Full
12	MORPHINE SULPHATE PROLONGED RELEASE TABLETS BP 60MG	VERMOR SR 30	TABLETS	Leader Pharma Agency Pvt Ltd	Verve Human Care Laboratories	INDIA	04-May-18	Full
13	MORPHINE SULPHATE TABLETS BP 15MG	VERMOR 15	TABLETS	Leader Pharma Agency Pvt Ltd	Verve Human Care Laboratories	INDIA	04-May-18	Full
14	MORPHINE TABLETS BP 15MG	***	TABLETS	Yaden International (Pvt) Ltd	Kwality Pharmaceuticals Pvt Ltd	INDIA	04-May-18	Provisional
15	PETHIDINE HYDROCHLORIDE INJECTION 50MG/1ML	PETHIDINE HAMELN	INJECTION	Akbar Pharmaceuticals (Pvt) Ltd	Hameln Pharmaceuticals GmbH/Germany Hospira Australia (Pvt) Ltd	GERMANY	04-Nov-14	Full
16	PETHIDINE INJECTION B.P 50MG/1ML	VERPAT 50	INJECTION	Leader Pharma Agency Pvt Ltd	Verve Human Care Laboratories	INDIA	19-May-16	Full
17	PETHIDINE INJECTION B.P 50MG/1ML	****	INJECTION	Niix Holdings (Pvt) Ltd	Macarthys Laboratories Ltd	UNITED KINGDOM	28-Sep-16	Full
	PETHIDINE INJECTION B.P 75MG/ 1.5ML	VARPAT 75	INJECTION	Leader Pharma Agency Pvt Ltd	Verve Human Care Laboratories	INDIA	02-Jun-15	Full

10 - 805

PRINTED AT THE DEPARTMENT OF GOVERNMENT PRINTING, SRI LANKA.

(ආ) එම්ඊසී සහ එන්එම්කිව්ඒඑල් විසින් ඉදිරිපත් කරන ලද වාර්තා සහ අනෙකුත් සියලු වෙනත් කරුණු සැලකිල්ලට ගනිමින් අධිකාරිය විසින් නිශ්චිත කාල සීමාවක් ඇතුළත එම ඖෂධය ලියාපදිංචි කරනු ලැබිය හැකිය. නැතහොත් එම ලියාපදිංචිය ප්‍රතික්ෂේප කරනු ලැබිය හැකි ය. ලියාපදිංචි කිරීමේ සහතිකය නිකුත් කිරීම.

(2) අධිකාරිය විසින් ඖෂධය ලියාපදිංචි කරනු ලබන අවස්ථාවක, එම ලියාපදිංචිය පිළිබඳව ඉල්ලුම්කරු වෙත ලිඛිතව දැනුම් දෙනු ලැබිය යුතු අතර ගැසට් පත්‍රයේ පළකරනු ලබන නියමයක් මගින් එම ලියාපදිංචිය පිළිබඳව මහජනතාව වෙත දැනුම් දෙනු ලැබිය හැකි ය.

61. අධිකාරිය විසින් ඖෂධය ලියාපදිංචි කිරීම ප්‍රතික්ෂේප කරන අවස්ථාවක, නිශ්චිත කාලසීමාවක් ඇතුළත එම ප්‍රතික්ෂේප කිරීම ඒ සඳහා වූ හේතු දක්වමින් ඉල්ලුම්කරු වෙත දැනුම් දෙනු ලැබිය යුතු අතර එම ප්‍රතික්ෂේප කිරීම පිළිබඳ නියමයක් ගැසට් පත්‍රයේ පළ කර මහජනතාව වෙත දැනුම් දෙනු ලැබිය යුතු ය.

62. (1) (අ) යම් ඖෂධයක් ලියාපදිංචි කිරීමෙන් පසු අධිකාරිය විසින් ඉල්ලුම්කරු වෙත ලියාපදිංචි කිරීමේ සහතිකයක් නිකුත් කරනු ලැබිය යුතු අතර, එම ඉල්ලුම්කරු මෙහි මින්මතු මේ පනතේ මේ කොටසෙන් "සහතිකය දරන්නා" යනුවෙන් සඳහන් කරනු ලැබිය යුතු ය.

(ආ) ඖෂධය සම්බන්ධයෙන් අධිකාරිය විසින් සම්පූර්ණ හෝ තාවකාලික ලියාපදිංචියක් ප්‍රදානය කරනු ලැබිය හැකි අතර එක් එක් වර්ගයේ ලියාපදිංචිය සඳහා වූ කොන්දේසි නියම කරනු ලැබිය යුතු ය.

(ඇ) අධිකාරිය විසින් සුදුසු ආකාරයට ලියාපදිංචිය ලබාදෙන කාලපරිච්ඡේදය තීරණය කරනු ලැබිය යුතු ය. බලපත්‍ර නිකුත් කිරීම.

(2) ලියාපදිංචි කිරීමේ සහතිකයේ ලියාපදිංචිය ප්‍රදානය කරනු ලැබූ කාර්යය, එහි වලංගු කාලය සහ ඊට අදාළ නියම හා කොන්දේසි ඇතුළත් විය යුතු ය.

(3) ලියාපදිංචි කිරීමේ සහතිකය ලබා ගැනීමෙන් පසු, ඖෂධය භාවිතාවේ සිදුවන වෙනස්කම්, අතුරු ආබාධ, සුපරීක්ෂාකාරී විය

44.

(ii) ජාතික ඖෂධ තත්ත්ව ආරක්ෂණ පර්යේෂණාගාරයෙහි (එන්එම්කිව්ඒල්) ප්‍රධානියා;

(ආ) නම්කළ සාමාජිකයන්—

(i) පිළිවෙලින් වූ ස්වකීය වෘත්තීය ආයතන විසින් නම්කරනු ලබන පහත සඳහන් ක්ෂේත්‍ර නියෝජනය කරනු ලබන සෞඛ්‍ය අමාත්‍යාංශයට අනුයුක්ත කර ඇති විශේෂඥ වෛද්‍යවරුන් සිව්දෙනෙකු -

(අ) කායික වෛද්‍ය වේදය;

(ආ) ශල්‍ය වෛද්‍ය වේදය;

(ඇ) ළමා රෝග වේදය; සහ

(ඈ) ප්‍රසව සහ නාරී වේදය;

වෛද්‍ය පීඨයේ පීඨාධිපති විසින් නම් කරනු ලබන 1978 අංක 16 දරන විශ්වවිද්‍යාල පනත යටතේ පිහිටුවනු ලැබූ කොළඹ විශ්වවිද්‍යාලයේ ඖෂධ වෛද්‍ය වේදය පිළිබඳ මහාචාර්යවරයකු;

(iii) අදාළ පීඨයන්හි පීඨාධිපතිවරුන් විසින් නම් කරනු ලබන 1978 අංක 16 දරන විශ්ව විද්‍යාල පනත යටතේ පිහිටුවනු ලැබූ යම් විශ්වවිද්‍යාලයක ඖෂධවේදය පිළිබඳ මහාචාර්යවරයකු හෝ ජ්‍යෙෂ්ඨ කථිකාචාර්යවරයකු;

(iv) අධිකාරිය යටතේ ක්‍රියාකරනු ලබන ඖෂධවේදියකු.

විශේෂඥ මණ්ඩලය.

(2) රැස්වීම් සඳහා ගණපූරණය විශේෂඥ මණ්ඩලයේ සාමාජිකයන් හැර සාමාජිකයන් පස්දෙනෙකු විය යුතු ය.

(3) නම් කළ සාමාජිකයකුගේ ධුර කාලය අවුරුදු තුනක් විය යුතු ය.

ඖෂධ ඇගයීම් කමිටු සඳහා පත් කර තිබුණු කමිටු සාමාජිකයින්ගේ සහභාගීත්වය අවම මට්ටමක පැවති අවස්ථා

ඖෂධ ඇගයීම් කමිටුව පැවැත් වූ දිනය	කමිටු අංකය	කමිටුවට නම් කර තිබුණු සාමාජිකයින් සංඛ්‍යාව	සහභාගී වූ සාමාජිකයින් සංඛ්‍යාව	සහභාගී නොවූ සාමාජිකයින් සංඛ්‍යාව	සහභාගී වූ සාමාජිකයින් සංඛ්‍යාව ප්‍රතිශතයක් ලෙස
2022.01.25	62	25	15	10	60%
2022.02.22	63	25	17	8	68%
2022.03.22	64	28	19	9	68%
2022.04.25	65	28	16	12	57%
2022.05.24	66	27	19	8	70%
2022.06.28	67	27	16	11	59%
2022.07.26	68	28	20	8	71%
2022.08.23	69	27	17	10	63%
2022.09.27	70	27	21	6	78%
2022.10.25	71	27	19	8	70%
2022.11.22	72	25	17	8	68%
2022.12.27	73	26	12	14	46%
2023.01.24	74	27	20	7	74%
2023.02.28	75	28	16	12	57%
2023.03.28	76	31	18	13	58%
2023.04.25	77	30	21	9	70%
2023.05.23	78	31	18	13	58%
2023.06.27	79	30	17	13	57%
2023.07.25	80	28	17	11	61%
2023.08.22	81	27	16	11	59%

(i) ඖෂධ ලියාපදිංචිය සඳහා ඉදිරිපත් කරනු ලබන ඉල්ලීම් සහ එම ලියාපදිංචිය නැවත අලුත් කිරීම සඳහා වන ඉල්ලීම් සම්බන්ධීකරණය කිරීම;

(ii) ඖෂධ ලියාපදිංචිය අවලංගු කිරීම හෝ අත්හිටුවීමට අදාළ කරුණු සම්බන්ධීකරණය කිරීම;

(iii) ඖෂධ ආනයනකරුවන් සහ බෙදාහරින්නන් ලියාපදිංචි කිරීමට අදාළ කරුණු සම්බන්ධීකරණය කිරීම;

(iv) මෙම වගන්තිය යටතේ බලපත්‍ර නිකුත් කිරීම සම්බන්ධීකරණය කිරීම; සහ

(v) මේ පනතේ 43 වන වගන්තිය යටතේ පත්කරන ලද ඖෂධ ඇගයීම් කමිටුව වෙත පරිපාලන සහාය ලබාදීම. ඖෂධ ඇගයීම් කමිටුව.

II වන කොටස

ඖෂධ ඇගයීම්

43. (1) මෙම පනතේ කාර්ය සඳහා (මෙහි මින්මතු "එම්ඊසී" යනුවෙන් සඳහන් කරනු ලබන) ඖෂධ ඇගයීම් කමිටුව යනුවෙන් හඳුන්වනු ලබන කමිටුවක් පත්කරනු ලැබිය යුතු ය.

(2) (අ) ලියාපදිංචිය සඳහා ඉදිරිපත් කරනු ලබන ඖෂධ, තාක්ෂණික ඇගයීම සිදුකිරීම සහ ඒ පිළිබඳ වාර්තාවක් අධිකාරිය වෙත ඉදිරිපත් කිරීම එම්ඊසී හි ප්‍රධාන කර්තව්‍ය වේ. එම්ඊසී හි සංයුතිය.

(ආ) එම වාර්තාවේ, ජාතික ඖෂධ ප්‍රතිපත්තිය ප්‍රකාරව ඖෂධවලට අදාළ ප්‍රතිලාභ, අවදානම්, එම ඖෂධවල තත්ත්වය, ප්‍රත්‍යක්ෂභාවය, ආරක්ෂාකාරී බව, අවශ්‍යතාවය, මිල සහ අවශ්‍ය අවස්ථාවල දී එම ඖෂධවල ඖෂධ ආර්ථික විශ්ලේෂණ පිළිබඳව නිශ්චිතව දැක්විය යුතු ය.

(1) අධිකාරිය විසින් පත්කරනු ලබන පහත දැක්වෙන තැනැත්තන්ගෙන් එම්ඊසී සමන්විත විය යුතු ය:—

(අ) නිලබලයෙන් පත්වන සාමාජිකයන් එනම්—

(i) කමිටුවේ සභාපති විය යුතු එම්ආර් අංශයේ ප්‍රධානියා;

(2) නිෂ්පාදන නියාමන අංශයේ අනෙකුත් කර්තව්‍ය වනුයේ -

(අ) අනාගත නිෂ්පාදකයන්ට තාක්ෂණික දැනුම ලබාදීම ඇතුළු අවශ්‍ය සියලු සහාය ලබා දීම සඳහා යෝජනා ක්‍රම සකස් කිරීම;

(ආ) නිෂ්පාදකයන්ට තම නිෂ්පාදන දේශීය වශයෙන් අලෙවි කර ගැනීමට අවශ්‍ය සහාය ලබාදීම;

(ඇ) නිෂ්පාදකයන්ට තම නිෂ්පාදන අපනයනයන කිරීමට අවශ්‍ය සහාය ලබාදීම;

(ඈ) දේශීය වශයෙන් නිෂ්පාදනය කරන ලද යම් නිෂ්පාදන ශ්‍රී ලංකාව තුළ ප්‍රමාණවත් ලෙස තිබෙන අවස්ථාවලදී එවැනි නිෂ්පාදන ආනයනය කිරීම සීමා කරන ලෙස අධිකාරියට උපදෙස් දීම.

(3) මේ වගන්තියේ කාර්ය සඳහා "නිෂ්පාදන" යන්නෙන් ඖෂධයක්, වෛද්‍ය උපකරණයක් හෝ සීමාස්ථ නිෂ්පාදනයක් අදහස් වේ.

නියෝග.

117. මේ පනතේ මේ කොටසේ විධිවිධාන සියල්ල හෝ යම් විධිවිධානයක් බලාත්මක කිරීම සඳහා අමාත්‍යවරයා විසින් නියෝග සාදනු ලැබිය හැකි ය.

III වන කොටස

ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදන සඳහා මිල නියම කිරීම

ඖෂධ ආදිය සඳහා මිල නියම කිරීම.

(1) (අ) අධිකාරිය විසින් මිල නියම කිරීමේ කමිටුව ලෙස හඳුන්වනු ලබන කමිටුවක් පත් කරනු ලැබිය යුතු ය.

(ආ) මිල නියම කිරීමේ කමිටුවේ සංයුතිය, බලතල සහ කර්තව්‍ය නියෝග මගින් නියම කරනු ලැබිය යුතු ය.

[redacted]ධිකාරිය විසින්, නියම කරනු ලැබිය හැකි නිර්ණායක මත පදනම්ව, මිල නියම කිරීමේ කමිටුව විමසා, ලියාපදිංචි කරනු ලබන අවස්ථාවේදී ඖෂධයක, වෛද්‍ය උපකරණයක සහ සීමාස්ථ නිෂ්පාදනයක හඳුන්වාදීමේ මිල නියම කරනු ලැබිය යුතු ය.

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

අංක 2123/35 - 2019 මැයි මස 15 වැනි බදාදා - 2019.05.15

(රජයේ බලයපිට ප්‍රසිද්ධ කරන ලදි)

I වැනි කොටස: (I) වැනි ඡෙදය - සාමාන්‍ය

රජයේ නිවේදන

එල්.ඩි-බී 9/2016

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 118 වන වගන්තිය සමඟ කියවිය යුතු 142 වන වගන්තිය යටතේ සෞඛ්‍ය, පෝෂණ සහ දේශීය වෛද්‍ය අමාත්‍යවරයා විසින් සාදනු ලබන නියෝග.

වෛද්‍ය රාජිත සේනාරත්න,
සෞඛ්‍ය, පෝෂණ සහ දේශීය වෛද්‍ය අමාත්‍ය.

2019 මැයි මස 11,
කොළඹ දී ය.

නියෝග

1. මෙම නියෝග 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝග යනුවෙන් හඳුන්වනු ලබන අතර (මෙහි මින්මතු "අදාළ දිනය" යනුවෙන් සඳහන් කරනු ලබන) ගැසට් පත්‍රයේ මෙම නියෝග පළ කරනු ලබන දින සිට බලාත්මක විය යුතු ය.

2. අදාළ දිනයේ සිට සහ එදිනට පසුව (මෙහි මින්මතු "උපලේඛනගත ඖෂධ" යනුවෙන් සඳහන් කරනු ලබන) මෙහි උපලේඛනයේ දක්වා ඇති ඖෂධ වල මිල මත ඉහළ සීමාවක් පැවිතිය යුත්තේ ය.

3. උපලේඛනගත ඖෂධ පිළිබඳ එන උපරිම සිල්ලර මිල සීමාවන්, උපලේඛනගත ඖෂධවල සියලු වෙළඳ නාමයන් සහ ඖෂධීය නාමයන් සම්බන්ධයෙන් අදාළ විය යුතු ය.

4. අදාළ දිනයේ සිට සහ එදිනට පසුව මෙහි උපලේඛනයේ II වන තීරුවේ දක්වා ඇති යම් උපලේඛනගත ඖෂධයක් විකිණීමේ කාර්යය සඳහා සත්තකයේ තබාගෙන සිටින කිසිදු නිෂ්පාදකයකු, ආනයනකරුවකු, වෙළෙන්දකු, බෙදාහරින්නකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, දන්ත වෛද්‍යවරයකු, පශු වෛද්‍යවරයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු වෛද්‍ය ආයතනයක්, ඔසුසලයක් හෝ තැනැත්තකු විසින්, එම කිසිදු ඖෂධයක් එහි v වන තීරුවේ අනුරූපී සටහනේ දක්වා ඇති උපරිම සිල්ලර මිලට වඩා වැඩි මිලකට අලෙවි නොකළ යුතු ය.

5. මෙහි උපලේඛනයේ දක්වා ඇති යම් ඖෂධයක් විකුණනු ලබන හෝ විකිණීම සඳහා ඉදිරිපත් කරනු ලබන 4 වන නියෝගයේ සඳහන් සෑම තැනැත්තකු හෝ ආයතනයක් විසින් ම, එම විකිණීම සිදු කිරීමේ දී එම ඖෂධයට අදාළ නාමය සහ එහි මිල පැහැදිලිව දක්වමින් ලදුපතක් නිකුත් කරනු ලැබිය යුතු ය.

IA - PG 4518 — 617 (2019/05)

මෙම අති විශෙෂ ගැසට් පත්‍රය www.documents.gov.lk වෙබ් අඩවියෙන් බාගත කළ හැක.

6. විකිණීමේ කාර්යය සඳහා යම් උපලේඛනගත ඖෂධයක් සන්තකයේ තබාගෙන සිටින යම් නිෂ්පාදකයකු හෝ ආනයනකරුවකු විසින් එම ඖෂධය වර්තමානයේ දී උපලේඛනයේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිලට වඩා අඩු යම් මිලකට විකුණනු ලබන විට, ඔහු විසින් දැනට පවතින මිල සියයට දාහතරයි දශම හතරක (14.4%) ප්‍රතිශතයකින් පමණක් වැඩි කරනු ලැබිය හැකි අතර, එකී උපලේඛනගත ඖෂධය විකිණීමේ කාර්යය සඳහා සන්තකයේ තබාගෙන සිටින යම් වෙළෙන්දකු, බෙදාහරින්නකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, දන්ත වෛද්‍යවරයකු, පශු වෛද්‍යවරයකු, යම් පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු වෛද්‍ය ආයතනයක්, ඔසුසලක් හෝ තැනැත්තකු විසින්, එම ප්‍රතිශෝධිත මිල පවත්වා ගෙන යායුතු ය.

7. උපලේඛනගත ඖෂධවල මාත්‍රා ස්වරූපය හෝ ප්‍රබලතාවය, එම උපලේඛනයේ නිශ්චිතව දක්වා නොමැති අවස්ථාවක, එසේ නිශ්චිතව දක්වා නොමැති මාත්‍රා ස්වරූපය හෝ ප්‍රබලතාවය සඳහා වන උපරිම සිල්ලර මිල සීමාව, ජාතික ඖෂධ නියාමන අධිකාරිය විසින් නියම කරනු ලැබිය යුතු ය.

8. නිෂ්පාදිත හෝ අදාළ දිනයේ දී උපලේඛනගත ඖෂධ විකිණීමේ කාර්යය සඳහා සන්තකයේ තබා ගෙන ඇති වෙළඳපලේ, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු වෛද්‍ය ආයතනයක, ඔසුසලේ හෝ තැනැත්තකු සතුව විකිණීමට තිබෙන උපලේඛනගත ඖෂධ තොගයේ අයිතමවල එක් එක් ඒකකයේ වර්තමාන සිල්ලර මිල හෝ මෙහි උපලේඛනයේ දක්වා ඇති අදාළ උපරිම සිල්ලර මිල යන දෙකෙන් වඩාත් අඩු මිල, ප්‍රායෝගිකව හැකිතාක් ඉක්මනින්, එසේ වුව ද අදාළ දිනයේ සිට දින හතලිස් පහක කාල සීමාවක් ඉකුත් වීමට පෙර අදාළ වෙළඳ ඇසුරුමේ හෝ ලේබලයේ මුද්‍රණය හෝ සළකුණු කළ යුතු ය.

9. 8 වන නියෝගයේ විධිවිධානවල කුමක් සඳහන් වුව ද අදාළ දිනයේ සිට සහ එදිනට පසුව එක් එක් ඒකකයේ උපරිම සිල්ලර මිල, උපලේඛනයේ දක්වා ඇති පරිදි විය යුතු ය. උපලේඛනයේ දක්වා ඇති උපරිම සිල්ලර මිල අදාළ දිනයේ සිට වලංගුව සහ බලාත්මකව පැවතිය යුතු ය.

10. මෙම නියෝගවල විධිවිධාන උල්ලංඝනය කරනු ලබන විකිණීමේ කාර්යය සඳහා යම් උපලේඛනගත ඖෂධයක් සන්තකයේ තබාගෙන සිටින යම් නිෂ්පාදකයකු, ආනයනකරුවකු, වෙළෙන්දකු, බෙදාහරින්නකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, දන්ත වෛද්‍යවරයකු, පශු වෛද්‍යවරයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු වෛද්‍ය ආයතනයක්, ඔසුසලක් හෝ තැනැත්තකු විසින් වරදක් සිදුකරනු ලබන අතර 2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 131 වන වගන්තිය යටතේ ඔහුට එරෙහිව නඩු පැවරිය යුතු ය.

11. මෙහි උපලේඛනයේ දක්වා ඇති උපලේඛනගත ඖෂධවල උපරිම සිල්ලර මිල සෑම සිල්ලර අලෙවි සලකම ප්‍රදර්ශනය කිරීම, විකිණීමේ කාර්යය සඳහා උපලේඛනගත ඖෂධ සන්තකයේ තබාගෙන සිටින සෑම නිෂ්පාදකයකු, ආනයනකරුවකු, වෙළෙන්දකු, බෙදාහරින්නකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, දන්ත වෛද්‍යවරයකු, පශු වෛද්‍යවරයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු වෛද්‍ය ආයතනයක, ඔසුසලක හෝ තැනැත්තකුගේම වගකීම විය යුතු ය.

12. 2017 දෙසැම්බර් මස 14 වැනි දින අංක 2049/31 දරන අති විශේෂ ගැසට් පත්‍රයේ පළකරන ලද නියෝග මගින් සහ 2018 අගෝස්තු මස 31 වැනි දින අංක 2086/37 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළකරන ලද නියෝග මගින් සංශෝධිත 2016 ඔක්තෝබර් 21 වැනි දින අංක 1989/61 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2016 අංක 2 දරන (මිල ඉහළ සීමා) නියෝග මෙයින් පරිච්ඡින්න කරනු ලැබේ.

13. මෙම නියෝගවල කාර්යය සඳහා -

"දන්ත වෛද්‍යවරයකු" යන්නට වෛද්‍ය ආඥාපනතේ (105 වන අධිකාරය) දී ඇති අර්ථයම තිබිය යුතු ය ;

"වෛද්‍ය වෘත්තිකයකු" යන්නට වෛද්‍ය ආඥාපනතේ (105 වන අධිකාරය) දී ඇති අර්ථයම තිබිය යුතු ය ;

"පෞද්ගලික වෛද්‍ය ආයතනය" යන්නට 2006 අංක 21 දරන පෞද්ගලික වෛද්‍ය ආයතන (ලියාපදිංචි කිරීමේ) පනත මගින් ඊට ලබා දී ඇති අර්ථයම තිබිය යුතු ය ;

"පශු වෛද්‍යවරයා" යන්නෙන්, 1956 අංක 46 දරන පශු වෛද්‍ය සහ පශු වෛද්‍ය වෘත්තික පනත යටතේ පශු වෛද්‍යවරයකු හෝ පශු වෛද්‍ය වෘත්තිකයකු වශයෙන් ලියාපදිංචි කරනු ලැබූ තැනැත්තකු අදහස් වේ.

522

උපලේඛනය

ඖෂධවල උපරිම සිල්ලර මිල

I වන තීරුව	*II වන තීරුව* *ඖෂධීය නාමය* *(Genric name)*	*III වන තීරුව* *ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය* *(Dosage Form)*	*IV වන තීරුව* *ප්‍රබලතාවය* *(Strength)*	*V වන තීරුව* *උපරිම සිල්ලර මිල/* *ශ්‍රී ලංකා රුපියල්*
1	ඇල්බෙන්ඩසෝල්	පෙති/කරල්	400 මි.ග්‍රෑ	36.04
2	ඇමොක්සිලීන් - ක්ලැවුලිනික්ඇසිඩ්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	156 මි.ග්‍රෑ/5 මි.ලි.	345.35
	ඇමොක්සිලීන් -ක්ලැවුලිනික්ඇසිඩ්	පෙති/ කරල්	375 මි.ග්‍රෑ	42.52
	ඇමොක්සිලීන් -ක්ලැවුලිනික්ඇසිඩ්	පෙති/ කරල්	625 මි.ග්‍රෑ	72.07
	ඇමොක්සිලීන් -ක්ලැවුලිනික්ඇසිඩ්	එන්නත්	1.2 ග්‍රෑ	757.96
3	ක්ලැරිත්‍රෝමයිසින්	පෙති/ කරල්	250 මි.ග්‍රෑ	43.85
	ක්ලැරිත්‍රෝමයිසින්	පෙති/ කරල්	500 මි.ග්‍රෑ	88.89
	ක්ලැරිත්‍රෝමයිසින්	මුඛ මාර්ගයෙන් දියරවශයෙන් ලබාගැනීම	125 මි.ග්‍රෑ/5 මි.ලි.	523.72
4	ඇසිත්‍රෝමයිසින්	පෙති/ කරල්	250 මි.ග්‍රෑ	45.17
	ඇසිත්‍රෝමයිසින්	පෙති/ කරල්	500 මි.ග්‍රෑ	63.37
	ඇසිත්‍රෝමයිසින්	මුඛ මාර්ගයෙන් දියරවශයෙන් ලබා ගැනීම	200 මි.ග්‍රෑ/5 මි.ලි	210.21
5	සෙෆියුරොක්සිම්	පෙති/ කරල්	250 මි.ග්‍රෑ	54.66
	සෙෆියුරොක්සිම්	පෙති/ කරල්	500 මි.ග්‍රෑ	87.21
6	ඩොක්සිසයික්ලීන්	පෙති/ කරල්	100 මි.ග්‍රෑ	12.14
7	ඇසික්ලොවිර්	පෙති/ කරල්	200 මි.ග්‍රෑ	44.44
8	සිප්‍රොෆ්ලොක්සසින්	පෙති/ කරල්	250 මි.ග්‍රෑ	6.91
	සිප්‍රොෆ්ලොක්සසින්	පෙති/ කරල්	500 මි.ග්‍රෑ	10.22
9	ලෙවොෆ්ලොක්සසින්	පෙති/ කරල්	250 මි.ග්‍රෑ	29.07
	ලෙවොෆ්ලොක්සසින්	පෙති/ කරල්	500 මි.ග්‍රෑ	48.05
10	සෙපලෙක්සින්	පෙති/ කරල්	250 මි.ග්‍රෑ	9.85
	සෙපලෙක්සින්	පෙති/ කරල්	500 මි.ග්‍රෑ	18.02
	සෙපලෙක්සින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	125 මි.ග්‍රෑ/5 මි.ලි.	318.32
11	සෙෆික්සිම්	පෙති/ කරල්	100 මි.ග්‍රෑ	27.63
	සෙෆික්සිම්	පෙති/ කරල්	200 මි.ග්‍රෑ	51.30
	සෙෆික්සිම්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	100මි.ග්‍රෑ/5 මි.ලි.	414.41
12	ඇම්ලොඩිපින්	පෙති/ කරල්	5 මි.ග්‍රෑ	18.38
	ඇම්ලොඩිපින්	පෙති/ කරල්	10 මි.ග්‍රෑ	25.59
13	බිල්ටියසම්	පෙති/ කරල්	30 මි.ග්‍රෑ	3.25
	බිල්ටියසම්	පෙති/ කරල්	60 මි.ග්‍රෑ	10.70
	බිල්ටියසම්	පෙති/ කරල්	90 මි.ග්‍රෑ	25.71

උපලේඛනය (සම්බන්ධිකයි)

ඖෂධවල උපරිම සිල්ලර මිල

I වන තීරුව	*II වන තීරුව* *ඖෂධීය නාමය* *(Genric name)*	*III වන තීරුව* *ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය* *(Dosage Form)*	*IV වන තීරුව* *ප්‍රබලතාවය* *(Strength)*	*V වන තීරුව* *උපරිම සිල්ලර මිල/* *ශ්‍රී ලංකා රුපියල්*
14	ලොසාටන් පොටෑසියම්	පෙති/ කරල්	25 මි.ග්‍රෑ	8.83
	ලොසාටන් පොටෑසියම්	පෙති/ කරල්	50 මි.ග්‍රෑ	12.38
15	ලොසාටන්+හයිඩ්‍රොක්ලෝරෝතයෝසයිඩ්	පෙති/ කරල්	62.5මි.ග්‍රෑ	23.36
16	එනලප්‍රිල්	පෙති/ කරල්	5 මි.ග්‍රෑ	7.21
	එනලප්‍රිල්	පෙති/ කරල්	10 මි.ග්‍රෑ	12.14
17	ඇටනොලෝල්	පෙති/ කරල්	25 මි.ග්‍රෑ	3.60
	ඇටනොලෝල්	පෙති/ කරල්	50 මි.ග්‍රෑ	5.29
	ඇටනොලෝල්	පෙති/ කරල්	100 මි.ග්‍රෑ	15.62
18	නිෆඩිපින්- දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/කරල්	20 මි.ග්‍රෑ	4.45
19	ක්ලෝපිඩොග්‍රෙල්	පෙති/කරල්	75 මි.ග්‍රෑ	21.03
20	ඇටෝවාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑම්	7.72
	ඇටෝවාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ	13.40
	ඇටෝවාස්ටැටින්	පෙති/කරල්	20 මි.ග්‍රෑ	21.14
	ඇටෝවාස්ටැටින්	පෙති/කරල්	40 මි.ග්‍රෑම්	29.74
21	රොසුවාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑ	25.83
	රොසුවාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ	44.44
22	ටෙල්මිසාටන්	පෙති/කරල්	20 මි.ග්‍රෑ	12.25
	ටෙල්මිසාටන්	පෙති/කරල්	40 මි.ග්‍රෑ	19.46
	ටෙල්මිසාටන්	පෙති/කරල්	80 මි.ග්‍රෑ	36.52
23	ඇස්පිරින්	පෙති/කරල්	75 මි.ග්‍රෑ	3.60
	ඇස්පිරින්	පෙති/කරල්	100 මි.ග්‍රෑ	6.37
24	මෙට්ෆෝමින්	පෙති/කරල්	500 මි.ග්‍රෑ	4.75
	මෙට්ෆෝමින් - දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/ කරල්	500 මි.ග්‍රෑ	9.25
	මෙට්ෆෝමින්	පෙති/ කරල්	850 මි.ග්‍රෑ	8.89
25	ග්ලිබෙන්ක්ලමයිඩ්	පෙති/ කරල්	5 මි.ග්‍රෑ	2.64
26	ග්ලයිකසයිඩ්	පෙති/ කරල්	80 මි.ග්‍රෑ	13.58
27	තයිරොක්සින්	පෙති/ කරල්	50 මයික්‍රෝ ග්‍රෑ.	7.33
	තයිරොක්සින්	පෙති/ කරල්	100 මයික්‍රෝ ග්‍රෑ.	10.94

උපලේඛනය (සම්බන්ධිතයි)

ඖෂධවල උපරිම සිල්ලර මිල

I වන තීරුව	*II වන තීරුව* *ඖෂධීය නාමය* *(Generic name)*	*III වන තීරුව* *ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය* *(Dosage Form)*	*IV වන තීරුව* *ප්‍රබලතාවය* *(Strength)*	*V වන තීරුව* *උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්*
28	ග්ලිපිසයිඩ්	පෙති/ කරල්	5 මි.ග්‍රෑ	9.50
29	ඉබියුප්‍රොෆෙන්	පෙති/ කරල්	200 මි.ග්‍රෑ	1.33
	ඉබියුප්‍රොෆෙන්	පෙති/ කරල්	400 මි.ග්‍රෑ	4.45
30	ඩයික්ලොෆෙනැක් සෝඩියම්	පෙති/ කරල්	50 මි.ග්‍රෑ	15.62
	ඩයික්ලොෆෙනැක් සෝඩියම්	පෙති/ කරල්	100 මි.ග්‍රෑ	18.14
31	ඩයික්ලොෆෙනැක් පොටෑසියම්	පෙති/ කරල්	50 මි.ග්‍රෑ	13.16
32	පැරසිටමෝල්	පෙති/ කරල්	500 මි.ග්‍රෑ	1.57
33	සෝඩියම් වැල්ප්‍රොඒට්	පෙති/ කරල්	200 මි.ග්‍රෑ	10.81
34	රිස්පෙරිඩෝන්	පෙති/ කරල්	1 මි.ග්‍රෑ	9.50
	රිස්පෙරිඩෝන්	පෙති/ කරල්	2 මි.ග්‍රෑ	11.11
35	ඔලන්සපින්	පෙති/ කරල්	5 මි.ග්‍රෑ	12.01
	ඔලන්සපින්	පෙති/ කරල්	10 මි.ග්‍රෑ	24.98
36	කාබමසපින්	පෙති/ කරල්	200 මි.ග්‍රෑ	14.41
37	ඇල්ප්‍රසෝලෑම්	පෙති/ කරල්	0.25 මි.ග්‍රෑ	7.81
	ඇල්ප්‍රසෝලෑම්	පෙති/ කරල්	0.5 මි.ග්‍රෑ	11.90
38	ෆ්ලූඔක්සටින්	පෙති/ කරල්	20 මි.ග්‍රෑ	13.21
39	ගැබාපෙන්ටින්	පෙති/ කරල්	100 මි.ග්‍රෑ	20.12
	ගැබාපෙන්ටින්	පෙති/ කරල්	300 මි.ග්‍රෑ	39.82
40	බෙක්ලොමෙතසෝන්	ඩී.පී කරල් (ආශ්වාස කිරීම)	200 මයික්‍රෝ ග්‍රෑ.	7.21
	බෙක්ලොමෙතසෝන්	ඩී.පී කරල් (ආශ්වාස කිරීම)	400 මයික්‍රෝ ග්‍රෑ.	8.17
	බෙක්ලොමෙතසෝන්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	100 මයික්‍රෝ ග්‍රෑ.	609.61
	බෙක්ලොමෙතසෝන්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	250 මයික්‍රෝ ග්‍රෑ.	673.87
41	සැල්බියුටමෝල්	ඩී.පී කරල්(ආශ්වා සකිරීම)	200 මයික්‍රෝ ග්‍රෑ.	4.80
	සැල්බියුටමෝල්	ඩී.පී කරල්(ආශ්වාස කිරීම)	400 මයික්‍රෝ ග්‍රෑ.	6.61
	සැල්බියුටමෝල්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	100 මයික්‍රෝ ග්‍රෑ.	372.37
42	මිතයිල්ප්‍රෙඩ්නිසෝලෝන්	පෙති/ කරල්	4 මි.ග්‍රෑ	14.23
	මිතයිල්ප්‍රෙඩ්නිසෝලෝන්	පෙති/ කරල්	16 මි.ග්‍රෑ	49.25
43	ඔමෙප්‍රසෝල්	පෙති/ කරල්	20 මි.ග්‍රෑ	5.41

(519)

උපලේඛනය (සම්බන්ධිකයි)

ඖෂධවල උපරිම සිල්ලර මිල

I වන තීරුව	*II වන තීරුව* *ඖෂධීය නාමය* ***(Genric name)***	*III වන තීරුව* *ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය* ***(Dosage Form)***	*IV වන තීරුව* *ප්‍රබලතාවය* ***(Strength)***	*V වන තීරුව* *උපරිම සිල්ලර මිල/* *ශ්‍රී ලංකා රුපියල්*
44	පැන්ටොප්‍රසෝල්	පෙති/ කරල්	20 මි.ග්‍රෑ	20.42
	පැන්ටොප්‍රසෝල්	පෙති/ කරල්	40 මි.ග්‍රෑ	33.63
45	ඉසොමෙප්‍රසෝල්	පෙති/ කරල්	20 මි.ග්‍රෑ	24.26
	ඉසොමෙප්‍රසෝල්	පෙති/ කරල්	40 මි.ග්‍රෑ	46.13
46	ඩොම්පෙරිඩෝන්	පෙති/ කරල්	10 මි.ග්‍රෑ	6.49
47	රැබිප්‍රසෝල්	පෙති/ කරල්	10 මි.ග්‍රෑ	13.58
	රැබිප්‍රසෝල්	පෙති/ කරල්	20 මි.ග්‍රෑ	25.89
48	ඇලෙන්ඩ්‍රොනික් ඇසිඩ්	පෙති/ කරල්	70 මි.ග්‍රෑ	121.80
49	සෙෆ්ටසිඩීම්	නික්ෂේපන	500 මි.ග්‍රෑ	549.12
	සෙෆ්ටසිඩීම්	නික්ෂේපන	1 ග්‍රෑ	915.20
50	සෙෆ්ට්‍රියැක්සෝන්	නික්ෂේපන	250 මි.ග්‍රෑ	274.56
	සෙෆ්ට්‍රියැක්සෝන්	නික්ෂේපන	500 මි.ග්‍රෑ	514.80
	සෙෆ්ට්‍රියැක්සෝන්	නික්ෂේපන	1ග්‍රෑ	800.80
51	සෙෆොටැක්සීම්	නික්ෂේපන	500 මි.ග්‍රෑ	257.40
	සෙෆොටැක්සීම්	නික්ෂේපන	1ග්‍රෑ	429.00
52	ෆ්ලුකොනසෝල්	පෙති/ කරල්	50 මි.ග්‍රෑ	28.60
	ෆ්ලුකොනසෝල්	පෙති/ කරල්	150 මි.ග්‍රෑ	51.48
53	ඉන්සියුලින් සොලියුබල් හියුමන්	නික්ෂේපන	100 අයි.යූ/ 1 මි.ලී (10 මි.ලී. කුප්පිය)	1,372.80
	ඉන්සියුලින් සොලියුබල් හියුමන්	නික්ෂේපන	100 අයි.යූ/1 මි.ලී (3 මි.ලී. කාට්‍රිජය)	686.40
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නික්ෂේපන	100 අයි.යූ/ 1 මි.ලී (10 මි.ලී. කුප්පිය)	1,372.80
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නික්ෂේපන	100 අයි.යූ/ 1 මි.ලී (3 මි.ලී. කාට්‍රිජය)	686.40
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින් (ඉන්සියුලින් සොලියුබල් හියුමන් 30 අයි.යූ/1 මි.ලී., ඉන්සියුලින් අසෝෆෙන් හියුමන් 70 අයි.යූ/1 මි.ලී.) මිශ්‍රණය ලෙස	නික්ෂේපන	100 අයි.යූ/ 1 මි.ලී (10 මි.ලී. කුප්පිය)	1,372.80
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින් (ඉන්සියුලින් සොලියුබල් හියුමන් 30 අයි.යූ/1මි.ලී., ඉන්සියුලින් **අයිසෝෆෙන්** හියුමන් 70 අයි.යූ/1 මි.ලී) මිශ්‍රණය ලෙස	නික්ෂේපන	100 අයි.යූ/ 1 මි.ලී (3 මි.ලී. කාට්‍රිජය)	686.40

උපලේඛනය (සම්බන්ධිතයි)

ඖෂධවල උපරිම සිල්ලර මිල

I වන තීරුව	*II වන තීරුව* ඖෂධීය නාමය *(Genric name)*	*III වන තීරුව* ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය *(Dosage Form)*	*IV වන තීරුව* ප්‍රබලතාවය *(Strength)*	*V වන තීරුව* උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
54	ග්ලිමිපිරයිඩ්	පෙති	1 මි.ග්‍රෑ	8.18
	ග්ලිමිපිරයිඩ්	පෙති	2 මි.ග්‍රෑ	11.61
	ග්ලිමිපිරයිඩ්	පෙති	3 මි.ග්‍රෑ	19.45
	ග්ලිමිපිරයිඩ්	පෙති	4 මි.ග්‍රෑ	21.16
55	සිටාග්ලිප්ටින්	පෙති	25 මි.ග්‍රෑ	17.16
	සිටාග්ලිප්ටින්	පෙති	50 මි.ග්‍රෑ	32.60
	සිටාග්ලිප්ටින්	පෙති	100 මි.ග්‍රෑ	55.48
56	ඩැමසුලොසින්	පෙති/කරල්	0.40 මි.ග්‍රෑ	24.02
57	මොන්ටිලූකාස්ට්	පෙති	4 මි.ග්‍රෑ	13.73
	මොන්ටිලූකාස්ට්	පෙති	5 මි.ග්‍රෑ	17.16
	මොන්ටිලූකාස්ට්	පෙති	10 මි.ග්‍රෑ	24.02
58	ප්‍රෙගබලීන්	පෙති/කරල්	50 මි.ග්‍රෑ	14.01
	ප්‍රෙගබලීන්	පෙති/කරල්	75 මි.ග්‍රෑ	17.73
	ප්‍රෙගබලීන්	පෙති/කරල්	100 මි.ග්‍රෑ	22.02
	ප්‍රෙගබලීන්	පෙති/කරල්	150 මි.ග්‍රෑ	27.46
	ප්‍රෙගබලීන්	පෙති/කරල්	300 මි.ග්‍රෑ	45.19
59	ටොපිරමේට්	පෙති/කරල්	25 මි.ග්‍රෑ	22.88
	ටොපිරමේට්	පෙති/කරල්	50 මි.ග්‍රෑ	36.61
	ටොපිරමේට්	පෙති/කරල්	100 මි.ග්‍රෑ	59.49
60	ලැමෝට්‍රිජින්	පෙති	25 මි.ග්‍රෑ	13.73
	ලැමෝට්‍රිජින්	පෙති	50 මි.ග්‍රෑ	24.02
	ලැමෝට්‍රිජින්	පෙති	100 මි.ග්‍රෑ	40.04

05 - 755

ශ්‍රී ලංකා රජයේ මුද්‍රණ දෙපාර්තමේන්තුවේ මුද්‍රණය කරන ලදී.

517

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

අංක 2241/43 - 2021 අගෝස්තු මස 19 වැනි බ්‍රහස්පතින්දා - 2021.08.19

(රජයේ බලයවිම ප්‍රසිද්ධ කරන ලදී)

I වැනි ඉකාටස: (I) වැනි ඉජ්දය - සාමාන්‍ය

රජයේ නිවේදන

ඵල්.ඩී.සී-9/2016 (ii)

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 05 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 3 වන වගන්තිය යමග කියවිය යුතු, 142 වන වගන්තිය යටතේ සෞඛ්‍ය අමාත්‍යවරයා විසින් සාදන ලද නියෝග.

ආචාර්ය කෙහෙළිය රඹුක්වැල්ල,
සෞඛ්‍ය අමාත්‍ය.

2021 අගෝස්තු මස 19 වැනි දින,
කොළඹ දී ය.

නියෝග

2019 මැයි මස 15 වන දින අංක 2123/35 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝගයේ උපලේඛනය ඉවත් කොට ඒ වෙනුවට පහත දැක්වෙන උපලේඛනය ආදේශ කිරීමෙන් මෙයින් සංශෝධනය කරනු ලැබේ:-

උපලේඛනය

(2 වන නියෝගය)

අංකය	I වන තීරුව	II වන තීරුව	III වන තීරුව	IV වන තීරුව
	ඖෂධීය නාමය (Generic name)	ලබාගනු ලබන ක්‍රමය/ මාත්‍රා ආකාරය (Root of administration or Dosage form)	ප්‍රභලතාවය (Strength)	උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
1	ඇල්බෙන්ඩසෝල්	පෙති/කැප්සියුල්	400 මි.ග්‍රෑ.	39.28
2	ඇමොක්සිලීන් -ක්ලැවුලිනික්ඇසිඩ්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	156 මි.ග්‍රෑ./5 මි.ලී.	376.43
	ඇමොක්සිලීන් -ක්ලැවුලිනික්ඇසිඩ්	පෙති/කැප්සියුල්	375 මි.ග්‍රෑ.	46.35

1A - G 34897 — 45 (2021/08)

මෙම අති විශෙෂ ගැසට් පත්‍රය www.documents.gov.lk වෙබ් අඩවියෙන් බාගත හැක.

අංකය	I වන තීරුව	II වන තීරුව	III වන තීරුව	IV වන තීරුව
	ඖෂධීය නාමය (Generic name)	ලබාගනු ලබන ක්‍රමය/ මාත්‍රා ආකාරය (Root of administration or Dosage form)	ප්‍රභලතාවය (Strength)	උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
	ඇමොක්සිලින් -ක්ලැවුලිනික්ඇසිඩ්	පෙති/කරල්	625 මි.ග්‍රෑ.	78.55
	ඇමොක්සිලින් -ක්ලැවුලිනික්ඇසිඩ්	එන්නත්	1.2 ග්‍රෑ.	826.17
3.	ක්ලැරිත්‍රොමයිසින්	පෙති/කරල්	250 මි.ග්‍රෑ.	47.79
	ක්ලැරිත්‍රොමයිසින්	පෙති/කරල්	500 මි.ග්‍රෑ.	96.89
	ක්ලැරිත්‍රොමයිසින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	125 මි.ග්‍රෑ./5 මි.ලී.	570.85
4.	ඇසිත්‍රෝමයිසින්	පෙති/කරල්	250 මි.ග්‍රෑ.	49.23
	ඇසිත්‍රෝමයිසින්	පෙති/කරල්	500 මි.ග්‍රෑ.	69.07
	ඇසිත්‍රෝමයිසින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	200 මි.ග්‍රෑ. / 5 මි.ලී.	229.12
5.	සෙෆියුරොක්සිම්	පෙති/කරල්	250 මි.ග්‍රෑ.	59.57
	සෙෆියුරොක්සිම්	පෙති/කරල්	500 මි.ග්‍රෑ.	95.05
6.	ඩොක්සියසික්ලීන්	පෙති/කරල්	100 මි.ග්‍රෑ.	13.23
7.	ඇසික්ලොව්ර්	පෙති/කරල්	200 මි.ග්‍රෑ.	48.43
8.	සිප්‍රොෆ්ලොක්සසින්	පෙති/කරල්	250 මි.ග්‍රෑ.	7.53
	සිප්‍රොෆ්ලොක්සසින්	පෙති/කරල්	500 මි.ග්‍රෑ.	11.13
9.	ලෙවොෆ්ලොක්සසින්	පෙති/කරල්	250 මි.ග්‍රෑ.	31.68
	ලෙවොෆ්ලොක්සසින්	පෙති/කරල්	500 මි.ග්‍රෑ.	52.37
10.	සෙපලෙක්සිත්	පෙති/කරල්	250 මි.ග්‍රෑ.	10.73
	සෙපලෙක්සින්	පෙති/කරල්	500 මි.ග්‍රෑ.	19.65
	සෙපලෙක්සින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	125 මි.ග්‍රෑ./5 මි.ලී.	346.96

අංකය	I වන තීරුව	II වන තීරුව	III වන තීරුව	IV වන තීරුව
	ඖෂධීය නාමය (Generic name)	ලබාගනු ලබන ක්‍රමය/ මාත්‍රා ආකාරය (Root of administration or Dosage form)	ප්‍රභලතාවය (Strength)	උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
11.	සෙෆික්සිම්	පෙති/කරල්	100 මි.ග්‍රෑ.	30.11
	සෙෆික්සිම්	පෙති/කරල්	200 මි.ග්‍රෑ.	55.91
	සෙෆික්සිම්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	100 මි.ග්‍රෑ./5 මි.ලී.	451.70
12.	ඇම්ලොඩිපින්	පෙති/කරල්	5 මි.ග්‍රෑ.	20.03
	ඇම්ලොඩිපින්	පෙති/කරල්	10 මි.ග්‍රෑ.	27.89
13.	ඩිල්ටියසම්	පෙති/කරල්	30 මි.ග්‍රෑ.	3.54
	ඩිල්ටියසම්	පෙති/කරල්	60 මි.ග්‍රෑ.	11.66
	ඩිල්ටියසම්	පෙති/කරල්	90 මි.ග්‍රෑ.	28.02
14.	ලොසාටන් පොටෑසියම්	පෙති/කරල්	25 මි.ග්‍රෑ.	9.62
	ලොසාටන් පොටෑසියම්	පෙති/කරල්	50 මි.ග්‍රෑ.	13.49
15.	ලොසාටන්- හයිඩ්‍රොක්ලෝරෝතයෝසයිඩ්	පෙති/කරල්	62.5 මි.ග්‍රෑ.	25.46
16.	එනලප්‍රිල්	පෙති/කරල්	5 මි.ග්‍රෑ.	7.85
	එනලප්‍රිල්	පෙති/කරල්	10 මි.ග්‍රෑ.	13.23
17.	ඇටනොලෝල්	පෙති/කරල්	25 මි.ග්‍රෑ.	3.92
	ඇටනොලෝල්	පෙති/කරල්	50 මි.ග්‍රෑ.	5.76
	ඇටනොලෝල්	පෙති/කරල්	100 මි.ග්‍රෑ.	17.02
18.	නිෆඩිපීන් - දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/කරල්	20 මි.ග්‍රෑ.	4.85
19.	ක්ලෝපිඩොග්‍රෙල්	පෙති/කරල්	75 මි.ග්‍රෑ.	22.92
20.	ඇටෝවාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑ.	8.41
	ඇටෝවාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ.	14.60
	ඇටෝවාස්ටැටින්	පෙති/කරල්	20 මි.ග්‍රෑ.	23.04
	ඇටෝවාස්ටැටින්	පෙති/කරල්	40 මි.ග්‍රෑ.	32.41

අංකය	I වන තීරුව	II වන තීරුව	III වන තීරුව	IV වන තීරුව
	ඖෂධීය නාමය (Generic name)	ලබාගනු ලබන ක්‍රමය/ මාත්‍රා ආකාරය (Root of administration or Dosage form)	ප්‍රභලතාවය (Strength)	උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
21.	රොසුවාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑ.	28.15
	රොසුවාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ.	48.43
22.	ටෙල්මිසාටන්	පෙති/කරල්	20 මි.ග්‍රෑ.	13.35
	ටෙල්මිසාටන්	පෙති/කරල්	40 මි.ග්‍රෑ.	21.21
	ටෙල්මිසාටන්	පෙති/කරල්	80 මි.ග්‍රෑ.	39.80
23.	ඇස්පිරින්	පෙති/කරල්	75 මි.ග්‍රෑ.	3.92
	ඇස්පිරින්	පෙති/කරල්	100 මි.ග්‍රෑ.	6.94
24.	මෙට්පෝමින්	පෙති/කරල්	500 මි.ග්‍රෑ.	5.17
	මෙට්පෝමින් - දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/කරල්	500 මි.ග්‍රෑ.	10.08
	මෙට්පෝමින්	පෙති/කරල්	850 මි.ග්‍රෑ.	9.69
25.	ග්ලිබෙන්ක්ලමයිඩ්	පෙති/කරල්	5 මි.ග්‍රෑ.	2.87
26.	ග්ලික්ලයසයිඩ්	පෙති/කරල්	80 මි.ග්‍රෑ.	14.80
27.	නයිරොක්සින්	පෙති/කරල්	50 මයික්‍රෝ ග්‍රෑ.	7.98
	තයිරොක්සින්	පෙති/කරල්	100 මයික්‍රෝ ග්‍රෑ.	11.92
28.	ග්ලිපිසයිඩ්	පෙති/කරල්	5 මි.ග්‍රෑ.	10.35
29.	ඉබියුප්‍රොෆෙන්	පෙති/කරල්	200 මි.ග්‍රෑ.	1.44
	ඉබියුප්‍රොෆෙන්	පෙති/කරල්	400 මි.ග්‍රෑ.	4.85
30.	ඩයික්ලොෆෙනැක් සෝඩියම්	පෙති/කරල්	50 මි.ග්‍රෑ.	17.02
	ඩයික්ලොෆෙනැක් සෝඩියම්	පෙති/කරල්	100 මි.ග්‍රෑ.	19.77
31.	ඩයික්ලොෆෙනැක් පොටැසියම්	පෙති/කරල්	50 මි.ග්‍රෑ.	14.34

513

අංකය	I වන තීරුව	II වන තීරුව	III වන තීරුව	IV වන තීරුව
	ඖෂධීය නාමය (Generic name)	ලබාගනු ලබන ක්‍රමය/ මාත්‍රා ආකාරය (Root of administration or Dosage form)	ප්‍රභලතාවය (Strength)	උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
32.	පැරසිටමෝල්	පෙති/කරල්	500 මි.ග්‍රෑ.	1.71
33.	සෝඩියම් වැල්ප්‍රොඒට්	පෙති/කරල්	200 මි.ග්‍රෑ.	11.78
34.	රිස්පෙරිඩෝන්	පෙති/කරල්	1 මි.ග්‍රෑ.	10.35
	රිස්පෙරිඩෝන්	පෙති/කරල්	2 මි.ග්‍රෑ.	12.10
35.	ඔලන්සපින්	පෙති/කරල්	5 මි.ග්‍රෑ.	13.09
	ඔලන්සපින්	පෙති/කරල්	10 මි.ග්‍රෑ.	27.22
36.	කාබමසපීන්	පෙති/කරල්	200 මි.ග්‍රෑ.	15.70
37.	ඇල්ප්‍රසෝලැම්	පෙති/කරල්	0.25 මි.ග්‍රෑ.	8.51
	ඇල්ප්‍රසෝලැම්	පෙති/කරල්	0.5 මි.ග්‍රෑ.	12.97
38.	ෆ්ලූඔක්සටීන්	පෙති/කරල්	20 මි.ග්‍රෑ.	14.40
39.	ගැබාපෙන්ටීන්	පෙති/කරල්	100 මි.ග්‍රෑ.	21.93
	ගැබාපෙන්ටීන්	පෙති/කරල්	300 මි.ග්‍රෑ.	43.40
40.	බෙක්ලොමෙතසෝන්	ඩී. පී. කරල් (ආශ්වාස කිරීම)	200 මයික්‍රෝ ග්‍රෑ.	7.85
	බෙක්ලොමෙතසෝන්	ඩී. පී. කරල් (ආශ්වාස කිරීම)	400 මයික්‍රෝ ග්‍රෑ.	8.90
	බෙක්ලොමෙතසෝන්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	100 මයික්‍රෝ ග්‍රෑ.	664.47
	බෙක්ලොමෙතසෝන්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	250 මයික්‍රෝ ග්‍රෑ.	734.51
41.	සැල්බියුටමෝල්	ඩී. පී. කරල් (ආශ්වාස කිරීම)	200 මයික්‍රෝ ග්‍රෑ.	5.23
	සැල්බියුටමෝල්	ඩී. පී. කරල් (ආශ්වාස කිරීම)	400 මයික්‍රෝ ග්‍රෑ.	7.20

අංකය	I වන තීරුව	II වන තීරුව	III වන තීරුව	IV වන තීරුව
	ඖෂධීය නාමය (Generic name)	ලබාගනු ලබන ක්‍රමය/ මාත්‍රා ආකාරය (Root of administration or Dosage form)	ප්‍රභලතාඩය (Strength)	උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
	සැල්බියුටමෝල්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	100 මයික්‍රෝ ග්‍රෑ.	405.88
42.	මීතයිල්ප්‍රෙඩ්නිසෝලෝන්	පෙති/කරල්	4 මි.ග්‍රෑ.	15.51
	මීතයිල්ප්‍රෙඩ්නිසෝලෝන්	පෙති/කරල්	16 මි.ග්‍රෑ.	53.68
43.	ඔමෙප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	5.89
44.	පැන්ටොප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	22.25
	පැන්ටොප්‍රසෝල්	පෙති/කරල්	40 මි.ග්‍රෑ.	36.65
45.	ඉසොමෙප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	26.44
	ඉසොමෙප්‍රසෝල්	පෙති/කරල්	40 මි.ග්‍රෑ.	50.28
46.	ඩොම්පෙරිඩෝන්	පෙති/කරල්	10 මි.ග්‍රෑ.	7.07
47.	රබ්ප්‍රසෝල්	පෙති/කරල්	10 මි.ග්‍රෑ.	14.80
	රබ්ප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	28.22
48.	ඇලෙන්ඩ්‍රොනික් ඇසිඩ්	පෙති/කරල්	70 මි.ග්‍රෑ.	132.76
49.	සෙෆ්ටසිඩීම්	නික්ෂේපන	500 මි.ග්‍රෑ.	598.54
	සෙෆ්ටසිඩීම්	නික්ෂේපන	1 ග්‍රෑම්	997.57
50.	සෙෆ්ට්‍රියැක්සෝන්	නික්ෂේපන	250 මි.ග්‍රෑ.	299.27
	සෙෆ්ට්‍රියැක්සෝන්	නික්ෂේපන	500 මි.ග්‍රෑ.	561.13
	සෙෆ්ට්‍රියැක්සෝන්	නික්ෂේපන	1 ග්‍රෑම්	872.87
51.	සෙෆොටැක්සිම්	නික්ෂේපන	500 මි.ග්‍රෑ.	280.57
	සෙෆොටැක්සිම්	නික්ෂේපන	1 ග්‍රෑම්	467.61

අංකය	I වන තීරුව	II වන තීරුව	III වන තීරුව	IV වන තීරුව
	ඖෂධීය නාමය (Generic name)	ලබාගනු ලබන ක්‍රමය/ මාත්‍රා ආකාරය (Root of administration or Dosage form)	ප්‍රභලතාවය (Strength)	උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
52.	ෆ්ලූකොනසෝල්	පෙති/කරල්	50 මි.ග්‍රෑම්	31.17
	ෆ්ලූකොනසෝල්	පෙති/කරල්	150 මි.ග්‍රෑම්	56.11
53.	ඉන්සියුලින් සොලියුබල් හියුමන්	නික්ෂේපන	100 අයි.යූ/1මි. ලී. (10 මි.ලී. කුප්පිය)	1,496.35
	ඉන්සියුලින් සොලියුබල් හියුමන්	නික්ෂේපන	100 අයි.යූ/1මි. ලී. (3 මි.ලී. හා කාට්‍රිජය)	748.18
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නික්ෂේපන	100 අයි.යූ/1මි. ලී. (10 මි.ලී. කුප්පිය)	1,496.35
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නික්ෂේපන	100 අයි.යූ/1මි. ලී. (3 මි.ලී. හා කාට්‍රිජය)	748.18
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින් (ඉන්සියුලින් සොලියුබල් හියුමන් 30අයි.යූ/1 මි.ලී. ඉන්සියුලින් අයිසෝෆෙන් හියුමන් 70 අයි.යූ/1 මි.ලී.) මිශ්‍රණය ලෙස	නික්ෂේපන	100 අයි.යූ/1මි. ලී. (10 මි.ලී. කුප්පිය)	1,496.35
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින් (ඉන්සියුලින් සොලියුබල් හියුමන් 30අයි.යූ/1 මි.ලී. ඉන්සියුලින් අයිසෝෆෙන් හියුමන් 70 අයි.යූ/1 මි.ලී.) මිශ්‍රණය ලෙස	නික්ෂේපන	100 අයි.යූ/1මි. ලී. (3 මි.ලී. හා කාට්‍රිජය)	748.18
54.	ග්ලිමිපිරයිඩ	පෙති	1 මි.ග්‍රෑම්	8.92
	ග්ලිමිපිරයිඩ	පෙති	2 මි.ග්‍රෑම්	12.65
	ග්ලිමිපිරයිඩ	පෙති	3 මි.ග්‍රෑම්	21.20
	ග්ලිමිපිරයිඩ	පෙති	4 මි.ග්‍රෑම්	23.06
55.	සිටාග්ලිප්ටින්	පෙති	25 මි.ග්‍රෑම්	18.70
	සිටාග්ලිප්ටින්	පෙති	50 මි.ග්‍රෑම්	35.53
	සිටාග්ලිප්ටින්	පෙති	100 මි.ග්‍රෑම්	60.47
56.	ඇම්ලොඩිපින්	පෙති/කරල්	0.40 මි.ග්‍රෑම්	26.18
57.	මොන්ටිලුකාස්ට්	පෙති	4 මි.ග්‍රෑම්	14.97
	මොන්ටිලුකාස්ට්	පෙති	5 මි.ග්‍රෑම්	18.70
	මොන්ටිලුකාස්ට්	පෙති	10 මි.ග්‍රෑම්	26.18

අංකය	I වන තීරුව	II වන තීරුව	III වන තීරුව	IV වන තීරුව
	ඖෂධීය නාමය (Generic name)	ලබාගනු ලබන ක්‍රමය/ මාත්‍රා ආකාරය (Root of administration or Dosage form)	ප්‍රභලතාවය (Strength)	උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
58.	ප්‍රෙගබලින්	පෙති/කරල්	50 මි.ග්‍රෑම්	15.27
	ප්‍රෙගබලින්	පෙති/කරල්	75 මි.ග්‍රෑම්	19.33
	ප්‍රෙගබලින්	පෙති/කරල්	100 මි.ග්‍රෑම්	24.00
	ප්‍රෙගබලින්	පෙති/කරල්	150 මි.ග්‍රෑම්	29.93
	ප්‍රෙගබලින්	පෙති/කරල්	300 මි.ග්‍රෑම්	49.26
59.	ටොපිරමේට්	පෙති/කරල්	25 මි.ග්‍රෑම්	24.94
	ටොපිරමේට්	පෙති/කරල්	50 මි.ග්‍රෑම්	39.90
	ටොපිරමේට්	පෙති/කරල්	100 මි.ග්‍රෑම්	64.84
60.	ලැමෝට්‍රිජින්	පෙති	25 මි.ග්‍රෑම්	14.97
	ලැමෝට්‍රිජින්	පෙති	50 මි.ග්‍රෑම්	26.18
	ලැමෝට්‍රිජින්	පෙති	100 මි.ග්‍රෑම්	43.64".

09–50/1

එල්.ඩී.බී.9/2016 (ii)

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 3 වන වගන්තිය සමඟ කියවිය යුතු, 142 වන වගන්තිය යටතේ සෞඛ්‍ය අමාත්‍යවරයා විසින් සාදන ලද නියෝග.

ආචාර්ය කෙහෙළිය රඹුක්වැල්ල,
සෞඛ්‍ය අමාත්‍ය.

2021 අගෝස්තු මස 19 වැනි දින,
කොළඹ දී ය.

නියෝග

2019 මාර්තු මස 15 වන දින අංක 2114/54 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝග මඟින් සංශෝධිත 2017 අංක 1 දරන වෛද්‍ය උපකරණ මිල නියම කිරීමේ නියෝගයෙහි උපලේඛනය ඉවත් කොට ඒ වෙනුවට පහත දැක්වෙන උපලේඛනය ආදේශ කිරීමෙන් මෙයින් සංශෝධනය කරනු ලැබේ:-

උපලේඛනය

අක්මී කාච/සිලිලරි සිස්ටම් සමඟ අත්මී කාච (ප්‍රීලෝඩඩ්/කාට්‍රිජය සහිත)

(2 වන නියෝගය)

I වැනි තීරුව	II වැනි තීරුව වෙළඳ නාමය/අනුමත නාමය	III වැනි තීරුව නිෂ්පාදකයා	IV වැනි තීරුව උපරිම සිල්ලර මිල (MRP) (ශ්‍රී ලංකා රුපියල්)
1	ඇක්සෆිවි ප්‍රීලෝඩඩ් සිලිවරි සිස්ටම්	ඇල්කෝන්	21,200.50
2	ඇක්සෝෆ් IQ SN 60WF කාට්‍රිජය සහිත	ඇල්කෝන්	20,448.40
3	ටෙක්නිස් 1 පීස්	ඇබෝට් මෙඩිකල්	20,197.70
4	එන් විස්ටා	බොෂ් ඇන්ඩ් ලෝම්බ්	19,325.70
5	ටෙක්නිස් මොනොෆොකල්	ඇබෝට් මෙඩිකල්	19,325.70
6	හෝයා අයිසර්ටි 251	හෝයා	15,096.50
7	නයිඩෙක් නොක්ස්-ලෝඩ් සිස්ටම් SP SZ-1	නයිඩෙක්	15,096.50
8	ඇක්වා සෙන්ස් ආරිස්	ආරෙන් සයන්ටිෆික්	12,218.90
9	බයි-ෆ්ලෙක්ස් HB (877 FABY ස්ටැන්ඩඩ් අයි ඕ ඵල්)	මෙඩිකොන්ටූර්	11,118.00
10	බනි HP	හනිටා මාකටින්	10,845.50
11	අයි-ස්ට්‍රීම් ප්‍රීලෝඩඩ	MD ටෙක්	9,226.85
12	ඕරොවිවි EV	ඕරොලැබ්	6,174.85
13	ඇක්සෝෆ් SP SA 60 AT කාට්‍රිජය සහිත	ඇල්කෝන්	16,350.00
14	ඇක්සෝෆ් එක්ස්පැන්ඩ් MA 60 MA කාට්‍රිජය සහිත	ඇල්කෝන්	16,350.00
15	සෙන්සර් 1 පීස්	ඇබෝට් මෙඩිකල්	15,963.50
16	සෙන්සර්	ඇබෝට් මෙඩිකල්	14,660.50
17	ඇක්සෝෆ් MP MA 60 AC	ඇල්කෝන්	13,341.60
18	හෝයා PY 60R	හෝයා	9,853.60
19	ඇක්විවා UD (බිලූ පිල්ටර්)	VSY බයෝටෙක්	8,611.00
20	සුප්‍රා ෆෝබි ප්‍රීලෝඩඩ් සිස්ටම්	අප්පයාම්	8,109.60
21	ඇක්විවා UD	VSY බයෝටෙක්	8,175.00
22	ඇක්‍රිඔස් - MI 60	බෝෂ් ඇන්ඩ් ලෝම්බ්	18,459.15
23	ඇක්‍රිඔස් - AO	බෝෂ් ඇන්ඩ් ලෝම්බ්	14,464.30
24	ඇක්‍රිඔස් ඇඩප්ට්	බෝෂ් ඇන්ඩ් ලෝම්බ්	13,516.00
25	බනි AFM	හනිටා මාකටින්	13,243.50
26	CT ඇස්ෆිනා 404	කාල් සීස් මෙඩිටෙක්	13,080.00
27	CT ස්ෆෙරිස් 204	කාල් සීස් මෙඩිටෙක්	10,224.20

I වැනි තීරුව	II වැනි තීරුව වෙළඳ නාමය/අනුමත නාමය	III වැනි තීරුව නිෂ්පාදකයා	IV වැනි තීරුව උපරිම සිල්ලර මිල (MRP) (ශ්‍රී ලංකා රුපියල්)
28	ඛනි AF	හනිට්ා මාකවින්	8,981.60
29	C- ෆ්ලෙක්ස් ඇස්ෆෙරික් 970 C/920 H	ඇල්කන්(ඊ)	7,521.00
30	ඇස්ෆිරා - aAY	හයුමන් ඔප්ටික්ස්	7,106.80
31	ඔක්‍යුවා	VSY බයොටෙක්	4,992.20
32	ඕරොෆ්ලෙක්ස්	ඕරොලැබ	2,245.40
33	සීලෙන්ස්	හනිට්ා මාකවින්	7,733.55
34	C- ෆ්ලෙක්ස් IOL (ස්ෆෙරිකල් 570 C)	ඇල්කන්(ඊ)	6,376.50
35	ඇස්ෆිරා AS	හයුමන් ඔප්ටික්ස්	6,485.50
36	ටෙක්සොෆ්ට් ටෙට්‍රා	ෆ්‍රෙඩ් හොලෝවිස්	5,995.00
37	ටෙක්සොෆ්ට් ෆ්ලෙක්ස්	ෆ්‍රෙඩ් හොලෝවිස්	5,613.50
38	ඇක්‍රිෆෝල්ඩ්	අප්පසාමි	3,815.00

09–50/2

ඵල්.සී.බී-9/2016 (II)

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 3 වන වගන්තිය සමඟ කියවිය යුතු, 142 වන වගන්තිය යටතේ සෞඛ්‍ය අමාත්‍යවරයා විසින් සාදන ලද නියෝග.

ආචාර්ය කෙහෙළිය රඹුක්වැල්ල,
සෞඛ්‍ය අමාත්‍ය.

2021 අගෝස්තු මස 19 වැනි දින,
කොළඹ දී ය.

නියෝග

2019 මාර්තු මස 15 වන දින අංක 2114/34 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝග මඟින් සංශෝධිත 2018 අගෝස්තු මස 31 වන දින අංක 2,086/37 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2018 වෛද්‍ය උපකරණ (මිල නියම කිරීමේ) නියෝගයේ උපලේඛනය ඉවත් කොට ඒ වෙනුවට පහත දැක්වෙන උපලේඛනය ආදේශ කිරීමෙන් මෙයින් සංශෝධනය කරනු ලැබේ:-

උපලේඛනය

(2 වන නියෝගය)

කොරෝනාවෛරස උපකරණ නිෂ්පාදන දෙකක උපරිම සිල්ලර මිල

අංකය	I තීරුව	II තීරුව
	වෙළඳ නාමය/අනුමත නාමය	උපරිම සිල්ලර මිල (MRP) (ශ්‍රී ලංකා රුපියල්)
1	රුධිර ග්ලූකෝස් මාපක	එක් ඒකකයක් 3,433.50
2	රුධිර ග්ලූකෝස් මාපකවල භාවිතා කරන පරීක්ෂණ තීරු	එක් පරීක්ෂණ තීරුවක් 62.13

09–50/3

එල්.ඩී.බී-9/2016 (ii)

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 3 වන වගන්තිය සමඟ කියවිය යුතු, 142 වන වගන්තිය යටතේ සෞඛ්‍ය අමාත්‍යවරයා වීසින් සාදනු ලබන නියෝග.

ආචාර්ය කෙහෙළිය රඹුක්වැල්ල,
සෞඛ්‍ය අමාත්‍ය.

2021 අගෝස්තු මස 19 වැනි දින,
කොළඹ දී ය.

නියෝග

2019 මාර්තු මස 15 වන දින අංක 2114/54 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝග මඟින් සංශෝධිත 2017 අගෝස්තු මස 04 වන දින අංක 2030/47 දරන අති විශේෂ ගැසට් පත්‍රයේ පළ කරන ලද 2017 අංක 5 දරන වෛද්‍ය උපකරණ මිල නියම් කිරීමේ නියෝගයෙහි උපලේඛනය ඉවත් කොට ඒ වෙනුවට පහත දැක්වෙන උපලේඛනය ආදේශ කිරීමෙන් මෙයින් සංශෝධනය කරනු ලැබේ:-

උපලේඛනය

(3 වන නියෝගය)

අංකය	I තීරුව	II තීරුව
	අයිතමය	උපරිම සිල්ලර මිල (MRP) රු.
1.	ලෝහමය වටැනේය (Bare Metal Stent)	29,920.50
2.	ඖෂධ ඕදාහරින වටැනේය (Drug Eluting Stent)	130, 800.00

09-50/4

ශ්‍රී ලංකා රජයේ මුද්‍රණ දෙපාර්තමේන්තුවේ මුද්‍රණය කරන ලදී.

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

අංක 2086/37 - 2018 අගෝස්තු මස 31 වැනි සිකුරාදා - 2018.08.31

(රජයේ බලයපිට ප්‍රසිද්ධ කරන ලදි)

I වැනි ඡෙදය: (I) වැනි ඡෙදය - සාමාන්‍ය

රජයේ නිවේදන

එල්.ඩී.බී. 9/2016

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 3 වන සහ 118 වන වගන්ති සමඟ කියවිය යුතු, එම පනතේ 142 වන වගන්තිය යටතේ සෞඛ්‍ය, පෝෂණ සහ දේශීය වෛද්‍ය අමාත්‍යවරයා විසින් සාදනු ලබන නියෝග.

වෛද්‍ය රාජිත සේනාරත්න,
සෞඛ්‍ය, පෝෂණ සහ දේශීය වෛද්‍ය අමාත්‍ය.

2018 අගෝස්තු මස 29 වැනි දින,
කොළඹ දී ය.

නියෝග

2017 දෙසැම්බර් මස 14 වන දින අංක 2049/31 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝග මඟින් සංශෝධිත, 2016 ඔක්තෝබර් මස 21 වන දින අංක 1989/61 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2016 අංක 2 දරන ජාතික ඖෂධ නියාමන අධිකාරී (ඉහළ මිල සීමා) නියෝග පහත දැක්වෙන පරිදි මෙයින් සංශෝධනය කරනු ලැබේ:-

(1) එහි 3 වන නියෝගය ඉවත් කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"3. උපලේඛනගත ඖෂධ සම්බන්ධයෙන් වන උපරිම සිල්ලර මිල (MRP) සීමා උපලේඛනගත ඖෂධවල සියලු වෙළඳ නාමයන් (brand names), ඖෂධ නාමයන් (generic names), ඖෂධ ස්වරූපයන් (dosage forms) සහ ප්‍රබලතාවයන් (strengths) සම්බන්ධයෙන් ද අදාළ විය යුතු ය.".

(2) එහි 5 වන නියෝගයට ඉක්බිතිවම පහත දැක්වෙන නියෝගය ආදේශ කරනු ලබන අතර, එය එහි 5අ නියෝගය ලෙස බලාත්මක විය යුතු ය:-

"5අ. මෙම නියෝග ක්‍රියාත්මක වන දිනයේ සිට හා ඉන්පසුව මෙහි උපලේඛනයේ II වන කොටසේ II වන තීරුවේ නිශ්චිතව දක්වා ඇති යම් උපලේඛනගත ඖෂධයක් විකිණීමේ කාර්යය සඳහා සිය සන්තකයේ තබා ගෙන සිටින යම් පෞද්ගලික වෛද්‍ය ආයතනයක්, ඔසුසලක් හෝ යම් තැනැත්තෙකු ඇතුළු නිෂ්පාදකයෙකු, ආනයනකරුවෙකු, වෙළෙන්දෙකු, බෙදාහරින්නෙකු, ඖෂධවේදීයෙකු, වෛද්‍ය ආයතනයක් විසින් එවැනි කිසිදු ඖෂධයක් ඉහත සී උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිලට (MRP) වඩා වැඩි මිලකට අලෙවි කිරීම නොකළ යුතු ය.".

(3) එහි 5 වන නියෝගයට ඉක්බිතිව ම පහත නියෝගය ඇතුළත් කිරීමෙන්:-

"5අ. යම් උපලේඛනගත ඖෂධයක මාත්‍රා ස්වරූපය හෝ ප්‍රබලතාවය එකී උපලේඛනයේ නිශ්චිතව දක්වා නොමැති අවස්ථාවක, එසේ නිශ්චිතව දක්වා නොමැති එම මාත්‍රාවේ හෝ ප්‍රබලතාවයේ හෝ උපරිම සිල්ලර මිල ජාතික ඖෂධ නියාමන අධිකාරිය විසින් නියම කරනු ලැබිය යුතු ය.

(4) එහි 10 වන නියෝගයට ඉක්බිතිව ම පහත නියෝගය ඇතුළත් කිරීමෙන්:-

"11. මෙම නියෝගවල කාර්යය සඳහා-

"වෛද්‍ය වෘත්තිකයා" යන්නට (105 වන අධිකාරය වූ) වෛද්‍ය ආඥා පනතේ ඊට ඇති අර්ථයම තිබිය යුතු ය.

"පෞද්ගලික වෛද්‍ය ආයතනය" යන්නට 2006 අංක 21 දරන පෞද්ගලික වෛද්‍ය ආයතන (ලියාපදිංචි කිරීමේ) පනතේ ඊට දී ඇති අර්ථයම තිබිය යුතු ය.".

(5) උපලේඛනය යන මාතෘකාවට ඉක්බිතිවම පහත කොටස ඇතුළත් කිරීමෙන්:-

"I වන කොටස"

(6) උපලේඛනයේ I වන කොටසට ඉක්බිතිවම පහත දැක්වෙන කොටස ඇතුළත් කිරීමෙන්:-

"II වන කොටස"

උපලේඛනය

II වන කොටස

තෝරාගත් ඖෂධ නිෂ්පාදන දහකුනක උපරිම සිල්ලර මිල

I තීරුව	*II තීරුව*	*III තීරුව*	*IV තීරුව*	*V තීරුව*
	ඖෂධීය නාමය **(Generic name)**	ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය **(Dosage form)**	ප්‍රබලතාවය **(Strength)**	උපරිම සිල්ලර මිල (ශ්‍රී ලංකා රුපියල්)
1	සෙෆ්ටසිඩිම්	නික්ෂේපන	500 මි.ග්‍රෑම්	480.00
	සෙෆ්ටසිඩිම්	නික්ෂේපන	1 ග්‍රෑම්	800.00
2	සෙෆ්ට්‍රිඇක්සෝන්	නික්ෂේපන	250 මි.ග්‍රෑම්	240.00
	සෙෆ්ට්‍රිඇක්සෝන්	නික්ෂේපන	500 මි.ග්‍රෑම්	450.00
	සෙෆ්ට්‍රිඇක්සෝන්	නික්ෂේපන	1 ග්‍රෑම්	700.00

I නිරුවල	II නිරුවල	III නිරුවල	IV නිරුවල	V නිරුවල
	ඖෂධීය නාමය (Generic name)	ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය (Dosage form)	ප්‍රබලතාවය (Strength)	උපරිම සිල්ලර මිල (ශ්‍රී ලංකා රුපියල්)
3	සෙෆොටැක්සීම්	නික්ෂේපන	500 මි. ග්‍රෑම්	225.00
	සෙෆොටැක්සිම්	නික්ෂේපන	1 ග්‍රෑම්	375.00
4	ෆ්ලුකොනසෝල්	පෙති/කරල්	50 මි.ග්‍රෑම්	25.00
	ෆ්ලුකොනසෝල්	පෙති/කරල්	150 මි.ග්‍රෑම්	45.00
5	ඉන්සියුලින් සොලියුබල් හියුමන්	නික්ෂේපන	100 අයි.යු/1මි.ලී. (10 මි.ලී.කුප්පිය)	1200.00
	ඉන්සියුලින් සොලියුබල් හියුමන්	නික්ෂේපන	100 අයි.යු/1 මි.ලී. (3 මි.ලී. කාට්‍රිජය)	600.00
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නික්ෂේපන	100 අයි.යු/1 මි.ලී. (10 මි.ලී. කුප්පිය)	1200.00
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නික්ෂේපන	100 අයි.යු/1 මි.ලී (3 මි.ලී. කාට්‍රිජය)	600.00
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින්(ඉන්සියුලින් සොලියුබල් හියුමන් 30 අයි.යු/ 1 මි.ලී., ඉන්සියුලින් අයිසොෆෙන් හියුමන් 70 අයි.යු/ 1 මි.ලී. මිශ්‍රණය ලෙස)	නික්ෂේපන	100 අයි.යු/1 මි.ලී. (10 මි.ලී. කුප්පිය)	1200.00
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින්(ඉන්සියුලින් සොලියුබල් හියුමන් 30 අයි.යු/ 1 මි.ලී.) ඉන්සියුලින් අයිසොෆෙන් හියුමන් 70 අයි.යු/ 1 මි.ලී. මිශ්‍රණය ලෙස)	නික්ෂේපන	100 අයි.යු/1 මි.ලී (3 මි.ලී. කාට්‍රිජය)	600.00
6	ග්ලිමිපිරයිඩ්	පෙති	1 මි.ග්‍රෑම්	7.15
	ග්ලිමිපිරයිඩ්	පෙති	2 මි.ග්‍රෑම්	10.15
	ග්ලිමිපිරයිඩ්	පෙති	3 මි.ග්‍රෑම්	17.00
	ග්ලිමිපිරයිඩ්	පෙති	4 මි.ග්‍රෑම්	18.50
7	සිටාග්ලිප්ටින්	පෙති	25 මි.ග්‍රෑම්	15.00
	සිටාග්ලිප්ටින්	පෙති	50 මි.ග්‍රෑම්	28.50
	සිටාග්ලිප්ටින්	පෙති	100 මි.ග්‍රෑම්	48.50
8	ටැම්සුලොසින්	පෙති/කරල්	0.40 මි.ග්‍රෑම්	21.00
9	මොන්ටිලුකාස්ට්	පෙති	4 මි.ග්‍රෑම්	12.00
	මොන්ටිලුකාස්ට්	පෙති	5 මි.ග්‍රෑම්	15.00
	මොන්ටිලුකාස්ට්	පෙති	10 මි.ග්‍රෑම්	21.00

I තීරුව	II තීරුව	III තීරුව	IV තීරුව	V තීරුව
	ඖෂධීය නාමය (Generic name)	ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය (Dosage form)	ප්‍රබලතාවය (Strength)	උපරිම සිල්ලර මිල (ශ්‍රී ලංකා රුපියල්)
10	ප්‍රෙගබලීන්	පෙති/කරල්	50 මි.ග්‍රෑම්	12.25
	ප්‍රෙගබලීන්	පෙති/කරල්	75 මි.ග්‍රෑම්	15.50
	ප්‍රෙගබලීන්	පෙති/කරල්	100 මි.ග්‍රෑම්	19.25
	ප්‍රෙගබලීන්	පෙති/කරල්	150 මි.ග්‍රෑම්	24.00
	ප්‍රෙගබලීන්	පෙති/කරල්	300 මි.ග්‍රෑම්	39.50
11	ටොපිරමේට්	පෙති/කරල්	25 මි.ග්‍රෑම්	20.00
	ටොපිරමේට්	පෙති/කරල්	50 මි.ග්‍රෑම්	32.00
	ටොපිරමේට්	පෙති/කරල්	100 මි.ග්‍රෑම්	52.00
12	ලැමෝට්‍රිජින්	පෙති	25 මි.ග්‍රෑම්	12.00
	ලැමෝට්‍රිජින්	පෙති	50 මි.ග්‍රෑම්	21.00
	ලැමෝට්‍රිජින්	පෙති	100 මි.ග්‍රෑම්	35.00
13	ඇටෝවාස්ටැටින්	පෙති	5 මි.ග්‍රෑම්	6.75
	ඇටෝවාස්ටැටින්	පෙති	40 මි.ග්‍රෑම්	26.00

09 - 322/01

ඵල්.ඊ.බී. 9/2016

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 3 වන සහ 118 වන වගන්ති සමග කියවිය යුතු, එම පනතේ 142 වන වගන්තිය යටතේ සෞඛ්‍ය, පෝෂණ සහ දේශීය වෛද්‍ය අමාත්‍යවරයා විසින් සාදනු ලබන නියෝග.

වෛද්‍ය රාජිත සේනාරත්න,
සෞඛ්‍ය, පෝෂණ සහ දේශීය වෛද්‍ය අමාත්‍ය.

2018 අගෝස්තු මස 29 වැනි දින,
කොළඹ දී ය.

නියෝග

1. මෙම නියෝග 2018 ඖෂධ (ටෙන්ඩර් මිල නියම කිරීමේ) නියෝග යනුවෙන් හඳුන්වනු ලැබේ.

2. මෙහි උපලේඛනයේ නිශ්චිතව දක්වා ඇති ඖෂධ (මෙහි මින්මතු "උපලේඛනගත ඖෂධ" යනුවෙන් සඳහන් කරනු ලබන) සඳහා වන උපරිම ටෙන්ඩර් මිල (මෙහි මින්මතු "උපරිම ටෙන්ඩර මිල (MTP)" යනුවෙන් සඳහන් කරනු ලබන) සඳහා උපරිම මිල සීමාවක් පැවතිය යුත්තේ ය.

3. උපලේඛනගත ඖෂධ සම්බන්ධයෙන් වන උපරිම ටෙන්ඩර් මිල (MTP) සීමා උපලේඛනගත ඖෂධවල සියලු වෙළඳ නාමයන් (Brand names), ඖෂධ නාමයන් (Generic names), මාත්‍රා ස්වරූපයන් (Dosage forms) සහ ප්‍රබලතාවයන් (Strengths) සම්බන්ධයෙන් ද අදාළ විය යුතු ය.

4. මේ නියෝග ක්‍රියාත්මක වන දිනයේ සිට හා ඉන්පසුව මෙහි උපලේඛනයේ II වන තීරුවේ දක්වා ඇති යම් උපලේඛනගත ඖෂධයක් ප්‍රසම්පාදනය කිරීමේ දී හෝ හදිසි මිලදී ගැනීමක් සඳහා මිල ගණන් ඉදිරිපත් කිරීමේ දී කිසිදු නිෂ්පාදකයකු, ආනයනකරුවෙකු, වෙළෙන්දෙකු, බෙදාහරින්නෙකු හෝ වෙනත් යම් තැනැත්තකු විසින් එකී කිසිදු ඖෂධයක් සඳහා ඉහත කී උපලේඛනයේ V වන තීරුවේ දක්වා ඇති උපරිම ටෙන්ඩර් මිලට (MTP) වඩා වැඩි මිලකට ලංසු තැබීම හෝ මිල ගණන් ඉදිරිපත් කිරීම හෝ නොකළ යුතු ය.

5. මේ නියෝග ක්‍රියාත්මක වන දිනයේ සිට, මෙහි උපලේඛනයේ II වන තීරුවේ දක්වා ඇති යම් උපලේඛනගත ඖෂධයක් වෙනුවෙන් යම් රාජ්‍ය හෝ අර්ධ රාජ්‍යය ආයතනයක් විසින් ටෙන්ඩරයක් පිළිගැනීමේ දී හෝ හදිසි මිල දී ගැනීමක් සිදු කිරීමේ දී එකී ඖෂධය සඳහා ඉහත කී උපලේඛනයේ V වන තීරුවේ දක්වා ඇති උපරිම ටෙන්ඩර් මිලට (MTP) වඩා වැඩි මිලකට ටෙන්ඩරය පිළිගැනීම හෝ හදිසි මිල දී ගැනීම සිදු නොකළ යුතු ය.

6. ප්‍රසම්පාදනය හෝ හදිසි මිල දී ගැනීමේ කාර්යය සඳහා යම් උපලේඛනගත ඖෂධයක මාත්‍රා ස්වරූපයන් හෝ ප්‍රබලතාවන් හෝ එකී උපලේඛනයේ නිශ්චිතව දක්වා නොමැති අවස්ථාවක, එකී මාත්‍රාවේ හෝ ප්‍රබලතාවයේ හෝ උපරිම ටෙන්ඩර් මිල ජාතික ඖෂධ නියාමන අධිකාරිය විසින් නියම කරනු ලැබිය යුතු ය.

7. ඉහත නියෝගවල විධිවිධානවල කුමක් සඳහන් ව ඇත ද, උපලේඛනයේ නිශ්චිතව දක්වා ඇති එක් එක් උපලේඛනගත ඖෂධවල මාත්‍රා ස්වරූපයේ එක් ඒකකයක උපරිම ටෙන්ඩර් මිල එකී උපලේඛනයේ නිශ්චිතව දක්වා ඇති පරිදි විය යුතු වන අතර, ප්‍රතිශෝධනය කරනු ලබන තෙක් එකී උපරිම ටෙන්ඩර් මිල මේ නියෝග ක්‍රියාත්මක වන දින සිට හා ඉන්පසුව බලාත්මකව පැවතිය යුතු ය.

8. මේ නියෝගවල විධිවිධාන උල්ලංඝනය කරනු ලබන යම් තැනැත්තෙකු හෝ ආයතනයක් විසින් 2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත යටතේ වරදක් සිදු කරනු ලබන අතර, එකී පනතේ IV වන කොටස යටතේ එම තැනැත්තාට හෝ ආයතනයට එරෙහිව නඩු පවරනු ලැබිය යුතු ය.

උපලේඛනය

නොරාගත් ඖෂධ නිෂ්පාදන දහයක උපරිම ටෙන්ඩර් මිල

I තීරුව	*II තීරුව*	*III තීරුව*	*IV තීරුව*	*V තීරුව*
	ඖෂධීය නාමය (Generic name)	ලබා ගනු ලබන ක්‍රමය/ මාත්‍රා ආකාරය (Dosage form)	ප්‍රබලතාවය (Strength)	උපරිම ටෙන්ඩර් මිල (ශ්‍රී ලංකා රුපියල්)
1	ට්‍රැස්ටුසුමැබ්	නික්ෂේපක	150 මි.ග්‍රෑම්	32,390.00
	ට්‍රැස්ටුසුමැබ්	නික්ෂේපන	440 මි.ග්‍රෑම්	95,000.00
2	බෙවැසිසුමැබ්	නික්ෂේපන	100 මි.ග්‍රෑම්/4 මි.ලි.	35,000.00

I තීරුව	II තීරුව	III තීරුව	IV තීරුව	V තීරුව
	ඖෂධීය නාමය (Generic name)	ලබා ගනු ලබන ක්‍රමය/ මාත්‍රා ආකාරය (Dosage form)	ප්‍රබලතාවය (Strength)	උපරිම තෙන්ඩර් මිල (ශ්‍රී ලංකා රුපියල්)
3	රිටුක්සිමැබ්	නික්ෂේපන	100 මි.ග්‍රෑම්/10 මි.ලී.	11,000.00
	රිටුක්සිමැබ්	නික්ෂේපන	500 මි.ග්‍රෑම්/50 මි.ලී.	55,000.00
4	මයිකොෆිනොලේට් මොෆෙටිල්	පෙති/කරල්	500 මි.ග්‍රෑම්	15.00
5	පෙග් ඇස්පරජිනේස් (පෙග් ඇස්පාරේස්)	නික්ෂේපන	3750 අයි.යු.	140,000.00
6	පෙමිට්‍රෙක්සඩ් ඩයිසෝඩියම්	නික්ෂේපන	100 මි.ග්‍රෑම්	3,120.00
	පෙමිට්‍රෙක්සඩ් ඩයිසෝඩියම්	නික්ෂේපන	500 මි.ග්‍රෑම්	15,600.00
7	බෝටිසෝමිබ්	නික්ෂේපන	2 මි.ග්‍රෑම්	14,500.00
8	පෙග් ඉන්ටෙරෝන් ඇල්ෆා 2 ඒ	නික්ෂේපන	180 මයික්‍රෝ.ග්‍රෑම්	27,700.00
9	ඇබිරටෙරෝන් ඇසිටේට්	පෙති	250 මි.ග්‍රෑම්	275.00
10	පෙග් ෆිල්ග්‍රැස්ටිම්	නික්ෂේපන	6 මි.ග්‍රෑම්/0.6 මි.ලී., 6 මි.ග්‍රෑම්/1 මි.ලී.	22,000.00

09 - 322/02

එල්.ඩී.බී. 9/2016

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 3 වන සහ 118 වන වගන්ති සමඟ කියවිය යුතු, එකී පනතේ 142 වන වගන්තිය යටතේ සෞඛ්‍ය, පෝෂණ සහ දේශීය වෛද්‍ය අමාත්‍යවරයා විසින් සාදනු ලබන නියෝග.

වෛද්‍ය රාජිත සේනාරත්න,
සෞඛ්‍ය, පෝෂණ සහ දේශීය වෛද්‍ය අමාත්‍ය.

2018 ක් වූ අගෝස්තු මස 29 වැනි දින,
කොළඹ දී ය.

නියෝග

1. මෙම නියෝග 2018 වෛද්‍ය උපකරණ (මිල නියම කිරීමේ) නියෝග යනුවෙන් හඳුන්වනු ලැබේ.

2. කිසිදු නිෂ්පාදකයකු, ආනයනකරුවකු, බෙදාහරින්නකු, වෙළෙන්දෙකු, සැපයුම්කරුවකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු යම් වෛද්‍ය ආයතනයක් හෝ යම් වෛද්‍ය උපකරණ සන්තකයේ දරන්නකු විසින් යම් වෙළඳ නාමයකින් (Brand Name), අනුමත නාමයකින් (Approved Name), මාදිලියකින් (Models), ප්‍රමාණයකින්(Sizes), හෝ ඇසුරුම් ප්‍රමාණයකින් (Pack Sizes) විස්තර වන මෙහි උපලේඛනයේ දක්වා ඇති යම් වෛද්‍ය උපකරණයක් එහි දක්වා ඇති උපරිම සිල්ලර මිලට (MRP) වඩා වැඩි මිලකට අලෙවි කිරීම, අලෙවි කිරීම සඳහා ඉදිරිපත් කිරීම හෝ ඒ සඳහා අය කිරීම නොකළ යුතු ය.

3. නිෂ්පාදකයකු, ආනයනකරුවකු, බෙදාහරින්නකු, වෙළෙන්දෙකු, සැපයුම්කරුවකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු යම් වෛද්‍ය ආයතනයක් හෝ යම් වෛද්‍ය උපකරණ සන්තකයේ දරන්නකු විසින් මෙහි උපලේඛනයේ දක්වා ඇති යම් වෛද්‍ය උපකරණයක් දැනට එහි දක්වා ඇති උපරිම සිල්ලර මිලට වඩා අඩු යම් මිලකට විකුණනු ලබන විට ඔහු විසින් එහි මිල වැඩිකිරීමෙන් තොරව එහි පවත්නා මිල අබන්ඩව පවත්වාගෙන යා යුතු ය.

4. වෙළඳ නාමයෙන්, අනුමත නාමයෙන්, මාදිලියෙන්, ප්‍රමාණයෙන් හෝ ඇසුරුම් ප්‍රමාණයෙන් මෙහි උපලේඛනයේ විස්තර කර ඇති යම් වෛද්‍ය උපකරණයක් අලෙවි කරන හෝ අලෙවිය සඳහා ඉදිරිපත් කරනු ලබන හෝ ඒ සඳහා අය කරන සෑම තැනැත්තකුම් හෝ 2 වන නියෝගයේ දක්වා ඇති ආයතනයක් එම වෛද්‍ය උපකරණය වෙනම අයිතමයක් ලෙස දක්වමින් වෛද්‍ය උපකරණයේ වෙළඳ නාමය හෝ අනුමත නාමය, ඇසුරුම් ප්‍රමාණය සහ මිල පැහැදිලිව දක්වන රිසිට් පතක් නිකුත් කළ යුතු ය.

5. නිෂ්පාදිත හෝ විකිණීමට තිබෙන වෛද්‍ය උපකරණ තොගයේ අයිතම්වල එක් එක් ඒකකයේ මෙහි උපලේඛනයේ දක්වා ඇති අදාළ උපරිම සිල්ලර මිල ප්‍රායෝගිකව හැකිතාක් ඉක්මණින් එසේ වුව ද, මෙම නියෝග පළ කරන ලද දිනයේ සිට දින හතළිස් පහක කාලසීමාවක් ඉකුත් වීමට පෙර අදාළ වෙළඳ ඇසුරුමේ හෝ ලේබලයේ මුද්‍රණය හෝ සළකුණු කළ යුතු ය.

6. මේ නියෝගවල විධිවිධාන උල්ලංඝනය කරනු ලබන යම් නිෂ්පාදකයකු, ආනයනකරුවකු, බෙදාහරින්නකු, වෙළෙන්දෙකු, සැපයුම්කරුවකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු යම් වෛද්‍ය ආයතනයක් හෝ යම් වෛද්‍ය උපකරණ සන්තකයේ දරන තැනැත්තකු විසින් වරදක් සිදු කරනු ලබන අතර, 2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ IV වන කොටස යටතේ ඔහුට එරෙහිව නඩු විභාග කරනු ලැබිය යුතු ය.

7. මෙහි උපලේඛනයේ දක්වා ඇති වෛද්‍ය උපකරණවල උපරිම සිල්ලර මිල සෑම සිල්ලර අලෙවිසලකම ප්‍රදර්ශනය කිරීම සෑම නිෂ්පාදකයකු, ආනයනකරුවකු, බෙදාහරින්නකු, වෙළෙන්දෙකු, සැපයුම්කරුවකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු යම් වෛද්‍ය ආයතනයක් සහ යම් වෛද්‍ය උපකරණ සන්තකයේ දරන්නකුගේ වගකීම විය යුතු ය.

8. එම වෛද්‍ය උපකරණවල වෙළඳ නාමය, මාදිලිය, ප්‍රමාණය හෝ ඇසුරුම් ප්‍රමාණයේ උපරිම සිල්ලර මිල උපලේඛනයේ නිශ්චිතව දක්වා නොමැති අවස්ථාවක, එම උපරිම සිල්ලර මිල ජාතික ඖෂධ නියාමන අධිකාරිය මඟින් නියම කළ යුතු ය.

9. මේ නියෝගවල -

"වෛද්‍ය වෘත්තිකයා" යන්නට (105 වන අධිකාරය) වූ වෛද්‍ය ආඥා පනතේ ඊට දී ඇති අර්ථයම තිබිය යුතු ය.

"පෞද්ගලික වෛද්‍ය ආයතනය" යන්නට 2006 අංක 21 දරන පෞද්ගලික වෛද්‍ය ආයතන (ලියාපදිංචි කිරීමේ) පනතේ ඊට දී ඇති අර්ථය ම තිබිය යුතු ය.

526

උපලේඛනය

නෝරාගත් වෛද්‍ය උපකරණ නිෂ්පාදන දෙකක උපරිම සිල්ලර මිල

I තීරුව	II තීරුව	III තීරුව
	වෙළඳ නාමය/ අනුමත නාමය **(Brand name /Approved name)**	උපරිම සිල්ලර මිල *(MRP)* (ශ්‍රී ලංකා රුපියල්)
1	රුධිර ග්ලූකෝස් මාපක	එක් ඒකකයක් 2,750.00
2	රුධිර ග්ලූකෝස් මාපකවල භාවිතා කරන පරීක්ෂණ තීරු	එක් පරීක්ෂණ තීරුවක් 50.00

09 - 322/03

ශ්‍රී ලංකා රජයේ මුද්‍රණ දෙපාර්තමේන්තුවේ මුද්‍රණය කරවා ලදි.

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

අංක 2110/8 - 2019 පෙබරවාරි මස 11 වැනි සඳුදා - 2019.02.11

(රජයේ බලයඩිට ප්‍රසිද්ධ කරන ලදී)

I වැනි කොටස: (I) වැනි ඡෙදය - සාමාන්‍ය

රජයේ නිවේදන

එල්.ඩී-බී 9/2016.

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 3 වන සහ 118 වන වගන්ති සමග කියවිය යුතු, එම පනතේ 142 වන වගන්තිය යටතේ සෞඛ්‍ය, පෝෂණ හා දේශීය වෛද්‍ය අමාත්‍යවරයා විසින් සාදනු ලබන නියෝග.

වෛද්‍ය රාජිත සේනාරත්න,
සෞඛ්‍ය, පෝෂණ හා දේශීය වෛද්‍ය අමාත්‍ය.

2019 පෙබරවාරි මස 11 වැනි දින,
කොළඹ දී ය.

නියෝග

2018 අගෝස්තු මස 31 වන දින අංක 2086/37 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2018 ඖෂධ (ටෙන්ඩර් මිල නියම කිරීමේ) නියෝග, එහි උපලේඛනයේ 4 වන අයිතමය ඉවත්කොට ඒ වෙනුවට පහත දැක්වෙන කොටස ආදේශ කිරීමෙන් මෙයින් සංශෝධනය කරනු ලැබේ :—

4	මැඩිකොෆිනොලේට් මොෆෙටිල්	පෙති/කැප්ල්	500 මි.ග්‍රෑම්	45.00

IA - G 29377 — 517 (2019/02) ශ්‍රී ලංකා රජයේ මුද්‍රණ දෙපාර්තමේන්තුවේ මුද්‍රණය කරන ලදී.
මෙම අති විශෙෂ ගැසට් පත්‍රය www.documents.gov.lk වෙබ් අඩවියෙන් බාගත කළ හැක.

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

අංක 2271/23 - 2022 මාර්තු මස 15 වැනි අඟහරුවාදා - 2022.03.15

(රජයේ බලයපිට ප්‍රසිද්ධ කරන ලදී)

I වැනි කොටස: (I) වැනි ඡෙදය - සාමාන්‍ය

රජයේ නිවේදන

එල්.ඩී.බී. 9/2016 (II)

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 142 වන වගන්තිය යටතේ සෞඛ්‍ය අමාත්‍යවරයා විසින් සාදනු ලබන නියෝග.

ආචාර්ය කෙහෙළිය රඹුක්වැල්ල,
සෞඛ්‍ය අමාත්‍ය.

2022 මාර්තු මස 15 වැනි දින,
කොළඹ දී ය.

නියෝග

2021 අගෝස්තු මස 19 වැනි දින අංක 2241/43 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළකරන ලද නියෝග මගින් සංශෝධිත 2019 මැයි මස 15 වැනි දින අංක 2123/35 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2019 ඖෂධ (මිල ඉහළ සීමා)නියෝග පහත දැක්වෙන පරිදි මෙයින් සංශෝධනය කරනු ලැබේ:-

(1) එහි 1 වන නියෝගය ඉවත්කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"1. මෙම නියෝග 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝග යනුවෙන් හඳුන්වනු ලැබේ.";

1A - G 36378— 15 (2022/03)
මෙම අති විශෙෂ ගැසට් පත්‍රය www.documents.gov.lk වෙබ් අඩවියෙන් බාගත කළ හැක.

(2) එහි 2 වන නියෝගය ඉවත් කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"2. මෙහි උපලේඛනයේ II වන තීරුවේ නිශ්චිතව දක්වා ඇති ඖෂධීය නාමය සහිත එහි III වන තීරුවේ අනුරූපි සටහනේ නිශ්චිතව දක්වා ඇති මාත්‍රා ආකාරයෙන් හෝ ලබා ගනු ලබන ක්‍රමයෙන් යුත් මෙහි IV වන තීරුවේ අනුරූපි සටහනේ නිශ්චිතව දක්වා ඇති ප්‍රබලතාවයෙන් යුත් ඖෂධවල (මෙහි ඉන්මඳු "උපලේඛනගත ඖෂධ"යනුවෙන් සඳහන් කරනු ලබන) උපරිම සිල්ලර මිල මෙහි උපලේඛනයේ V වන තීරුවේ අනුරූපි සටහනේ නිශ්චිතව දක්වා ඇති පරිදි විය යුතු ය.";

(3) එහි 3 වන නියෝගය ඉවත් කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"3. උපලේඛනගත ඖෂධ පිළිබඳ වන උපරිම සිල්ලර මිල, එම උපලේඛනගත ඖෂධවල ඖෂධීය නාමයේ සියලු වෙළඳ නාමයන් සඹඳපැවසෙන් අදාළ විය යුතු ය.";

(4) එහි 4 වන නියෝගය ඉවත් කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"4. වික්‍රිණීමේ කාර්යය සඳහා උපලේඛනගත ඖෂධ සන්තකයේ තබාගෙන සිටින යම් නිෂ්පාදකයකු, ආනයනකරුවකු, වෙළෙන්දකු, බෙදාහරින්නකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, දන්ත වෛද්‍යවරයකු, පශු වෛද්‍යවරයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු වෛද්‍ය ආයතනයක්, ඔසුසලක් හෝ තැනැත්තකු විසින් ඒ උපලේඛනගත ඖෂධ උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිලට හෝ 6 වන නියෝගයේ විධිවිධානවලට අනුකූලව නිශ්චය කරනු ලැබිය හැකි ප්‍රතිශෝධිත සිල්ලර මිලට හෝ වඩා වැඩි මිලකට විකුණනු නොලැබිය යුතු ය.";

(5) එහි 6 වන නියෝගය ඉවත් කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"6. (1) මේ නියෝග පළ කරනු ලබන දිනයේ දී, 2019 මැයි මස 15 වැනි දින අංක 2123/35 දරන අතිවිශේෂ ගැසට් පත්‍රයේ පළ කරන ලද 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝගවල උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිලට වඩා අඩු මිලක් වන යම් ප්‍රතිශෝධිත සිල්ලර මිලකට 2021 අගෝස්තු මස 19 වැනි දින අංක 2241/43 දරන අතිවිශේෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝග මගින් සංශෝධිත 2019 මැයි මස 15 දින අංක 2123/35 දරන අතිවිශේෂ ගැසට් පත්‍රයේ පළ කරන ලද 2019 ඖෂධ (මිළ ඉහළ සීමා) නියෝග යටතේ පැරසිටමෝල් නොවන යම් උපලේඛනගත ඖෂධයක් විකුණනු ලබන යම් නිෂ්පාදකයකු හෝ ආනයනකරුවකු විසින් එම ප්‍රතිශෝධිත සිල්ලර මිල සමානුපාතිකව සම්පූර්ණ වශයෙන් සියයට නිස් අටක ප්‍රතිශතයකින් (38%) වැඩි කරනු ලැබිය හැකි ය. එම සියයට නිස් අටක (38%) සම්පූර්ණ වැඩිවීම සඳහා 2021 අගෝස්තු මස 19 වැනි දින අංක 2241/43 දරන අතිවිශේෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝග මගින් වැඩි කරන ලද සියයට නවයක ප්‍රතිශතය (9%) සහ මෙම නියෝග මගින් වැඩි කරන ලද අනෙක් සියයට විසි නවයක ප්‍රතිශතය (29%) ඇතුළත් විය යුතු ය:

(2) (අ) මේ නියෝග පළ කරනු ලබන දිනයේ දී, 2022 පෙබරවාරි මස 28 වැනි දින අංක 2269/11 දරන අතිවිශේෂ ගැසට් පත්‍රයේ පළ කරන ලද 2022 ඖෂධ (මි.ග්‍රෑ 500 පැරසිටමෝල් පෙති/කැප්ලට් මිල නියම කිරීමේ) නියෝග යටතේ මෙහි උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිලට වඩා අඩු යම් ප්‍රතිශෝධිත සිල්ලර මිලකට පැරසිටමෝල් විකුණනු ලබන යම් නිෂ්පාදකයකු හෝ ආනයනකරුවකු විසින් එම ප්‍රතිශෝධිත සිල්ලර මිල සමානුපාතිකව සම්පූර්ණ වශයෙන් සියයට විසි නවයක ප්‍රතිශතයකින් (29%)වැඩි කරනු ලැබිය හැකි ය.

(අ) සැක දුරු කිරීමේ කාර්යය සඳහා, 2022 පෙබරවාරි මස 28 වැනි දින අංක 2269/11 දරන අතිවිශේෂ ගැසට් පත්‍රයේ පළකරන ලද 2022 ඖෂධ (මි.ග්‍රෑ. 500 පැරසිටමෝල් පෙති/කැප්ලට් මිල නියම කිරීමේ) නියෝග මගින් වැඩි කරන ලද සම්පූර්ණ වැඩි වීම වන සියයට තිස් පහක ප්‍රතිශතය (35%) සඳහා 2021 අගෝස්තු මස 19 වැනි දින අංක 2241/43 දරන අතිවිශේෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝග මගින් පැරසිටමෝල් සඳහා වැඩි කරන ලද සියයට නවයක (9%) ප්‍රතිශතය ඇතුළත් විය යුතු බවට මෙයින් ප්‍රකාශ කරනු ලැබේ.

(3) (1) වන සහ (2) වන අනු නියෝගවල විධිවිධානවල කුමක් සඳහන් වුව ද, උපලේඛනගත ඖෂධවල ප්‍රතිශෝධිත සිල්ලර මිලෙහි එවැනි වැඩි කිරීමක් මෙහි උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිල නොඉක්මවිය යුතු ය.

(4) වික්‍රිණීමේ කාර්යය සඳහා උපලේඛනගත ඖෂධ සන්තකයේ තබාගෙන සිටින සෑම වෙළෙන්දකු, බෙදාහරින්නකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, දන්ත වෛද්‍යවරයකු, පශු වෛද්‍යවරයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු වෛද්‍ය ආයතනයක්, ඔසුසලක් හෝ තැනැත්තකු විසින් උපලේඛනගත ඖෂධවල මිල, උපරිම සිල්ලර මිල හෝ ප්‍රතිශෝධිත සිල්ලර මිල යන දෙකෙන් වඩාත් අඩු මිලෙහි පවත්වාගෙන යා යුතු ය."

(6) එහි 7 වන නියෝගය ඉවත් කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"7. උපලේඛනගත ඖෂධවල යම් මාත්‍රා ආකාරයක් හෝ ප්‍රබලතාවයක් සහ උපලේඛනගත ඖෂධවල එම මාත්‍රා ආකාරයේ හෝ ප්‍රබලතාවයේ උපරිම සිල්ලර මිල මෙහි උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා නොමැති අවස්ථාවක දී, ජාතික ඖෂධ නියාමන අධිකාරිය විසින් ඒ මාත්‍රා ආකාරයේ හෝ ප්‍රබලතාවයේ උපලේඛනගත ඖෂධ සඳහා වන මිල නියම කරනු ලැබිය යුතු ය.";

(7) එහි 8 වන නියෝගය ඉවත් කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"8. යම් නිෂ්පාදකයකු හෝ ආනයනකරුවකු විසින් මෙහි උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිල හෝ ප්‍රතිශෝධිත සිල්ලර මිල යන දෙකෙන් වඩාත් අඩු මිල නිෂ්පාදිත හෝ වෙළඳපොලේ පවතින තොගයේ උපලේඛනගත ඖෂධවල වෙළඳ ඇසුරුම් හෝ ලේබලය මත ප්‍රායෝගිකව හැකිතාක් ඉක්මනින් මුද්‍රණය හෝ සලකුණු කරනු ලැබිය යුතු ය:

එසේ වුවද, මේ නියෝග පළකරනු ලබන දින සිට දින හතළිස් පහක කාලසීමාවක් ඉකුත්වීමට පෙර උපරිම සිල්ලර මිල හෝ ප්‍රතිශෝධිත සිල්ලර මිල යන දෙකෙන් වඩාත් අඩුමිල උපලේඛනගත ඖෂධවල වෙළඳ ඇසුරුම් හෝ ලේබලය මත මුද්‍රණය හෝ සලකුණු කරනු ලැබිය යුතු ය.";

(8) එහි 9 වන නියෝගය ඉවත් කිරීමෙන්;

(9) එහි 10 වන නියෝගය ඉවත්කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"10. මේ නියෝගවල විධිවිධාන ඵලදායීකරනය කරනු ලබන යම් තැනැත්තකු විසින් විරුද්ධ සිදුකරනු ලබන අතර 2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 131 වන වගන්තිය යටතේ ඔහුට එරෙහිව නඩු පවරනු ලැබිය යුතු ය.";

(10) එහි 11 වන නියෝගය ඉවත්කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"11. උපලේඛනගත ඖෂධවල උපරිම සිල්ලර මිල හෝ ප්‍රතිශෝධිත සිල්ලර මිල යන දෙකෙන් වඩාත් අඩු මිල සෑම සිල්ලර අලෙවි සලකම ප්‍රදර්ශනය කිරීම, විකිණීමේ කාර්යය සඳහා උපලේඛනගත ඖෂධ සන්තකයේ තබාගෙන සිටින සෑම නිෂ්පාදකයකු, ආනයනකරුවකු, වෙළෙන්දකු, බෙදාහරින්නකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, දන්ත වෛද්‍යවරයකු, පශු වෛද්‍යවරයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු වෛද්‍ය ආයතනයක, ඔසුසලක හෝ තැනැත්තකුගේම වගකීම විය යුතු ය.";

(11) "වෛද්‍ය වෘත්තිකයා" යන යෙදුමේ අර්ථ නිරූපණයට ඉක්බිතිවම පහත දැක්වෙන අර්ථ නිරූපණය ඇතුළත් කිරීමෙන්:-

"තැනැත්තා" යන්නට, සංයෝගත කළ හෝ නොකළ පුද්ගල මණ්ඩලයක් ඇතුළත් වේ;"; සහ

(12) එහි උපලේඛනය ඉවත්කර ඒ වෙනුවට පහත දැක්වෙන උපලේඛනය ආදේශ කිරීමෙන්:-

"උපලේඛනය

(2 වන නියෝගය)

ඖෂධවල උපරිම සිල්ලර මිල

I වන තීරුව	*II වන තීරුව* *ඖෂධීය නාමය*	*III වන තීරුව* *ලබා දෙනු ලබන ප්‍රමාණය/ඖෂධ ආකාරය*	*IV වන තීරුව* *ප්‍රබලතාවය*	*V වන තීරුව* *උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්*
1	ඇල්බෙන්ඩසෝල්	පෙති/කරල්	400 මි.ග්‍රෑ	50.67
2	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	156 මි.ග්‍රෑ/5 මි.ලි	485.59

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා දෙනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	පෙති/කරල්	375 මි.ග්‍රෑ	59.79
	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	පෙති/කරල්	625 මි.ග්‍රෑ	101.33
	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	එන්නත්	1.2 ග්‍රෑ	1065.76
3	ක්ලැරිත්‍රෝමයිසින්	පෙති/කරල්	250 මි.ග්‍රෑ	61.65
	ක්ලැරිත්‍රෝමයිසින්	පෙති/කරල්	500 මි.ග්‍රෑ	124.99
	ක්ලැරිත්‍රෝමයිසින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	125 මි.ග්‍රෑ/5 මි.ලී.	736.40
4	ඇසිත්‍රෝමයිසීන්	පෙති/කරල්	250 මි.ග්‍රෑ	63.51
	ඇසිත්‍රෝමයිසින්	පෙති/කරල්	500 මි.ග්‍රෑ	89.10
	ඇසිත්‍රෝමයිසීන්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	200 මි.ග්‍රෑ/5 මි.ලී.	295.56
5	සෙෆියුරොක්සිම්	පෙති/කරල්	250 මි.ග්‍රෑ	76.85
	සෙෆියුරොක්සිම්	පෙති/කරල්	500 මි.ග්‍රෑ	122.61
6	ඩොක්සිසයික්ලීන්	පෙති/කරල්	100 මි.ග්‍රෑ	17.07
7	ඇසික්ලොවීර්	පෙති/කරල්	200 මි.ග්‍රෑ	62.47
8	සිප්‍රොෆ්ලොක්සසීන්	පෙති/කරල්	250 මි.ග්‍රෑ	9.71
	සිප්‍රොෆ්ලොක්සසීන්	පෙති/කරල්	500 මි.ග්‍රෑ	14.36
9	ලෙවොෆ්ලොක්සසීන්	පෙති/කරල්	250 මි.ග්‍රෑ	40.87
	ලෙවොෆ්ලොක්සසීන්	පෙති/කරල්	500 මි.ග්‍රෑ	67.56
10	සෙපලෙක්සින්	පෙති/කරල්	250 මි.ග්‍රෑ	13.84
	සෙපලෙක්සින්	පෙති/කරල්	500 මි.ග්‍රෑ	25.35
	සෙපලෙක්සින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	125 මි.ග්‍රෑ/5 මි.ලී.	447.58
11	සෙෆික්සිම්	පෙති/කරල්	100 මි.ග්‍රෑ	38.84
	සෙෆික්සිම්	පෙති/කරල්	200 මි.ග්‍රෑ	72.12
	සෙෆික්සිම්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	100 මි.ග්‍රෑ/5 මි.ලී.	582.69

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා දෙනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
12	ඇම්ලොඩිපින්	පෙති/කරල්	5 මි.ග්‍රෑ	25.84
	ඇම්ලොඩිපින්	පෙති/කරල්	10 මි.ග්‍රෑ	35.98
13	බිල්ටියසම්	පෙති/කරල්	30 මි.ග්‍රෑ	4.57
	බිල්ටියසම්	පෙති/කරල්	60 මි.ග්‍රෑ	15.04
	බිල්ටියසම්	පෙති/කරල්	90 මි.ග්‍රෑ	36.15
14	ලොසාටන් පොටෑසියම්	පෙති/කරල්	25 මි.ග්‍රෑ	12.41
	ලොසාටන් පොටෑසියම්	පෙති/කරල්	50 මි.ග්‍රෑ	17.40
15	ලොසාටන්-හයිඩ්‍රොක්ලෝරෝතයෝසයිඩ්	පෙති/කරල්	62.5 මි.ග්‍රෑ	32.84
16	එනලප්‍රිල්	පෙති/කරල්	5 මි.ග්‍රෑ	10.13
	එනලප්‍රිල්	පෙති/කරල්	10 මි.ග්‍රෑ	17.07
17	ඇටිනොලෝල්	පෙති/කරල්	25 මි.ග්‍රෑ	5.06
	ඇටිනොලෝල්	පෙති/කරල්	50 මි.ග්‍රෑ	7.43
	ඇටනොලෝල්	පෙති/කරල්	100 මි.ග්‍රෑ	21.96
18	නිෆඩිපින්-දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/කරල්	20 මි.ග්‍රෑ	6.26
19	ක්ලෝපිඩොග්‍රෙල්	පෙති/කරල්	75 මි.ග්‍රෑ	29.57
20	ඇටෝවාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑම්	10.85
	ඇටෝවාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ	18.83
	ඇටෝවාස්ටැටින්	පෙති/කරල්	20 මි.ග්‍රෑ	29.72
	ඇටෝවාස්ටැටින්	පෙති/කරල්	40 මි.ග්‍රෑම්	41.81
21	රොසුවාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑ	36.31
	රොසුවාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ	62.47
22	ටෙල්මිසාටන්	පෙති/කරල්	20 මි.ග්‍රෑ	17.22
	ටෙල්මිසාටන්	පෙති/කරල්	40 මි.ග්‍රෑ	27.36
	ටෙල්මිසාටන්	පෙති/කරල්	80 මි.ග්‍රෑ	51.34

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/ඖෂධ ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
23	ඇස්පිරින්	පෙති/කරල්	75 මි.ග්‍රෑ.	5.06
	ඇස්පිරින්	පෙති/කරල්	100 මි.ග්‍රෑ.	8.95
24	මෙට්ෆෝමින්	පෙති/කරල්	500 මි.ග්‍රෑ.	6.67
	මෙට්ෆෝමින් - දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/කරල්	500 මි.ග්‍රෑ.	13.00
	මෙට්ෆෝමින්	පෙති/කරල්	850 මි.ග්‍රෑ.	12.50
25	ග්ලිබෙන්ක්ලමයිඩ්	පෙති/කරල්	5 මි.ග්‍රෑ.	3.70
26	ග්ලික්ලැසයිඩ්	පෙති/කරල්	80 මි.ග්‍රෑ.	19.09
27	නයිරොක්සින්	පෙති/කරල්	50 මයික්‍රෝ ග්‍රෑ.	10.29
	නයිරොක්සින්	පෙති/කරල්	100 මයික්‍රෝ ග්‍රෑ.	15.38
28	ග්ලිමිපයිඩ්	පෙති/කරල්	5 මි.ග්‍රෑ.	13.35
29	ඉබියුප්‍රොෆෙන්	පෙති/කරල්	200 මි.ග්‍රෑ.	1.86
	ඉබියුප්‍රොෆෙන්	පෙති/කරල්	400 මි.ග්‍රෑ.	6.26
30	ඩයික්ලොෆෙනැක් සෝඩියම්	පෙති/කරල්	50 මි.ග්‍රෑ.	21.96
	ඩයික්ලොෆෙනැක් සෝඩියම්	පෙති/කරල්	100 මි.ග්‍රෑ.	25.50
31	ඩයික්ලොෆෙනැක් පොටෑසියම්	පෙති/කරල්	50 මි.ග්‍රෑ.	18.50
32	පැරසිටමෝල්	පෙති/කරල්	500 මි.ග්‍රෑ.	2.97
33	සෝඩියම් වැල්ප්‍රොඒට්	පෙති/කරල්	200 මි.ග්‍රෑ.	15.20
34	රිස්පෙරිඩොන්	පෙති/කරල්	1 මි.ග්‍රෑ.	13.35
	රිස්පෙරිඩොන්	පෙති/කරල්	2 මි.ග්‍රෑ.	15.61
35	ඔලන්සපින්	පෙති/කරල්	5 මි.ග්‍රෑ.	16.89
	ඔලන්සපින්	පෙති/කරල්	10 මි.ග්‍රෑ.	35.11
36	කාබමසපින්	පෙති/කරල්	200 මි.ග්‍රෑ.	20.25

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ත්‍රම්ය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
37	ඇල්ප්‍රසෝලැම්	පෙති/කරල්	0.25 මි.ග්‍රෑ.	10.98
	ඇල්ප්‍රසෝලැම්	පෙති/කරල්	0.5 මි.ග්‍රෑ.	16.73
38	ෆ්ලූඔක්සටින්	පෙති/කරල්	20 මි.ග්‍රෑ.	18.58
39	ගැබාපෙන්ටින්	පෙති/කරල්	100 මි.ග්‍රෑ.	28.29
	ගැබාපෙන්ටින්	පෙති/කරල්	300 මි.ග්‍රෑ.	55.99
40	බෙක්ලොමේතසෝන්	ඩී. පී කරල් (ආශ්වාස කිරීම)	200 මයික්‍රෝ ග්‍රෑ.	10.13
	බෙක්ලොමේතසෝන්	ඩී. පී කරල් (ආශ්වාස කිරීම)	400 මයික්‍රෝ ග්‍රෑ.	11.48
	බෙක්ලොමේතසෝන්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	100 මයික්‍රෝ ග්‍රෑ.	857.17
	බෙක්ලොමේතසෝන්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	250 මයික්‍රෝ ග්‍රෑ.	947.52
41	සැල්බියුටමෝල්	ඩී. පී කරල් (ආශ්වාස කිරීම)	200 මයික්‍රෝ ග්‍රෑ.	6.75
	සැල්බියුටමෝල්	ඩී. පී කරල් (ආශ්වාස කිරීම)	400 මයික්‍රෝ ග්‍රෑ.	9.29
	සැල්බියුටමෝල්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	100 මයික්‍රෝ ග්‍රෑ.	523.59
42	මිතයිල්ප්‍රෙඩ්නිසෝලෝන්	පෙති/කරල්	4 මි.ග්‍රෑ.	20.01
	මිතයිල්ප්‍රෙඩ්නිසෝලෝන්	පෙති/කරල්	16 මි.ග්‍රෑ.	69.25
43	ඔමෙප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	7.60
44	පැන්ටොප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	28.70
	පැන්ටොප්‍රසෝල්	පෙති/කරල්	40 මි.ග්‍රෑ.	47.28
45	ඉසොමෙප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	34.11
	ඉසොමෙප්‍රසෝල්	පෙති/කරල්	40 මි.ග්‍රෑ.	64.86
46	ඩොම්පෙරිඩෝන්	පෙති/කරල්	10 මි.ග්‍රෑ.	9.12
47	රැබිප්‍රසෝල්	පෙති/කරල්	10 මි.ග්‍රෑ.	19.09
	රැබිප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	36.40
48	ඇලෙන්ඩ්‍රොනික් ඇසිඩ්	පෙති/කරල්	70 මි.ග්‍රෑ.	171.26

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
49	සෙෆ්ටසිඩීම්	නිත්ශේපන	500 මි.ග්‍රෑම්	772.12
	සෙෆ්ටසිඩීම	නිත්ශේපන	1 ග්‍රෑම්	1286.87
50	සෙෆ්ට්‍රිඇක්සෝන්	නිත්ශේපන	250 මි.ග්‍රෑම්	386.06
	සෙෆ්ට්‍රිඇක්සෝන්	නිත්ශේපන	500 මි.ග්‍රෑම්	723.86
	සෙෆ්ට්‍රිඇක්සෝන්	නිත්ශේපන	1 ග්‍රෑම්	1126.00
51	සෙෆොටැක්සිම්	නිත්ශේපන	500 මි. ග්‍රෑම්	361.94
	සෙෆොටැක්සිම්	නිත්ශේපන	1 ග්‍රෑම්	603.22
52	ෆ්ලුකොනසෝල්	පෙති/කරල්	50 මි.ග්‍රෑම්	40.21
	ෆ්ලුකොනසෝල්	පෙති/කරල්	150 මි.ග්‍රෑම්	72.38
53	ඉන්සියුලින් සොලියුබල් හියුමන්	නිත්ශේපන	100 අයි.යු/1මි.ලි. (10 මි.ලි.කුප්පිය)	1930.29
	ඉන්සියුලින් සොලියුබල් හියුමන්	නිත්ශේපන	100 අයි.යු/1 මි.ලී. (3 මි.ලී. කාට්‍රිජය)	965.15
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නිත්ශේපන	100 අයි.යු/1 මි.ලී. (10 මි.ලී. කුප්පිය)	1930.29
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නිත්ශේපන	100 අයි.යු/1 මි.ලී (3 මි.ලී. කාට්‍රිජය)	965.15
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින් (ඉන්සියුලින් සොලියුබල් හියුමන් 30 අයි. යු/1 මි. ලී, ඉන්සියුලින් අයිසෝෆෙන් හියුමන් 70 අයි.යු./1 මි.ලී.) මිශ්‍රණයක් ලෙස	නිත්ශේපන	100 අයි.යු/1 මි.ලී. (10 මි.ලී. කුප්පිය)	1930.29
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින් (ඉන්සියුලින් සොලියුබල් හියුමන් 30 අයි. යු/1 මි. ලී, ඉන්සියුලින් අයිසෝෆෙන් හියුමන් 70 අයි.යු./1 මි.ලී.) මිශ්‍රණයක් ලෙස	නිත්ශේපන	100 අයි.යු/1 මි.ලී (3 මි.ලී. කාට්‍රිජය)	965.15
54	ග්ලිමිපිරයිඩ්	පෙති	1 මි.ග්‍රෑම්	11.51
	ග්ලිමිපිරයිඩ්	පෙති	2 මි.ග්‍රෑම්	16.32
	ග්ලිමිපිරයිඩ්	පෙති	3 මි.ග්‍රෑම්	27.35
	ග්ලිමිපිරයිඩ්	පෙති	4 මි.ග්‍රෑම්	29.75
55	සිටාග්ලිප්ටින්	පෙති	25 මි.ග්‍රෑම්	24.12
	සිටාග්ලිප්ටින්	පෙති	50 මි.ග්‍රෑම්	45.83
	සිටාග්ලිප්ටින්	පෙති	100 මි.ග්‍රෑම්	78.01

I වන තීරුව	II වන තීරුව ඖෂධීය ද්‍රව්‍යය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
56	ටැම්සුලොසින්	පෙති/කරල්	0.40 මි.ග්‍රෑම්	33.77
57	මොන්ටිලුකාස්ට්	පෙති	4 මි.ග්‍රෑම්	19.31
	මොන්ටිලුකාස්ට්	පෙති	5 මි.ග්‍රෑම්	24.12
	මොන්ටිලුකාස්ට්	පෙති	10 මි.ග්‍රෑම්	33.77
58	ප්‍රෙගබලීන්	පෙති/කරල්	50 මි.ග්‍රෑම්	19.70
	ප්‍රෙගබලීන්	පෙති/කරල්	75 මි.ග්‍රෑම්	24.94
	ප්‍රෙගබලීන්	පෙති/කරල්	100 මි.ග්‍රෑම්	30.96
	ප්‍රෙගබලීන්	පෙති/කරල්	150 මි.ග්‍රෑම්	38.61
	ප්‍රෙගබලීන්	පෙති/කරල්	300 මි.ග්‍රෑම්	63.55
59	ටොපිරමේට්	පෙති/කරල්	25 මි.ග්‍රෑම්	32.17
	ටොපිරමේට්	පෙති/කරල්	50 මි.ග්‍රෑම්	51.47
	ටොපිරමේට්	පෙති/කරල්	100 මි.ග්‍රෑම්	83.64
60	ලැමෝට්‍රිජීන්	පෙති	25 මි.ග්‍රෑම්	19.31
	ලැමෝට්‍රිජීන්	පෙති	50 මි.ග්‍රෑම්	33.77
	ලැමෝට්‍රිජීන්	පෙති	100 මි.ග්‍රෑම්	56.30

(13) 2022 පෙබරවාරි මස 28 වැනි දින අංක 2269/11 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළකරන ලද 2022 ඖෂධ (මි.ග්‍රෑ. 500 පැරසිටමෝල් පෙති/කරල්වල මිල නියම කිරීමේ) නියෝග මෙයින් පරිවර්ජන්න කරනු ලැබේ.

EOG 03 - 0897

ශ්‍රී ලංකා රජයේ මුද්‍රණ දෙපාර්තමේන්තුවේ මුද්‍රණය කරන ලදී.

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

අංක 2277/55 - 2022 අප්‍රේල් මස 29 වැනි සිකුරාදා - 2022.04.29

(රජයේ බලයවිට ප්‍රසිද්ධ කරන ලදී)

I වැනි කොටස: (I) වැනි ඡෙදය - සාමාන්‍ය

රජයේ නිවේදන

ඒල්.සී.බී. 9/2016 (III)

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 142 වන වගන්තිය යටතේ සෞඛ්‍ය අමාත්‍යවරයා විසින් සාදනු ලබන නියෝග.

මහාචාර්ය චන්න ජයසුමන,
සෞඛ්‍ය අමාත්‍ය.

2022 අප්‍රේල් මස 28 වැනි දින,
කොළඹ දී ය.

නියෝග

2021 අගෝස්තු මස 19 වැනි දින අංක 2241/43 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝගවලින් සහ 2022 මාර්තු මස 15 වැනි දින අංක 2271/23 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝගවලින් සංශෝධිත 2019 මැයි මස 15 වැනි දින අංක 2123/35 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝග පහත දැක්වෙන පරිදි තවදුරටත් මෙයින් සංශෝධනය කරනු ලැබේ:-

1A - G 36712 — 12 (2022/04)
මෙම අති විශෙෂ ගැසට් පත්‍රය www.documents.gov.lk වෙබ් අඩවියෙන් බාගත කළ හැක.

(1) එහි 6 වන නියෝගය ඉවත්කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"6. (1) මේ නියෝග පළ කරනු ලබන දිනයේ දී, සංශෝධිත පරිදි 2019 මැයි මස 15 වැනි දින අංක 2123/35 දරන අතිවිශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝගවල උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිලට වඩා අඩු මිලක් වන යම් ප්‍රතිශෝධිත සිල්ලර මිලකට 2021 අගෝස්තු මස 19 වැනි දින අංක 2241/43 දරන අතිවිශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝගවලින් සහ 2022 මාර්තු මස 15 වැනි දින අංක 2271/23 දරන අතිවිශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝගවලින් සංශෝධිත 2019 මැයි මස 15 වැනි දින අංක 2123/35 දරන අතිවිශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝග යටතේ යම් උපලේඛනගත ඖෂධයක් විකුණනු ලබන යම් නිෂ්පාදකයකු හෝ ආනයනකරුවකු විසින් එම ප්‍රතිශෝධිත සිල්ලර මිල සමානුපාතිකව සම්පූර්ණ වශයෙන් සියයට ආතළිහක ප්‍රතිශතයක් (40%) වැඩි කරනු ලැබිය හැකි ය.

(2) විකිණීමේ කාර්යය සඳහා උපලේඛනගත ඖෂධ සන්නකයේ තබාගෙන සිටින සෑම වෙළෙන්දකු, බෙදාහරින්නකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, දන්ත වෛද්‍යවරයකු, පශු වෛද්‍යවරයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු වෛද්‍ය ආයතනයක්, ඔසුසලක් හෝ තැනැත්තකු විසින් උපලේඛනගත ඖෂධවල මිල, උපරිම සිල්ලර මිල හෝ ප්‍රතිශෝධිත සිල්ලර මිල යන දෙකෙන් වඩාත් අඩු මිලෙහි පවත්වාගෙන යා යුතු ය."

(2) එහි උපලේඛනය ඉවත්කර ඒ වෙනුවට පහත දැක්වෙන උපලේඛනය ආදේශ කිරීමෙන්:-

"උපලේඛනය

(2 වන නියෝගය)

ඖෂධවල උපරිම සිල්ලර මිල

I වන තීරුව	*II වන තීරුව* *ඖෂධීය නාමය*	*III වන තීරුව* *ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය*	*IV වන තීරුව* *ප්‍රබලතාවය*	*V වන තීරුව* *උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්*
1	ඇල්බෙන්ඩසෝල්	පෙති/කරල්	400 මි.ග්‍රෑ	70.94
2	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	156 මි.ග්‍රෑ/5 මි.ලී	679.83
	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	පෙති/කරල්	375 මි.ග්‍රෑ	83.71
	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	පෙති/කරල්	625 මි.ග්‍රෑ	141.86
	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	එන්නත්	1.2 ග්‍රෑ	1492.06
3	ක්ලැරිත්‍රෝමයිසින්	පෙති/කරල්	250 මි.ග්‍රෑ	86.31
	ක්ලැරිත්‍රෝමයිසින්	පෙති/කරල්	500 මි.ග්‍රෑ	174.99
	ක්ලැරිත්‍රෝමයිසින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	125 මි.ග්‍රෑ/5 මි.ලී.	1030.96
4	ඇසිත්‍රෝමයිසින්	පෙති/කරල්	250 මි.ග්‍රෑ	88.91
	ඇසිත්‍රෝමයිසින්	පෙති/කරල්	500 මි.ග්‍රෑ	124.74
	ඇසිත්‍රෝමයිසින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	200 මි.ග්‍රෑ/5 මි.ලී.	413.78
5	සෙෆියුරොක්සිම්	පෙති/කරල්	250 මි.ග්‍රෑ	107.59
	සෙෆියුරොක්සිම්	පෙති/කරල්	500 මි.ග්‍රෑ	171.65

489

උපලේඛනය (සම්බන්ධිතයි)

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාමය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
6	ඩොක්සිසයික්ලීන්	පෙති/කරල්	100 මි.ග්‍රෑ	23.90
7	ඇසික්ලොවිර්	පෙති/කරල්	200 මි.ග්‍රෑ	87.46
8	සිප්රොෆ්ලොක්සසින්	පෙති/කරල්	250 මි.ග්‍රෑ	13.59
	සිප්රොෆ්ලොක්සසින්	පෙති/කරල්	500 මි.ග්‍රෑ	20.10
9	ලෙවෝෆ්ලොක්සසින්	පෙති/කරල්	250 මි.ග්‍රෑ	57.22
	ලෙවෝෆ්ලොක්සසින්	පෙති/කරල්	500 මි.ග්‍රෑ	94.58
10	සෙපලෙක්සින්	පෙති/කරල්	250 මි.ග්‍රෑ	19.38
	සෙපලෙක්සින්	පෙති/කරල්	500 මි.ග්‍රෑ	35.49
	සෙපලෙක්සින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	125 මි.ග්‍රෑ/5 මි.ලී.	626.61
11	සෙෆික්සිම්	පෙති/කරල්	100 මි.ග්‍රෑ	54.38
	සෙෆික්සිම්	පෙති/කරල්	200 මි.ග්‍රෑ	100.97
	සෙෆික්සිම්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	100 මි.ග්‍රෑ/5 මි.ලී.	815.77
12	ඇම්ලොඩිපින්	පෙති/කරල්	5 මි.ග්‍රෑ	36.18
	ඇම්ලොඩිපින්	පෙති/කරල්	10 මි.ග්‍රෑ	50.37
13	බිල්ටියසම්	පෙති/කරල්	30 මි.ග්‍රෑ	6.40
	බිල්ටියසම්	පෙති/කරල්	60 මි.ග්‍රෑ	21.06
	බිල්ටියසම්	පෙති/කරල්	90 මි.ග්‍රෑ	50.61
14	ලොසාටන් පොටෑසියම්	පෙති/කරල්	25 මි.ග්‍රෑ	17.37
	ලොසාටන් පොටෑසියම්	පෙති/කරල්	50 මි.ග්‍රෑ	24.36
15	ලොසාටන්-හයිඩ්‍රොක්ලෝරෝතයෝසයිඩ්	පෙති/කරල්	62.5 මි.ග්‍රෑ	45.98
16	ඵනලප්‍රිල්	පෙති/කරල්	5 මි.ග්‍රෑ	14.18
	ඵනලප්‍රිල්	පෙති/කරල්	10 මි.ග්‍රෑ	25.90
17	ඇටනොලෝල්	පෙති/කරල්	25 මි.ග්‍රෑ	7.08

උපලේඛනය (සම්බන්ධිතයි)

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
	ඇටනොලෝල්	පෙති/කරල්	50 මි.ග්‍රෑ	10.40
	ඇටනොලෝල්	පෙති/කරල්	100 මි.ග්‍රෑ	30.74
18	නිෆඩිපින්-දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/කරල්	20 මි.ග්‍රෑ	8.76
19	ක්ලෝපිඩොග්‍රෙල්	පෙති/කරල්	75 මි.ග්‍රෑ	41.40
20	ඇටෝර්වාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑම්	15.19
	ඇටෝර්වාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ	26.36
	ඇටෝර්වාස්ටැටින්	පෙති/කරල්	20 මි.ග්‍රෑ	41.61
	ඇටෝර්වාස්ටැටින්	පෙති/කරල්	40 මි.ග්‍රෑම්	58.53
21	රොසුවාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑ	50.83
	රොසුවාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ	87.46
22	ටෙල්මිසාටන්	පෙති/කරල්	20 මි.ග්‍රෑ	24.11
	ටෙල්මිසාටන්	පෙති/කරල්	40 මි.ග්‍රෑ	38.30
	ටෙල්මිසාටන්	**පෙති/කරල්**	80 මි.ග්‍රෑ	71.88
23	ඇස්පිරින්	පෙති/කරල්	75 මි.ග්‍රෑ.	7.08
	ඇස්පිරින්	පෙති/කරල්	100 මි.ග්‍රෑ.	12.53
24	මෙට්පෝමින්	පෙති/කරල්	500 මි.ග්‍රෑ.	9.34
	මෙට්පෝමින් - දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/කරල්	500 මි.ග්‍රෑ.	18.20
	මෙට්පෝමින්	පෙති/කරල්	850 මි.ග්‍රෑ.	17.50
25	ග්ලිබෙන්ක්ලමයිඩ්	පෙති/කරල්	5 මි.ග්‍රෑ.	5.18
26	ග්ලික්ලසයිඩ්	පෙති/කරල්	80 මි.ග්‍රෑ.	26.73
27	තයිරොක්සින්	පෙති/කරල්	50 මයික්‍රෝ ග්‍රෑ.	14.41
	තයිරොක්සින්	පෙති/කරල්	100 මයික්‍රෝ ග්‍රෑ.	21.53
28	ග්ලිපිසයිඩ්	පෙති/කරල්	5 මි.ග්‍රෑ.	18.69
29	**ඉබ්‍යුප්‍රොෆෙන්**	පෙති/කරල්	200 මි.ග්‍රෑ.	2.60

487

උපලේඛනය (සම්බන්ධීනයි)

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
	ඉබියුප්‍රොෆෙන්	පෙති/කරල්	400 මි.ග්‍රෑ.	8.76
30	ඩයික්ලොෆෙනැක් සෝඩියම්	පෙති/කරල්	50 මි.ග්‍රෑ.	30.74
	ඩයික්ලොෆෙනැක් සෝඩියම්	පෙති/කරල්	100 මි.ග්‍රෑ.	35.70
31	ඩයික්ලොෆෙනැක් පොටැසියම්	පෙති/කරල්	50 මි.ග්‍රෑ.	25.90
32	පැරසිටමෝල්	පෙති/කරල්	500 මි.ග්‍රෑ.	4.16
33	සෝඩියම් වැල්ප්‍රොඒට්	පෙති/කරල්	200 මි.ග්‍රෑ.	21.28
34	රිස්පෙරිඩෝන්	පෙති/කරල්	1 මි.ග්‍රෑ.	18.69
	රිස්පෙරිඩෝන්	පෙති/කරල්	2 මි.ග්‍රෑ.	21.85
35	ඔලන්සපින්	පෙති/කරල්	5 මි.ග්‍රෑ.	23.65
	ඔලන්සපින්	පෙති/කරල්	10 මි.ග්‍රෑ.	49.15
36	කාබමසපින්	පෙති/කරල්	200 මි.ග්‍රෑ.	28.35
37	ඇල්ප්‍රසෝලෑම්	පෙති/කරල්	0.25 මි.ග්‍රෑ.	15.37
	ඇල්ප්‍රසෝලෑම්	පෙති/කරල්	0.5 මි.ග්‍රෑ.	23.42
38	ෆ්ලුඔක්සටීන්	පෙති/කරල්	20 මි.ග්‍රෑ.	26.01
39	ගැබාපෙන්ටින්	පෙති/කරල්	100 මි.ග්‍රෑ.	39.61
	ගැබාපෙන්ටින්	පෙති/කරල්	300 මි.ග්‍රෑ.	78.39
40	බෙක්ලොමෙතසෝන්	ඩී. පී කරල් (ආශ්වාස කිරීම)	200 මයික්‍රෝ ග්‍රෑ.	14.18
	බෙක්ලොමෙතසෝන්	ඩී. පී කරල් (ආශ්වාස කිරීම)	400 මයික්‍රෝ ග්‍රෑ.	16.07
	බෙක්ලොමෙතසෝන්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	100 මයික්‍රෝ ග්‍රෑ.	1,200.04
	බෙක්ලොමෙතසෝන්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	250 මයික්‍රෝ ග්‍රෑ.	1,326.53
41	සැල්බියුටමෝල්	ඩී. පී කරල් (ආශ්වාස කිරීම)	200 මයික්‍රෝ ග්‍රෑ.	9.45
	සැල්බියුටමෝල්	ඩී. පී කරල් (ආශ්වාස කිරීම)	400 මයික්‍රෝ ග්‍රෑ.	13.01

උපලේඛනය (සම්බන්ධීතයි)

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
	සැල්බියුටමෝල්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	100 මයික්‍රෝ ග්‍රෑ.	733.03
42	මීතයිල්ප්‍රෙඩ්නිසෝලෝන්	පෙති/කරල්	4 මි.ග්‍රෑ.	28.01
	මීතයිල්ප්‍රෙඩ්නිසෝලෝන්	පෙති/කරල්	16 මි.ග්‍රෑ.	96.95
43	ඔමෙප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	10.64
44	පැන්ටොප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	40.18
	පැන්ටොප්‍රසෝල්	පෙති/කරල්	40 මි.ග්‍රෑ.	66.19
45	ඉසොමෙප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	47.75
	ඉසොමෙප්‍රසෝල්	පෙති/කරල්	40 මි.ග්‍රෑ.	90.80
46	ඩොම්පෙරිඩෝන්	පෙති/කරල්	10 මි.ග්‍රෑ.	12.77
47	රබ්ප්‍රසෝල්	පෙති/කරල්	10 මි.ග්‍රෑ.	26.73
	රබ්ප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	50.96
48	ඇලෙන්ඩ්‍රොනික් ඇසිඩ්	පෙති/කරල්	70 මි.ග්‍රෑ.	239.76
49	සෙෆ්ටසිඩීම්	නික්ෂේපන	500 මි.ග්‍රෑම්	1080.97
	සෙෆ්ටසිඩීම්	නික්ෂේපන	1 ග්‍රෑම්	1801.62
50	සෙෆ්ට්‍රිඇක්සෝන්	නික්ෂේපන	250 මි.ග්‍රෑම්	540.48
	සෙෆ්ට්‍රිඇක්සෝන්	නික්ෂේපන	500 මි.ග්‍රෑම්	1013.40
	සෙෆ්ට්‍රිඇක්සෝන්	නික්ෂේපන	1 ග්‍රෑම්	1576.40
51	සෙෆොටැක්සිම්	නික්ෂේපන	500 මි. ග්‍රෑම්	506.72
	සෙෆොටැක්සිම්	නික්ෂේපන	1 ග්‍රෑම්	844.51
52	ෆ්ලූකොනසෝල්	පෙති/කරල්	50 මි.ග්‍රෑම්	56.29
	ෆ්ලූකොනසෝල්	පෙති/කරල්	150 මි.ග්‍රෑම්	101.33
53	ඉන්සියුලින් සොලියුබල් හියුමන්	නික්ෂේපන	100 අයි.සු/1මි.ලී. (10 මි.ලී.කුප්පිය)	2702.41

485

උපලේඛනය (සම්බන්ධීකෘති)

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
	ඉන්සියුලින් සොලියුබල් හියුමන්	නිත්ක්ෂේපන	100 අයි.යු/1 මි.ලී. (3 මි.ලී. කාට්‍රිජය)	1351.21
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නිත්ක්ෂේපන	100 අයි.යු/1 මි.ලී. (10 මි.ලී. කුප්පිය)	2702.41
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නිත්ක්ෂේපන	100 අයි.යු/1 මි.ලී (3 මි.ලී. කාට්‍රිජය)	1351.21
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින් (ඉන්සියුලින් සොලියුබල් හියුමන් 30 අයි. යූ/1 මි. ලී, ඉන්සියුලින් අයිසෝෆෙන් හියුමන් 70 අයි.යූ./1 මි.ලී.) මිශ්‍රණය ලෙස	නිත්ක්ෂේපන	100 අයි.යු/1 මි.ලී. (10 මි.ලී. කුප්පිය)	2702.41
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින් (ඉන්සියුලින් සොලියුබල් හියුමන් 30 අයි. යූ/1 මි. ලී, ඉන්සියුලින් අයිසෝෆෙන් හියුමන් 70 අයි.යූ./1 මි.ලී.) මිශ්‍රණය ලෙස	නිත්ක්ෂේපන	100 අයි.යු/1 මි.ලී (3 මි.ලී. කාට්‍රිජය)	1351.21
54	ග්ලිමිපිරයිඩ්	පෙති	1 මි.ග්‍රෑම්	16.11
	ග්ලිමිපිරයිඩ්	පෙති	2 මි.ග්‍රෑම්	22.85
	ග්ලිමිපිරයිඩ්	පෙති	3 මි.ග්‍රෑම්	38.29
	ග්ලිමිපිරයිඩ්	පෙති	4 මි.ග්‍රෑම්	41.65
55	සිටාග්ලිප්ටින්	පෙති	25 මි.ග්‍රෑම්	33.77
	සිටාග්ලිප්ටින්	පෙති	50 මි.ග්‍රෑම්	64.16
	සිටාග්ලිප්ටින්	පෙති	100 මි.ග්‍රෑම්	109.21
56	ට්‍රෝමියුලොයින්	පෙති/කරල්	0.40 මි.ග්‍රෑම්	47.28
57	මොන්ටිලුකාස්ට්	පෙති	4 මි.ග්‍රෑම්	27.03
	මොන්ටිලුකාස්ට්	පෙති	5 මි.ග්‍රෑම්	33.77
	මොන්ටිලුකාස්ට්	පෙති	10 මි.ග්‍රෑම්	47.28
58	ප්‍රෙගබලින්	පෙති/කරල්	50 මි.ග්‍රෑම්	27.58
	ප්‍රෙගබලින්	පෙති/කරල්	75 මි.ග්‍රෑම්	34.92
	ප්‍රෙගබලින්	පෙති/කරල්	100 මි.ග්‍රෑම්	43.34
	ප්‍රෙගබලින්	පෙති/කරල්	150 මි.ග්‍රෑම්	54.05
	ප්‍රෙගබලින්	පෙති/කරල්	300 මි.ග්‍රෑම්	88.97
59	ටොපිරමේට්	පෙති/කරල්	25 මි.ග්‍රෑම්	45.04
	ටොපිරමේට්	පෙති/කරල්	50 මි.ග්‍රෑම්	72.06
	ටොපිරමේට්	පෙති/කරල්	100 මි.ග්‍රෑම්	117.10

උපලේඛනය (සම්බන්ධීතාව)

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
60	ලැමෝට්‍රිජින්	පෙති	25 මි.ග්‍රෑම්	27.03
	ලැමෝට්‍රිජින්	පෙති	50 මි.ග්‍රෑම්	47.28
	ලැමෝට්‍රිජින්	පෙති	100 මි.ග්‍රෑම්	78.82

EOG 04 - 0233

ශ්‍රී ලංකා රජයේ මුද්‍රණ දෙපාර්තමේන්තුවේ මුද්‍රණය කරන ලදී.

(1) එහි 6 වන නියෝගය ඉවත්කර ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"6. (1) මේ නියෝග පළ කරනු ලබන දිනයේ දී, සංශෝධිත පරිදි 2019 මැයි මස 15 වැනි දින අංක 2123/35 දරන අතිවිශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝගවල උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිලට වඩා අඩු මිලක් වන යම් ප්‍රතිශෝධිත සිල්ලර මිලකට 2021 අගෝස්තු මස 19 වැනි දින අංක 2241/43 දරන අතිවිශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝගවලින් සහ 2022 මාර්තු මස 15 වැනි දින අංක 2271/23 දරන අතිවිශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝගවලින් සංශෝධිත 2019 මැයි මස 15 වැනි දින අංක 2123/35 දරන අතිවිශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝග යටතේ යම් උපලේඛනගත ඖෂධයක් විකුණනු ලබන යම් නිෂ්පාදකයකු හෝ ආනයනකරුවකු විසින් එම ප්‍රතිශෝධිත සිල්ලර මිල සමානුපාතිකව සම්පූර්ණ වශයෙන් සියයට හතළිහක ප්‍රතිශතයක් (40%) වැඩි කරනු ලැබිය හැකි ය.

(2) විකිණීමේ කාර්යය සඳහා උපලේඛනගත ඖෂධ සත්තකයේ තබාගෙන සිටින සෑම වෙළෙන්දකු, බෙදාහරින්නකු, ඖෂධවේදියකු, වෛද්‍ය වෘත්තිකයකු, දන්ත වෛද්‍යවරයකු, පශු වෛද්‍යවරයකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු වෛද්‍ය ආයතනයක්, මිසුසලක් හෝ හැනැත්තකු විසින් උපලේඛනගත ඖෂධවල මිල, උපරිම සිල්ලර මිල හෝ ප්‍රතිශෝධිත සිල්ලර මිල යන දෙකෙන් වඩාත් අඩු මිලෙහි පවත්වාගෙන යා යුතු ය."

(2) එහි උපලේඛනය ඉවත්කර ඒ වෙනුවට පහත දැක්වෙන උපලේඛනය ආදේශ කිරීමෙන්:-

"උපලේඛනය

(2 වන නියෝගය)

ඖෂධවල උපරිම සිල්ලර මිල

I වන තීරුව	*II වන තීරුව* *ඖෂධීය නාමය*	*III වන තීරුව* *ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය*	*IV වන තීරුව* *ප්‍රබලතාවය*	*V වන තීරුව* *උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්*
1	ඇල්බෙන්ඩසෝල්	පෙති/කරල්	400 මි.ග්‍රෑ	70.94
2	ඇමොක්සිලින් - ක්ලැවුලිනික් ඇසිඩ්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	156 මි.ග්‍රෑ/5 මි.ලී	679.83
	ඇමොක්සිලින් - ක්ලැවුලිනික් ඇසිඩ්	පෙති/කරල්	375 මි.ග්‍රෑ	83.71
	ඇමොක්සිලින් - ක්ලැවුලිනික් ඇසිඩ්	පෙති/කරල්	625 මි.ග්‍රෑ	141.86
	ඇමොක්සිලින් - ක්ලැවුලිනික් ඇසිඩ්	එන්නත්	1.2 ග්‍රෑ	1492.06
3	ක්ලැරිත්‍රෝමයිසින්	පෙති/කරල්	250 මි.ග්‍රෑ	86.31
	ක්ලැරිත්‍රෝමයිසින්	පෙති/කරල්	500 මි.ග්‍රෑ	174.99
	ක්ලැරිත්‍රෝමයිසින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	125 මි.ග්‍රෑ/5 මි.ලී.	1030.96
4	ඇසිත්‍රෝමයිසින්	පෙති/කරල්	250 මි.ග්‍රෑ	88.91
	ඇසිත්‍රෝමයිසින්	පෙති/කරල්	500 මි.ග්‍රෑ	124.74
	ඇසිත්‍රෝමයිසින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	200 මි.ග්‍රෑ/5 මි.ලී.	413.78
5	සෙෆියුරොක්සිම්	පෙති/කරල්	250 මි.ග්‍රෑ	107.59
	සෙෆියුරොක්සිම්	පෙති/කරල්	500 මි.ග්‍රෑ	171.65

උපලේඛනය (සම්බන්ධයිනයි)

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
6	ඩොක්සිසයික්ලීන්	පෙති/කරල්	100 මි.ග්‍රෑ	23.90
7	ඇසික්ලොවීර්	පෙති/කරල්	200 මි.ග්‍රෑ	87.46
8	සිප්රොෆ්ලොක්සසීන්	පෙති/කරල්	250 මි.ග්‍රෑ	13.59
	සිප්රොෆ්ලොක්සසීන්	පෙති/කරල්	500 මි.ග්‍රෑ	20.10
9	ලෙවෝෆ්ලොක්සසීන්	පෙති/කරල්	250 මි.ග්‍රෑ	57.22
	ලෙවෝෆ්ලොක්සසීන්	පෙති/කරල්	500 මි.ග්‍රෑ	94.58
10	මෙපලෙක්සින්	පෙති/කරල්	250 මි.ග්‍රෑ	19.38
	මෙපලෙක්සින්	පෙති/කරල්	500 මි.ග්‍රෑ	35.49
	මෙපලෙක්සින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	125 මි.ග්‍රෑ/5 මි.ලි.	626.61
11	මෙෆික්සිම්	පෙති/කරල්	100 මි.ග්‍රෑ	54.38
	මෙෆික්සිම්	පෙති/කරල්	200 මි.ග්‍රෑ	100.97
	මෙෆික්සිම්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	100 මි.ග්‍රෑ/5 මි.ලි.	815.77
12	ඇම්ලොඩිපින්	පෙති/කරල්	5 මි.ග්‍රෑ	36.18
	ඇම්ලොඩිපින්	පෙති/කරල්	10 මි.ග්‍රෑ	50.37
13	ඩිල්ටියසම්	පෙති/කරල්	30 මි.ග්‍රෑ	6.40
	ඩිල්ටියසම්	පෙති/කරල්	60 මි.ග්‍රෑ	21.06
	ඩිල්ටියසම්	පෙති/කරල්	90 මි.ග්‍රෑ	30.61
14	ලොසාටන් පොටැසියම්	පෙති/කරල්	25 මි.ග්‍රෑ	17.37
	ලොසාටන් පොටැසියම්	පෙති/කරල්	50 මි.ග්‍රෑ	24.36
15	ලොසාටන්-හයිඩ්‍රොක්ලෝරෝතයෝසයිඩ්	පෙති/කරල්	62.5 මි.ග්‍රෑ	45.98
16	එනලප්‍රිල්	පෙති/කරල්	5 මි.ග්‍රෑ	14.18
	එනලප්‍රිල්	පෙති/කරල්	10 මි.ග්‍රෑ	23.90
17	ඇටනොලෝල්	පෙති/කරල්	25 මි.ග්‍රෑ	7.08

481

උපලේඛනය (සම්බන්ධීතයි)

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
	ඇටිනොලෝල්	පෙති/කරල්	50 මි.ග්‍රෑ	10.40
	ඇටනොලෝල්	පෙති/කරල්	100 මි.ග්‍රෑ	30.74
18	නිෆඩිපින්-දිර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/කරල්	20 මි.ග්‍රෑ	8.76
19	ක්ලෝපිඩොග්‍රෙල්	පෙති/කරල්	75 මි.ග්‍රෑ	41.40
20	ඇටෝවාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑම්	15.19
	ඇටෝවාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ	26.36
	ඇටෝවාස්ටැටින්	පෙති/කරල්	20 මි.ග්‍රෑ	41.61
	ඇටෝවාස්ටැටින්	පෙති/කරල්	40 මි.ග්‍රෑම්	58.53
21	රොසුවාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑ	50.83
	රොසුවාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ	87.46
22	ටෙල්මිසාටන්	පෙති/කරල්	20 මි.ග්‍රෑ	24.11
	ටෙල්මිසාටන්	පෙති/කරල්	40 මි.ග්‍රෑ	38.30
	ටෙල්මිසාටන්	පෙති/කරල්	80 මි.ග්‍රෑ	71.88
23	ඇස්පිරින්	පෙති/කරල්	75 මි.ග්‍රෑ.	7.08
	ඇස්පිරින්	පෙති/කරල්	100 මි.ග්‍රෑ.	12.53
24	මෙට්ෆෝමින්	පෙති/කරල්	500 මි.ග්‍රෑ.	9.34
	මෙට්ෆෝමින් - දිර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/කරල්	500 මි.ග්‍රෑ.	18.20
	මෙට්ෆෝමින්	පෙති/කරල්	850 මි.ග්‍රෑ.	17.50
25	ග්ලිබෙන්ක්ලමයිඩ්	පෙති/කරල්	5 මි.ග්‍රෑ.	5.18
26	ග්ලික්ලසයිඩ්	පෙති/කරල්	80 මි.ග්‍රෑ.	26.73
27	කයිරොක්සින්	පෙති/කරල්	50 මයික්‍රෝ ග්‍රෑ.	14.41
	කයිරොක්සින්	පෙති/කරල්	100 මයිමක්‍රෝ ග්‍රෑ.	21.53
28	ග්ලිමිපයිඩ්	පෙති/කරල්	5 මි.ග්‍රෑ.	18.69
29	ඉබ්‍යුප්‍රොෆෙන්	පෙති/කරල්	200 මි.ග්‍රෑ.	2.60

ඇමුණුම 106

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/CEO/Price/SLCPI/01	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	11.03.2022

Mr Sanjeewa Wijesekara
President
Sri Lanka Chamber of the Pharmaceutical Industry

Dear Mr Wijesekara

RE: NOTIFICATION OF PRICE ADJUSTMENT OF NON-GAZETTE PHARMACEUTICAL PRODUCTS

With reference to your letter dated 10th March 2022 on above mentioned matter, I would like to inform you that the NMRA, being the legal regulator of pricing of pharmaceuticals in Sri Lanka, will not accept your unilateral announcement of price increase which is not legally in accordance with Sections 3b, 14q and 108 of NMRA Act no 05 of 2015.

Whilst we acknowledge the consequences of the devaluation of LKR, I would like to inform you that, with consultation and guidance of the Hon Minister of Health and Hon. State Minister of Production, Supply and Regulation of Pharmaceuticals, NMRA will communicate further adjustments to the already conveyed 20% increase of non – gazette medicines very soon. Until such time you are not legally entitled to increase the price of any medicine stipulated by NMRA.

Further, please be informed that Gazette notification of price controlled medicine will be published as soon as possible.

Your kind corporation in this regard is highly appreciated.

Thank you

Dr. Saveen Semage
MBBS, MSc
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

Brig (Dr) Saveen Semage
Chief Executive Officer
National Medicines Regulatory Authority

CC: 1. Hon. Prof. Channa Jayasumana, State Minister of Production, Supply, and Regulation of Pharmaceuticals, State Ministry of Production, Supply, and Regulation of Pharmaceuticals

+94 11 269 51 73 | +94 11 269 88 96/7 +94 11252 33 85 www.nmra.gov.lk info@nmra.gov.lk

461

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.		ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	11.03.2022

2. Chairman, Pricing Committee
3. Chairman, National Medicines Regulatory Authority
4. Legal Officer, National Medicines Regulatory Authority

O/C

+94 11 269 51 73 | +94 11 269 88 96/7 +94 11252 33 85 www.nmra.gov.lk info@nmra.gov.lk

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/CEO/Price/SLCPI/02	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	11.03.2022

Mr Sanjeewa Wijesekara
President
Sri Lanka Chamber of the Pharmaceutical Industry

Dear Mr Wijesekara

NOTIFICATION OF PRICE ADJUSTMENT OF NON-GAZETTED PHARMACEUTICAL PRODUCTS

This has reference to your letter dated 10th March 2022.

Whilst we acknowledge the consequences of the devaluation of LKR, I would like to inform you that, with consultation, guidance and approval of the Hon Minister of Health and Hon. State Minister of Ministry of Production, Supply and Regulation of Pharmaceuticals NMRA has decided to grant a maximum 29% (*per centum*) price increase for non-gazetted Medicine under powers vested with the NMRA as the central regulator responsible for the regulation and control of all aspects pertaining to medicinal products by the National Medicines Regulatory Authority Act, No 5 of 2015 under Sections 3(b), 114(q) 118 and regulation made thereunder with effect from 11th March 2022.

Please kindly note that the following condition will be applied in this regard:

1. The MRP increase may be revised after sixty (60) days' time.
2. The maximum twenty-nine per cent (29%) increase will include the increase of twenty per cent (20%) increase informed on 10th March 2022.

If any pharmaceutical product which has already obtained the fourteen per cent (14%) increase from the previously declared MRP, only a maximum fifteen per cent (15%) increase of the MRP will be allowed.

Further, please be informed that we are in the processing issue gazette notification of price controlled of Scheduled Medicine and which will be published as soon as possible.

Your kind corporation in this regard is highly appreciated.

+94 11 269 51 73 | +94 11 269 88 96/7 +94 11252 33 85 www.nmra.gov.lk info@nmra.gov.lk

459

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/CEO/Price/SLCPI/02	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	11.03.2022

Thank you

Brig (Dr) Saveen Semage
Chief Executive Officer
National Medicines Regulatory Authority

Dr. Saveen Semage
MBBS, MSc, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

CC: 1. Hon. Prof. Channa Jayasumana, State Minister of Production, Supply, and Regulation of Pharmaceuticals, State Ministry of Production, Supply, and Regulation of Pharmaceuticals
2. Chairman, Pricing Committee
3. Chairman, National Medicines Regulatory Authority
4. Legal Officer, National Medicines Regulatory Authority

O/C

15/3/2022

Pricing file

458

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/CEO/Price/SLCPI/03	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	08.04.2022

(3)

Mr Sanjeewa Wijesekara
President
Sri Lanka Chamber of the Pharmaceutical Industry

Dear Mr Wijesekara

NOTIFICATION OF PRICE ADJUSTMENT OF NON-GAZETTED PHARMACEUTICAL PRODUCTS

This has reference to your letter dated 06th April 2022.

Whilst we acknowledge the consequences of the devaluation of LKR, I would like to inform you that, with consultation, guidance and approval of the Hon. State Minister of Ministry of Production, Supply and Regulation of Pharmaceuticals, NMRA has decided to grant a maximum 20% (*per centum*) price increase for non-gazetted Medicines with effect from 08th April 2022, under the powers vested with the NMRA as the central regulator responsible for the regulation and control of all aspects pertaining to medicinal products by the National Medicines Regulatory Authority Act, No 5 of 2015 under Sections 3(b), 114(q) 118 and regulation made thereunder.

Please kindly note that this price adjustment is in addition to the price adjustment granted by my letter dated 11th March 2022. All the conditions stated in that letter will further apply.

In addition, considering your request and the current situation of the country, NMRA would grant a conditional approval to over paste the price tags with permitted revised maximum retail price only for the existing stocks which are already price marked with the previous prices.

457

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/CEO/Price/SLCPI/03	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	08.04.2022

However, I do hereby advise you to inform the importers to notify the batch numbers along with the revised retail prices of particular stocks currently available in the market to the kind attention of the Chairman, Consumer Affairs Authority with a copy to the NMRA in order to avoid inconveniences.

Your kind corporation in this regard is highly appreciated.

Thank you

Dr. Saveen Semage
MBBS, MSc, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

Brig (Dr) Saveen Semage
Chief Executive Officer
National Medicines Regulatory Authority

CC:
1. Hon. Prof. Channa Jayasumana, State Minister of Production, Supply, and Regulation of Pharmaceuticals, State Ministry of Production, Supply, and Regulation of Pharmaceuticals
2. Secretary, Ministry of Health
3. ~~Director General~~, Chairman, Consumer affairs Authority- To notify the Authority.
4. Chairman, National Medicines Regulatory Authority –To notify the Board
5. Chairman, State Pharmaceutical Corporation
6. Chairman, State Pharmaceutical Manufacturing Corporation
7. Chairman, Pricing Committee, National Medicines Regulatory Authority
8. Legal Officer, National Medicines Regulatory Authority

Pricing file

Pricing file

456

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/CEO/Price/SLCPI/03	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	25.04.2022

29/1.
20/1.
20/1.
69/1

Mr Sanjeewa Wijesekara,
President,
Sri Lanka Chamber of the Pharmaceutical Industry.

Dear Mr Wijesekara

NOTIFICATION OF PRICE ADJUSTMENT OF NON-GAZETTED PHARMACEUTICAL PRODUCTS

This has reference to the above-captioned matter.

Whilst we acknowledge the consequences of the devaluation of LKR, I would like to inform you that, with consultation, guidance and approval of the Hon. Minister of Ministry of Health, NMRA has decided to grant further a maximum 20% (*per centum*) price increase for non-gazetted Medicines with effect from 25th April 2022, under the powers vested with the NMRA as the central regulator responsible for the regulation and control of all aspects pertaining to medicinal products by the National Medicines Regulatory Authority Act, No 5 of 2015 under Sections 3(b), 114(q) 118 and regulation made thereunder.

Please kindly note that this price adjustment is in addition to the price adjustment granted by my letter dated 08th April 2022. All the conditions stated in that letter will further apply.

Your kind corporation in this regard is highly appreciated.

Thank you

Dr. Saveen Semage
MBBS, MSc, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

Brig (Dr) Saveen Semage
Chief Executive Officer
National Medicines Regulatory Authority

CC:
1. Hon. Prof. Channa Jayasumana, Minister of Health
2. Secretary, Ministry of Health

+94 11 269 51 73 | +94 11 269 88 96/7 +94 11252 33 85 www.nmra.gov.lk info@nmra.gov.lk
NMRA, No. 120, Norris Canal Road, Colombo 10, Sri Lanka.

455

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/CEO/Price/SLCPI/03	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	25.04.2022

3. Secretary, State Ministry of Production, Supply, and Regulation of Pharmaceuticals
4. Chairman, Consumer affairs Authority- for your information and necessary action.
5. Chairman, National Medicines Regulatory Authority –to notify the Board.
6. Chairman, State Pharmaceutical Corporation
7. Chairman, State Pharmaceutical Manufacturing Corporation
8. President, Sri Lanka Pharmaceutical Manufacturers Association
7. Chairman, Pricing Committee, National Medicines Regulatory Authority
8. Legal Officer, National Medicines Regulatory Authority

+94 11 269 51 73 | +94 11 269 88 96/7 +94 11 252 33 85 www.nmra.gov.lk info@nmra.gov.lk

NMRA, No. 120, Norris Canal Road, Colombo 10, Sri Lanka.

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

අංක 2336/53 - 2023 ජූනි මස 15 වැනි බ්‍රහස්පතින්දා - 2023.06.15

(රජයේ බලයෙන් ප්‍රසිද්ධ කරන ලදී)

I වැනි කොටස: (I) වැනි ඡෙදය - සාමාන්‍ය

රජයේ නිවේදන

එල්.ඩී.බී. 9/2016 (III)

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 142 වන වගන්තිය යටතේ සෞඛ්‍ය අමාත්‍යවරයා විසින් සාදනු ලබන නියෝග.

ආචාර්ය කෙහෙළිය රඹුක්වැල්ල,
සෞඛ්‍ය අමාත්‍ය.

2023 ජූනි මස 12 වැනි දින,
කොළඹ දී ය.

නියෝග

2021 අගෝස්තු මස 19 වැනි දින අංක 2241/43 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝගවලින් සහ 2022 මාර්තු මස 15 වැනි දින අංක 2271/23 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝගවලින් සහ 2022 අප්‍රේල් මස 29 වැනි දින අංක 2277/55 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද නියෝගවලින් සංශෝධිත 2019 මැයි මස 15 වැනි දින අංක 2123/35 දරන අති විශෙෂ ගැසට් පත්‍රයේ පළ කරන ලද 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝග පහත දැක්වෙන පරිදි කවදුරටත් මෙයින් සංශෝධනය කරනු ලැබේ:-

(1) ඉහි 6 වන නියෝගය ඉවත් කර, ඒ වෙනුවට පහත දැක්වෙන නියෝගය ආදේශ කිරීමෙන්:-

"6. (1) 2022 අප්‍රේල් මස 29 වැනි දින අංක 2277/55 දරන *අති විශෙෂ ගැසට් පත්‍රයේ* පළ කරන ලද නියෝගවලින් අවසන් වරට සංශෝධිත 2019 මැයි මස 15 වැනි දින අංක 2123/35 දරන *අති විශෙෂ ගැසට් පත්‍රයේ* පළ කරන ලද 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝගවල උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිලට යම් උපලේඛනගත ඖෂධයක් විකුණනු ලබන යම් නිෂ්පාදකයෙකු හෝ ආනයනකරුවෙකු විසින් එම උපලේඛනගත ඖෂධය මෙම නියෝගවල උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිලට වඩා වැඩි වන්නා වූ යම් මිලකට විකුණනු නොලැබිය යුතු ය.

(2) 2022 අප්‍රේල් මස 29 වැනි දින අංක 2277/55 දරන *අති විශෙෂ ගැසට් පත්‍රයේ* පළ කරන ලද නියෝගවලින් අවසන් වරට සංශෝධිත 2019 ඖෂධ (මිල ඉහළ සීමා) නියෝගවල උපලේඛනයේ V වන තීරුවේ නිශ්චිතව දක්වා ඇති උපරිම සිල්ලර මිලට වඩා අඩු වන්නා වූ යම් ප්‍රතිගෝධිත සිල්ලර මිලකට යම් උපලේඛනගත ඖෂධයක් විකුණනු ලබන යම් නිෂ්පාදකයෙකු හෝ ආනයනකරුවෙකු විසින් එම ප්‍රතිගෝධිත සිල්ලර මිල ද්‍රව්‍යාතුපාතිකව සම්පූර්ණ වශයෙන් සියයට දහයක ප්‍රතිශතයකින් (16%) අඩු කරනු ලැබිය යුතු ය.

(3) විකිණීමේ කාර්යය සඳහා උපලේඛනගත ඖෂධ සත්තකයේ තබාගෙන සිටින සෑම වෙළෙන්දෙකු, බෙදාහරින්නෙකු, ඖෂධවේදියෙකු, වෛද්‍ය වෘත්තිකයෙකු, දන්ත වෛද්‍යවරයෙකු, පශු වෛද්‍යවරයෙකු, පෞද්ගලික වෛද්‍ය ආයතනයක් ඇතුළු වෛද්‍ය ආයතනයක්, ඔසුසලක් හෝ තැනැත්තෙකු විසින් උපලේඛනගත ඖෂධවල මිල, උපරිම සිල්ලර මිල හෝ ප්‍රතිගෝධිත සිල්ලර මිල යන දෙකෙන් වඩාත් අඩු මිලෙහි පවත්වාගෙන යා යුතු ය.".

(2) එහි උපලේඛනය ඉවත්කර ඒ වෙනුවට පහත දැක්වෙන උපලේඛනය ආදේශ කිරීමෙන්:-

"උපලේඛනය

(2 වන නියෝගය)

ඖෂධවල උපරිම සිල්ලර මිල

I වන තීරුව	*II වන තීරුව* *ඖෂධීය නාමය*	*III වන තීරුව* *ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය*	*IV වන තීරුව* *ප්‍රබලතාවය*	*V වන තීරුව* *උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්*
1	ඇල්බෙන්ඩසෝල්	පෙති/කරල්	400 මි.ග්‍රෑ.	59.59
2	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	156 මි.ග්‍රෑ./5 මි.ලී	571.06
	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	පෙති/කරල්	375 මි.ග්‍රෑ.	70.32
	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	පෙති/කරල්	625 මි.ග්‍රෑ.	119.16

I වන තීරුව	*II වන තීරුව* *ඖෂධීය නාමය*	*III වන තීරුව* *ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය*	*IV වන තීරුව* *ප්‍රබලතාවය*	*V වන තීරුව* *උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්*
	ඇමොක්සිලීන් - ක්ලැවුලිනික් ඇසිඩ්	එන්නත්	1.2 ග්‍රෑ.	1,253.33
3	ක්ලැරිත්‍රෝමයිසීන්	පෙති/කරල්	250 මි.ග්‍රෑ.	72.50
	ක්ලැරිත්‍රෝමයිසීන්	පෙති/කරල්	500 මි.ග්‍රෑ.	146.99
	ක්ලැරිත්‍රෝමයිසීන්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	125 මි.ග්‍රෑ./5 මි.ලි.	866.01
4	ඇසිත්‍රෝමයිසීන්	පෙති/කරල්	250 මි.ග්‍රෑ.	74.68
	ඇසිත්‍රෝමයිසීන්	පෙති/කරල්	500 මි.ග්‍රෑ.	104.78
	ඇසිත්‍රෝමයිසීන්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	200 මි.ග්‍රෑ./5 මි.ලි.	347.58
5	සෙෆියුරොක්සිම්	පෙති/කරල්	250 මි.ග්‍රෑ.	90.38
	සෙෆියුරොක්සිම්	පෙති/කරල්	500 මි.ග්‍රෑ.	144.19
6	ඩොක්සිසයික්ලීන්	පෙති/කරල්	100 මි.ග්‍රෑ.	20.08
7	ඇසික්ලොවීර්	පෙති/කරල්	200 මි.ග්‍රෑ.	73.47
8	සිප්‍රොෆ්ලොක්සසින්	පෙති/කරල්	250 මි.ග්‍රෑ.	11.42
	සිප්‍රොෆ්ලොක්සසීන්	පෙති/කරල්	500 මි.ග්‍රෑ.	16.88
9	ලෙවෝෆ්ලොක්සසින්	පෙති/කරල්	250 මි.ග්‍රෑ.	48.06
	ලෙවෝෆ්ලොක්සසින්	පෙති/කරල්	500 මි.ග්‍රෑ.	79.45
10	සෙපලෙක්සින්	පෙති/කරල්	250 මි.ග්‍රෑ.	16.23
	සෙපලෙක්සින්	පෙති/කරල්	500 මි.ග්‍රෑ.	29.81

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
	සෙපලෙක්සින්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	125 මි.ග්‍රෑ./5 මි.ලි.	526.35
11	සෙෆික්සිම්	පෙති/කරල්	100 මි.ග්‍රෑ.	45.68
	සෙෆික්සිම්	පෙති/කරල්	200 මි.ග්‍රෑ.	84.81
	සෙෆික්සිම්	මුඛ මාර්ගයෙන් දියර වශයෙන් ලබා ගැනීම	100 මි.ග්‍රෑ./5 මි.ලි.	685.25
12	ඇම්ලොඩිපින්	පෙති/කරල්	5 මි.ග්‍රෑ.	30.39
	ඇම්ලොඩිපින්	පෙති/කරල්	10 මි.ග්‍රෑ.	42.31
13	ඩිල්ටියසම්	පෙති/කරල්	30 මි.ග්‍රෑ.	5.38
	ඩිල්ටියසම්	පෙති/කරල්	60 මි.ග්‍රෑ.	17.69
	ඩිල්ටියසම්	පෙති/කරල්	90 මි.ග්‍රෑ.	42.51
14	ලොසාටන් පොටෑසියම්	පෙති/කරල්	25 මි.ග්‍රෑ.	14.59
	ලොසාටන් පොටෑසියම්	පෙති/කරල්	50 මි.ග්‍රෑ.	20.46
15	ලොසාටන්-හයිඩ්‍රොක්ලෝරෝතයෝසයිඩ්	පෙති/කරල්	62.5 මි.ග්‍රෑ.	38.62
16	එනලප්‍රිල්	පෙති/කරල්	5 මි.ග්‍රෑ.	11.91
	එනලප්‍රිල්	පෙති/කරල්	10 මි.ග්‍රෑ.	20.08
17	ඇටනොලෝල්	පෙති/කරල්	25 මි.ග්‍රෑ.	5.95
	ඇටනොලෝල්	පෙති/කරල්	50 මි.ග්‍රෑ.	8.74
	ඇටනොලෝල්	පෙති/කරල්	100 මි.ග්‍රෑ.	25.82

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
18	නිෆඩිපින්-දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/කරල්	20 මි.ග්‍රෑ.	7.36
19	ක්ලෝපිඩොග්‍රෙල්	පෙති/කරල්	75 මි.ග්‍රෑ.	34.78
20	ඇටෝවාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑ.	12.76
	ඇටෝවාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ.	22.14
	ඇටෝවාස්ටැටින්	පෙති/කරල්	20 මි.ග්‍රෑ.	34.95
	ඇටෝවාස්ටැටින්	පෙති/කරල්	40 මි.ග්‍රෑ.	49.17
21	රොසුවාස්ටැටින්	පෙති/කරල්	5 මි.ග්‍රෑ.	42.70
	රොසුවාස්ටැටින්	පෙති/කරල්	10 මි.ග්‍රෑ.	73.47
22	ටෙල්මිසාටන්	පෙති/කරල්	20 මි.ග්‍රෑ.	20.25
	ටෙල්මිසාටන්	පෙති/කරල්	40 මි.ග්‍රෑ.	32.17
	ටෙල්මිසාටන්	පෙති/කරල්	80 මි.ග්‍රෑ.	60.38
23	ඇස්පිරින්	පෙති/කරල්	75 මි.ග්‍රෑ.	5.95
	ඇස්පිරින්	පෙති/කරල්	100 මි.ග්‍රෑ.	10.53
24	**මෙට්පෝමින්**	පෙති/කරල්	500 මි.ග්‍රෑ.	7.85
	මෙට්පෝමින් - දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	පෙති/කරල්	500 මි.ග්‍රෑ.	15.29
	මෙට්පෝමින්	පෙති/කරල්	850 මි.ග්‍රෑ.	14.70
25	**ග්ලිබෙන්ක්ලමයිඩ්**	**පෙති/කරල්**	**5 මි.ග්‍රෑ.**	**4.35**
26	**ග්ලික්ලසයිඩ්**	**පෙති/කරල්**	80 මි.ග්‍රෑ.	**22.45**

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
27	තයිරොක්සින්	පෙති/කරල්	50 මයික්‍රෝ ග්‍රෑ.	12.10
	තයිරොක්සින්	පෙති/කරල්	100 මයික්‍රෝ ග්‍රෑ.	18.09
28	ග්ලිපිසයිඩ්	පෙති/කරල්	5 මි.ග්‍රෑ.	15.70
29	ඉබියුප්‍රොෆෙන්	පෙති/කරල්	200 මි.ග්‍රෑ.	2.18
	ඉබියුප්‍රොෆෙන්	පෙති/කරල්	400 මි.ග්‍රෑ.	7.36
30	ඩයික්ලොෆෙනැක් සෝඩියම්	පෙති/කරල්	50 මි.ග්‍රෑ.	25.82
	ඩයික්ලොෆෙනැක් සෝඩියම්	පෙති/කරල්	100 මි.ග්‍රෑ.	29.99
31	ඩයික්ලොෆෙනැක් පොටෑසියම්	පෙති/කරල්	50 මි.ග්‍රෑ.	21.76
32	පැරසිටමෝල්	පෙති/කරල්	500 මි.ග්‍රෑ.	3.49
33	සෝඩියම් වැල්ප්‍රොඒට්	පෙති/කරල්	200 මි.ග්‍රෑ.	17.88
34	රිස්පෙරිඩෝන්	පෙති/කරල්	1 මි.ග්‍රෑ.	15.70
	රිස්පෙරිඩෝන්	පෙති/කරල්	2 මි.ග්‍රෑ.	18.35
35	ඔලන්සපින්	පෙති/කරල්	5 මි.ග්‍රෑ.	19.87
	ඔලන්සපින්	පෙති/කරල්	10 මි.ග්‍රෑ.	41.29
36	කාබම්සපින්	පෙති/කරල්	200 මි.ග්‍රෑ.	23.81

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
37	ඇල්ප්‍රසෝලැම්	පෙති/කරල්	0.25 මි.ග්‍රෑ.	12.91
	ඇල්ප්‍රසෝලැම්	පෙති/කරල්	0.5 මි.ග්‍රෑ.	19.67
38	ෆ්ලූඔක්සටින්	පෙති/කරල්	20 මි.ග්‍රෑ.	21.85
39	ගැබාපෙන්ටින්	පෙති/කරල්	100 මි.ග්‍රෑ.	33.27
	ගැබාපෙන්ටින්	පෙති/කරල්	300 මි.ග්‍රෑ.	65.85
40	බෙක්ලොමෙතසෝන්	ඩී. පී කරල් (ආශ්වාස කිරීම)	200 මයික්‍රෝ ග්‍රෑ.	11.91
	බෙක්ලොමෙතසෝන්	ඩී. පී කරල් (ආශ්වාස කිරීම)	400 මයික්‍රෝ ග්‍රෑ.	13.50
	බෙක්ලොමෙතසෝන්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	100 මයික්‍රෝ ග්‍රෑ.	1,008.03
	බෙක්ලොමෙතසෝන්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	250 මයික්‍රෝ ග්‍රෑ.	1,114.29
41	සැල්බියුටමෝල්	ඩී. පී කරල් (ආශ්වාස කිරීම)	200 මයික්‍රෝ ග්‍රෑ.	7.94
	සැල්බියුටමෝල්	ඩී. පී කරල් (ආශ්වාස කිරීම)	400 මයික්‍රෝ ග්‍රෑ.	10.93
	සැල්බියුටමෝල්	මීටර් මාත්‍රා ආශ්වාස උපකරණය (මාත්‍රා 200)	100 මයික්‍රෝ ග්‍රෑ.	615.75
42	මීතයිල්ප්‍රෙඩ්නිසෝලෝන්	පෙති/කරල්	4 මි.ග්‍රෑ.	23.53
	මීතයිල්ප්‍රෙඩ්නිසෝලෝන්	පෙති/කරල්	16 මි.ග්‍රෑ.	81.44
43	ඔමෙප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	8.94

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
44	පැන්ටොප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	33.75
	පැන්ටොප්‍රසෝල්	පෙති/කරල්	40 මි.ග්‍රෑ.	55.60
45	ඉසොමෙප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	40.11
	ඉසොමෙප්‍රසෝල්	පෙති/කරල්	40 මි.ග්‍රෑ.	76.27
46	ඩොම්පෙරිඩෝන්	පෙති/කරල්	10 මි.ග්‍රෑ.	10.73
47	රබිප්‍රසෝල්	පෙති/කරල්	10 මි.ග්‍රෑ.	22.45
	රබිප්‍රසෝල්	පෙති/කරල්	20 මි.ග්‍රෑ.	42.81
48	ඇලෙන්ඩ්‍රොනික් ඇසිඩ්	පෙති/කරල්	70 මි.ග්‍රෑ.	201.40
49	සෙෆ්ටසිඩීම්	නිත්ශේපන	500 මි.ග්‍රෑ.	908.01
	සෙෆ්ටසිඩීම්	නිත්ශේපන	1 ග්‍රෑ.	1,513.36
50	සෙෆ්ට්‍රියැක්සෝන්	නිත්ශේපන	250 මි.ග්‍රෑ.	454.00
	සෙෆ්ට්‍රියැක්සෝන්	නිත්ශේපන	500 මි.ග්‍රෑ.	851.26
	සෙෆ්ට්‍රියැක්සෝන්	නිත්ශේපන	1 ග්‍රෑ.	1,324.18
51	සෙෆොටැක්සිම්	නිත්ශේපන	500 මි. ග්‍රෑ.	425.64
	සෙෆොටැක්සිම්	නිත්ශේපන	1 ග්‍රෑ.	709.39
52	ෆ්ලුකොනසෝල්	පෙති/කරල්	50 මි.ග්‍රෑ.	47.28
	ෆ්ලුකොනසෝල්	පෙති/කරල්	150 මි.ග්‍රෑ.	85.12

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
53	ඉන්සියුලින් සොලියුබල් හියුමන්	නික්ෂේපන	100 අයි.යු/1මි.ලී. (10 මි.ලී.කුප්පිය)	2,270.02
	ඉන්සියුලින් සොලියුබල් හියුමන්	නික්ෂේපන	100 අයි.යු/1 මි.ලී. (3 මි.ලී. කාට්‍රිජය)	1,135.02
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නික්ෂේපන	100 අයි.යු/1 මි.ලී. (10 මි.ලී. කුප්පිය)	2,270.02
	ඉන්සියුලින් අයිසොෆෙන් හියුමන්	නික්ෂේපන	100 අයි.යු/1 මි.ලී (3 මි.ලී. කාට්‍රිජය)	1,135.02
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින් (ඉන්සියුලින් සොලියුබල් හියුමන් 30 අයි.යු/1 මී.ලී, ඉන්සියුලින් අයිසෝෆෙන් හියුමන් 70 අයි.යු/1 මී.ලී) මිශ්‍රණය ලෙස	නික්ෂේපන	100 අයි.යු/1 මි.ලී. (10 මි.ලී. කුප්පිය)	2,270.02
	බයිෆෙසික් අයිසෝෆෙන් ඉන්සියුලින් (ඉන්සියුලින් සොලියුබල් හියුමන් 30 අයි.යු/1 මී.ලී, ඉන්සියුලින් අයිසෝෆෙන් හියුමන් 70 අයි.යු/1 මී.ලී) මිශ්‍රණය ලෙස	නික්ෂේපන	100 අයි.යු/1 මි.ලී (3 මි.ලී. කාට්‍රිජය)	1,135.02
54	ග්ලිමිපිරයිඩ්	පෙති	1 මි.ග්‍රෑ.	13.53
	ග්ලිමිපිරයිඩ්	පෙති	2 මි.ග්‍රෑ.	19.19
	ග්ලිමිපිරයිඩ්	පෙති	3 මි.ග්‍රෑ.	32.16
	ග්ලිමිපිරයිඩ්	පෙති	4 මි.ග්‍රෑ.	34.99
55	සිටාග්ලිප්ටින්	පෙති	25 මි.ග්‍රෑ.	28.37
	සිටාග්ලිප්ටින්	පෙති	50 මි.ග්‍රෑ.	53.89
	සිටාග්ලිප්ටින්	පෙති	100 මි.ග්‍රෑ.	91.74

I වන තීරුව	II වන තීරුව ඖෂධීය නාමය	III වන තීරුව ලබා ගනු ලබන ක්‍රමය/මාත්‍රා ආකාරය	IV වන තීරුව ප්‍රබලතාවය	V වන තීරුව උපරිම සිල්ලර මිල/ ශ්‍රී ලංකා රුපියල්
56	වැම්සුලොසීන්	පෙති/කරල්	0.40 මි.ග්‍රෑ.	39.72
57	මොන්ටිලුකාස්ට්	පෙති	4 මි.ග්‍රෑ.	22.71
	මොන්ටිලුකාස්ට්	පෙති	5 මි.ග්‍රෑ.	28.37
	මොන්ටිලුකාස්ට්	පෙති	10 මි.ග්‍රෑ.	39.72
58	ප්‍රෙගබලීන්	පෙති/කරල්	50 මි.ග්‍රෑ.	23.17
	ප්‍රෙගබලීන්	පෙති/කරල්	75 මි.ග්‍රෑ.	29.33
	ප්‍රෙගබලීන්	පෙති/කරල්	100 මි.ග්‍රෑ.	36.41
	ප්‍රෙගබලීන්	පෙති/කරල්	150 මි.ග්‍රෑ.	45.40
	ප්‍රෙගබලීන්	පෙති/කරල්	300 මි.ග්‍රෑ.	74.73
59	ටොපිරමේට්	පෙති/කරල්	25 මි.ග්‍රෑ.	37.83
	ටොපිරමේට්	පෙති/කරල්	50 මි.ග්‍රෑ.	60.53
	ටොපිරමේට්	පෙති/කරල්	100 මි.ග්‍රෑ.	98.36
60	ලැමෝට්‍රිජීන්	පෙති	25 මි.ග්‍රෑ.	22.71
	ලැමෝට්‍රිජීන්	පෙති	50 මි.ග්‍රෑ.	39.72
	ලැමෝට්‍රිජීන්	පෙති	100 මි.ග්‍රෑ.	66.21"

(3) මෙම නියෝගවල විධිවිධාන 2023 ජූනි මස 26 වැනි දින සිට බලපැවැත්වෙයි.

EOG 06 - 0101

ශ්‍රී ලංකා රජයේ මුද්‍රණ දෙපාර්තමේන්තුවේ මුද්‍රණය කරන ලදි.

2023.06.15 දිනැති ගැසට් පත්‍රය මඟින් ඖෂධ 60 හි මිල අඩු කළ ද, අනෙකුත් ඖෂධවල මිල පහළ නොදැමූ ප්‍රතිශතය ගණනය කිරීම

	ඖෂධය	මාත්‍රාව	ගැසට් දිනය		පහළ දැමූ මිල රු.	මිල පහළ දැමූ % (Rounded)
			2022.04.29	2023.06.15		
1	ඇල්බෙන්ඩසෝල්	400mg	70.94	59.59	11.35	16
2	ඇමොක්සිලින් - ක්ලැවුලිනික් ඇසිඩ්	156 mg/5ml	679.83	571.06	108.77	16
	ඇමොක්සිලින් - ක්ලැවුලිනික් ඇසිඩ්	375mg	83.71	70.32	13.39	16
	ඇමොක්සිලින් - ක්ලැවුලිනික් ඇසිඩ්	652mg	141.86	119.16	22.7	16
	ඇමොක්සිලින් - ක්ලැවුලිනික් ඇසිඩ්	1.2g	1492.06	1253.33	238.73	16
3	ක්ලැරිත්‍රෝමයිසින්	250mg	86.31	72.5	13.81	16
	ක්ලැරිත්‍රෝමයිසින්	500mg	174.99	146.99	28	16
	ක්ලැරිත්‍රෝමයිසින්	125mg/5ml	1030.96	866.01	164.95	16
4	ඇසිත්‍රෝමයිසින්	250mg	88.91	74.68	14.23	16
	ඇසිත්‍රෝමයිසින්	500mg	124.74	104.78	19.96	16
	ඇසිත්‍රෝමයිසින්	200mg/5ml	413.78	347.58	66.2	16
5	සෙෆියුරොක්සිම්	250mg	107.59	90.38	17.21	16
	සෙෆියුරොක්සිම්	500mg	171.65	144.19	27.46	16
6	ඩොක්සිසයික්ලින්	100mg	23.9	20.08	3.82	16
7	ඇසික්ලොව්ර්	200mg	87.46	73.47	13.99	16
8	සිප්‍රොෆ්ලොක්සසින්	250mg	13.59	11.42	2.17	16
	සිප්‍රොෆ්ලොක්සසින්	500mg	20.1	16.88	3.22	16
9	ලෙවෝෆ්ලොක්සසින්	250mg	57.22	48.06	9.16	16
	ලෙවෝෆ්ලොක්සසින්	500mg	94.58	79.45	15.13	16
10	සෙපලෙක්සින්	250mg	19.38	16.28	3.1	16

	සෙපලෙක්සින්	500mg	35.38	29.81	5.57	16
	සෙපලෙක්සින්	125mg/5ml	626.61	526.35	100.26	16
11	සෙෆික්සිම්	100mg	54.38	45.68	8.7	16
	සෙෆික්සිම්	200mg	100.97	84.81	16.16	16
	සෙෆික්සිම්	100mg/5ml	815.77	685.25	130.52	16
12	ඇම්ලොඩිපින්	5mg	36.18	30.39	5.79	16
	ඇම්ලොඩිපින්	10mg	50.37	42.31	8.06	16
13	ඩිල්ටියසම්	30mg	6.4	5.38	1.02	16
	ඩිල්ටියසම්	60mg	21.06	17.69	3.37	16
	ඩිල්ටියසම්	90mg	50.61	42.51	8.1	16
14	ලොසාටන් පොටැසියම්	25mg	17.37	14.59	2.78	16
	ලොසාටන් පොටැසියම්	50mg	24.36	20.46	3.9	16
15	ලොසාටන් - හයිඩ්‍රොක්ලෝරෝතයෝසයිඩ්	62.5mg	45.98	38.62	7.36	16
16	එනලප්‍රිල්	5mg	14.18	11.91	2.27	16
	එනලප්‍රිල්	10mg	23.9	20.08	3.82	16
17	ඇටනොලෝල්	25mg	7.08	5.95	1.13	16
	ඇටනොලෝල්	50mg	10.4	8.74	1.66	16
	ඇටනොලෝල්	100mg	30.74	25.82	4.92	16
18	නිෆඩිපින් - දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	20mg	8.76	7.36	1.4	16
19	ක්ලෝපිඩොග්‍රෙල්	75mg	41.4	34.78	6.62	16
20	ඇටෝවාස්ටැටින්	5mg	15.19	12.76	2.43	16
	ඇටෝවාස්ටැටින්	10mg	26.36	22.14	4.22	16
	ඇටෝවාස්ටැටින්	20mg	41.61	34.95	6.66	16
	ඇටෝවාස්ටැටින්	40mg	58.53	49.17	9.36	16

21	රොසුවාස්ටැටින්	5mg	50.83	42.7	8.13	16
	රොසුවාස්ටැටින්	10mg	87.46	73.47	13.99	16
22	ටෙල්මිසාටන්	20mg	24.11	20.25	3.86	16
	ටෙල්මිසාටන්	40mg	38.3	32.17	6.13	16
	ටෙල්මිසාටන්	80mg	71.88	60.38	11.5	16
23	ඇස්පිරින්	75mg	7.08	5.95	1.13	16
	ඇස්පිරින්	100mg	12.53	10.53	2	16
24	මෙට්පෝමින්	500mg	9.34	7.85	1.49	16
	මෙට්පෝමින් - දීර්ඝ ක්‍රියාකාරිත්වයක් සහිත	500mg	18.2	15.29	2.91	16
	මෙට්පෝමින්	850mg	17.5	14.7	2.8	16
25	ග්ලිබෙන්ක්ලමයිඩ්	5mg	5.18	4.35	0.83	16
26	ග්ලික්ලසයිඩ්	80mg	26.73	22.45	4.28	16
27	නයිරොක්සින්	50mcg	14.41	12.1	2.31	16
	නයිරොක්සින්	100mcg	21.53	18.09	3.44	16
28	ග්ලිපිසයිඩ්	5mg	18.69	15.7	2.99	16
29	ඉබියුප්‍රොෆෙන්	200mg	2.6	2.18	0.42	16
	ඉබියුප්‍රොෆෙන්	400mg	8.76	7.36	1.4	16
30	ඩයික්ලොෆෙනැක් සෝඩියම්	50mg	30.74	25.82	4.92	16
	ඩයික්ලොෆෙනැක් සෝඩියම්	100mg	35.7	29.99	5.71	16
31	ඩයික්ලොෆෙනැක් පොටැසියම්	50mg	25.9	21.76	4.14	16
32	පැරසිටමෝල්	500mg	4.16	3.49	0.67	16
33	සෝඩියම් වැල්ප්‍රොඒට්	200mg	21.28	17.88	3.4	16

34	රිස්පෙරිඩොන්	1mg	18.69	15.7	2.99	16
	රිස්පෙරිඩොන්	2mg	21.85	18.35	3.5	16
35	ඔලන්සපින්	5mg	23.65	19.87	3.78	16
	ඔලන්සපින්	10mg	49.15	41.29	7.86	16
36	කාබමසපින්	200mg	28.35	23.81	4.54	16
37	ඇල්ප්‍රසෝලෑම්	0.25mg	15.37	12.91	2.46	16
	ඇල්ප්‍රසෝලෑම්	0.5mg	23.42	19.67	3.75	16
38	ෆ්ලුඔක්සටින්	20mg	26.01	21.85	4.16	16
39	ගැබාපෙන්ටින්	100mg	39.61	33.27	6.34	16
	ගැබාපෙන්ටින්	300mg	78.39	65.85	12.54	16
40	බෙක්ලොමෙතසෝන්	200mcg	14.18	11.91	2.27	16
	බෙක්ලොමෙතසෝන්	400mcg	16.07	13.5	2.57	16
	බෙක්ලොමෙතසෝන්	100mcg	1200.04	1008.03	192.01	16
	බෙක්ලොමෙතසෝන්	250mcg	1326.53	1114.29	212.24	16
41	සැල්බියුටමෝල්	200mcg	9.45	7.94	1.51	16
	සැල්බියුටමෝල්	400mcg	13.01	10.93	2.08	16
	සැල්බියුටමෝල්	100mcg	733.03	615.75	117.28	16
42	මීතයිල්ප්‍රෙඩ්නිසෝලෝන්	4mg	28.01	23.53	4.48	16
	මීතයිල්ප්‍රෙඩ්නිසෝලෝන්	16mg	96.95	81.44	15.51	16
43	ඔමෙප්‍රසෝල්	20mg	10.64	8.94	1.7	16
44	පැන්ටොප්‍රසෝල්	20mg	40.18	33.75	6.43	16
	පැන්ටොප්‍රසෝල්	40mg	66.19	55.6	10.59	16
45	ඉසොමෙප්‍රසෝල්	20mg	47.75	40.11	7.64	16
	ඉසොමෙප්‍රසෝල්	40mg	90.8	76.27	14.53	16

46	ඩොම්පෙරිඩෝන්	10mg	12.77	10.73	2.04	16
47	රබිප්‍රසෝල්	10mg	26.73	22.45	4.28	16
	රබිප්‍රසෝල්	20mg	50.96	42.81	8.15	16
48	ඇලෙන්ඩ්‍රොනික් ඇසිඩ්	70mg	239.76	201.4	38.36	16
49	සෙෆ්ටසිඩිම්	500mg	1080.97	908.01	172.96	16
	සෙෆ්ටසිඩිම්	1g	1801.62	1513.36	288.26	16
50	සෙෆ්ට්‍රිඇක්සෝන්	250mg	540.48	454	86.48	16
	සෙෆ්ට්‍රිඇක්සෝන්	500mg	1013.4	851.26	162.14	16
	සෙෆ්ට්‍රිඇක්සෝන්	1g	1576.4	1324.18	252.22	16
51	සෙෆොටැක්සිම්	500mg	506.72	425.64	81.08	16
	සෙෆොටැක්සිම්	1g	844.51	709.39	135.12	16
52	ෆ්ලූකොනසෝල්	50mg	56.29	47.28	9.01	16
	ෆ්ලූකොනසෝල්	150mg	101.33	85.12	16.21	16
53	ඉන්සියුලින් සොලියුබල් හියුමන්	100IU/1ml (10ml කුප්පිය)	2702.41	2270.02	432.39	16
	ඉන්සියුලින් සොලියුබල් හියුමන්	100IU/1ml (3ml කාට්‍රිජය)	1351.21	1135.02	216.19	16
	ඉන්සියුලින් සොලියුබල් හියුමන්	100IU/1ml (10ml කුප්පිය)	2702.41	2270.02	432.39	16
	ඉන්සියුලින් සොලියුබල් හියුමන්	100IU/1ml (3ml කාට්‍රිජය))	1351.21	1135.02	216.19	16
	බයිෆෙසික් අයිසෝෆේන් ඉන්සියුලින් (ඉන්සියුලින් ෙ	100IU/1ml (10ml කුප්පිය)	2702.41	2270.02	432.39	16
	බයිෆෙසික් අයිසෝෆේන් ඉන්සියුලින් (ඉන්සියුලින් ෙ	100IU/1ml (3ml කාට්‍රිජය))	1351.21	1135.02	216.19	16
54	ග්ලිමිපිරයිඩ්	1mg	16.11	13.53	2.58	16
	ග්ලිමිපිරයිඩ්	2mg	22.85	19.19	3.66	16
	ග්ලිමිපිරයිඩ්	3mg	38.29	32.16	6.13	16
	ග්ලිමිපිරයිඩ්	4mg	41.65	34.99	6.66	16
55	සිටාග්ලිප්ටින්	25mg	33.77	28.37	5.4	16
	සිටාග්ලිප්ටින්	50mg	64.16	53.89	10.27	16

	සිටාග්ලිප්ටින්	100mg	109.21	91.74	17.47	16
56	ටැම්සුලොසින්	0.40mg	47.28	39.72	7.56	16
57	මොන්ටිලුකාස්ට්	4mg	27.03	22.71	4.32	16
	මොන්ටිලුකාස්ට්	5mg	33.77	28.37	5.4	16
	මොන්ටිලුකාස්ට්	10mg	47.28	39.72	7.56	16
58	ප්‍රෙගබලීන්	50mg	27.58	23.17	4.41	16
	ප්‍රෙගබලීන්	75mg	34.92	29.33	5.59	16
	ප්‍රෙගබලීන්	100mg	43.34	36.41	6.93	16
	ප්‍රෙගබලීන්	150mg	54.05	45.4	8.65	16
	ප්‍රෙගබලීන්	300mg	88.97	74.73	14.24	16
59	ටොපිරමේට්	25mg	45.04	37.83	7.21	16
	ටොපිරමේට්	50mg	72.06	60.53	11.53	16
	ටොපිරමේට්	100mg	117.1	98.36	18.74	16
60	ලැමෝට්‍රිජින්	25mg	27.03	22.71	4.32	16
	ලැමෝට්‍රිජින්	50mg	47.28	39.72	7.56	16
	ලැමෝට්‍රිජින්	100mg	78.82	66.21	12.61	16

14.

(ච) අවශ්‍ය බවට සලකනු ලබන යම් ඖෂධයක්, වෛද්‍ය උපකරණයක් හෝ සීමාස්ථ නිෂ්පාදනයක් පරීක්ෂා කිරීම සඳහා දේශීය හෝ විදේශීය පර්යේෂණාගාර පිළිගැනීම සහ පත් කිරීම;

(ජ) නියෝග මගින් නියමකර ඇති ආකාරයට යහපත් නියාමන පරිචයන් (ජීආර්පී) අනුගමනය කිරීම;

ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදනවල ආරම්භක මිල තීරණය කිරීම සහ පසුකාලීන මිල ප්‍රතිශෝධනය පිළිබඳ අමාත්‍යවරයාට උපදෙස් ලබාදීම;

(ඩ) අධිකාරියේ කර්තව්‍ය පිළිබඳව උනන්දුවක් දක්වන සියලු දෙනා සහ පොදු මහජනතාව වෙත අවශ්‍ය තොරතුරු සැපයීම; සහ

(ත) ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදනවලට අදාළ මාර්ගෝපදේශ, නිර්දේශ, විධාන සහ රීති නිකුත් කිරීම, අධීක්ෂණය සහ යාවත්කාලීන කිරීම.

II වන කොටස

අධිකාරියේ ප්‍රධාන විධායක නිලධරයා සහ කාර්ය මණ්ඩලය පත්කිරීම

අධිකාරියේ ප්‍රධාන විධායක නිලධරයා පත්කිරීම.

15. (1) අධිකාරිය විසින් අමාත්‍යවරයා විමසා පිළිගත් විශ්වවිද්‍යාලයක වෛද්‍ය වේදය, ඖෂධ වෛද්‍ය වේදය, ඖෂධ වේදය හෝ ඒ අදාළ යම් වෙනත් විෂයක් සම්බන්ධයෙන් පශ්චාත් උපාධියක් සහිත ජ්‍යෙෂ්ඨ විධායක මට්ටමේ අවම වශයෙන් අවුරුදු පහක කළමනාකරණ පළපුරුද්දක් සහිත තැනැත්තන් අතරින් (මෙහි මින්මතු "ප්‍රධාන විධායක නිලධරයා" යනුවෙන් සඳහන් කරනු ලබන) අධිකාරියේ කාර්ය මණ්ඩලය සඳහා ප්‍රධාන විධායක නිලධරයකු පත්කරනු ලැබිය යුතු ය.

(2) අධිකාරියේ පොදු විධානයන්ට සහ අධීක්ෂණයට යටත්ව ප්‍රධාන විධායක නිලධරයා විසින් -

(අ) කාර්ය මණ්ඩලයේ පරිපාලනය සහ පාලනය ඇතුළු අධිකාරියේ කටයුතු පරිපාලනය පිළිබඳ වගකිව යුතු ය;

To : Focal Point Pricing Unit
From : Chief Executive Officer
Copies : Chairman, Administrative Officer, Chief Pharmacist, Ms. S L I Heshani (APA Pricing)
Subject : Appoint a new Pricing Committee to regulate the prices of therapeutic goods
Reference No : NMRA/CEO/BdMemo/2023 (89)
Board Paper No : 92.4.7
Date of the Board Meeting : 19.05.2023

Action to be taken:

☐ Web Notice / Publication ☐ Inform the MEC / MDEC / BPEC / CESC

☑ Action as related to the decision

☑ Other: letters to be prepared.

Decision:

The Board approved the new Pricing Committee consisting of the following members:

Ex-officio Members:

1. Prof. S D Jayaratne – Chairman / NMRA
2. Dr. Vijith Gunasekera – Chief Executive Officer / NMRA
3. Representative of the Consumer Affairs Authority
4. Mr. B M W Balasooriya – Pharmacist

Other Members:

5. A physician
6. Prof. Sirimal Abeyratne
7. Mr. Indrajith Aponsu
8. Dr. Chandrasiri Abeysinghe
9. Prof. Ruwan Jayathilaka
10. Mr. Achintha Hewanayake
11. Ms. S.L I Heshani – Assistant Pharmaceutical Assessor / Pricing Unit

Dr. Vijith Gunasekera
MBBS, MSc, MEcon, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

Dr. Vijith Gunasekera
Chief Executive Officer
National Medicines Regulatory Authority

24/10/23

(404)

Board Paper - National Medicines Regulatory Authority – May, 2023

A. Board Paper No: 92.4.7.. **Year:** 2023 **Month:** May **Date:** .....19.....

B. Subject: Appoint a new pricing committee to regulate the prices of therapeutic goods

C. Title of the Board Paper: Appoint a new pricing committee to regulate the prices of therapeutic goods

D. Reference to Previous Board Papers (If any): Not Applicable.

E. Department / Division / Unit: Office of the Chief Executive Officer, NMRA.

1. Brief Introduction :
The term of the current Pricing Committee has expired on 14th May 2023. Therefore, a new Pricing Committee needs to be appointed.

2. Background: The period of current pricing committee expired on 14th May 2023. Therefore, a new pricing committee should be appointed.
The pricing committee shall consist of the following:
(a) ex-officio members
(i) the Chairman of the National Medicines Regulatory Authority.
(ii) the Chief Executive Officer of the National Medicines Regulatory Authority.
(iii) a representative of the Consumer Affairs Authority. and
(iv) a pharmacist of the National Medicines Regulatory Authority.
(b) seven persons from among persons who have expertise, experience, or proven capacity in the fields of Medicine, Pharmacy, Economics, Commerce, Accountancy, Law or any other related field.

3. Expected Outcomes: Appoint a new pricing committee under the National Medicines Regulatory Authority to regulate the prices of therapeutic goods.

4. Financial Implications: The members of the Pricing Committee shall be paid such allowances as the Authority may determine.

5. Risk Analysis

Identified Risk	Risk Likelihood (H, M, L)	Impact (H, M, L)	Strategy to Manage Risk
Appoint a new pricing committee is an urgent requirement to regulate the prices without delay.	H	H	Appoint a new pricing committee as soon as possible.

6. Corporate Governance and Compliance

PAS
24/10/23

According to the existing price regulations, pricing committee is a vital component to regulate the prices of therapeutic goods under NMRA.

7. Certification and Recommendation

"This is to certify that the proposal herein before described in this board paper has been prepared having considered all the relevant provisions in the governing Act, regulations, circulars, procurement procedures etc and as such I recommend the aforesaid proposal **Appoint a new pricing committee to regulate the prices of therapeutic goods** to the members of the Board of NMRA for consideration and approval"

Dr. Vijith Gunasekera
MBBS, MSc, MEcon, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

Name and Signature of HOD / name of Division / Unit / Department.

8. Submission to Board Approval

"I recommend the aforesaid proposal submitted by Head of ..... with his/her recommendations to the members of the Board of NMRA for consideration /determination and approval"

Dr. Vijith Gunasekera
MBBS, MSc, MEcon, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

(Dr. Vijith Gumasekara)
Name and Signature of CEO, NMRA

PAR
24/10/23

තොර | ඇමුණුම 111

Pricing Committee Members list

No	Name	Designation	Appointed Date
01	Prof. S.D. Jayarathna	Chairman,National Medicines Regulatory Authority	2023.06.14
02	Dr.Vijith Gunasekara	Chief Exceutive Officer, National Medicines Regulatory Authority	2023.06.14
03	Prof.Sirimal Abeyrathne (Chairman,Pricing Committee)	Professor, Department of Economics, University of Colombo	2023.06.14
04	Prof.Chandrasiri Abeysinghe	Professor, Department of Accounting ,University of Colombo	2023.06.14
05	Mr. Achintha Hewanayake	Chief Executive Officer,CL Synergy Limited	2023.06.14
06	Prof. Ruwan Jayathilaka	Associate Professor,Sri Lanka Institute of Information Technology	2023.06.14
07	Mr. Indrajith Aponsu	Professor, Department of Economics, University of Colombo	2023.06.14
08	Dr. Mahanama Gunasekara	Consultant Surgeon, National Hospital	2023.06.14
09	Ms. W.M. Niluka Weerasekara (Secretary ,Pricing Committee)	Pharmaceutical Assessor,NMRA	2023.08.08
10	Ms.S.L.I. Heshani (Minute Secretary)	Assistant Pharmaceutical Assessor, NMRA	2023.06.14
11	Ms.Imasha Vidyangani (Cover-up Legal Officer)	Development Officer ,NMRA	2023.08.31

PAS
24/10/2023

401

සොරතුරු ඇමුණුම් අංක 02

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/DO3/05/2023	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	2023.06. 13

Prof. S.D. Jayaratne
Chairman
National Medicines Regulatory Authority
Colombo 10.

Appointment as a member of the Pricing Committee of the NMRA

As per the board decision taken at the Board Meeting held on 19.05.2023, I am pleased to inform you that you have been appointed as a member of the Pricing Committee. This appointment would be valid for period of 3 years with effect from 14.06.2023 unless vacated earlier by resignation or removal and shall be eligible for re-appointment.

A copy of the declaration form that should be filled by the members of all the expert committees will be received in the near future.

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond),
FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.

Prof. S.D. Jayaratne
Chairman
National Medicines Regulatory Authority

CC:

1. CEO /NMRA - FYI
2. Accountant/ NMRA - FYI & FNA
3. Administrative Officer/NMRA - FYI & FNA
4. Focal Point (Pricing Unit)/NMRA - FYI & FNA
5. Office Copy

PAS
24/10/2023

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/DO3/05/2023	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	2023.06.13

Dr. Vijith Gunasekera
Chief Executive Officer
National Medicines Regulatory Authority
Colombo 10.

Appointment as a member of the Pricing Committee of the NMRA

As per the board decision taken at the Board Meeting held on 19.05.2023, I am pleased to inform you that you have been appointed as a member of the Pricing Committee. This appointment would be valid for period of 3 years with effect from 14.06.2023 unless vacated earlier by resignation or removal and shall be eligible for re-appointment.

A copy of the declaration form that should be filled by the members of all the expert committees will be received in the near future.

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond), FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.

Prof. S.D. Jayaratne
Chairman
National Medicines Regulatory Authority

CC:

1. CEO /NMRA - FYI
2. Accountant/ NMRA - FYI & FNA
3. Administrative Officer/NMRA - FYI & FNA
4. Focal Point (Pricing Unit)/NMRA - FYI & FNA
5. Office Copy

PAB
21/10/23

(399)

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/DO3/05/2023	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	2023.06.13

Prof. Sirimal Abeyratne
Professor in Economics
Department of Economics
University of Colombo
Colombo 03.

Appointment as the Chairman of the Pricing Committee of the NMRA

As per the board decision taken at the Board Meeting held on 19.05.2023, I am pleased to inform you that you have been appointed as the Chairman of the Pricing Committee. This appointment would be valid for period of 3 years with effect from 14.06.2023 unless vacated earlier by resignation or removal and shall be eligible for re-appointment.

A copy of the declaration form that should be filled by the members of all the expert committees will be received in the near future.

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond), FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.

Prof. S.D. Jayaratne
Chairman
National Medicines Regulatory Authority

CC:

1. CEO /NMRA - FYI
2. Accountant/ NMRA - FYI & FNA
3. Administrative Officer/NMRA - FYI & FNA
4. Focal Point (Pricing Unit)/NMRA - FYI & FNA
5. Office Copy

PAS
24/10/23

398

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/DO3/05/2023	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	2023.06.13

Prof. Chandrasiri Abeysinghe
Professor of Accounting
Department of Accounting
Faculty of Management & Finance
University of Colombo
Colombo 03.

Appointment as a member of the Pricing Committee of the NMRA

As per the board decision taken at the Board Meeting held on 19.05.2023, I am pleased to inform you that you have been appointed as a member of the Pricing Committee. This appointment would be valid for period of 3 years with effect from 14.06.2023 unless vacated earlier by resignation or removal and shall be eligible for re-appointment.

A copy of the declaration form that should be filled by the members of all the expert committees will be received in the near future.

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond),
FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.

Prof. S.D. Jayaratne
Chairman
National Medicines Regulatory Authority

CC:

1. CEO /NMRA - FYI
2. Accountant/ NMRA - FYI & FNA
3. Administrative Officer/NMRA - FYI & FNA
4. Focal Point (Pricing Unit)/NMRA - FYI & FNA
5. Office Copy

PAB
24/10/23

(397)

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/DO3/05/2023	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	2023.06. 13

Mr. Achintha Hewanayake
Chief Executive Officer
CL Synergy Limited
No. 30, 6th Floor,
R. A. De Mel Mawatha,
Colombo 03.

Appointment as a member of the Pricing Committee of the NMRA

As per the board decision taken at the Board Meeting held on 19.05.2023, I am pleased to inform you that you have been appointed as a member of the Pricing Committee. This appointment would be valid for period of 3 years with effect from 14.06.2023 unless vacated earlier by resignation or removal and shall be eligible for re-appointment.

A copy of the declaration form that should be filled by the members of all the expert committees will be received in the near future.

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond),
FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.

Prof. S.D. Jayaratne
Chairman
National Medicines Regulatory Authority

CC:

1. CEO /NMRA - FYI
2. Accountant/ NMRA - FYI & FNA
3. Administrative Officer/NMRA - FYI & FNA
4. Focal Point (Pricing Unit)/NMRA - FYI & FNA
5. Office Copy

PAS
24/10/23

396

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/DO3/05/2023	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	2023.06.13

Prof. Ruwan Jayathilaka
Associate Professor
Department of Information Management
Sri Lanka Institute of Information Technology
New Kandy Road
Malabe.

Appointment as a member of the Pricing Committee of the NMRA

As per the board decision taken at the Board Meeting held on 19.05.2023, I am pleased to inform you that you have been appointed as a member of the Pricing Committee. This appointment would be valid for period of 3 years with effect from 14.06.2023 unless vacated earlier by resignation or removal and shall be eligible for re-appointment.

A copy of the declaration form that should be filled by the members of all the expert committees will be received in the near future.

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond),
FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
120, Norris Canal Road, Colombo 10.

Prof. S.D. Jayaratne
Chairman
National Medicines Regulatory Authority

CC:

1. CEO /NMRA - FYI
2. Accountant/ NMRA - FYI & FNA
3. Administrative Officer/NMRA - FYI & FNA
4. Focal Point (Pricing Unit)/NMRA - FYI & FNA
5. Office Copy

PAS
20/10/23

(395)

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/DO3/05/2023	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	2023.06. 13

Mr. Indrajith Aponsu
Senior Lecturer
Department of Economics
University of Colombo
Colombo 03.

Appointment as a member of the Pricing Committee of the NMRA

As per the board decision taken at the Board Meeting held on 19.05.2023, I am pleased to inform you that you have been appointed as a member of the Pricing Committee. This appointment would be valid for period of 3 years with effect from 14.06.2023 unless vacated earlier by resignation or removal and shall be eligible for re-appointment.

A copy of the declaration form that should be filled by the members of all the expert committees will be received in the near future.

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond),
FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.

Prof. S.D. Jayaratne
Chairman
National Medicines Regulatory Authority

CC:

1. CEO /NMRA - FYI
2. Accountant/ NMRA - FYI & FNA
3. Administrative Officer/NMRA - FYI & FNA
4. Focal Point (Pricing Unit)/NMRA - FYI & FNA
5. Office Copy

PAS
24/10/23

(394)

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/DO3/05/2023	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	2023.07.20

Dr. Mahanama Gunasekera
Consultant Surgeon
National Hospital
Colombo 10

Appointment as a member of the Pricing Committee of the NMRA

As per the board decision taken at the Board Meeting held on 19.05.2023, I am pleased to inform you that you have been appointed as a member of the Pricing Committee. This appointment would be valid for period of 3 years with effect from 14.06.2023 unless vacated earlier by resignation or removal and shall be eligible for re-appointment.

A copy of the declaration form that should be filled by the members of all the expert committees will be received in the near future.

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond), FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.

Prof. S.D. Jayaratne
Chairman
National Medicines Regulatory Authority

CC:

1. CEO /NMRA - FYI
2. Accountant/ NMRA - FYI & FNA
3. Administrative Officer/NMRA - FYI & FNA
4. Focal Point (Pricing Unit)/NMRA - FYI & FNA
5. Office Copy

PAS
24/10/23

393

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/CH/59/2022	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	04.09.2023

Ms. W.M.Niluka Weerasekara,
Pharmaceutical Assessor,
National Medicines Regulatory Authority,
No.120, Norris Canal Road,
Colombo 10.

Appointment as the Secretary of the Pricing Committee of the NMRA

This is to inform you that you have been appointed as a member of the Pricing Committee of the NMRA. This appointment would be valid for period of 3 years with effect from 08.08.2023 unless vacated earlier by resignation or removal and shall be eligible for re-appointment.

A copy of the declaration form that should be filled by the members of all the expert committees will be received in the near future.

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond),
FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.

Prof.S.D.Jayaratne,
Chairman,
National Medicines Regulatory Authority

CC:

1. CEO/NMRA - FYI
2. Accountant/NMRA - FYI & FNA
3. Administrative Officer/NMRA - FYI & FNA
4. Focal Point (Pricing Unit)/NMRA - FYI & FNA
5. Office Copy

PAS
24/01/23

+94 11 269 51 73 | +94 11 269 88 96/7 +94 11252 33 85 www.nmra.gov.lk info@nmra.gov.lk
NMRA, No. 120, Norris Canal Road, Colombo 10, Sri Lanka.

(392)

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/DO3/05/2023	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	2023.06. 13

Ms. S.L.I. Heshani
Assistant Pharmaceutical Assessor
National Medicines Regulatory Authority
Colombo 10.

Appointment as the minute secretary of the Pricing Committee of the NMRA

As per the board decision taken at the Board Meeting held on 19.05.2023, I am pleased to inform you that you have been appointed as the minute secretary of the Pricing Committee. This appointment would be valid for period of 3 years with effect from 14.06.2023 unless vacated earlier by resignation or removal and shall be eligible for re-appointment.

A copy of the declaration form that should be filled by the members of all the expert committees will be received in the near future.

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond),
FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.

Prof. S.D. Jayaratne
Chairman
National Medicines Regulatory Authority

CC:

1. CEO /NMRA - FYI
2. Accountant/ NMRA - FYI & FNA
3. Administrative Officer/NMRA - FYI & FNA
4. Focal Point (Pricing Unit)/NMRA - FYI & FNA
5. Office Copy

PAS
24/10/23

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

මගේ අංකය எனது இல. My No.	NMRA/CH/59/2022	ඔබේ අංකය உங்கள் இல. Your No.		දිනය திகதி Date	04.09.2023

Ms.Imasha Vidyangani,
National Medicines Regulatory Authority,
No.120, Norris Canal Road,
Colombo 10.

Appointment as a member of the Pricing Committee of the NMRA

This is to inform you that you have been appointed as a member of the Pricing Committee of the NMRA. This appointment would be valid for period of 3 years with effect from 31.08.2023 unless vacated earlier by resignation or removal and shall be eligible for re-appointment.

A copy of the declaration form that should be filled by the members of all the expert committees will be received in the near future.

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond),
FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.

Prof.S.D.Jayaratne,
Chairman,
National Medicines Regulatory Authority

CC:

1. CEO/NMRA - FYI
2. Accountant/NMRA - FYI & FNA
3. Administrative Officer/NMRA - FYI & FNA
4. Focal Point (Pricing Unit)/NMRA - FYI & FNA
5. Office Copy

PAS
24/10/23

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருத்துவ ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

දිනය திகதி Date: 17.07.2023

මගේ අංකය எனது இல. My No.: NMRA/CEO/BdMemo/2023

To : Focal Point Pricing Unit, Ms. S L I Heshani, APA Pricing Unit

From : Chief Executive Officer

Copies : Administrative Officer

Subject : Confirmation for the approved MRPs of the medicines

Reference No : NMRA/CEO/BdMemo/2023 (119)

Board Paper No : 93.5.2

Date of the Board Meeting : 16.06.2023

Action to be taken:

☐ Web Notice / Publication

☐ Inform the MEC / MDEC / BPEC / CESC

☑ Action as related to the decision

☐ Other:

Decision:

Due to the huge backlog for import licences and dossier evaluations pending pricing decisions, the Board approved the Note to the Board submitted by the pricing unit and the indicated Maximum Retail Prices (MRPs) for the products given in the annexure.

Dr. Vijith Gunasekera
MBBS, MSc, MEcon, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

Dr. Vijith Gunasekera
Chief Executive Officer
National Medicines Regulatory Authority

389

Note to the Board- National Medicines Regulatory Authority - 2023

A. **Board Paper: No**...93:5:2..... **Year:** 2023 **Month:** June **Date**.....16.....

B. **Subject:** confirmation for the approved MRPs of the medicine

C. **Title of the Board Paper:** confirmation for the approved MRPs of the medicine

D. **Reference to Previous Board Papers (If any):** Not applicable.

E. **Department/Division / Unit:** Pricing Unit.

1. Brief Introduction: As instructed by the chairman and CEO; NMRA, pricing unit discussed and approved the MRPs of some medicines to avoid the delays of the registration process.

2. Background: Validity period of the pricing committee was ended after 14th of May 2023 and there is no pricing committee has conducted after 13th May 2023. Hence, there is a huge back log for the import licenses and dossier evaluations in the pricing unit which is affected to slower the process of registration. As per the advises of the chairman and CEO; NMRA, Pricing unit has discussed and approved some prices based on the previously approved prices and with the support of internal and external reference prices. (Import Licenses page 01 to 06 / Item No 01 to 129 , Dossiers page no 01 to 02 / Item No 01 to 30)

3. Expected Outcomes: to continue the duties of the pricing committee of NMRA without delay.

4. Financial Implications: No spent of extra allocation.

5. Risk Analysis:

Identified Risk	Risk Likelihood (H, M, L)	Impact (H, M, L)	Strategy to Manage Risk
There is no pricing committee to determine the MRP s of medicine. Hence, temporary the staff of pricing unit has engaged in determined the MRPs.	High	High	Immediately appoint the new pricing committee

6. Corporate Governance and Compliance:

7. Certification and Recommendation:

"This is to certify that the proposal herein before described in this board paper has been prepared having considered all the relevant provisions in the governing Act, regulations, circulars, procurement procedures etc. and as such I recommend the aforesaid proposal to the members of the Board of NMRA for consideration and approval"

Name and Signature of HOD / Name of Division / Unit / Dpt.

(B. M. W. Balasooriya, Pricing Unit)

388

8. Submission to Board Approval:

"I recommend the aforesaid proposal submitted by Head of **Pricing Unit** with his / ~~her~~ recommendations to **Performance report of Pricing Unit – January 2022** to the members of the Board of NMRA for consideration / determination and approval"

Dr. Vijith Gunasekera
MBBS, MSc, MEcon, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

Name and Signature of CEO

(Dr. Vijith Gunasekara)

ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

අංක 2146/3 - 2019 ඔක්තෝබර් මස 21 වැනි සඳුදා - 2019.10.21

(රජයේ බලයපිට ප්‍රසිද්ධ කරන ලදී)

I වැනි කොටස: (I) වැනි ඡෙදය - සාමාන්‍ය

රජයේ නිවේදන

එල්.සී.බී. 9/2016 (II)

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනත

2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 118 වන වගන්තිය සමග කියවිය යුතු 142 වන වගන්තිය යටතේ සෞඛ්‍ය, පෝෂණ සහ දේශීය වෛද්‍ය අමාත්‍යවරයා විසින් සාදන ලද නියෝග.

වෛද්‍ය රාජිත සේනාරත්න (පා.ම.),
සෞඛ්‍ය, පෝෂණ සහ දේශීය වෛද්‍ය අමාත්‍ය.

2019 ඔක්තෝබර් මස 11 වැනි දින,
කොළඹ දී ය.

නියෝග

1. මෙම නියෝග 2019, මිල නියම කිරීමේ නියෝග යනුවෙන් හඳුන්වනු ලැබේ.

2. මෙම නියෝගවල (මෙහි මින්මතු "ඖෂධ නිෂ්පාදන" යනුවෙන් සඳහන් කරනු ලබන) ඖෂධ, වෛද්‍ය උපකරණ සහ සීමාස්ථ නිෂ්පාදන වල මිල නියම කිරීම සඳහා සහ ඒ හා සම්බන්ධව මෙම නියෝග අදාළ කරගනු ලැබිය යුතු ය.

3. අධිකාරිය විසින්, ඖෂධ නිෂ්පාදනවල හඳුන්වාදීමේ මිල තීරණය කිරීමේ දී, එකම ප්‍රතිකාරක කාණ්ඩයට අයත් සමාන නිෂ්පාදන වල ශ්‍රී ලංකාව තුළ සහ වෙනත් යම් රටවල පවතින වෙළඳපල මිල, කලාපීය සහ ජාත්‍යන්තර සැසඳුම් මිල ගණන් සහ ඖෂධ නිෂ්පාදනවල පිරිවැය, රක්ෂණය සහ ප්‍රවාහන ගාස්තු සහ අදාළ විනිමය අනුපාතය යන වෙනත් යම් අදාළ මූලාශ්‍ර වල තොරතුරු ඇතුළුව මිල නියම කිරීමේ කමිටුව විසින් තීරණය කරනු ලබන වෙනත් යම් සාධක පිළිබඳ සලකා බලනු ලැබිය යුතු ය.

4. මිල නියම කිරීමේ කමිටුව පහත දැක්වෙන තැනැත්තන්ගෙන් සමන්විත විය යුතු ය:-

(අ) නිල බලයෙන් පත්වන සාමාජිකයන් -
(i) ජාතික ඖෂධ නියාමන අධිකාරියේ සහාපතිවරයා;
(ii) ජාතික ඖෂධ නියාමන අධිකාරියේ ප්‍රධාන විධායක නිලධරයා;
(iii) පාරිභෝගික කටයුතු අධිකාරියේ නියෝජිතයකු; සහ
(iv) ජාතික ඖෂධ නියාමන අධිකාරියෙ ඖෂධවේදියකු;

1A - PG 4713 — 617 (2019/10)

505

(ආ) වෛද්‍ය, ඖෂධවේදය, ආර්ථික විද්‍යාව, වාණිජ්‍යය, ගිණුම්කරණය, නීතිය හෝ වෙනත් යම් ආශ්‍රිත ක්ෂේත්‍රවල නිපුණතාවයක්, පළපුරුද්දක් හෝ හැකියාවක් පෙන්නුම් කර ඇති තැනැත්තන් අතරින් තැනැත්තන් හත්දෙනෙකු.

5. අධිකාරිය විසින්, මිල නියම කිරීමේ කමිටුවේ සභාපතිවරයා ලෙස කමිටුවේ සාමාජිකයන්ගෙන් එක් අයකු පත් කරනු ලැබිය යුතු ය.

6. මිල නියම කිරීමේ කමිටුවේ යම් රැස්වීමක ගණ පූරණය සාමාජිකයන් හත්දෙනෙකු විය යුතු ය.

7. මිල නියම කිරීමේ කමිටුව විසින්, එහි රැස්වීම් සහ ඒ රැස්වීම්වල කටයුතු පැවැත්වීම සම්බන්ධයෙන් වන ස්වකීය කාර්ය පටිපාටිය විධිමත් කරනු ලැබිය හැකි ය.

8. මිල නියම කිරීමේ කමිටුවේ සාමාජිකයන්ට අධිකාරිය විසින් තීරණය කරනු ලැබිය හැකි පරිදි යම් දීමනා ගෙවනු ලැබිය යුතු ය.

9. මිල නියම කිරීමේ කමිටුවේ බලතල සහ කර්තව්‍ය වලට-

(අ) යම් තනි ඖෂධ නිෂ්පාදනයක හෝ ඖෂධ නිෂ්පාදන කාණ්ඩයක මිල තීරණය කිරීමේ දී බලපාන්නා වූ අදාළ තොරතුරු සහ දත්ත ශ්‍රී ලංකාව තුළ හෝ වෙනත් යම් රටවල නිෂ්පාදකයන්ගෙන්, ආනයනකරුවන්ගෙන්, තොග වෙළෙඳුන්ගෙන්, සිල්ලර ඖෂධවේදීන්ගෙන්, ඖෂධ නිර්දේශ කරන්නන්ගෙන්, ඖෂධ නිකුත්කරන්නන් සහ වෙනත් යම් තැනැත්තන්ගෙන් ලබා ගැනීම සඳහා අධිකාරිය වෙත සහාය ලබා දීම;

(ආ) යම් ඖෂධ නිෂ්පාදනයක හෝ ඖෂධ නිෂ්පාදන කාණ්ඩයක මිල අඩු කිරීමක් හෝ වැඩි කිරීමකට හෝ පවතින මිල පවත්වා ගෙන යාමට අධිකාරිය වෙත නිර්දේශ කිරීම;

(ඇ) යම් ඖෂධ නිෂ්පාදනයක මිල උච්චාවචනය වීම අධීක්ෂණය කිරීම;

(ඈ) ශ්‍රී ලංකාව තුළ යම් ඖෂධ නිෂ්පාදනයක් හෝ ඖෂධ නිෂ්පාදන කාණ්ඩයක් භාවිත කිරීම පිළිබඳ දත්ත රැස්කිරීම;

(ඉ) ඖෂධ නිෂ්පාදනවල හඳුන්වාදීමේ මිල සහ උපරිම සිල්ලර මිල සහ ඒ ඖෂධ නිෂ්පාදනවල මිල ප්‍රතිශෝධනයන් පිළිබඳ ක්‍රම අධිකාරිය වෙත නිර්දේශ කිරීම;

(ඊ) යම් ඖෂධ නිෂ්පාදනයක මිල නියම කිරීමට අදාළ වෙනත් යම් කාරණයක් පිළිබඳ අධිකාරිය වෙත උපදෙස් ලබා දීම.

(උ) කලින් කලට, මිල ප්‍රතිශෝධනයන්ට යටත්විය යුතු ඖෂධ නිෂ්පාදන පිළිබඳව සලකා බැලීම.
යන කාරණා ඇතුළත් විය යුතු ය.

10. යම් ඖෂධ නිෂ්පාදනයක ලියාපදිංචි සහතිකය දරන්නා හෝ දේශීය නිෂ්පාදකයා විසින් යම් ලියාපදිංචි කරන ලද ඖෂධ නිෂ්පාදන, ආනයනය කරන ලද හෝ වෙළඳපලට සපයන ලද ප්‍රමාණය පිළිබඳ වාර්තා සෑම මාස හයකට වරක් අධිකාරිය වෙත ඉදිරිපත් කළ යුතු ය.

11. අමාත්‍යවරයා විසින් නියම කරන ලද උපරිම සිල්ලර මිල සහ එය ක්‍රියාත්මකවන දිනය පිළිබඳව සිල්ලර අලෙවිකරුවන්ට, තොග වෙළඳුන්ට සහ වෙනත් අදාළ පාර්ශවයන්ට දැනුම් දීම ආනයනකරුගේ හෝ දේශීය නිෂ්පාදකයාගේ වගකීම විය යුතු ය.

12. සෑම නිෂ්පාදකයකු හෝ ආනයනකරුවකු විසින් ම, එක් එක් ඖෂධ නිෂ්පාදනයක සිල්ලර ඒකක මිල එහි වෙළඳ අසුරුමේ සලකුණු කළ යුතු ය.

13. උපරිම සිල්ලර මිල ලෙස නියම කර ඇති මිලට වඩා වැඩි මිලකට යම් නිශ්චිත ඖෂධ නිෂ්පාදනයක් විකුණනු ලබන යම් තැනැත්තකු වරදකට වරදකරු විය යුතු ය.

14. ඉහත විධිවිධානවල කුමක් සඳහන් වුව ද, මිල නියම කිරීමේ කමිටුව විසින්, කලින් කලට, උපරිම මහජන සුබසිද්ධිය වෙනුවෙන් යම් නිශ්චිත ඖෂධ නිෂ්පාදනයක් හෝ ඖෂධ නිෂ්පාදන කාණ්ඩයක් සඳහා උපරිම සිල්ලර මිලක් නියම කිරීමේ අවශ්‍යතාවය සැලකිල්ලට ගනිමින් උපරිම සිල්ලර මිල ප්‍රතිශෝධනය කිරීමට අමාත්‍යවරයා වෙත නිර්දේශ ඉදිරිපත් කළ හැකි අතර යම් ඖෂධ නිෂ්පාදනයක ලියාපදිංචි සහතිකය දරන්නකුගෙන් හෝ දේශීය නිෂ්පාදකයකුගෙන් අදාළ දත්ත ඉල්ලා සිටිය හැකි ය.

15. මිල නියම කිරීමේ කමිටුව විසින්, කලින් කලට, යම් ලිත් වර්ෂයක් තුළ යම් ඖෂධ නිෂ්පාදනයක මිල ප්‍රතිශෝධන වාර ගණන පිළිබඳව තීරණය කරනු ලැබිය හැකි ය.

16. යම් ඖෂධ නිෂ්පාදනයක් ලියාපදිංචි කිරීම හෝ ලියාපදිංචිය අලුත් කිරීම සඳහා වන යම් ඉල්ලුම් පත්‍රයක එම ඖෂධ නිෂ්පාදනයේ පවතින උපරිම සිල්ලර මිල සහ අපේක්ෂිත උපරිම සිල්ලර මිල සමග උපරිම සිල්ලර මිල තීරණය කිරීමේ ක්‍රම දක්වා තිබිය යුතු ය. ඉල්ලුම් පත්‍රය අධිකාරියේ නිර්දේශය පරිදි විය යුතු ය. උචිත යම් අවස්ථාවක දී, මිල තීරණය කිරීමේ කමිටුව විසින්, යම් ඖෂධ නිෂ්පාදනයක මිල අධ්‍යයනය කිරීමෙන් පසුව, 2015 අංක 5 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 43 වන වගන්තිය යටතේ පිහිටුවන ලද ඖෂධ ඇගයීමේ කමිටුව වෙත උපරිම සිල්ලර මිල සම්බන්ධයෙන් එහි නිර්දේශ ලබා දිය හැකි ය.

17. මිල නියම කිරීමේ කමිටුව විසින්, ප්‍රවාහන, රක්ෂණ සහ වෙනත් යම් පිරිවැය ඇතුළුව පිරිවැය පිළිබඳ එය විසින් අවශ්‍යයයි සලකනු ලබන යම් තොරතුරු නිෂ්පාදකයන්ගෙන්, ආනයනකරුවන්ගෙන් හෝ වෙළඳුන්ගෙන් ඉල්ලා සිටිය හැකි අතර එම අවශ්‍යකරන ලද තොරතුරු මනා පැහැදිලි කිරීමක් සහ දත්ත සමග එම නිෂ්පාදකයන්, ආනයනකරුවන් හෝ වෙළඳුන් විසින් ලබා දිය යුතු ය.

18. යම් ඖෂධයක මිල හෝ එහි වෙළඳපල පැවැත්ම කෙරෙහි බලපාන්නා වූ සහ -

(අ) ඒකාධිකාර තත්ත්වයක් පැවතීම හෝ ඒකාධිකාර තත්ත්වයක් පැවතීමට ඉඩ තිබීම;
(ආ) ඒකාබද්ධ කිරීමේ තත්ත්වයක් ඇති කිරීම හෝ ඇති කිරීමට ඉඩ තිබීම;
(ඇ) යම් තරඟ විරෝධී චර්යාවක් ප්‍රචලිතව පැවතීම,

යන කාරණා සඳහා හේතු වන්නා වූ යම් ක්‍රියාවක් කිසිදු නිෂ්පාදකයකු, ආනයනකරුවකු හෝ වෙනත් යම් තැනැත්තකු විසින් සිදු නොකළ යුතු ය.

19. මෙම නියෝගවල විධිවිධාන උල්ලංඝනය කරනු ලබන යම් තැනැත්තකු වරදක් සිදු කරනු ලබන අතර 2015 අංක 05 දරන ජාතික ඖෂධ නියාමන අධිකාරිය පනතේ 131 වන වගන්තිය යටතේ අධිකරණය ඉදිරියේ නඩු පවරනු ලැබිය යුතු ය.

11 - 628

ශ්‍රී ලංකා රජයේ මුද්‍රණ දෙපාර්තමේන්තුවේ මුද්‍රණය කරන ලදී.

39. (1) එන්එම්කිව්ඒඑල් හි කර්තව්‍යය වනුයේ:—

(අ) (i) ලියාපදිංචිය සඳහා වූ ඉල්ලීම සමග ඉදිරිපත් කරන ලද ද්‍රව්‍ය;

(ii) රටට ගෙන ඒමේ දී එකතුකරන ලද ද්‍රව්‍ය;

(iii) භාවිත කරන්නන් විසින් පැමිණිල්ලක් වශයෙන් ඉදිරිපත් කරන ලද ද්‍රව්‍ය;

(iv) අධිකාරිය විසින් පශ්චාත් අලෙවි සමීක්ෂණයේ දී එකතු කරන ලද ද්‍රව්‍ය;

(v) ඉහත සඳහන් හේතු හැර වෙනත් යම් හේතුවක් නිසා අධිකාරිය විසින් ඉදිරිපත් කරනු ලබන ද්‍රව්‍ය,

ඇතුළුව අධිකාරිය විසින් ඉදිරිපත් කරනු ලබන ඖෂධ, වෛද්‍ය උපකරණ හෝ සීමාස්ථ නිෂ්පාදනයක තත්ත්වය පිළිබඳව පරීක්ෂණ පැවැත්වීම;

(ආ) අවස්ථානුගත කරුණු අනුව, අනුමත අනිරේක රසපරීක්ෂකවරයකු ලෙස ක්‍රියාත්මක වීම;

(ඇ) අධිකාරිය විසින් නිරූපණය කරනු ලබන ආකාරයට දේශීය හා විදේශීය පර්යේෂණාගාරවල සේවා අවශ්‍ය බවට සලකන අවස්ථාවල දී දේශීය හෝ විදේශීය පර්යේෂණාගාර සමග සම්බන්ධීකරණය කිරීම;

(ඈ) ඖෂධ, වෛද්‍ය උපකරණ හෝ සීමාස්ථ නිෂ්පාදනවල තත්ත්වය සහතික කිරීම් සම්බන්ධයෙන් පරීක්ෂණ ව්‍යාපෘති පවත්වාගෙන යාම,

(2) අධිකාරිය විසින් සහ අධිකාරිය මගින් සෞඛ්‍ය දෙපාර්තමේන්තුව විසින් ඉල්ලා සිටිනු ලබන වෙනත් කර්තව්‍ය එන්එම්කිව්ඒඑල් විසින් ක්‍රියාත්මක කරනු ලැබිය යුතු ය.

(3) අධිකාරිය විසින්, කලින් කල් නඳුන්වාදෙනු ලබන තත්ත්ව සහ ප්‍රමිති මාර්ගෝපදේශවලට දැඩි ලෙස අනුකූලව, එන්එම්කිව්ඒඑල් වෙත ඉදිරිපත් කරනු ලබන ද්‍රව්‍ය පිළිබඳ පරීක්ෂණ හෝ විශ්ලේෂණ කටයුතු එන්එම්කිව්ඒඑල් විසින් සිදු කරනු ලැබිය යුතු ය.

INTERNATIONAL STANDARD

ISO/IEC 17025

ඇමුණුම 115

Third edition
2017-11

General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

Reference number
ISO/IEC 17025:2017(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. In the field of conformity assessment, ISO and the International Electrotechnical Commission (IEC) develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment (ISO/CASCO).

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO) and circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This third edition cancels and replaces the second edition (ISO/IEC 17025:2005), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;

— there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;

— a definition of "laboratory" has been added (see 3.6).

Introduction

This document has been developed with the objective of promoting confidence in the operation of laboratories. This document contains requirements for laboratories to enable them to demonstrate they operate competently, and are able to generate valid results. Laboratories that conform to this document will also operate generally in accordance with the principles of ISO 9001.

This document requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.

The use of this document will facilitate cooperation between laboratories and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures. The acceptance of results between countries is facilitated if laboratories conform to this document.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions. Click on the link below to take part in the online survey:

17025_ed3_usersurvey

General requirements for the competence of testing and calibration laboratories

1 Scope

This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel.

Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*[1)]

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and ISO/IEC 17000 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
impartiality
presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the *laboratory* (3.6).

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handedness", "detachment", "balance".

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — The words "the certification body" have been replaced by "the laboratory" in Note 1 to entry, and the word "independence" has been deleted from the list in Note 2 to entry.]

1) Also known as JCGM 200.

3.2
complaint
expression of dissatisfaction by any person or organization to a *laboratory* (3.6), relating to the activities or results of that laboratory, where a response is expected

[SOURCE: ISO/IEC 17000:2004, 6.5, modified — The words "other than appeal" have been deleted, and the words "a conformity assessment body or accreditation body, relating to the activities of that body" have been replaced by "a laboratory, relating to the activities or results of that laboratory".]

3.3
interlaboratory comparison
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[SOURCE: ISO/IEC 17043:2010, 3.4]

3.4
intralaboratory comparison
organization, performance and evaluation of measurements or tests on the same or similar items within the same *laboratory* (3.6) in accordance with predetermined conditions

3.5
proficiency testing
evaluation of participant performance against pre-established criteria by means of *interlaboratory comparisons* (3.3)

[SOURCE: ISO/IEC 17043:2010, 3.7, modified — Notes to entry have been deleted.]

3.6
laboratory
body that performs one or more of the following activities:

— testing;

— calibration;

— sampling, associated with subsequent testing or calibration

Note 1 to entry: In the context of this document, "laboratory activities" refer to the three above-mentioned activities.

3.7
decision rule
rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

3.8
verification
provision of objective evidence that a given item fulfils specified requirements

EXAMPLE 1 Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.

EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system are achieved.

EXAMPLE 3 Confirmation that a target measurement uncertainty can be met.

Note 1 to entry: When applicable, measurement uncertainty should be taken into consideration.

Note 2 to entry: The item may be, for example, a process, measurement procedure, material, compound, or measuring system.

Note 3 to entry: The specified requirements may be, for example, that a manufacturer's specifications are met.

Note 4 to entry: Verification in legal metrology, as defined in VIML, and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system.

Note 5 to entry: Verification should not be confused with calibration. Not every verification is a *validation* (3.9).

Note 6 to entry: In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

[SOURCE: ISO/IEC Guide 99:2007, 2.44]

3.9
validation
verification (3.8), where the specified requirements are adequate for an intended use

EXAMPLE A measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement of mass concentration of nitrogen in human serum.

[SOURCE: ISO/IEC Guide 99:2007, 2.45]

4 General requirements

4.1 Impartiality

4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The laboratory management shall be committed to impartiality.

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

4.2 Confidentiality

4.2.1 The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

4.2.2 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

5 Structural requirements

5.1 The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.

NOTE For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

5.2 The laboratory shall identify management that has overall responsibility for the laboratory.

5.3 The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

5.4 Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

5.5 The laboratory shall:

a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;

b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;

c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system or from the procedures for performing laboratory activities;

c) initiation of actions to prevent or minimize such deviations;

d) reporting to laboratory management on the performance of the management system and any need for improvement;

e) ensuring the effectiveness of laboratory activities.

5.7 Laboratory management shall ensure that:

a) communication takes place regarding the effectiveness of the management
importance of meeting customers' and other requirements;

b) the integrity of the management system is maintained when changes to the manage
are planned and implemented.

6 Resource requirements

6.1 General

The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

6.2 Personnel

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.

6.2.3 The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.

6.2.5 The laboratory shall have procedure(s) and retain records for:

a) determining the competence requirements;

b) selection of personnel;

c) training of personnel;

d) supervision of personnel;

e) authorization of personnel;

f) monitoring competence of personnel.

6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

a) development, modification, verification and validation of methods;

b) analysis of results, including statements of conformity or opinions and interpretations;

c) report, review and authorization of results.

6.3 Facilities and environmental conditions

6.3.1 The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results.

NOTE Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented.

6.3.3 The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

6.3.4 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:

a) access to and use of areas affecting laboratory activities;

b) prevention of contamination, interference or adverse influences on laboratory activities;

c) effective separation between areas with incompatible laboratory activities.

6.3.5 When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.

6.4 Equipment

6.4.1 The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.

NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.

NOTE 2 ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.

6.4.2 When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.

6.4.3 The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

6.4.4 The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.

6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4.6 Measuring equipment shall be calibrated when:

— the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or

— calibration of the equipment is required to establish the metrological traceability of the reported results.

NOTE Types of equipment having an effect on the validity of the reported results can include:

— those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;

— those used to make corrections to the measured value, e.g. temperature measurements;

— those used to obtain a measurement result calculated from multiple quantities.

6.4.7 The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

6.4.8 All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

6.4.9 Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).

6.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.

6.4.11 When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.

6.4.13 Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:

a) the identity of equipment, including software and firmware version;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) evidence of verification that equipment conforms with specified requirements;

d) the current location;

e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;

f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;

g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;

h) details of any damage, malfunction, modification to, or repair of, the equipment.

6.5 Metrological traceability

6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

NOTE 1 In ISO/IEC Guide 99, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".

NOTE 2 See Annex A for additional information on metrological traceability.

6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:

a) calibration provided by a competent laboratory; or

NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent.

b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or

NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

NOTE 3 Details of practical realization of the definitions of some important units are given in the SI brochure.

6.5.3 When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.:

a) certified values of certified reference materials provided by a competent producer;

b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

6.6 Externally provided products and services

6.6.1 The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

a) are intended for incorporation into the laboratory's own activities;

b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;

c) are used to support the operation of the laboratory.

NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

6.6.2 The laboratory shall have a procedure and retain records for:

a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;

b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;

d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

6.6.3 The laboratory shall communicate its requirements to external providers for:

a) the products and services to be provided;

b) the acceptance criteria;

c) competence, including any required qualification of personnel;

d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:

a) the requirements are adequately defined, documented and understood;

b) the laboratory has the capability and resources to meet the requirements;

c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;

NOTE 1 It is recognized that externally provided laboratory activities can occur when:

— the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;

— the laboratory does not have the resources or competence to perform the activities.

d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

NOTE 2 For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.

7.1.2 The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

7.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the

decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.

NOTE For further guidance on statements of conformity, see ISO/IEC Guide 98-4.

7.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.

7.1.5 The customer shall be informed of any deviation from the contract.

7.1.6 If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.

7.1.7 The laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.

NOTE Such cooperation can include:

a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;

b) preparation, packaging, and dispatch of items needed by the customer for verification purposes.

7.1.8 Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

NOTE "Method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.

7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3).

7.2.1.3 The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.

7.2.1.4 When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant

scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.

7.2.1.5 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.

7.2.1.6 When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.

7.2.1.7 Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

NOTE Customer acceptance of deviations can be agreed in advance in the contract.

7.2.2 Validation of methods

7.2.2.1 The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items.

NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:

a) calibration or evaluation of bias and precision using reference standards or reference materials;

b) systematic assessment of the factors influencing the result;

c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;

d) comparison of results achieved with other validated methods;

e) interlaboratory comparisons;

f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

7.2.2.3 The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.

NOTE Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.

7.2.2.4 The laboratory shall retain the following records of validation:

a) the validation procedure used;

b) specification of the requirements;

c) determination of the performance characteristics of the method;

d) results obtained;

e) a statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

7.3.1 The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.

7.3.2 The sampling method shall describe:

a) the selection of samples or sites;

b) the sampling plan;

c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.

NOTE When received into the laboratory, further handling can be required as specified in 7.4.

7.3.3 The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:

a) reference to the sampling method used;

b) date and time of sampling;

c) data to identify and describe the sample (e.g. number, amount, name);

d) identification of the personnel performing sampling;

e) identification of the equipment used;

f) environmental or transport conditions;

g) diagrams or other equivalent means to identify the sampling location, when appropriate;

h) deviations, additions to or exclusions from the sampling method and sampling plan.

7.4 Handling of test or calibration items

7.4.1 The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed.

7.4.2 The laboratory shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the laboratory. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.

7.4.3 Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.

7.4.4 When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

7.5 Technical records

7.5.1 The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

7.5.2 The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

7.6 Evaluation of measurement uncertainty

7.6.1 Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

7.6.3 A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.

NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.

NOTE 3 For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.

7.7 Ensuring the validity of results

7.7.1 The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

a) use of reference materials or quality control materials;

b) use of alternative instrumentation that has been calibrated to provide traceable results;

c) functional check(s) of measuring and testing equipment;

d) use of check or working standards with control charts, where applicable;

e) intermediate checks on measuring equipment;

f) replicate tests or calibrations using the same or different methods;

g) retesting or recalibration of retained items;

h) correlation of results for different characteristics of an item;

i) review of reported results;

j) intralaboratory comparisons;

k) testing of blind sample(s).

7.7.2 The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing;

NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing.

7.7.3 Data from monitoring activities shall be analysed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

7.8 Reporting of results

7.8.1 General

7.8.1.1 The results shall be reviewed and authorized prior to release.

7.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.

NOTE 1 For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.

NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.

7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

a) a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling");

b) the name and address of the laboratory;

c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;

d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;

e) the name and contact information of the customer;

f) identification of the method used;

g) a description, unambiguous identification, and, when necessary, the condition of the item;

h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;

i) the date(s) of performance of the laboratory activity;

j) the date of issue of the report;

k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;

l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;

m) the results with, where appropriate, the units of measurement;

n) additions to, deviations, or exclusions from the method;

o) identification of the person(s) authorizing the report;

p) clear identification when results are from external providers.

NOTE Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.

7.8.2.2 The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

7.8.3 Specific requirements for test reports

7.8.3.1 In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:

a) information on specific test conditions, such as environmental conditions;

b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:

— it is relevant to the validity or application of the test results;

— a customer's instruction so requires, or

— the measurement uncertainty affects conformity to a specification limit;

d) where appropriate, opinions and interpretations (see 7.8.7);

e) additional information that may be required by specific methods, authorities, customers or groups of customers.

7.8.3.2 Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

7.8.4 Specific requirements for calibration certificates

7.8.4.1 In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:

a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);

NOTE According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.

b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;

c) a statement identifying how the measurements are metrologically traceable (see Annex A);

d) the results before and after any adjustment or repair, if available;

e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

f) where appropriate, opinions and interpretations (see 7.8.7).

7.8.4.2 Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.

7.8.4.3 A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

7.8.5 Reporting sampling – specific requirements

Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:

a) the date of sampling;

b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);

c) the location of sampling, including any diagrams, sketches or photographs;

d) a reference to the sampling plan and sampling method;

e) details of any environmental conditions during sampling that affect the interpretation of the results;

f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.

NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

7.8.6.2 The laboratory shall report on the statement of conformity, such that the statement clearly identifies:

a) to which results the statement of conformity applies;

b) which specifications, standards or parts thereof are met or not met;

c) the decision rule applied (unless it is inherent in the requested specification or standard).

NOTE For further information, see ISO/IEC Guide 98-4.

7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.

NOTE It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6.

7.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

7.8.8 Amendments to reports

7.8.8.1 When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

7.8.8.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report, serial number... [or as otherwise identified]", or an equivalent form of wording.

Such amendments shall meet all the requirements of this document.

7.8.8.3 When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

7.9 Complaints

7.9.1 The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.

7.9.2 A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

7.9.3 The process for handling complaints shall include at least the following elements and methods:

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

b) tracking and recording complaints, including actions undertaken to resolve them;

c) ensuring that any appropriate action is taken.

7.9.4 The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

NOTE This can be performed by external personnel.

7.9.7 Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

7.10 Nonconforming work

7.10.1 The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are defined;

b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;

c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

d) a decision is taken on the acceptability of the nonconforming work;

e) where necessary, the customer is notified and work is recalled;

f) the responsibility for authorizing the resumption of work is defined.

7.10.2 The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

7.11 Control of data and information management

7.11.1 The laboratory shall have access to the data and information needed to perform laboratory activities.

7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

NOTE 1 In this document "laboratory information management system(s)" includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.

NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

7.11.3 The laboratory information management system(s) shall:

a) be protected from unauthorized access;

b) be safeguarded against tampering and loss;

c) be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

d) be maintained in a manner that ensures the integrity of the data and information;

e) include recording system failures and the appropriate immediate and corrective actions.

7.11.4 When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5 The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

7.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.

8 Management system requirements

8.1 Options

8.1.1 General

The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B.

NOTE See Annex B for more information.

8.1.2 Option A

As a minimum, the management system of the laboratory shall address the following:

— management system documentation (see 8.2);

— control of management system documents (see 8.3);

— control of records (see 8.4);

— actions to address risks and opportunities (see 8.5);

— improvement (see 8.6);

— corrective actions (see 8.7);

— internal audits (see 8.8);

— management reviews (see 8.9).

8.1.3 Option B

A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.

8.2 Management system documentation (Option A)

8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.

8.2.3 Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.

8.2.5 All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Control of management system documents (Option A)

8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.

NOTE In this context, "documents" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

8.3.2 The laboratory shall ensure that:

a) documents are approved for adequacy prior to issue by authorized personnel;

b) documents are periodically reviewed, and updated as necessary;

c) changes and the current revision status of documents are identified;

d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

e) documents are uniquely identified;

f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

8.4 Control of records (Option A)

8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.

8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.

NOTE Additional requirements regarding technical records are given in 7.5.

8.5 Actions to address risks and opportunities (Option A)

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

a) give assurance that the management system achieves its intended results;

b) enhance opportunities to achieve the purpose and objectives of the laboratory;

c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;

d) achieve improvement.

8.5.2 The laboratory shall plan:

a) actions to address these risks and opportunities;

b) how to:

— integrate and implement these actions into its management system;

— evaluate the effectiveness of these actions.

NOTE Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

8.6 Improvement (Option A)

8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions.

NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

8.6.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system, laboratory activities and customer service.

NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

8.7 Corrective actions (Option A)

8.7.1 When a nonconformity occurs, the laboratory shall:

a) react to the nonconformity and, as applicable:
   - take action to control and correct it;
   - address the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
   - reviewing and analysing the nonconformity;
   - determining the causes of the nonconformity;
   - determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the management system, if necessary.

8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 The laboratory shall retain records as evidence of:

a) the nature of the nonconformities, cause(s) and any subsequent actions taken;

b) the results of any corrective action.

8.8 Internal audits (Option A)

8.8.1 The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:

a) conforms to:

— the laboratory's own requirements for its management system, including the laboratory activities;

— the requirements of this document;

b) is effectively implemented and maintained.

8.8.2 The laboratory shall:

a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;

b) define the audit criteria and scope for each audit;

c) ensure that the results of the audits are reported to relevant management;

d) implement appropriate correction and corrective actions without undue delay;

e) retain records as evidence of the implementation of the audit programme and the audit results.

NOTE ISO 19011 provides guidance for internal audits.

8.9 Management reviews (Option A)

8.9.1 The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

a) changes in internal and external issues that are relevant to the laboratory;

b) fulfilment of objectives;

c) suitability of policies and procedures;

d) status of actions from previous management reviews;

e) outcome of recent internal audits;

f) corrective actions;

g) assessments by external bodies;

h) changes in the volume and type of the work or in the range of laboratory activities;

i) customer and personnel feedback;

j) complaints;

k) effectiveness of any implemented improvements;

l) adequacy of resources;

m) results of risk identification;

n) outcomes of the assurance of the validity of results; and

o) other relevant factors, such as monitoring activities and training.

8.9.3 The outputs from the management review shall record all decisions and actions related to at least:

a) the effectiveness of the management system and its processes;

b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;

c) provision of required resources;

d) any need for change.

Annex A
(informative)

Metrological traceability

A.1 General

This annex provides additional information on metrological traceability, which is an important concept to ensure comparability of measurement results both nationally and internationally.

A.2 Establishing metrological traceability

A.2.1 Metrological traceability is established by considering, and then ensuring, the following:

a) the specification of the measurand (quantity to be measured);

b) a documented unbroken chain of calibrations going back to stated and appropriate references (appropriate references include national or international standards, and intrinsic standards);

c) that measurement uncertainty for each step in the traceability chain is evaluated according to agreed methods;

d) that each step of the chain is performed in accordance with appropriate methods, with the measurement results and with associated, recorded measurement uncertainties;

e) that the laboratories performing one or more steps in the chain supply evidence for their technical competence.

A.2.2 The systematic measurement error (sometimes called "bias") of the calibrated equipment is taken into account to disseminate metrological traceability to measurement results in the laboratory. There are several mechanisms available to take into account the systematic measurement errors in the dissemination of measurement metrological traceability.

A.2.3 Measurement standards that have reported information from a competent laboratory that includes only a statement of conformity to a specification (omitting the measurement results and associated uncertainties) are sometimes used to disseminate metrological traceability. This approach, in which the specification limits are imported as the source of uncertainty, is dependent upon:

— the use of an appropriate decision rule to establish conformity;

— the specification limits subsequently being treated in a technically appropriate way in the uncertainty budget.

The technical basis for this approach is that the declared conformance to a specification defines a range of measurement values, within which the true value is expected to lie, at a specified level of confidence, which considers both any bias from the true value, as well as the measurement uncertainty.

EXAMPLE The use of OIML R 111 class weights to calibrate a balance.

A.3 Demonstrating metrological traceability

A.3.1 Laboratories are responsible for establishing metrological traceability in accordance with this document. Calibration results from laboratories conforming to this document provide metrological

traceability. Certified values of certified reference materials from reference material producers conforming to ISO 17034 provide metrological traceability. There are various ways to demonstrate conformity with this document: third party recognition (such as an accreditation body), external assessment by customers or self-assessment. Internationally accepted paths include, but are not limited to, the following.

a) Calibration and measurement capabilities provided by national metrology institutes and designated institutes that have been subject to suitable peer-review processes. Such peer-review is conducted under the CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement). Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which details the range and measurement uncertainty for each listed service.

b) Calibration and measurement capabilities that have been accredited by an accreditation body subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement or to Regional Arrangements recognized by ILAC have demonstrated metrological traceability. Scopes of accredited laboratories are publicly available from their respective accreditation bodies.

A.3.2 The Joint BIPM, OIML (International Organization of Legal Metrology), ILAC and ISO Declaration on Metrological Traceability provides specific guidance when there is a need to demonstrate international acceptability of the metrological traceability chain.

Annex B
(informative)

Management system options

B.1 Growth in the use of management systems generally has increased the need to ensure that laboratories can operate a management system that is seen as conforming to ISO 9001, as well as to this document. As a result, this document provides two options for the requirements related to the implementation of a management system.

B.2 Option A (see 8.1.2) lists the minimum requirements for implementation of a management system in a laboratory. Care has been taken to incorporate all those requirements of ISO 9001 that are relevant to the scope of laboratory activities that are covered by the management system. Laboratories that comply with Clauses 4 to 7 and implement Option A of Clause 8 will therefore also operate generally in accordance with the principles of ISO 9001.

B.3 Option B (see 8.1.3) allows laboratories to establish and maintain a management system in accordance with the requirements of ISO 9001, in a manner that supports and demonstrates the consistent fulfilment of Clauses 4 to 7. Laboratories that implement Option B of Clause 8 will therefore also operate in accordance with ISO 9001. Conformity of the management system within which the laboratory operates to the requirements of ISO 9001 does not, in itself, demonstrate the competence of the laboratory to produce technically valid data and results. This is accomplished through compliance with Clauses 4 to 7.

B.4 Both options are intended to achieve the same result in the performance of the management system and compliance with Clauses 4 to 7.

NOTE Documents, data and records are components of documented information as used in ISO 9001 and other management system standards. Control of documents is covered in 8.3. The control of records is covered in 8.4 and 7.5. The control of data related to the laboratory activities is covered in 7.11.

B.5 Figure B.1 illustrates an example of a possible schematic representation of the operational processes of a laboratory, as described in Clause 7.

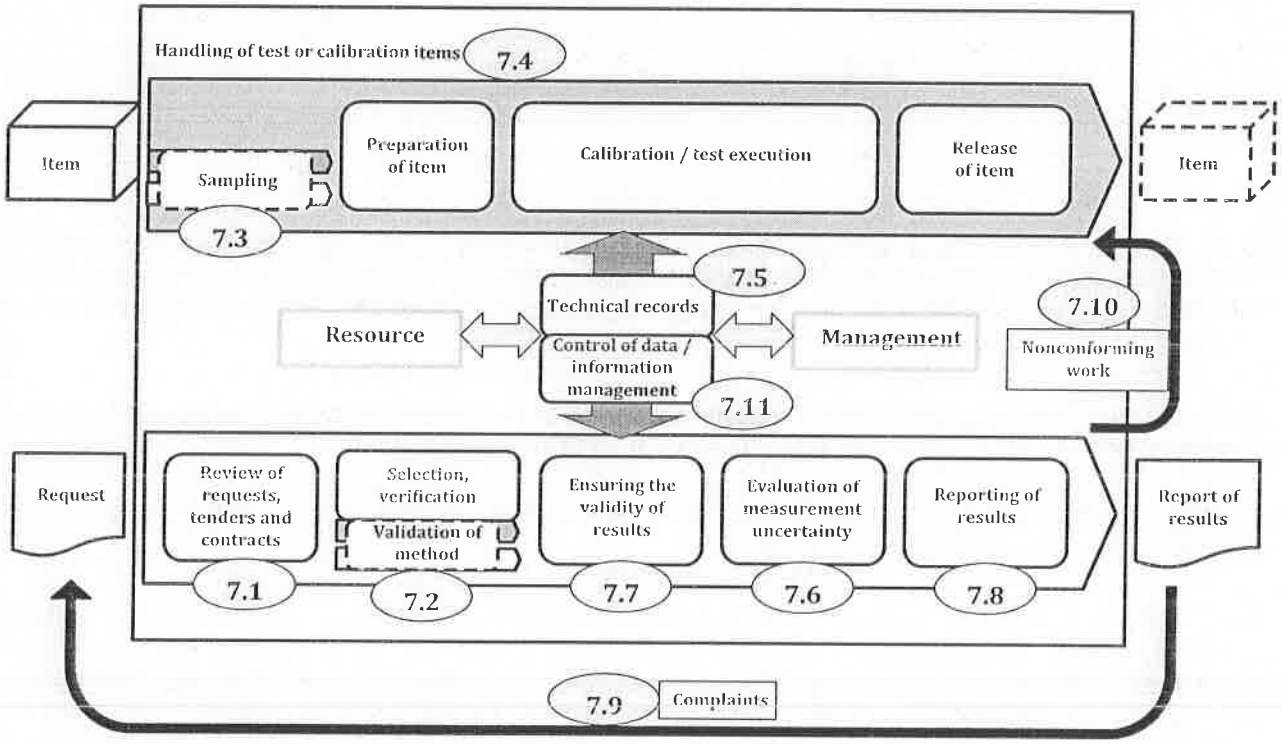


Figure B.1 — Possible schematic representation of the operational processes of a laboratory

Bibliography

[1] ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

[2] ISO 5725-2, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

[3] ISO 5725-3, *Accuracy (trueness and precision) of measurement methods and results — Part 3: Intermediate measures of the precision of a standard measurement method*

[4] ISO 5725-4, *Accuracy (trueness and precision) of measurement methods and results — Part 4: Basic methods for the determination of the trueness of a standard measurement method*

[5] ISO 5725-6, *Accuracy (trueness and precision) of measurement methods and results — Part 6: Use in practice of accuracy values*

[6] ISO 9000, *Quality management systems — Fundamentals and vocabulary*

[7] ISO 9001, *Quality management systems — Requirements*

[8] ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

[9] ISO/IEC 12207, *Systems and software engineering — Software life cycle processes*

[10] ISO 15189, *Medical laboratories — Requirements for quality and competence*

[11] ISO 15194, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation*

[12] ISO/IEC 17011, *Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies*

[13] ISO/IEC 17020, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

[14] ISO/IEC 17021-1, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*

[15] ISO 17034, *General requirements for the competence of reference material producers*

[16] ISO/IEC 17043, *Conformity assessment — General requirements for proficiency testing*

[17] ISO/IEC 17065, *Conformity assessment — Requirements for bodies certifying products, processes and services*

[18] ISO 17511, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials*

[19] ISO 19011, *Guidelines for auditing management systems*

[20] ISO 21748, *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation*

[21] ISO 31000, *Risk management — Guidelines*

[22] ISO Guide 30, *Reference materials — Selected terms and definitions*

[23] ISO Guide 31, *Reference materials — Contents of certificates, labels and accompanying documentation*

[24] ISO Guide 33, *Reference materials — Good practice in using reference materials*

[25] ISO Guide 35, *Reference materials — Guidance for characterization and assessment of homogeneity and stability*

[26] ISO Guide 80, *Guidance for the in-house preparation of quality control materials (QCMs)*

[27] ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

[28] ISO/IEC Guide 98-4, *Uncertainty of measurement — Part 4: Role of measurement uncertainty in conformity assessment*

[29] IEC Guide 115, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

[30] *Joint BIPM, OIML, ILAC and ISO declaration on metrological traceability*, 2011 [2)]

[31] International Laboratory Accreditation Cooperation (ILAC) [3)]

[32] *International vocabulary of terms in legal metrology (VIML)*, OIML V1:2013

[33] JCGM 106:2012, *Evaluation of measurement data — The role of measurement uncertainty in conformity assessment*

[34] *The Selection and Use of Reference Materials*, EEE/RM/062rev3, Eurachem [4)]

[35] *SI Brochure: The International System of Units (SI)*, BIPM [5)]

2) http://www.bipm.org/utils/common/pdf/BIPM-OIML-ILAC-ISO_joint_declaration_2011.pdf

3) http://ilac.org/

4) https://www.eurachem.org/images/stories/Guides/pdf/EEE-RM-062rev3.pdf

5) http://www.bipm.org/en/publications/si-brochure/

අලුත්වැඩියා කටයුතු අවසන් කර නොතිබීම හේතුවෙන් භාවිතයෙන් බැහැර කර තිබුණු අයිතම

	යන්ත්‍ර/උපකරණයේ නම	තත්ත්වය	අංශය	විස්තරය
1.	Fume Cupboard	Out of Order	M.bio	
2.	Fume hood	Out of Order	Devices & cytotoxic	requested the repair
3.	Fume Hood-Room 103	Out of Order	Chemical	Local agent checked on 03.11.2023. In the process of repairing
4.	Fume Hood-Room 108	Out of Order	Chemical	Local agent checked on 03.11.2023. In the process of repairing
5.	Fume Hood-Room 108	Out of Order	Chemical	Local agent checked on 03.11.2023. In the process of repairing
6.	Glassware Drying Cabinet DC1000/A	Out of Order	Chemical	Local agent checked. In the process of reparing
7.	Heating Magnetic Stirrer-AREX	Out of Order	Chemical	waiting for expert advice
8.	Hot Air Oven-MEMMERT	Out of order	Chemical	Requested to repair
9.	Hot plate-stirrers	Out of Order	M.bio	
10.	HPLC	Out of Order	Biological	Requested to repair 01.02.2022
11.	Incubator (Memmert)	Out of order	M.bio	
12.	Inhaler tester	Out of order	Devices & cytotoxic	informed to repair 2015.09.09
13.	Karl-Fischer Moisture Titrator	Out of order	Biological	Local agent checked the electrode and solvents. Couldn't recover the instrument yet.
14.	Laminar Flow Cabinet	Out of order	Devices & cytotoxic	
15.	Milli Q Water purification system	Out of Order	M.bio	
16.	Particle Measuring System	Out of Order	Biological	
17.	pH Meter (Mettler) Bench Type	Out of order	M.bio	
18.	pH Meter (Mettler) Hand held Type	Out of order	M.bio	
19.	Refrigerator (LG)	Out of order	M.bio	
20.	Refrigerator (Sisil)	Out of order	M.bio	
21.	Rotary - Evaporator	Out of order	Chemical	Requested to repair
22.	Shaker	Out of order	M.bio	
23.	Spiral Plater	Out of Order	M.bio	

(794)

24.	Sterilizing oven (Sanyo)	Out of Order	M.bio	
25.	UV Visible Spectrophotometer	Out of order	Biological	Instrument delivered to workshop on 08-03-2021
26.	Vacuum Oven-TOWNSON & MERCER	Out of Order	Chemical	
27.	Water Bath (Grant)	Out of order	M.bio	
28.	Water Bath-Single Row-GFL	Out of Order	Chemical	
29.	Water Distiller (Aquatron 8000)	Out of order	M.bio	

වසරකට වැඩි කාලයක් භාවිතයෙන් බැහැර කර තිබුණු උපකරණ

		No.	Name	Brand/Model	Equipment ID	Working/ Out of Order	Installation date	Division	Last used date	Status
1	28	3	Particle Measuring System	APSS - 2000	PC-PM-B1	Out of Order	2014	Biological	2021	2021
2	34	177	Shaker	GFL-3018	SH-GF-M1	Out of order	22.02.2006	M.bio	05.10.2022	
3	4	193	Double Door Steam Sterilizer	HS6610	AC-GN-M2	Out of order	27.06.2013	M.bio	20.5.2023	Repair requested 09.06.2023
4	22	8	Karl-Fischer Moisture Titrator	870KF Titrino Plus	KF-MH-B1	Out of order	10-08-2017	Biological	21-12-2021 Titer evaluation cannot be carried out properly	Local agent checked the electrode and solvents. Couldn't recover the instrument yet.
5	41	5	UV Visible Spectrophotometer	SHIMADZU UV-1650PC	UV-SH-B1	Out of order	20-08-2004	Biological	26.02.2020 Software and the instrument were not connected	Instrument delivered to workshop on 08-03-2021
6	18	1	HPLC	Agillent 1100 Series	HP-AG-B2	Out of Order	25.03.2004	Biological	31.01.2022	Requested to repair 01.02.2022

වාර්ෂික ක්‍රමාංකණ කටයුතු නියමිත දිනට සම්පූර්ණ කර නොනිබුණු යන්ත්‍රෝපකරණ

	යන්ත්‍ර/උපකරණයේ නම	අංශය	අවසාන වරට ක්‍රමාංකණය කළ දිනය	නැවත ක්‍රමාංකණය කළ යුතු දිනය
1.	Analytical Balance	Biological	06.12.2022	06.12.2023
2.	Analytical Balance	Reference stds.&calibration	06.12.2022	06.12.2023
3.	Analytical Balance	Biological	06.12.2022	06.12.2023
4.	Analytical Balance – METLER TOLEDO With printer	Chemical	06.12.2022	06.12.2023
5.	Analytical Balance With Printer(Mettler)	M.bio	06.12.2022	06.12.2023
6.	Dissolution Apparatus	Biological	25.10.2022	25.10.2023
7.	Dissolution Tester DT-828 ERWEKA	Chemical	08.10.2022	08.10.2023
8.	Drying Oven	Biological	06.12.2022	06.12.2023
9.	Explorer Semi Micro Balance-EX225D/AD	Chemical	06.12.2022	06.12.2023
10.	Universal testing machine	Devices&cytotoxic	06.12.2022	06.12.2023
11.	Vacuum Oven - BINDER	Chemical	06.12.2022	06.12.2023
12.	Vacuum Oven	Reference stds.&calibration	06.12.2022	06.12.2023
13.	Set of Weights	R&C	29.11.2022	29.11.2023
14.	Set of Weights - 10g, 20g	Chemical	17.11.2022	17.11.2023
15.	Liquid in glass Thermometer	Biology	14.12.2022	14.12.2023
16.	Thermometer	Chemical	14.12.2022	14.12.2023

ඇමුණුම 118

කළමනාකරණ සේවා දෙපාර්තමේන්තුව
முகாமைத்துவ சேவைகள் திணைக்களம்
DEPARTMENT OF MANAGEMENT SERVICES
මුදල්, ආර්ථික ස්ථායීකරණ සහ ජාතික ප්‍රතිපත්ති අමාත්‍යාංශය
நிதி, பொருளாதார உறுதிப்பாடு மற்றும் தேசியக் கொள்கைகள் அமைச்சு
MINISTRY OF FINANCE, ECONOMIC STABILIZATION AND NATIONAL POLICIES

18 DEC 2023

මුදල් කාණ්ඩාගාරය, කොළඹ 01. பொது திறைசேரி, கொழும்பு 01. General Treasury, Colombo 01.

මගේ අංකය / எனது இல. / My No. DMS/0016/NMRA/2023

ඔබේ අංකය / உமது இல. / Your No. MH/AD/01/05/NMRA/TEMP-II

දිනය / திகதி / Date 2023.08.22

ලේකම්
සෞඛ්‍ය අමාත්‍යාංශය

SAC(HS)(B)
For necessary action pl.
Secy(HS)
11/12

28 AUG 2023

ලේකම්තුමනි

ජාතික ඖෂධ නියාමන අධිකාරියට අනුමත කාර්ය මණ්ඩල තනතුරු සමාලෝචනය කිරීම

ඉහත කරුණට අදාළ ඔබගේ සමාංක හා 2023.05.26 දිනැති ලිපිය, ජාතික ඖෂධ නියාමන අධිකාරියේ සභාපතිගේ අංක NMRA/DO3/02/2022 හා 2023.07.31 දිනැති ලිපිය සහ 2023.07.11 දින මෙම දෙපාර්තමේන්තුවේදී පැවති සාකච්ඡාව හා බැඳේ.

02. වර්තමානයේදී 247කින් යුත් කාර්ය මණ්ඩලයක් ජාතික ඖෂධ නියාමන අධිකාරිය සඳහා අනුමතව පැවතියද, ඉන් 50%කට වැඩි ප්‍රමාණයක් පුරප්පාඩු වී ඇති බැවින්, කාලීන අවශ්‍යතාවයන්ට සරිලන පරිදි අනුමත කාර්ය මණ්ඩලය තුළ සංශෝධනයන් සිදුකර නව බඳවාගැනීම් සිදු කළ යුතු බවට ඉහත සාකච්ඡාවේදී ඉදිරිපත් වූ කරුණු සැලකිල්ලට ගෙන, ජාතික ඖෂධ නියාමන අධිකාරිය සඳහා "ඇමුණුම 01" හි සඳහන් පරිදි තනතුරු අනුමත කරමි. මෙම තනතුරු අනුමත කිරීමත් සමඟම, ජාතික ඖෂධ නියාමන අධිකාරිය සඳහා තනතුරු අනුමත කරමින් මීට පෙර නිකුත් කරන ලද සියලුම ලිපි (මගේ අංක DMS/1827/Vol.II හා 2020.12.21 දිනැති ලිපියෙහි 04. සහ 05. ඡේදයන්හි දක්වා ඇති කොන්දේසි හැර) අවලංගු වේ.

03. ඒ අනුව, "ඇමුණුම 01" හි පරිදි දැනට අනුමත තනතුරු සඳහා බඳවාගැනීම් / අනුයුක්ත කිරීම් අදාළ අනුමත බඳවාගැනීම් පරිපාටිවල සඳහන් විධිවිධානවලට අනුකූලව සිදු කළ යුතු වන අතර, අනුමත කරන ලද නව තනතුරු සඳහා බඳවාගැනීම් පරිපාටි සකස් කර කළමනාකරණ සේවා දෙපාර්තමේන්තුව වෙතින් අනුමත කරවා ගැනීමෙන් අනතුරුව එම තනතුරු සඳහා බඳවාගැනීම් සිදුකළ යුතුය.

04. එසේම, අදාළ බඳවාගැනීම් සඳහා වන සියළු වියදම් අනුමත ප්‍රතිපාදන සීමාව තුළ කළමනාකරණය කරගත යුතු අතර, අනුමත තනතුරු වලට පරිබාහිරව කිසිදු තනතුරක් සඳහා බඳවාගැනීම් / අනුයුක්ත කර ගැනීම් සිදු නොකළ යුතුය.

05. තවද, "රාජ්‍ය අංශයේ කාර්යමණ්ඩල තොරතුරු අමාත්‍ය මණ්ඩලය වෙත ඉදිරිපත් කිරීම" මැයෙන් වූ කළමනාකරණ සේවා චක්‍රලේඛ අංක 04/2017 හි සඳහන් පරිදි ජාතික ඖෂධ නියාමන අධිකාරියේ තත්‍ය සේවක සංඛ්‍යාව පිළිබඳ තොරතුරු සෑම වර්ෂයකම එක් එක් කාර්තුව අවසානයේ මෙම දෙපාර්තමේන්තුව වෙත ඉදිරිපත් කළ යුතු වේ.

06. එමෙන්ම, "විවක්ෂණශීලීව රාජ්‍ය වියදම් පාලනය කිරීම" යන මැයෙන් ඉදිරිපත් කරන ලද අංක අමප 22/0178/304/014 හා 2022.02.07 දිනැති අමාත්‍ය මණ්ඩල නිරණය, "රාජ්‍ය වියදම් පාලනය කිරීම"

කාර්යාලය / அலுவலகம் / Office 011 - 2484757 011 - 2484640
ෆැක්ස් / தொலைநகல் / Fax 011- 2430270 011- 2484846
ඊ-මේල් / மின்னஞ்சல் / E-mail dgms@msd.treasury.gov.lk
වෙබ් අඩවිය / இணையத்தளம் / Website www.treasury.gov.lk

(763)

මෑයෙන් නිකුත් කරන ලද 2022.04.26 දිනැති ජාතික අයවැය චක්‍රලේඛ අංක 03/2022 හා 2022.08.15 දිනැතිව ජනාධිපති ලේකම් කාර්යාලය විසින් නිකුත් කරන ලද චක්‍රලේඛ අංක PS/SB/Circular/10/2022 කෙරෙහි ද අවධානය යොමු කරන මෙන් කාරුණිකව දන්වා සිටිමි.

මෙයට - විශ්වාසී

හිරන්සා කළුතන්ත්‍රි
අධ්‍යක්ෂ ජනරාල්

පිටපත්:

1) විගණකාධිපති
2) සෞඛ්‍ය සේවා අධ්‍යක්ෂ ජනරාල්
3) අධ්‍යක්ෂ ජනරාල්, ජාතික අයවැය දෙපාර්තමේන්තුව
4) අධ්‍යක්ෂ ජනරාල්, රාජ්‍ය ව්‍යාපාර දෙපාර්තමේන්තුව
5) සභාපති, ජාතික ඖෂධ නියාමන අධිකාරිය
6) පොදු ගොනුව
7) දත්ත ගොනුව

"Annexure I"

ජාතික ඖෂධ නියාමන අධිකාරිය සඳහා කාර්ය මණ්ඩලය අනුමත කිරීම

අනු අංකය	තනතුර	වැටුප් කේතය (ක.සේ.ව. අංක 02/2016 අනුව)	ශ්‍රේණිය	අනුමත තනතුරු සංඛ්‍යාව
1	අධ්‍යක්ෂ ජනරාල්/ ප්‍රධාන විධායක නිලධාරී	HM 2-1	-	1
2	අධ්‍යක්ෂ (නියාමන)	HM 1-1	-	1
3	අධ්‍යක්ෂ (NMQAL)	HM 1-1	-	1
4	අධ්‍යක්ෂ (නීති)	HM 1-1	-	1
5	අධ්‍යක්ෂ (මානව සම්පත් හා පරිපාලන)	HM 1-1	-	1
6	අධ්‍යක්ෂ (මූල්‍ය)	HM 1-1	-	1
7	වෛද්‍ය නිලධාරී	MM 1-3	II/I	2
8	ජීව වෛද්‍ය ඉංජිනේරු	MM 1-1	II/I	2
9	සහකාර / නියෝජ්‍ය අධ්‍යක්ෂ (මානව සම්පත් හා පරිපාලන)	MM 1-1	II/I	1
10	සහකාර / නියෝජ්‍ය අධ්‍යක්ෂ (තොරතුරු හා සන්නිවේදන තාක්ෂණ)	MM 1-1	II/I	1
11	ගණකාධිකාරී	MM 1-1	II/I	1
12	පිරිවැය ගණකාධිකාරී	MM 1-1	II/I	1
13	අභ්‍යන්තර විගණක	MM 1-1	II/I	1
14	ඖෂධ විශ්ලේෂක *	MM 1-1	II/I	20
15	ඖෂධ ඇගයීම් නිලධාරී **	MM 1-1	II/I	25
16	සහකාර ඖෂධ ඇගයීම් නිලධාරී **	JM 1-1	II/I	50
17	සහකාර ඖෂධ විශ්ලේෂක	JM 1-1	II/I	25
18	පරිපාලන නිලධාරී	JM 1-1	II/I	1
19	තොරතුරු හා සන්නිවේදන තාක්ෂණ නිලධාරී	JM 1-1	II/I	1
20	ප්‍රසම්පාදන නිලධාරී	JM 1-1	II/I	1
21	පෞද්ගලික සහකාර	JM 1-1	II/I	2
22	සහකාර ඖෂධ පරීක්ෂක	MA 5-1	III/II/I	10
23	සංවර්ධන නිලධාරී	MA 3	III/II/I	5
24	දත්ත කළමනාකරණ නිලධාරී	MA 3	III/II/I	5
25	තාක්ෂණ නිලධාරී (සිවිල්/ප්‍රවාහන)	MA 2-2	III/II/I	1
26	තොරතුරු හා සන්නිවේදන තාක්ෂණ සහකාර	MA 2-1	III/II/I	3

ආර්.එම්.කේ. ගංගා සංජීවනී
අධ්‍යක්ෂ
කළමනාකරණ සේවා දෙපාර්තමේන්තුව
මහා භාණ්ඩාගාරය

15/05/2023

781

අනු අංකය	තනතුර	වැටුප් කේතය (ක.සේ.ව. අංක 02/2016 අනුව)	ශ්‍රේණිය	අනුමත තනතුරු සංඛ්‍යාව
27	කළමනාකරණ සහකාර	MA 1-1	III/II/I	53
28	රියදුරු	PL 3	III/II/I	10
29	නඩත්තු සහායක	PL 2	III/II/I	2
30	ජලනල කාර්මික	PL 2	III/II/I	1
31	විදුලි කාර්මික	PL 2	III/II/I	1
32	රසායනාගාර සහායක	PL 2	III/II/I	8
33	කාර්යාල කාර්ය සහායක	PL 1	III/II/I	30
TOTAL				**269**

* මගේ අංක DMS/1827 හා 2015.11.18 දිනැති ලිපියෙන් දරන්නාට පෞද්ගලික වන සේ අනුමත කර ඇති ඖෂධ විශ්ලේෂක තනතුරෙහි දැනට සේවය කරනු ලබන නිලධාරීන් හය දෙනා (06) අධිකාරියෙන් ඉවත් වීමත් සමඟ එම තනතුරු හයද ඖෂධ විශ්ලේෂක තනතුරු සංඛ්‍යාවට ඇතුළත් වීමට යටත්ව

** මගේ අංක DMS/1827/Vol.II හා 2020.12.21 දිනැති ලිපියෙහි 04. සහ 05. ඡේදයන්හි දක්වා ඇති කොන්දේසි වලට යටත්ව

18/08/2023

ආර්.එම්.කේ. ගංගා සංජීවනී
අධ්‍යක්ෂ
කළමනාකරණ සේවා දෙපාර්තමේන්තුව
මහා භාණ්ඩාගාරය
කොළඹ 01

Bench Mark නිර්දේශ ක්‍රියාත්මක කිරීම

Sub Indicator	WHO නිර්දේශය	වර්තමාන තත්ත්වය			ක්‍රියාත්මක කිරීම පිළිබඳ විස්තරය
		ක්‍රියාත්මක කර ඇත	අර්ධ වශයෙන් ක්‍රියාත්මක කර ඇත	ක්‍රියාත්මක කර නැත	
LT 03.02 : ①	Training of validation / verification should be conducted for all laboratory personnel as well as the method of analysis transferred.		Partially done		Training done. Implementation not complete
LT 03.04 : ②	Training of handling OOS, Deviation and nonconforming work.	Done			
LT 05.01 : ③	The laboratory must have separate weighing rooms with controlled environmental accommodation conditions.			Not done	
④	The laboratory must control all the environmental accommodation conditions which can have a direct impact on the quality of testing supported by the availability of clear procedure.			Not done	
⑤	The laboratory must improve the regent storage system.			Not done	
LT 06.01 : ⑥	Revise the procedure for sampling management GN-PR-01 rev 01 to provide detail procedure for specific sample storage conditions, the procedure for sample retained and the parameter of testing			Not done	

	should be carried out.				
LT 06.02 : (7)	Create procedure for performing test in according with MA documentation		Partially done		Initiated but due to data base problem was not proeeded
LT 06.03 : (8)	Revise the SOP Number GN-PR-02 procedure for reporting laboratory rev 1 and added the document number of certificate of analysis form and all the form used for reporting the testing.			Not done	
LT 08.02 : (9)	Revise the SOP secondary reference standards login and usage number RC-SP-03 by adding trend analysis procedures for secondary reference material and the procedure of primary reference standards RC-SP-01			Not done	SOP for overall trend analysis was created but not proceeded further
(10)	Create a trend of analysis program and conduct the trend analysis		Partially done		
LT 08.04 : (11)	Establish a system and mechanism to require the NRA to establish performance indicators along the entire laboratory testing chain and ensure that KPIs are actually contributing to monitoring of regulatory performance, measuring the effectiveness of laboratory testing regulatory activities, and making any necessary adjustments or optimizations.	Done			
LT 09.01 : (12)	Revise SOP safe handling, transportation and			Not done	

	storage of chemical number LB-SP-04 rev 01 to regulate the expired date of reagent, storing cabinet for reagent and the disposal procedure for a hazardous substance.				
(13)	Updating the list of hazardous substance and completed with the date and the responsible person			Not done	
LT 09.03 : (14)	Laboratory staff immunization programs should be established, implemented and monitored.			Not done	Done the immunisation against covid 19
LT 10.01 : (15)	Revise SOP outsourcing for laboratory testing number GN-SP-07 Rev: 00 to add provide clear information of specification or criteria for external laboratory and contract procedure.			Not done	

National Medicines Quality Assurance Laboratory
National Medicines Regulatory Authority

Quality Control of Medicinal Products

DCN : GN-PR-18

	Signature & Date (dd/mm/yyyy)
Written by: Amara Pinnawala Deputy Director/NMQAL	09/03/2021
Reviewed by: Ajith Priyadarshana Director/NMQAL	09/03/2021
Authorized by: Dr. Kamal Jayasinghe Chief Executive Officer National Medicines Regulatory Authority	09/03/2021

Effective Date: 01/04/2021
(dd/mm/yyyy)

Master Document: Quality Manager
Copies to: Laboratory: Chemical Division
Microbiological Division
Biological Division
Devices & Cytotoxics Division
Reference Standards and Calibration Division
Technical Unit

5. PROCEDURE

5.1. INTRODUCTION

Quality testing of medicinal products collected from the market, received as special requests, received during the granting, renewal or amendment of market authorizations and collected from various points of the distribution chain is prescribed by the NMRA Act No.05 of 2015 and subsequent regulations.

In addition, NMQAL conducts quality testing based on product complaints on herbal medicines and food supplements if required by NMRA, and also based on requests from the competent institutions of the government.

The deadline for the quality reports prescribed for the samples received from the Courts, by the section 127 of NMRA Act is 28 days. In all other cases the report should be issued within 90 days of receipt. In case of delays in certain process steps, the Head of the relevant division should immediately inform the Director/NMQAL and take necessary actions to issue the report before the new deadline assigned by the Director.
The deadline for outsourced quality tests of NMQAL which are not prescribed anywhere else should be defined in the relevant contract document.

5.1.1. General remarks

- The distribution of the received samples is carried out according to SOP GN-PR-01 "Procedure for Sample Management".
- In case of obtaining the laboratory test results outside the accepted quality specifications, the procedure is performed in accordance with the SOP GN-PR-05, "Procedure for Handling Out of Specification Results".
- In addition to the declaration of conformity with the quality specification, which is an integral part of the NMQAL Quality Report, the "Note" section indicates the statement of decision rule used:
  "In assessing the conformity of the results obtained with the tested quality parameters for which the measurement uncertainty assessment is carried out, the rule of simple acceptance shall apply, whereby the estimated measurement uncertainty shall not be associated with the results obtained."
  The decision rule of the NMQAL based on the estimated measurement uncertainty is described in more detail in SOP GN-PR-09 "Procedure for Estimation of Uncertainty Measurements"
- For cases where an assessment of measurement uncertainty has been carried out as per GN-PR-09: "Procedure for Estimation of Uncertainty Measurements", it is available for review by the applicant if requested.

බලයලත් නිලධරයා විසින් රඳවා තබා ගත් සාම්පලයෙන් කොටසක් අධිකරණයට ඉදිරිපත්කළ යුතු බව.

127. (1) බලයලත් නිලධරයකු විසින් ලබාගත් සාම්පලයක් ඔහු විසින් කොටස්වලට බෙදීය යුතු අවස්ථාවක දී, ඉන් එක් කොටසක් ඔහු විසින් රඳවා තබා ගත යුතු අතර ඔහු විසින් රඳවා තබා ගත් කොටස ඒ සාම්පලයට අදාළ නඩු විභාගය ආරම්භවන අවස්ථාවේ දී අධිකරණය වෙත ඉදිරිපත්කරනු ලැබිය යුතු ය.

(2) මහෙස්ත්‍රාත්වරයා විසින්, ස්වකීය මෝසමක් මගින් සහ නඩු පැවරීමට අදාළ යම් පාර්ශවයකගේ ඉල්ලීම මත (1) වන උපවගන්තිය යටතේ අධිකරණයට ඉදිරිපත්කළ ඒ සාම්පල කොටස විශ්ලේෂණය කිරීම හෝ පරීක්ෂණ කිරීම සඳහා අනුමත විශ්ලේෂකවරයකු වෙත ඉදිරිපත් කරනු ලැබිය යුතු ය.

(3) (2) වන උපවගන්තිය යටතේ ඒ සාම්පලයේ කොටසක් ඉදිරිපත් කරනු ලැබුවේ යම් අනුමත විශ්ලේෂකවරයකු වෙතට ද ඒ අනුමත විශ්ලේෂකවරයා විසින් එම සාම්පලයේ කොටස ඔහුට ලැබී දින විසි අටක් ඇතුළත ඔහුගේ වාර්තාව හෝ සහතිකය අධිකරණයට යැවිය යුතු ය.

(4) විශ්ලේෂණයේ හෝ පරීක්ෂණයේ වියදම් අධිකරණය විසින් නියම කරනු ලැබිය හැකි යම් පාර්ශවයක් විසින් ගෙවනු ලැබිය යුතු ය.

බලයලත් නිලධරයකු විසින් ලබාගත් ලේඛනයකින් ගනු ලැබූ පිටපතක්.

128. 125 (1) (ඈ) වන වගන්තිය යටතේ බලයලත් නිලධරයකු විසින් යම් පොතකින්, ලේඛනයකින් හෝ වාර්තාවකින් ලබාගත් පිටපතක් හෝ ලබාගත් උද්ධෘතයක්, බලයලත් නිලධරයා විසින් සත්‍ය පිටපතක් හෝ සත්‍ය උද්ධෘතයක් බවට සහතිකකර ඇත්නම් ඒ පොත, ලේඛනය හෝ වාර්තාව තබාගෙන ඇති හෝ පවත්වාගෙන යන නැතහොත් ඒ පොත, ලේඛනය හෝ වාර්තාව තබාගැනීමට හෝ පවත්වාගෙන යෑමට සලස්වන තැනැත්තාට එරෙහිව සාක්ෂි වශයෙන් ආවේෂ්‍ය කරගනු ලැබිය යුතු අතර ඒ පොතේ, ලේඛනයේ හෝ වාර්තාවේ ඇතුළත් අන්තර්ගතයන් බැලූ බැල්මට පෙනෙන සාක්ෂියක් විය යුතු ය.

විශ්ලේෂණ.

129. (1) බලයලත් නිලධරයකු තමා විසින් තහනමට ගත් යම් භාණ්ඩයක් හෝ තමා විසින් එයින් ලබාගත් යම් කොටසක් හෝ යම් සාම්පලයක් 126 (1) වන උපවගන්තිය යටතේ විනාශකර නැත්නම් මිස විශ්ලේෂණය කිරීම සඳහා හෝ පරීක්ෂණය කිරීම සඳහා අධිකාරියේ තීරණය අනුව අනුමත විශ්ලේෂකවරයකු වෙත බාරදෙනු ලැබිය යුතු ය.

(ඇ) විශේෂඥයන්ට ඡන්දය පාවිච්චි කිරීමේ අයිතියක් නොමැති විය යුතු ය.

අධිකාරියේ රැස්වීම් සඳහා සහභාගීවීම වෙනුවෙන් වූ පාරිශ්‍රමික.

13. අධිකාරියේ සාමාජිකයන් සහ විශේෂඥයන් විසින් අධිකාරියේ රැස්වීම් සඳහා සහභාගීවීම වෙනුවෙන් මුදල් විෂයය භාර අමාත්‍යවරයාගේ එකඟත්වය ඇතිව අමාත්‍යවරයා විසින් තීරණය කරනු ලැබිය හැකි යම් පාරිශ්‍රමික ගෙවනු ලැබිය හැකි ය.

අධිකාරියේ බලතල සහ කර්තව්‍ය.

14. අධිකාරියේ බලතල සහ කර්තව්‍ය වනුයේ:-

(අ) යම් නිෂ්පාදනයක්, ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ වෙනත් යම් නිෂ්පාදනයක් ද යන්න වර්ගීකරණය මත තීරණය කිරීම;

(ආ) මේ පනතේ නියම ප්‍රකාරව ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන සහ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන ලියාපදිංචි කිරීම සහ බලපත්‍ර ලබා දීම අනුමත කිරීම හෝ එවැනි යම් ලියාපදිංචි කිරීමක් හෝ බලපත්‍ර ලබාදීමක් අවලංගු කිරීම හෝ අත්හිටුවීම;

(ඇ) ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන, විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන, ලියාපදිංචි කිරීම, බලපත්‍ර ලබාදීම, නිෂ්පාදනය කිරීම, ආනයනය කිරීම, ගබඩා කිරීම, නැවත ඇසුරුම් කිරීම, ප්‍රවාහනය කිරීම, බෙදාහැරීම, විකිණීම, ප්‍රචාරණය කිරීම, ප්‍රවර්ධනය කිරීම, ආපසු කැඳවීම සහ බැහැර කිරීම නියාමනය කිරීම;

(ඈ) ඔසුසල් හා ඖෂධ ගබඩා ලියාපදිංචි කිරීම සහ නියාමනය කිරීම සඳහා බලය ලබාදීම;

(ඉ) ඖෂධ, වෛද්‍ය උපකරණ, සීමාස්ථ නිෂ්පාදන හෝ විමර්ශනාත්මක ඖෂධීය නිෂ්පාදන, නිෂ්පාදනය කිරීම, ආනයනය කිරීම, ගබඩා කිරීම, බෙදා හැරීම, ප්‍රවාහනය කිරීම සහ විකිණීම සඳහා බලපත්‍ර නිකුත් කිරීම සහ මේ පනතේ නියම ප්‍රකාරව එකී බලපත්‍ර අවලංගු කිරීම;

(ඊ) අධිකාරියේ කර්තව්‍ය ඵලදායී ලෙස ඉටුකිරීම සඳහා අවශ්‍යවන අනු කමිටු පත්කිරීම;

(උ) මේ පනතේ සහ වෙනත් යම් ලිඛිත නීතියක විධිවිධානවලට යටත්ව ඖෂධ, වෛද්‍ය උපකරණ,

NMRA
NATIONAL MEDICINES REGULATORY AUTHORITY

GUIDELINE ON GOOD DISTRIBUTION PRACTICES (GDP)

Pharmacy Regulatory Division

NATIONAL MEDICINE REGULATORY AUTHORITY
Norris Canal Rd, Colombo 01000, Sri Lanka

(919)

GUIDELINE ON GOOD DISTRIBUTION PRACTICES (GDP)

CONTENTS

(917)

01. INTRODUCTION

The National Medicines Regulatory Authority Act (NMRA Act) requires that "No person shall import or distribute any medicine without adhering to Good Distribution Practices (GDP) and any other prescribed guidelines and conditions. Section 49 (3) & "No person shall import or distribute any medical device without adhering to Good Distribution Practices (GDP) and any other prescribed guidelines or conditions." Section 75 (2).

The NMRA Act defines GDP as "Good Distribution Practice" means good distribution practice guidelines issued by the Authority;

Storage and distribution are important activities in the supply chain management Therapeutic goods. Therapeutic goods may be subjected to various risks at different stages in the supply chain, i.e. during purchasing, storage, distribution, transportation, repackaging, and relabelling. It is essential to protect against the penetration of substandard and falsified products supply chains that pose a real threat to public health and safety.

All persons and outlets involved in any aspect of the storage and distribution of medical products from the premises of the manufacturer of the therapeutic goods and/or its related materials to the person dispensing or providing therapeutic good directly to a patient or his or her agent are required to adopt proper distribution and store management procedures appropriate for the distribution and storage of therapeutic goods and its related materials destined for the consumer.

This includes all parties involved in trade, storage and distribution of medical products, manufacturers and wholesalers, as well as other parties such as brokers, suppliers, distributors, logistics providers, traders, transport companies, forwarding agents and their employees.

The relevant sections of this guideline should also be considered for implementation by, amongst others, governments, regulatory bodies, international procurement organizations, donor agencies and certifying bodies, as well as all parties involved in any aspect of the trade and distribution of pharmaceutical products, including health care workers.

The GDP also requires that materials and products classified as dangerous drugs under the Poison, Opium and Dangerous Drugs Act 1984, are stored and distributed in accordance with the requirements of the respective Act and Regulations.

Good Distribution Practice or GDP is defined by this guideline as: "The measures that need to be considered in the storage, transportation and distribution of any therapeutic good and its related materials such that the nature and quality intended is preserved when it reaches the consumer"

02. PURPOSE

Good Distribution Practice describes the standards that a wholesale distributor must meet to ensure the maintenance of high standard quality and integrity of therapeutic goods and related materials regulated under the NMRA Act throughout the supply chain. GDP promote uniformity in licensing of wholesaling of therapeutic goods and related materials and to further facilitate the removal of barriers to trade in therapeutic goods and related materials, the following Guide to Good Distribution Practice (GDP) for products regulated under NMRA Act has been adopted.

03. SCOPE

The standards set out herein apply therapeutic goods regulated under NMRA Act intended for human use which a prescription is required by the patient, products which may be provided to a patient without a prescription, biological, vaccines and medical devices. This guideline applicable for Investigational Medicinal Products (IMP) and also applies to the sourcing, storage and transportation of active pharmaceutical ingredients and other ingredients used in the production of the therapeutic goods. The document also cover the GMP aspects of distribution of labels and/or packaging. It is not intended to be a barrier to technical innovation or the pursuit of excellence or to place any restraint upon the development of new concepts or new technologies, which have been validated and provide a level of Quality Assurance and integrity of the distribution processes at least equivalent to those set out in this guide.

04. GLOSSARY

Consignment	The delivery batch of materials and products supplied at one time in response to a particular request or order.
Contamination	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter during manufacturing, sampling, packaging or repackaging, storage or transport.
Cross -contamination	Contamination of a material or product with another material or product.
Excipient	Any substances in the drug product other than the API
Finished product	A product that has undergone all stages of production, including packaging in its final container and labeling.
First Expired/ First Out (FEFO) principle concept	A distribution procedure that ensures the approved stock that has a nearer expiry date is distributed and / or utilized before an approved and identical stock item with later expiry is distributed and/ or utilized.
License	Any license issued under Regulation 12 of the NMRA Act or CDD Act
Manufacturer	Includes: a) The making or assembling of the product; b) The enclosing or packing of the product in any container in a form suitable for administration or application, and the labeling of the container; and c) The carrying out of any process in the course of any or the foregoing activities.
Material	A general term used to denote raw materials, starting materials, intermediates, excipients and packaging materials and labeling materials.
Packaging material	Any material employed in the packaging of a material including any other packaging used for transportation or shipment. Packaging materials are referred to as primary or

	secondary according to whether or not they are intended to be in direct contact with the product.
Product	Any product registered under NMRA Act 2015
Raw material	A general term used to denote starting materials, reagents, intermediates, process aids and solvents intended for used in the production of APIs or products.
Return material/ product	Material or product sent back from the customer to the supplier.
Storage	A term used to describe the safe keeping of materials and products such as starting materials and finished products received from suppliers, semi-finished products in process and finished products awaiting dispatch and products awaiting distribution to retailers and products (rejected, recalled and damaged) awaiting disposal.
Supplier	A person providing products or materials on request. Supplier may be agents, brokers, distributors, manufacturers or traders.

05. GENERAL PRINCIPLES AND RELATED LEGISLATION

All parties involved in the distribution of pharmaceutical products have a responsibility to ensure that the quality of pharmaceutical products and the integrity of the distribution chain is maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient or his or her agent.

There should be collaboration between all parties, including governments, customs agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors and entities responsible for the supply of medical products to patients, to ensure the quality and safety of these products; to prevent the exposure of patients to substandard and falsified products and to ensure that the integrity of the distribution chain is maintained.

1. The National Medicines Regulatory Authority Act (NMRA Act No.2015 of 5); Section 49 (3) "No person shall import or distribute any products regulated under NMRA Act without adhering to Good Distribution Practices (GDP) and any other prescribed guidelines or conditions.

The NMRA Act defines GDP as "Good Distribution Practice" means good distribution practice guidelines issued by the Authority;

2. Poison Opium and Dangerous Drugs Act (PODDA) as amended in 1984

06. QUALITY MANAGEMENT

Quality Management System should be implemented and maintain with an appropriate organizational structure, procedures, and resources, setting out responsibilities, processes and risk management principles in relation to their activities; and systematic actions necessary to ensure adequate confidence that a material and/or product and documentation will satisfy given requirements for

quality and integrity and remains within the legal supply chain during storage and/or transportation. Totality of these actions is termed "Quality System".

The quality system should be fully documented and its effectiveness monitored. Within an organization, quality assurance serves as a management tool. In contractual situations quality assurance also serves to generate confidence in the supplier. There should be a documented quality policy describing the overall intentions and policies of the distributor regarding quality, as formally expressed and authorized by management.

Where electronic commerce (e-commerce) is used, defined procedures and adequate systems should be in place to ensure traceability and confidence in the quality of materials and/or products. The provisions should guarantee the same degree of materials and/or products safety as it can be achieved in non-e-commerce.

All entities in the supply chain should be traceable as applicable, depending on the type of materials and/or products, and on the national policies and legislation. There should be written procedures and records to ensure traceability of the materials and/or products distributed.

Self-inspections should be conducted in order to monitor implementation and compliance with GDP principles and to propose necessary corrective measures. Certification of compliance with a quality system (such as the applicable International Organization for Standardization (ISO) series, or national or international guidelines) by external bodies is recommended. Such certification should not, however, be seen as a substitute for compliance with this guideline.

Quality system should also foster a safe, transparent and secure distribution system by establishing measures to ensure that materials and/or products have a form of documentation that can Guidelines on Good Distribution Practice (GDP) be used to permit traceability of the materials and/or products throughout distribution channels from the manufacturer/importer to the retailer.

The quality system should include an emergency plan which ensures effective recall of medicinal products from the market ordered by the manufacturer or the competent authorities or carried out in cooperation with the manufacturer or marketing authorization holder for the medicinal product concerned. The competent authorities must be immediately informed of any suspected falsified medicines offered in the supply chain.

07. QUALITY RISK MANAGEMENT

The quality system should include provisions that the holder of the marketing authorization labelled entity (if different from manufacturer) the appropriate national and/or international regulatory bodies, as well as other relevant competent authorities, should be informed immediately in case of confirmed or suspected counterfeit products. Such materials and/or products have to be stored in a secure segregated area and have to be clearly identified to prevent further distribution or sale.

All parties involved in the distribution of materials and/or products should share responsibility for the quality and safety of materials and/or products to ensure that they are fit for their intended use. There

should be a procedure in place that describes pedigree documentation as well as the visual and/or analytical identification of potential counterfeit materials and/or products. The procedure should include provisions for notification, as appropriate for the holder of the marketing authorization labelled entity (if different from manufacturer) the appropriate national and/or international regulatory bodies, as well as other relevant competent authorities, when a potential counterfeit drug is identified.

Authorized procurement and release procedures for all administrative and technical operations performed should be in place, to ensure that appropriate materials and/or products are sourced from approved suppliers and distributed by approved entities. The approval should come from the competent authority of the individual country where the legal entity is registered. There should be a written procedure in place to ensure and document traceability of materials and/or products and received and distributed based on batch numbers. While it is understood that a differentiated approach may be necessary for different materials and/or products and regions, pedigree record and/ track and trace technologies provide possible options to ensure traceability.

To support the avoidance of penetration of counterfeit materials and/or products into the supply chain pedigree procedures and records should be developed in order to allow the tracking and tracing of material and/or product in the supply chain. Each supplier should maintain and provide such pedigree records to the next recipient in the supply chain ending with the final recipient before purchase/use by end-user which is usually the patient or consumer.

08. MANAGEMENT REVIEW

A responsible person should be appointed by the management, who should have clearly specified authority and responsibility for ensuring that a quality system is implemented and maintained.

The management of the distributor should ensure that all parts of the quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

Review of the quality system and its effectiveness by using quality metrics and key performance indicators.

Identification of opportunities for continual improvement and follow-up on recommendations from previous management review meetings and all Records should be maintained.

09. COMPLAINTS

Complaints should be recorded with all the original details. A distinction should be made between complaints related to the quality of a medicinal product and those related to distribution. In the event of a complaint about the quality of a medicinal product and a potential product defect, the manufacturer and/or marketing authorization holder should be informed without delay. Any product distribution complaint should be thoroughly investigated to identify the origin of or reason for the

complaint and risk assessed and appropriate CAPA should be taken. Competent person should be appointed to handle complaints and allocated sufficient support personnel.

a) Principle

A complaint is defined as a situation whereby when a customer or any other (outside party) has reported a material (e.g. active pharmaceutical ingredients) or product defect or adverse reactions with any of the company's marketed materials or products. This is valid regardless of whether:

- The report is written or verbal.
- The sample of affected product is attached.

A report on a product and defect which has been identified within the company on a marketed product batch is also considered a complaint.

b) Classification of complaints

Complaints can be classified as:

Medical (e.g. adverse reactions)
Pharmaceutical (e.g. precipitation, lack of efficacy)
Technical (e.g. damaged packaging or labelling defects)

c) Procedure for complaints

The procedure for dealing with complaints shall ensure that:

- That complaints received are given proper due attention and promptness that measures are taken to prevent repeated complaints
- That, when adequate information is available, a decision is made whether to make a recall and if so, the degree to which a recall is to be made

Follow-up of complaints will contribute to a higher and more uniform product quality and as well as prevent further defects, improve quality and client satisfaction.

d) Persons responsible

Within each company, 2 persons responsible with adequate knowledge shall be assigned the task of dealing with complaints. The persons responsible must also have the authority to decide on measures to be taken. The required particulars for the responsible persons are as follows:

PERSON RESPONSIBLE I PERSON RESPONSIBLE II

- Name
- NIC / Passport No
- Position
- Home Address
- Telephone No
- NIC / Passport No

- Position
- Home Address
- Telephone No

e) Reporting

Procedures shall be developed within the company for the receipt of reports on complaints at any time. It is important that complaints reach the persons responsible. All complaints reported should be recorded and properly documented.

f) Investigation

The persons responsible should initiate the investigation immediately. The investigation shall be documented. If a material and/or product defect is discovered or suspected in a batch, consideration should be given to determine whether other batches are also affected.

The investigation should also cover:

- Distribution condition
- Condition under which the material and/or product is used

g) **Corrective and preventive action**

The persons responsible shall ensure that all the corrective and preventive actions are taken following the outcome of the investigation. All corrective and preventive actions should be recorded, reported and implemented. If a recall has been decided, some of the procedures stated in the Product Recall Procedure shall be applied. The company's management shall discuss possible steps to prevent future defects and take over any responsibility for further handling of the complaint from the persons responsible.

h) **Response to complainant**

The persons responsible should acknowledge the complainant within 24 hours after receipt of complaint(s). The persons responsible shall provide response to the complainant within an agreed timeframe after completion of the investigation. If the person who complains is informed of the outcome of the investigation over the telephone, the date and information provided shall be noted.

i) **Documentation**

Each individual complaint and its relevant attached documents shall be filed. A final report shall be prepared and kept in the Complaint File. One copy of the final report shall be forwarded to the relevant parties. A Complaint File should contain:

1. Written procedures describing the actions to be taken in the handling of all written and oral complaints regarding materials and products (procedures for dealing with complaints).
2. A written record of each individual complaint and as well as the completed investigation report.

10. RETURNED AND REJECTED PRODUCTS

Returned products must be handled according to a written, risk-based process taking into account the product concerned, any specific storage requirements and the time elapsed since the medicinal product was originally dispatched. Returns should be conducted in accordance with national law and contractual arrangements between the parties.

All returned and rejected materials and/or products should be placed in quarantine and be clearly marked as such. They should be stored separately in restricted area.
The fate of returned and rejected materials and/or products should be determined after sufficient evaluation by authorized person.

Provision should be made for the appropriate and safe transport and storage of returned or rejected materials and/or products in accordance with the relevant storage and other requirements.

All action taken should be approved and recorded.

11. PRODUCT RECALL

This section is referred to the "Guidelines on Recall procedure" published by the NMRA.

12. SELF INSPECTION

The quality assurance system should include self-inspections. These should be conducted in order to monitor implementation and compliance with the principles of GDP and to trigger necessary corrective and preventive measures.

Self-inspections should be conducted in an independent and detailed way by a designated, competent person, according to an approved written procedure.

The results of all self-inspection should be recorded. Reports should contain all observations made during the inspection and, where applicable, proposals for corrective measures. There should be an effective follow-up program. Management should evaluate the inspection report, and corrective actions taken and recorded

13. PREMISES AND FACILITIES

a) Premises

Should be suitably located, designed, constructed and maintained to ensure appropriate operations such as receiving, storage, picking, packing and dispatch of medical products.
There should be sufficient space, lighting and ventilation to ensure required egregation, appropriate storage conditions and cleanliness.
Sufficient security should be provided and access should be controlled.

Appropriate controls and segregation should be provided for products requiring specific handling or storage such as radio-active materials, products containing hazardous substances, and products to be stored under controlled temperature and relative humidity conditions.

Receiving and dispatch bays should be separate and should protect products from weather conditions.

Activities relating to receiving and dispatch such be done in accordance with authorized procedures. Areas should be suitably equipped for the operations.

Premises should be kept clean. Cleaning equipment and cleaning agents should not become possible sources of contamination.

Premises should be protected from the entry of birds, rodents, insects and other animals. A rodent and pest control programme should be in place.

Toilets, wash, rest and canteen facilities should be separate from other areas. Food, eating, drinking, and smoking should be prohibited in all areas where medical products are stored or handled.

b).Receiving

Each incoming delivery should be checked against the relevant documentation to ensure that the correct product is delivered from the correct supplier. This may include, e.g. the purchase order, each container, label description, batch number, product and quantity.

The consignment should be examined for uniformity of the containers and, if necessary, should be subdivided according to the supplier's batch number should the delivery comprise more than one batch. Each batch should be dealt with separately.

Each container should be carefully checked for possible contamination, tampering and damage. Any suspect containers or, if necessary, the entire delivery should be quarantined for further investigation.

Receiving areas should be of sufficient size to allow cleaning of incoming containers.

When required, samples should be taken only by appropriately trained and qualified personnel and in strict accordance with written sampling procedure and sampling plans. Containers from which samples have been taken should be labelled accordingly.

Following sampling, the goods should be subject to quarantine. Batch segregation should be maintained during quarantine and all subsequent storage.

Materials and products requiring storage under controlled conditions of temperature and relative humidity should be handled as a priority.

Materials and products should remain in quarantine until an authorized release or rejection is obtained. Measures should be taken to ensure that rejected materials and products cannot be used. They should be stored separately from other materials and products while awaiting destruction or return the supplier.

C).Storage areas

Precautions should be taken to prevent unauthorized persons from entering Storage areas.

Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of materials and products, such as starting and packaging materials, intermediates, finished products, products in quarantine, and released, rejected, returned or recalled products.

Storage areas should be appropriately designed, constructed, maintained or adapted. They should be kept clean and dry and there should be sufficient space and lighting. Storage areas should be maintained Within acceptable temperature limits.

Where special storage conditions are required on the label (e.g. temperature, relative614 humidity), these should be provided, controlled, monitored and recorded.

Materials and products should be stored off the floor and suitably spaced to permit ventilation, cleaning and inspection. Suitable pallets should be used and kept618 in a good state of cleanliness and repair.

A written sanitation programme should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas.

There should be a written programme for pest control. The pest-control agents used should be safe and there should be no risk of contamination of the materials and products.

There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

Where the status is ensured by storage in separate areas, these areas must be clearly marked and their access restricted to authorized personnel. Any system replacing physical separation and labelling or demarcation should provide equivalent security. For example, computerized systems can be used provided that they are validated to demonstrate security of access.

Where required, a separate sampling area should be in place. If sampling is performed in the storage area, it should be conducted in such a way that there is no risk of contamination or cross contamination. Adequate cleaning procedures should be in place for the sampling areas.

Certain materials and products such as highly active and radioactive materials, narcotics and other hazardous, sensitive and/or dangerous materials and products, as well as substances presenting special risks of abuse, fire or explosion (e.g. combustible liquids and solids and pressurized gases), should be stored in a dedicated area that is subject to appropriate additional safety and security measures.

Where required, mapping studies for temperature and relative humidity, as appropriate, should be done to show uniformity across the storage facility. (Ref: WHO 678 Technical Report – time- and temperature-sensitive pharmaceutical products). This applies, for example, to areas, refrigerators and freezers.. Temperature and relative humidity, as appropriate, should be controlled and monitored at regular intervals. Data should be recorded and the records should be684 reviewed. The equipment used for monitoring should be calibrated and be suitable for685 their intended use. All records pertaining to mapping and monitoring should be kept686 for a suitable period of time and as required by national legislation.

Temperature and relative humidity, as appropriate, should be controlled and monitored at regular intervals. Data should be recorded and the records should be reviewed. The equipment used for monitoring should be calibrated and be suitable for their intended use. All records pertaining to mapping and monitoring should be kept for a suitable period of time and as required by national legislation.

The storage conditions for materials and/or products should follow the required storage specification of the materials and/or products.

Where temperature is not stated (in terms of range) on the labels of the materials or products the following definitions should be followed:-

ON THE LABEL	MEANS
Freezer	The temperature is thermostatically controlled between -20°C and -10°C
Refrigerator	The temperature is thermostatically controlled between 2°C and 8°C
Protect from light	To be provided to the user in a light resistant container
Room temperature	The temperature is between 15°C and 30°C
Warm	The temperature is between 30°C and 40°C
Excessive heat	The temperature is above 40°C
Do not store over 30°C	The temperature is between 2°C and 30°C
Do not store over 25°C	The temperature is between 2°C and 25°C
Do not store over 15°C	The temperature is between 2°C and 15°C
Do not store over 8°C	The temperature is between 2°C and 8°C
Do not store below 8°C	The temperature is between 8°C and 25°C

14. STOCK CONTROL AND ROTATION

Periodic stock reconciliation should be performed at defined intervals by comparing the actual and recorded stocks.

Comprehensive records should be maintained showing all receipts and issues of materials and/or products according to batch number.
Periodic stock reconciliation should be performed comparing the actual and recorded materials and/or products quantity. All significant stock discrepancies should be subjected to investigation to check against inadvertent mix-ups and wrong issues.

Issues should normally observe the principle of stock rotation (FEFO) especially where expiry dated materials and/or products are concerned.

Materials and/or products with broken seals, damaged packaging or suspected of possible contamination must not be sold or supplied.
Goods bearing an expiry date must not be received or supplied after their expiry date or too close to their expiry date that this date is likely to occur before the goods are used by the consumer.

All labels and containers of materials and/or products should not be altered, tampered or changed. Acts and regulations relating to labels and containers should be adhered to at all times.

Partly used containers of materials and/or products should be securely re-closed to prevent spoilage and/or contamination during subsequent storage. Damaged containers should not be issued but should be brought to the attention of the authorized personnel.

Materials and/or products should be protected from excessive climatic conditions during storage and transit, such as heat, moisture and direct sunlight. They should be stored separately from other materials and/or products in conditions which satisfy the requirements for the materials and/or

products, so that shelf-life declaration may be maintained.

Control of expired stock

All stocks should be checked regularly for expired and degraded materials and/or products. All due precautions should be observed to preclude issue of expired materials and/or products.

15. EQUIPMENT AND VEHICLES

All equipment impacting on storage and distribution of medicinal products should be designed, located and maintained to a standard which suits its intended purpose. Planned maintenance should be in place for key equipment vital to the functionality of the operation.

Computerized systems should be capable of achieving the desired output and results.

Where electronic commerce (e-commerce) is used, i.e. electronic means are used for any of the steps, defined procedures and adequate systems should be in place to ensure traceability and confidence in the supply chain and products concerned.

Electronic transactions (including those conducted via the Internet) relating to the distribution of medical products should be performed only by authorized persons according to defined and authorized access and privileges.

Equipment used to control or to monitor the environment where the therapeutic goods are stored should be calibrated at defined intervals based on a risk and reliability assessment.
Calibration of equipment should be traceable to a national or international measurement standard.

Appropriate alert systems should be in place to provide alerts when there are excursions from pre-defined storage conditions. Alert levels should be appropriately set and should be regularly tested to ensure adequate functionality.

Equipment repair, maintenance and calibration operations should be carried out in such a way that the integrity of the medicinal products is not compromised.

Equipment and processes should be respectively qualified and/or validated before commencing use and after any significant changes, e.g. repair or maintenance.

Vehicles and equipment used to distribute or transport materials and/or products should be suitable for their use and appropriately equipped to prevent exposure of the materials and/or products to conditions that could affect their stability and packaging integrity, and prevent contamination of any kind.

Vehicles and equipment used must aim to minimize the risk of errors and permit effective cleaning and/or maintenance, to avoid contamination, accumulation of dust or dirt and/or any adverse effect on the quality of materials and/or products being distributed.

Dedicated vehicles and equipment should be used, where possible, when handling materials and/or products.

There should be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.

Vehicles, containers and equipment should be kept clean, dry and free from accumulated waste. Organizations in charge of the distribution must ensure that vehicles are cleared up on regular basis.

Vehicles, containers and equipment should be kept free from rodents, vermin, birds and other pests. There should also be written program for such pest control. Cleaning and fumigation agents should not have an adverse effect on material and/or product quality.

Special attention should be given to the design, use, cleaning and maintenance of all equipment used for the handling of materials and/or products which are not in a protective shipping carton or case.

Where special storage conditions (e.g. temperature and/or relative humidity), different from or limiting, the expected environmental conditions, are required during transit these should be provided, checked, monitored and recorded.

Equipment used for monitoring conditions within vehicles and containers, e.g. temperature and humidity, should be calibrated, at regular intervals.

Vehicles and containers should be of sufficient capacity to allow orderly storage of the various categories of materials and/or products during transportation.

Where possible, mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned materials and/or products as well as those suspected to be counterfeits. Where feasible, such goods must be securely packaged, clearly labeled, and be accompanied by appropriate supporting documentation.

Measures should be in place to prevent unauthorized persons from entering and/or tampering with vehicles and/or equipment, as well as to prevent the theft or misappropriation thereof.

16. QUALIFICATION AND VALIDATION

The scope and extent of qualification and validation should be determined using a documented risk assessment approach.
Premises, utilities, equipment and instruments, processes and procedures should be considered.
The scope and extent of qualification and validation in case of any significant changes should be identified.
Qualification and validation should be done following procedures and protocols. The results and outcome of the qualification and validation should be recorded in reports. Deviations should be investigated and the completion of the qualification and
validation should be concluded and approved by responsible personnel.

17. PERSONNEL

The company should designate a person as "responsible person". A registered pharmacist is desirable. The responsible person should have appropriate competence and experience as well as knowledge of and training in GDP.

The responsible person should carry out their duties in such a way as to ensure that can demonstrate GDP compliance.

The company should have an adequate number of personnel with the necessary qualifications and/or practical experience. The responsibilities placed on any individual should not be so extensive as to present any risk to quality.

Key personnel who perform supervisory and/or controlling store or warehouse functions should possess the necessary competency, knowledge and experience. They should also where necessary be in possession of the required professional and technical qualifications suitable for the tasks assigned to them.

The company must have an organization chart. Personnel in responsible positions should have specific duties recorded in written job descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the responsibilities of those personnel concerned with the application of GDP.

Personnel employed in storage facilities should be certified healthy and fit for their assigned responsibilities. They should receive medical examination upon recruitment. After the first medical examination, examinations should be carried out periodically.

Personnel employed in storage facilities should wear suitable protective or working garments, if necessary.

Besides the basic training on the theory and practice of GDP, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training program should be available and approved. Training records should be kept.

Visitors or untrained personnel should, preferably, not be taken into storage areas. If this is unavoidable, they should be closely supervised.

Personnel dealing with any products which require more stringent handling conditions should receive specific training. Examples of such products include hazardous products, radioactive materials, products presenting special risks of abuse (including narcotic and psychotropic substances), and temperature-sensitive products.

A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented.

Appropriate procedures relating to personnel hygiene, relevant to the activities being carried out, should be established and observed. Such procedures should cover health, hygiene and clothing.

18. DOCUMENTATION

Good documentation constitutes an essential part of the quality system. Written documentation should prevent errors from spoken communication and permits the tracking of relevant operations during the distribution of Therapeutic Goods

a. written instructions

Written instructions should describe the different operations which may affect the quality of the materials and/or products or of the distribution activity:
Receipt and checking of deliveries,

a) Storage, cleaning and maintenance of the premises (including pest control),
b) Recording of the storage conditions,

c) Security of stocks on site and of consignments in transit,
d) Withdrawal from saleable stock
e) Records, including records of clients' orders,
f) Returned materials and/or products, recall plans, etc.

These procedures should be approved, signed and dated by the authorized person.
Records should be made at the time each operation is taken and in such a way that all significant activities or events are traceable. Records should be clear and readily available. The retention of documentation relating to the distribution of materials and/or products should comply with the national requirements.

If records are computerized, only authorized persons should be able to enter or modify data in the computer. Access should be restricted by passwords or other means. User should have a unique identifier (User ID) for their personal and sole use so that activities can subsequently be traced to the responsible individual.

Records electronically stored should be protected by back-up transfer on paper or other means, at regular intervals. It is particularly important that the data, including audit trail, are readily available throughout the period of retention. Back-up data should be stored as long as necessary at a separate and secure location.

b. Inventory system

These should include;

1. Name of Materials or Products
2. Strength and Packing size of materials and products
3. Product Identification Number
4. Date of Transaction
5. Invoice No. / Delivery No.
6. Quantity Received
7. Quantity Supplied
8. Batch No. (where applicable)
9. Stock Balance
10. Initial / Signature

Entries of incoming goods should be clearly identified and inventory entry is required for each material and/or product as well as each strength of the same material and/or product.

c. Labeling of containers / packaging materials

All containers or packaging materials should be clearly and indelibly labeled with at least the name and/or of the material and/or product, and the lot number of the batch.

Written information should exist for each stored material and/or product indicating recommended storage conditions, along with any precautions to be observed. Pharmacopoeia requirements and other current national regulations concerning labels and containers should be respected at all times.

19. ACTIVITIES AND OPERATIONS

All activities and operations relating to procurement, storage and distribution of medical products should be conducted in accordance with national legislation, GSP, GDP and associated guidelines.

Storage and distribution of medical products should be done by persons so authorized, in accordance with national legislation. Activities and operations should be performed in accordance with documented procedures.

Receiving

Materials and products should be procured from appropriately authorized suppliers. Deliveries should be examined for damage, seal intactness, signs of tampering, labelling, completeness of order and other related aspects, at receipt. Containers and consignments not meeting acceptance criteria for receiving should be separated, quarantined and investigated. This includes suspected falsified products. Materials and products requiring specific storage conditions, or access control (e.g. Narcotics) should be processed without delay and stored in accordance with their requirements.

Storage

There should be sufficient space for the safe and secure storage of medical products. Appropriate controls should be implemented to prevent contamination and/or mix ups during storage. Storage areas should be clean and kept free from litter, birds, dust and pests. Controls and procedures should be in place to prevent and handle spillage and breakage. Materials and products should be stored under the conditions specified on the label, e.g. Controlled temperature and relative humidity when necessary.

When specific storage conditions are required, the storage area should be qualified and operated within the specified limits. The storage conditions should be monitored and records maintained. The records should be reviewed and trends and out of limit results investigated.

Stock should be rotated and the FEFO policy should be implemented.
Computerized systems used for stock management should be validated.
Materials and products reaching their expiry date should be separated from usable stock and not be supplied.

Repackaging and relabeling

Repackaging and relabeling of materials and products are not recommended. Where they do occur, they should only be performed by entities appropriately authorized to do so and in compliance with the applicable national, regional and international requirements, and in accordance with GMP.

Procedures should be in place for the controlled disposal of original packaging to prevent re-use.

Distribution and transport

Materials and products should be transported in accordance with the conditions stated on the labels. There should be no risk to the quality of the material or product during transport and distribution.

Product, batch and container identity should be maintained at all times.

All labels should remain legible.

Distribution records should be sufficiently detailed to allow for a recall when required.

A copy of the original certificate of analysis from the manufacturer should be provided to the customer.

Drivers of vehicles should be identified and present appropriate documentation to demonstrate that they are authorized to transport medical products.

Vehicles should be suitable for their purpose, with sufficient space and appropriately equipped to protect materials and products.

The design and use of vehicles and equipment must aim to minimize the risk of errors and permit effective cleaning and/or maintenance to avoid contamination, build-up of dust or dirt and/or any adverse effect on the quality of the products.

Where feasible, consideration should be given to adding technology, such as global positioning system (GPS) electronic tracking devices and engine-kill buttons to vehicles, which would enhance the security and traceability of vehicles with products.

Where possible, dedicated vehicles and equipment should be used for medical products. Where non-dedicated vehicles and equipment are used, procedures should be in place to ensure that the quality of the products will not be compromised. Defective vehicles and equipment should not be used. These should either be labelled as such or removed from service.

There should be procedures in place for the operation and maintenance of all vehicles and equipment. There should be written programmes and records for cleaning and pest control.

Records should be kept. The cleaning and fumigation agents used should not have any adverse effect on product quality.

Equipment chosen and used for the cleaning of vehicles should not constitute a source of contamination. Agents used for the cleaning of vehicles should be approved by management.

Appropriate environmental conditions should be provided, checked, monitored and recorded. All monitoring records should be kept for a minimum of the shelf life of the product distributed plus one year, or longer, if required by national legislation. Records of monitoring data should be made available for inspection by the regulatory or other oversight body.

Instruments used for monitoring conditions, e.g. temperature and humidity, within vehicles and containers should be calibrated at regular intervals.

Where possible, mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned products as well as those suspected as falsified. Such goods should be securely packaged, clearly labelled and be accompanied by appropriate supporting documentation.

Measures should be in place to prevent unauthorized persons from entering and/or tampering with vehicles and/or equipment, as well as to prevent the theft or misappropriation thereof.

Shipment containers should have no adverse effect on the quality of the products and should offer adequate protection to materials and products. Containers should be labelled indicating, e.g. handling and storage conditions, precautions, contents and source, safety symbols as appropriate.

Special care should be taken when using dry ice in shipment containers due to safety issues and possible adverse effects on the quality of products.

Written procedures should be available for the handling of damaged and/or broken shipment containers. Particular attention should be paid to those containing potentially toxic and hazardous products.

Dispatch

Products should only be sold and/or distributed to persons or entities that are authorized to acquire such products in accordance with the applicable national legislation.
Written proof of such authorization must be obtained prior to the distribution of products to Such persons or entities.

Dispatch and transportation should be undertaken only after the receipt of a valid order which should be documented.

There should be documented, detailed procedures for the dispatch of products.

Records for the dispatch of products should be prepared and should include information such as, but not limited to, date of dispatch; complete business name and address (no acronyms), type of entity responsible for the transportation, telephone number, names of contact persons; status of the addressee (e.g. retail pharmacy, hospital or community clinic); a description of the products including, e.g. name, dosage form and strength (if applicable); quantity of the products, i.e. number of containers and quantity per container (if applicable);applicable transport and storage conditions; a unique number to allow identification of the delivery order; and assigned batch number and expiry date (where not possible at dispatch, this information should at least be kept at receipt to facilitate traceability).

Records of dispatch should contain enough information to enable traceability of the product. Such records should facilitate the recall of a batch of a product, if necessary, as well as the investigation of falsified or potentially falsified products. In addition, the assigned batch number and expiry date of pharmaceutical products should be recorded at the point of receipt to facilitate traceability.

Vehicles and containers should be loaded carefully and systematically, where applicable on a first-out/last-in basis, to save time when unloading, prevent physical damage and reduce security risks. Extra care should be taken during loading and unloading of cartons to avoid damage.

Products should not be supplied or received after their expiry date, or so close to the expiry date that this date is likely to be reached before the products are used by the consumer.

Products and shipment containers should be secured to prevent or provide evidence of unauthorized access. Vehicles and operators should be provided with additional security, as appropriate, to prevent theft and other misappropriation of products during transportation.

Products should be stored and transported in accordance with procedures such that: the identity of the product is not lost; the product does not contaminate and is not contaminated by other products; adequate precautions are taken against spillage, breakage, misappropriation and theft; and appropriate environmental conditions are maintained, e.g. using cold chain for thermo labile products.

Written procedures should be in place for investigating and dealing with any failure to comply with storage requirements, e.g. temperature deviations. If a deviation has been noticed during transportation by the person or entity responsible for transportation, this should be reported to the distributor and recipient. In cases where the recipient notices the deviation, it should be reported to the distributor.

Transportation of products containing hazardous substances, or narcotics and other dependence-producing substances, should be transported in safe, suitably designed, secured containers and vehicles. In addition, the requirements of applicable international agreements and national legislation should be met.

Spillages should be cleaned up as soon as possible to prevent possible contamination, cross-contamination and hazards. Written procedures should be in place for the handling of such occurrences.

Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the relevant department, entity or authority, and investigated. Products in transit must be accompanied by the appropriate documentation.

Upon receipt, each incoming delivery should be checked against the relevant documentation and Physically verified by label description, type and quantity, against the relevant purchase order Information. The consignment should be examined for uniformity and if necessary should be Subdivided according to the supplier's lot numbers should the delivery comprise of more than one Batch.

All containers should be carefully inspected for tampering, contamination and damage and if necessary the suspected container or the entire delivery should be quarantined or set aside for further investigation. Records should be retained for each delivery.

They should include the description of the goods, quality (if applicable), quantity, supplier details, supplier's batch number, the date of receipt and assigned batch number.

Security measures should be taken to ensure that rejected materials and/or products cannot be used and they should be stored separately from other products while awaiting destruction or return to the supplier. The method adopted should possess adequate safeguards to prevent uncontrolled or unsatisfactory materials from being used or released. Relevant records should be maintained.

Quarantine status can be achieved either through the use of separate storage areas or by means of documentary or electronic data processing systems.

Materials and/or products should remain in quarantine status until a given written release or is rejected by an authorized personnel.

20. STOCK CONTROL

Comprehensive records should be maintained showing all receipts and issues of materials and/or products according to batch number.
Periodic stock reconciliation should be performed comparing the actual and recorded materials and/or products quantity.
All significant stock discrepancies should be subjected to investigation to check against inadvertent mix-ups and wrong issues.

Issues should normally observe the principle of stock rotation (FEFO) especially where expiry dated materials and/or products are concerned.

Materials and/or products with broken seals, damaged packaging or suspected of possible contamination must not be sold or supplied.

Goods bearing an expiry date must not be received or supplied after their expiry date or too close to their expiry date that this date is likely to occur before the goods are used by the consumer.

All labels and containers of materials and/or products should not be altered, tampered or changed. Acts and regulations relating to labels and containers should be adhered to at all times.

Partly used containers of materials and/or products should be securely re-closed to prevent spoilage and/or contamination during subsequent storage. Damaged containers should not be issued but should be brought to the attention of the authorized personnel.

Materials and/or products should be protected from excessive climatic conditions during storage and

transit, such as heat, moisture and direct sunlight. They should be stored separately from other materials and/or products in conditions which satisfy the requirements for the materials and/or products, so that shelf-life declaration may be maintained.

21. CONTROL OF EXPIRED STOCK

All stocks should be checked regularly for expired and degraded materials and/or products. All due precautions should be observed to preclude issue of expired materials and/or products.

23. DISTRIBUTION

The allocation of shipping materials should be carried out only after receipt of a sales order. Rules for distribution procedures should be established depending on the nature of the materials and/or products, and after taking into account any special precautions to be observed.

The shipping container should offer adequate protection from all external influences and should be indelibly and clearly labeled. When necessary, devices which allow monitoring during transportation should be used.

In the event of materials and/or products shipment, special care should be used when using dry ice in containers. In addition to safety issues, it must be ensured that the materials and/or products do not come into contact with the dry ice, as it may have adverse effect on the quality of the materials and/or products.

Distribution documents should comply with relevant regulations, and at least includes:

1. Date of dispatch
2. Customer's name and address
3. Product description, e.g. name, dosage form and strength, Date of Expiry, batch number and quantity.

24. DISPOSAL OF MATERIALS / PRODUCTS

Products regulated under NMRA Act intended for destruction should be appropriately identified, held separately and handled in accordance with a written procedure.

Disposal of materials and/or products should be carried out, according to proper destruction procedures,

approved by appropriate authorities such as NMRA, the Ministry of Environment and local authorities.

Disposal records should be maintained and be retained for a period of five year period from the date of disposal.

25. TRANSPORTATION AND GOODS IN TRANSIT

(897)

Materials and products should be secured in such a manner to prevent or provide evidence of unauthorized access.

Shipments should be secured and include the appropriate documentation to ensure that identification and verification of compliance with regulatory requirements is facilitated at ocean ports, truck borders, airports, custom warehouses and third party logistic providers.

Materials and/or products should be stored and transported in accordance with procedures in such a way that: the identity of the materials and/or products is not lost; the materials and/or products does not contaminate and is not contaminated by other materials and/or products; adequate precautions are taken against spillage, breakage, misappropriation and theft; and temperature and relative humidity conditions are maintained accordingly.

Measures should be established to ensure that materials and/or products have a form of documentation that can be used to permit traceability of the materials and/or products throughout the distribution activity.

Where special conditions are required during transportation that are different from or limited by the given environmental conditions (e.g. temperature, humidity) these should be provided, monitored and recorded.

Written procedures should be in place for investigating and dealing with any violations of storage requirements, e.g. temperature violations.

Transportation and storage of materials and/or products comprising highly active and radioactive materials, other dangerous drugs and substances presenting special risks of abuse, fire or explosion (e.g. combustible liquids, solids and pressurized gases) should be stored in safe, dedicated and secure areas and transported in safe, dedicated and secure containers and vehicles. In addition, applicable international agreements and national legislation should be complied with.

Materials and/or products containing narcotics and other dependence producing substances should be transported in safe and secure containers and vehicles and be stored in safe and secure areas, and where it is a mandatory requirement transported in safe and secure containers and vehicles. In addition, applicable international agreements and national legislation should be complied with.

Spillages should be cleaned as soon as possible to prevent possible contamination, cross-contamination and hazards. Written procedures should be in place for the handling of such occurrences.

Physical or other equivalent (e.g. electronic) segregation should be provided for the storage and distribution during transit of rejected, expired, recalled or returned materials and/or products and suspected counterfeits. The materials and/or products should be appropriately identified, securely packaged, clearly labelled, and be accompanied by appropriate supporting documentation.

Materials and/or products containing toxic and/or flammable substances should be stored and transported in suitably designed, separate and closed containers, taking into account national legislation and international agreements.

Packaging materials and transportation containers should be of suitable design to prevent damage of materials and/or products during transport. If there are seal control programs, such programs should be in place and managed properly (e.g. seals are issued and tracked in a sequential manner, seals are intact and numbers verified during transit and upon receipt). Third party drivers should be segregated from the warehouse and only allowed in the shipping/receiving area. They should also identify themselves and present paperwork to identify that they are authorized for the load. Subcontracting carriers is not recommended. If subcontracting occurs, they must uphold the same standards as the contracted carrier.

Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the relevant department, entity or authority and investigated.

Materials and/or products in transit must be accompanied by the appropriate documentation. For each importation, the Certificate of Analysis (CoA) for each batch of product must be kept by the importer.

26. OUTSOURCED ACTIVITIES

Any activity covered by the GDP guide that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product.

Any activities performed, referenced in the GDP guideline and delegated to another party, should be agreed upon in a contract which clearly establishes the duties of each party.

There should be a written and approved contract or formal agreements between the Contract Giver and Contract Acceptor that addresses and defines in detail the responsibilities and GDP requirements for each party.

The contract should permit the Contract Giver to visit the facilities of the Contract Acceptor.
Depending on the nature of activities performed, the Contract Acceptor should understand that he might be subject to inspection by the regulatory authority.

27. COUNTERFEIT MATERIALS/ PRODUCTS

Any counterfeit materials and/or products found in the distribution network should be physically segregated from other materials and/or products to avoid any confusion. They should be clearly labelled.

The regulatory authority and the holder of the marketing authorization of the original materials and/or products should be informed immediately

28. INSPECTION OF STORAGE & DISTRIBUTION FACILITIES

Storage and distribution facilities shall be inspected by authorized officers. This shall be done in general at each license renewal for the existing premises and before approval is granted for new request unless otherwise specified by the NMRA. The Authorized officer shall be appointed under the provisions of the Section 124 of NMRA Act 05 of 2015.The inspection shall be carried out by the team of inspectors and should access compliance with provisions of the NMRA act ,Regulations and GDP and GSP Guidelines. The inspection should cover the Premises ,equipment, Personal, activities, quality system, Qualification & Validation, and other related aspects as contained in this guidelines .Observation of the Inspection report may be categorized based on risk assessment and should be prepared and provided to the inspected entity within 60 days from the last day of inspection,

CAPA for the observations listed as non-compliance the inspecting report should be submitted for review by the Inspectors within the defined period as stated in the Inspection report.

29. REFERENCES

- PIC/S GUIDE TO GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS
- WHO Guideline for good distribution practices for pharmaceutical products
- WHO Guideline for Good storage and distribution practices for medical products

30. FEEDBACK

Staff and customers may provide feedback about this document by emailing info@nmra.gov.lk

31. APPROVAL AND REVIEW DETAILS

	Title	Signature	Date
Prepared by			
Reviewed By			
Authorized By			

Next Review Date	

ඖෂධවලට අදාළ වැරදි

49. (1) කිසිදු තැනැත්තකු විසින්-

(අ) සනීපාරක්ෂක නොවන තත්ත්වයන් යටතේ නිෂ්පාදිත, සකස්කළ, සංරක්ෂිත, ඇසුරුම් කරන ලද හෝ ගබඩා කරන ලද කිසිදු ඖෂධයක්;

(ආ) නරක් වූ හෝ වියෝජනය වූ ද්‍රව්‍ය සහිත හෝ ආගන්තුක ද්‍රව්‍ය පූර්ණ හෝ අර්ධ වශයෙන් අන්තර්ගත කිසිදු ඖෂධයක්;

(ඇ) භාවිතකරුගේ සෞඛ්‍යයට හානිකර විය හැකි යම් අහිතකර ද්‍රව්‍යයක් අන්තර්ගත හෝ මතුපිට ඇති කිසිදු ඖෂධයක්; හෝ

(ඈ) බාලකරන ලද ඖෂධයක්,

ආනයනය කිරීම, බෙදාහැරීම, ප්‍රදර්ශනය කිරීම හෝ විකිණීම නොකළ යුතු ය.

ලේබල් කිරීම යනාදිය නියමිත ප්‍රමිතියට අනුකූල විය යුතු බව.

(2) කිසිදු තැනැත්තකු විසින් යහපත් නිෂ්පාදන පරිචයන් (ජීඑම්පී) සහ වෙනත් නියමිත මාර්ගෝපදේශ සහ කොන්දේසිවලට අනුකූල නොවන ලෙස කිසිදු ඖෂධයක් නිෂ්පාදනය කිරීම, සකස් කිරීම, ගබඩා කිරීම, සංරක්ෂණය, ඇසුරුම් කිරීම හෝ නැවත ඇසුරුම් කිරීම නොකළ යුතු ය.

කිසිදු තැනැත්තකු විසින් යහපත් බෙදාහැරීමේ පරිචයන්ට (ජීඩීපී) සහ වෙනත් නියම කර ඇති මාර්ගෝපදේශ සහ කොන්දේසිවලට අනුකූල නොවන ලෙස කිසිදු ඖෂධයක් ආනයනය කිරීම හෝ බෙදාහැරීම නොකළ යුතු ය.

50. (1) යම් ඖෂධයක් සඳහා ප්‍රමිතිය නියමකර ඇති අවස්ථාවක දී, එම ප්‍රමිතියට අනුකූල නොවන්නා වූ යම් ඖෂධයක් හෝ එම ප්‍රමිතිය නියමකර ඇති ඖෂධ බවට වැරදි වැටහීමක් ලබා දෙන ආකාරයට, කිසිදු තැනැත්තකු විසින්, යම් ඖෂධයක් ලේබල් කිරීම, ඇසුරුම් කිරීම, විකිණීම, ප්‍රදර්ශනය කිරීම, බෙදාහැරීම හෝ ප්‍රචාරණය කිරීම නොකළ යුතු ය.

(2) යම් ඖෂධයක් සඳහා ප්‍රමිතිය නියමකර නොමැති නමුත් යම් නියමිත ප්‍රකාශනයක එම ඖෂධය සඳහා වූ ප්‍රමිතිය අන්තර්ගත වන

GUIDELINE ON REGISTRATION OF MEDICINES

OCTOBER 15, 2019

NATIONAL MEDICINE REGULATORY AUTHORITY
Norris Canal Rd, Colombo 01000, Sri Lanka

GUIDELINE ON GUIDELINES FOR REGISTRATION OF MEDICINES

CONTENTS

- For an sterile FPP with multiple container closure systems (Ampoule, Vials and Pre-filled syringes etc), a separate dossier is required for each FPPs;
- For different dosage forms of FPPs (e.g., tablets and capsule), a separate dossier is required for each FPP;
- For an FPP supplied with reconstitution diluents (s), one complete section should be provided for the FPP, followed by the information on the diluents (s) in a separate part as appropriate;

14. GUIDANCE FOR THE APPLICANT WITH REGARD TO COMPILATION AND FOLLOW-UP OF THE PD IS LISTED HERE:

1. The application form and the Dossier Overall Summary (DOS) of the PD should always be in electronic PDF format.
2. The attached data and documents should be in the English language.
3. Paper selection: Paper size is A4. Margins for top, bottom, header, and footer are 12.5 mm, and left and right margins are 25mm.
4. Paragraph: Single line spacing.
5. Font: Minimum type size 12point.

The weight of the font should be in such a way that it text is legible when copied.

6. Any abbreviation should be clearly defined.

15. FAST TRACK REVIEW:

Fast tract review for medicines is considered in following situations;

1. Drugs used for orphan diseases, drugs considered as "orphan" to Sri Lanka by the NMRA
2. Drugs for emergency situations shall have priority for evaluation and registration.

16. PRIORITY REVIEW:

Priority Review for medicines is considered in following situation;

1. Medicines having less than 05 products registered with the NMRA.

17. VARIATIONS

In case of requests to change the contents of specifications and test methods of the product, after reviewing of the screening application, the applicant needs to follow the "Variation Guideline" published by the NMRA.

18. BRAND (TRADE NAME):

Brand names indicating the licensed or unlicensed indications are not accepted. Brand names inappropriate for a medicine as decided by the MEC, are also not accepted.

Appoint a technical person

The local agent or the manufacturer should appoint a technical person, a pharmacist, who is able to understand regulations and related guidelines of the Authority and registration process of products, and who can communicate with the assessors in cases of need of clarification for the queries raised by the Authority that may either be product-related or administrative issues.

Module 1 – Administrative information and prescribing information

1. Cover Letter
2. Table of Contents of the Application, including Module 1 (Modules 1-5)

3. Application Form
4. Letter of Authorization by the manufacturer
5. Certificate of Pharmaceutical product – WOR .
6. Certificate of Suitability (CEP), if any – WOR -
7. Product Information
    a. Summary of Product Characteristics (SPC)
    b. Labeling Information (immediate and outer label) – WOR .
    c. Product information Leaflet (PI) – WOR .
    d. Patient Information Leaflet (PIL) where available or requested by the NMRA

Module 2 – Dossier Overall Summary of Product Dossier

1. PD Table of Contents (Modules 2-5)
2. PD Introduction
3. Quality Overall Summary of Product Dossier
4. Nonclinical Overview – generally not applicable for multisource products (some exceptions may apply)
5. Clinical Overview
6. Nonclinical Written and Tabulated Summaries – generally not applicable for multisource products (some exceptions may apply)

Module 3 – Quality

1. Table of Contents of Module 3
2. Body of Data
3. Literature References

Module 4 – Nonclinical Study Reports – generally not applicable for multisource products(some exceptions may apply)

1. Table of Contents of Module 4
2. Study Reports
3. Literature References

Module 5 – Clinical Study Reports

1. Table of Contents of Module 5
2. Tabular Listing of all Clinical Studies
3. Clinical Study Reports
4. Reports of Biopharmaceutical Studies (mainly BE study reports for generic products
5. Case Report Forms and Individual Patient Listings – generally not applicable for multisource products(some exceptions may apply)
6. Literature References

ඇමුණුම 126

686528-30
...DSTORES
941-697096
GOVTDRUG

MSU/B/MSD/C/2/23/02

(සෞඛ්‍ය සේවා දෙපාර්තමේන්තුව)
වෛද්‍ය සැපයුම් අංශය
(சுகாதார சேவைத் திணைக்களம்)
MEDICAL SUPPLIES DIVISION
(Department of Health Services)

අංක 357, බද්දේගම විමලවංශ මාවත, කොළඹ 10, ශ්‍රී ලංකාව.
இல. 357, படேதேகம விமலவங்ச மாவத்தை, கொழும்பு 10, இலங்கை.
No. 357, Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka.

පෝ. පෙ. 1679
P.O.Box

දිනය/திகதி: 2023.06.19

ඒ.ගණන අධිකාරී

ජාතික විගණන උප කාර්යාලය,

වෛද්‍ය සැපයීම් අංශය,

කොළඹ 10.

<u>හදිසි මිලදී ගැනීම සඳහා ලියාපදිංචියෙන් නිදහස් කිරීමේ සහතිකය (WOR) ලබා ගෙන ඇති සැපයුම්කරුවන්ගේ ඖෂධ වල තත්වය සම්බන්ධයෙන් වෛද්‍ය සැපයීම් අධ්‍යක්ෂකගේ වගකීම පිළිබඳ පරීක්ෂාව.</u>

උක්ත කරුණ සම්බන්ධයෙන් ඔබේ අංක MSU/B/MSD/C/2/23/02 හා 2023.06.07 දිනැති ලිපිය හා බැඳේ.

වෛද්‍ය සැපයීම් අංශය මගින් අදාල ඖෂධ ඇණවුම් (Order) පමණක් සිදු කරන අතර එහි ප්‍රසම්පාදන හා තාක්ෂණික ඇගයීම සම්බන්ධයෙන් වෛද්‍ය සැපයීම් අංශය කටයුතු නොකරනු ඇත.

ඖෂධ වල තත්වය, ආරක්ෂාව හා ප්‍රත්‍යක්ෂභාවය(Safety, quality& efficacy සම්බන්ධයෙන් වගකිව යුතු නීති රාමුව අදාල වනුයේ ජාතික ඖෂධ නියාමන අධිකාරිය (NMRA) වන බැවින් අදාල ලියාපදිංචිය නිදහස් කිරීමේ සහතිකය (WOR) ලබා දීම සම්පූර්ණ වගකීමද එම ආයතනය සතු වනු ඇත.

මේ තත්වය යටතේ වෛද්‍ය සැපයීම් අධ්‍යක්ෂක වන මා හට ඒ සම්බන්ධව වගකීම දැරීමට නොහැකි වන අතර එම කොන්දේසි මාගේ එකඟතාවයෙන් තොරව ජාතික ඖෂධ නියාමන අධිකාරිය (NMRA) විසින් යොදා ඇත. මේ සම්බන්ධයෙන් ගරු අමාත්‍යතුමා,සෞඛ්‍ය ලේකම්තුමා, සෞඛ්‍ය සේවා අධ්‍යක්ෂ ජෙනරාල්තුමා වාචිකව දැනුම් දෙන ලදි.

ඒ අනුව අදාල වගකීම් පැවරීම, WOR ඉල්ලීම් කරන නිළධාරීන්/ ආයතනය වෙත පැවරීම වෙනස් කළ යුතු බව CEO/Chairman NMRA වෙනට වාචිකව දැනුම් දෙන ලදි.

අධ්‍යක්ෂ
වෛද්‍ය සැපයීම් අංශය

වෛද්‍ය එච්.එම්.එස්. වික්‍රමනායක
අධ්‍යක්ෂ
වෛද්‍ය සැපයීම් අංශය
සුජාත බද්දේගම විමලවංශ මහ මාවත,
කොළඹ 10.

(1153)

(182)

යොමු අංකය : MSU/A/SPC/2023/Info 311

එච්.කේ.අයි.ගයානි,

විගණන අධිකාරි,

ජ්‍යෙෂ්ඨ සහකාර විගණකාධිපති වෙනුවට

13.11.2023

විශේෂ විගණනය සඳහා තොරතුරු ලබා ගැනීම

---

01. ප්‍රශ්නය

ජාතික ඖෂධ නියාමන අධිකාරිය විසින් ලියාපදිංචියෙන් නිදහස් කිරීමේ සහතිකය (Waiver of Registration) නිකුත් කිරීමේ දී ඖෂධ නීතිගත සංස්ථාවේ කළමනාකරු ආනයන වෙත යොමු කරනු ලබන පිටපතෙහි සඳහන් ඡේදය සම්බන්ධව ඔබ විසින් ප්‍රසම්පාදන කමිටුව හා තාක්ෂණික ඇගයීම් කමිටුව දැනුවත් කරන්නේ ද? එසේ නොවන්නේ නම් මේ සම්බන්ධව ඔබ විසින් ගනු ලබන ක්‍රියාමාර්ගය කුමක් ද?

"Manager Imports (DHS)/ SPC – This medicine was not evaluated by the NMRA. Therefore, the total responsibility of quality, safety and efficacy of this product is with the relevant procurement committee and the TEC which evaluated the product. Also obtain a Certificate Analysis (COA) of finished product for each batch of pre shipment samples issued by the manufacturer."

පිළිතුර

එසේ නැවත තාක්ෂණික ඇගයීම් කමිටුව හා ප්‍රසම්පාදන කමිටුව දැනුවත් කිරීමක් සිදු නොවේ.

ඒ පිළිබඳ විශේෂ ක්‍රියාමාර්ගයක් ගැනීමේ අවශ්‍යතාවක් නොමැත.

මෙම කරුණ සම්බන්ධයෙන් ඖෂධ ප්‍රසම්පාදනය සඳහා වූ මාර්ගෝපදේශයෙහි පහත පරිච්ඡේදය වෙත ඔබගේ කාරුණික අවධානය යොමු කරමි.

2.6 The requirement of registration stipulated above may be waived off in exceptional circumstances which is referred to as Emergency and Urgent Procurements under section 6.6 and 6.7 upon the issuance of a "no objection" letter by the CDDA, provided that the CDDA ascertained whether the particular consignment of a Pharmaceutical product meets the requisite Quality, Safety and Efficacy criteria and in the case of Medical Devices, satisfies Quality, Safety, Performance, Effectiveness criteria by:

(a) perusing the available documents accompanying the said consignment of Pharmaceuticals or Devices ; and/or

(b) on the submission by the manufacturer/supplier of any additional documentation as required by the CDDA for the said consignment; and/or

(c) on the submission by the manufacturer/supplier an analytical certificate issued by a recognized independent laboratory which is identified by the CDDA.

(1152)

(191)

ඒ අනුව, ලියාපදිංචියෙන් තොර ඖෂධ මිල දී ගනු ලබන්නේ, ඒ සඳහා ජාතික ඖෂධ නියාමන අධිකාරිය විසින් ලියාපදිංචියෙන් නිදහස් කිරීමේ අවසරය නිකුත් කරන්නේ නම් පමණි.

එවැනි අවසරයක් නිකුත් කරනු ලබන්නේ අදාළ ඖෂධයෙහි තත්වය, ආරක්ෂිත භාවය හා කාර් යක්ෂමතාවය පිළිබඳ ඖෂධ නියාමන අධිකාරිය විසින් සැහීමකට පත් වන්නේ නම් පමණි.

එම අවශ්‍යතාවය න් සපුරා ලන්නේ ද යන වග ඖෂධ නියාමන අධිකාරිය විසින් තහවුරු කර ගත යුතු ආකාරය ද අනු අංක "a", "b", "c" යටතේ දක්වා ඇත.

මීට අමතරව, ජාතික ඖෂධ නියාමන අධිකාරියෙහි නිල වෙබ් අඩවියෙහි, ලියාපදිංචියෙන් නිදහස් කර ගැනීමට ඉල්ලීමක් සිදු කිරීමේ දී ඉදිරිපත් කළ යුතු ලේඛන සියල්ල පැහැදිලිව දක්වා ඇත.

*(** ලියාපදිංචියෙන් නිදහස් කොට ගෙන්වනු ලබන ඖෂධයක තත්වය, ආරක්ෂිත භාවය හෝ කාර්යක්ෂමතාවය පිළිබඳ ව ජාතික ඖෂධ නියාමන අධිකාරිය වග නොකියන බවට / ප්‍රසම්පාදනා හා ඇගයීම් කමිටු එම වගකීම දැරිය යුතු බවට අදාළ කිසිදු මාර් ගෝපදේශයක හෝ ප්‍රකාශනයක සඳහන් කර නොමැත)*

රාජ්‍ය ඖෂධ සංස්ථාව විසින් රජය වෙනුවෙන් සිදු කරන ඖෂධ ප්‍රසම්පාදනයෙහිදී යම් ඖෂධයක් සඳහා ලියාපදිංචියෙන් නිදහස් කිරීමකට ඉල්ලීමක් සිදු කරන විට, එම අවශ්‍ය සියලු ලිපි ලේඛන ඖෂධ නියාමන අධිකාරිය වෙත ඉදිරිපත් කරනු ලබයි.

ඖෂධ නියාමන අධිකාරිය විසින් එම සියලු ලේඛන සලකා බලා ලියාපදිංචියෙන් නිදහස් කිරීමට අනුමැතිය ලබා දෙන්නේ නම් පමණක්, රාජ්‍ය ඖෂධ සංස්ථාව විසින් ඇණවුම ඉදිරියට ක්‍රියාත්මක කරනු ලබයි.

එම අනුමැතිය ලබා දීමට ඖෂධ නියාමන අධිකාරිය විසින් ප්‍රතික්ෂේප කරන අවස්ථාවල දී පමණක් ඒ පිළිබඳ ව අදාළ ප්‍රසම්පාදන කමිටුව දැනුවත් කරනු ලබයි.

තව ද, ප්‍රසම්පාදන කමිටු හා තාක්ෂණික ඇගයීම් කමිටු වල වගකීම් කවරේ ද යන්න ප්‍රසම්පාදන මාර් ගෝපදෙශයන් හි සවිස්තර ව දක්වා ඇත.

එබැවින් අදාළ කමිටු එම නිර් ණායකයන් ට අනුව කටයුතු කර ඇති බවට විශ්වාස කරනු ලබන අතර ඖෂධයෙහි තත්වය, ආරක්ෂිත භාවය හා කාර්යක්ෂමතාවය පිළිබඳ ව එම කමිටු වල කිව යුතු බවට අදාළ නිර් ණායකයන් හි /මාර් ගෝපදේහයන්හි දක්වා නොමැති බැවින් නැවත ඔවුන් දැනුවත් කිරීමේ අවශ්‍යතාවක් නොමැත.

ජාතික ඖෂධ නියාමන අධිකාරිය විසින් ලියාපදිංචියෙන් නිදහස් කිරීමේ සහතිකය (Waiver of Registration) නිකුත් කිරීමේ දී ඖෂධ නීතිගත සංස්ථාවේ කළමනාකරු ආනයන වෙත යොමු කරනු ලබන පිටපතෙහි සඳහන් "Also obtain a Certificate Analysis (COA) of finished product for each batch of pre shipment samples issued by the manufacturer." යන කරුණ සංස්ථාව විසින් නිසි පරිදි ඉටු කරනු ලබයි.

සෑම ඖෂධයක් ම නැව් ගත කිරීමට ප්‍රථම එම ඖෂධයන්හි සෑම කාණ්ඩ අංකයක් සඳහා ම නිෂ්පාදකයා විසින් නිකුත් කරනු ලබන "Certificates of Analysis" ගෙන්වා ගනු ලබන අතර, එහි අන්තර් ගතය සංස්ථාවෙහි තාක්ෂණික අංශය ලවා පරීක්ෂා කරවා ගෙන සැහීමකට පත් විය හැකි ද යන්න තහවුරු කරවා ගනු ලබයි.

යම් හෙයකින් එසේ සැහීමකට පත්වීමට නො හැකි බව හැඟී ගිය හොත්, එම තොග රේගුවෙන් නිදහස් කර ගැනීමෙන් වළක්වනු ලැබේ.

1151

180

01. <u>ප්‍රශ්නය</u>

ඖෂධ නීතිගත සංස්ථාවට අදාළ පිටපත නියමිත පරිදි ඔබ අංශය වෙත ලැබෙන්නේ ද?

<u>පිළිතුර</u>

ඔව්. අදාළ පිටපත නිසි පරිදි අප අංශය වෙත ලැබේ.

නියෝජ්‍ය ~~සාමාන්‍යාධිකාරිණී~~
ප්‍රසම්පාදන හා ආනයන (ඖෂධ

Guidelines for the Waivers of Registration (WOR) of Pharmaceutical Products Imported to Sri Lanka

OCTOBER 15, 2019

NATIONAL MEDICINE REGULATORY AUTHORITY
No.120, Norris Canal Rd, Colombo 01000, Sri Lanka

Contents

Introduction

Under section 109 of National Medicines Regulatory Authority Act No. 5 of 2015, the Authority may grant permission in special circumstances to import and supply a particular pharmaceutical product in specified quantities of a medicine without the registration. The special circumstances include a medicine used to save a life, to control an outbreak of an infection or an epidemic or any other national emergency or for national security.

Granting permission to import and supply a particular pharmaceutical product in specified quantities in special circumstances without the registration is referred to as WOR.

Purpose

This guidance describes the procedure of requesting for a WOR by an individual or an institution and also the reviewing procedure followed by National Medicines Regulatory Authority (NMRA) for consideration of such request for WOR.

The importer shall be responsible for the accountability and management of the product imported under WOR.

The importer shall maintain records of all the details of products imported under WOR and submit such data within 28 calendar dates of importation to NMRA.

Purpose

Granting permission to import and supply a particular pharmaceutical product in specified quantities in special circumstances without the registration after considering the need of that product to the country.

Scope

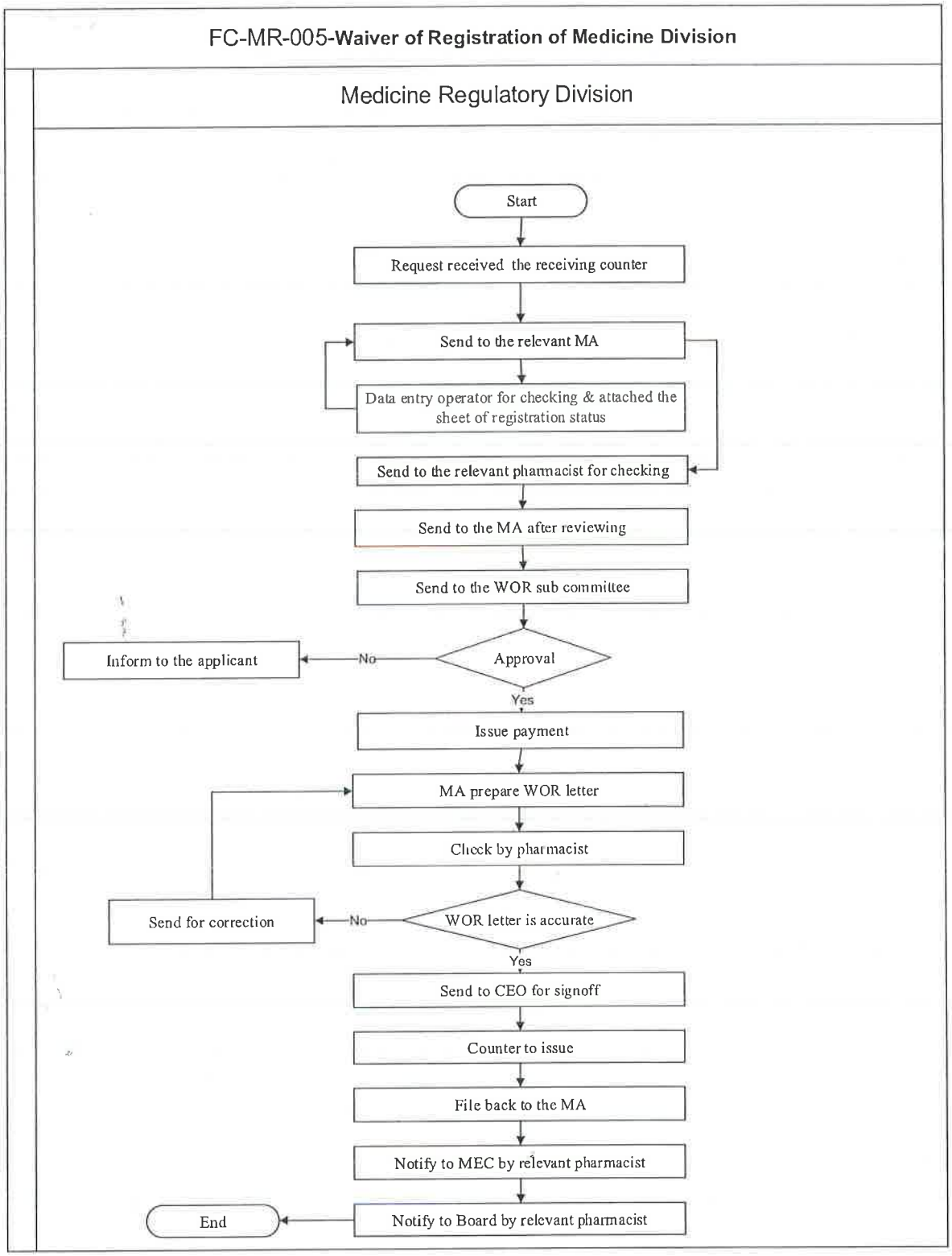
The procedures set out herein apply to medicines and similar products intended for human use. It is recommended. The permission for WOR may be granted;

a) On a request made by the Ministry of Health.
b) On a request made by an individuals or an organization.

Responsibilities

Head of the division and all staff assigned to carry out duties according to the Responsibility Matrix of Medicine Regulatory Division.

Waiver of Registration of Medicine Division - Flowchart



Required documents

1. Request letter from the applicant
2. Recommendation of Technical Evaluation Committee (TEC) when the request is made by the Ministry of Health or the request is made on behalf of the Ministry of Health.
3. Recommendation of the end-user
4. Indent/ commercial invoice

5. Certificate of Analysis (COA) of the relevant product ✓
6. Cerificate of Pharmaceutical Product (COPP) ✓
7. Real time stability report ✓
8. Quotation Document
9. Approval of relevant Procurement Committee
10. Purchase order
11. Custom detain document
12. Label of the product ✓
13. Product Information Leaflet (PIL) ✓

All the above documents need to be submitted by the applicant wherever possible. The Authority has powers to request for more details in special situations for a complete review.

Procedure

- The request with the relevant documents should be submitted to the NMRA.
- All submitted requests will be reviewed by the Waiver of Registration Sub Committee (WORSC) appointed by the NMRA. This committee meets once in two weeks.
- It is the responsibility of the NMRA to verify the registration status of the requested product (s) and inform to the WORSC.
- The final decision about the request is taken by the "Waiver of Registration Sub Committee (WORSC)" after considering relevant documents and registration status of the product.
- Once the approval is granted, the applicant should pay the relevant payment as per the gazette No. 2052/33 dated 2018.01.05
- After the payment is made by the applicant, the NMRA issues the WOR.
- This WOR approval addresses to the Director General/Customs and the Controller of Import and Export. The WOR letter will be copied to the Law and Enforcement Division of NMRA and the applicant as well.
- The validity period of a WOR is ONE YEAR from the date of issue of such a letter by the NMRA.
- In cases where the request for WOR is rejected, the reason for rejection will be informed to the applicant in writing within 14 calendar dates.
- Monthly summary report send to focal point for MEC submissions and the board of NMRA.

43
withhold

BOARD APPROVALS
FOR
SPECIAL PATHWAY

Board Paper No. 84.5.2 & 85.2.1

National Medicines Regulatory Authority

(1109)

(85)

ජාතික ඖෂධ නියාමන අධිකාරිය
தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை
National Medicines Regulatory Authority

දිනය Date: 05.12.2022

මගේ අංකය My No.: NMRA/LO/745/2020

To : HOD-Medicines Regulatory Division/Focal Point-WOR-MDR Division

From : Chief Executive Officer

Copies : Chief Pharmacist

Subject : Notification of approved special procedure for internal fast track pathway for WOR insurance for procurements from Indian credit line, Asian Development bank, World Bank, and Asia Infrastructure Investment Bank

Reference No : NMRA/LO/745/2020 (#80-Amended Memo

Board Paper No : 84.5.2

Date of the Board Meeting : 2022.09.16

Decision: -

The Board noted and approved as per the details presented. However, the Board Members felt that NMRA have no responsibility with the quality-failed medicines imported under this scheme, and it will rest with the accepting agencies.

The Board also decided to include Japan International Corporation Agency (JICA) and any other institution approved by Secretary, Ministry of Health.

Dr. Vijith Gunasekera
MBBS, Msc, MEcon, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

Dr. Vijith Gunasekera
Chief Executive Officer
National Medicines Regulatory Authority.

+94 11 269 51 73 | +94 11 269 88 96/7 +94 11 268 97 04 www.nmra.gov.lk info@nmra.gov.lk
NMRA No. 120, Norris Canal Road, Colombo 10, Sri Lanka

1108 84

Note to the Board- National Medicines Regulatory Authority -2022

A. Board Paper :No.....Year.....Month.....Date.....

B. Subject : Notification of approved special procedure for internal fast track pathway for WOR insurance for procurements from Indian credit line, Asian Development Bank (ADB), World Bank (WB) and Asian Infrastructure Investment Bank (AIIB)

C. Title of the Board Paper: Notification of approved special procedure for internal fast track pathway for WOR insurance for procurements from Indian credit line, Asian Development Bank (ADB), World Bank (WB) and Asian Infrastructure Investment Bank (AIIB)

D. Reference to Previous Board Papers (If any): Not applicable

E. Department/Division/Unit: Medicines regulatory Division/Medical Device Regulatory Division

1. Brief Introduction : NMRA has provisions to grant Waiver of Registration (WOR) in emergency and other circumstances under section 109 of the NMRA act No.15 of 2015. WOR recommendations are given by the WOR committee which was established as a subcommittee of the MEC/MDEC. Both government sector and private sector WOR come to this committee for recommendations in the usual procedure. This board paper is submitted to the board/NMRA to notify the new procedure to exempting WOR committee for issuance of WOR for limited time period for procurement related to the funds from various funding agencies approved by the ministry of health to minimize the delays and as a solution of current forex issue.

2. Background: There are number of WOR applications receive through the ministry of health for WOR issuance for procurements related to the various funding agencies approved by the ministry of health such as Indian credit line, Asian Development Bank (ADB), World Bank (WB) and Asian Infrastructure Investment Bank (AIIB). Secretary, Ministry of Health granted permission to follow special internal fast track pathway to issue WOR for Ministry of Health specified requests due to forex crisis in Sri Lanka. (Attachment 01) CEO/NMRA granted approval to fast track pathway to issue the WOR. (Attachment 02)

(107)

(83)

3. Expected Outcomes : To notify the board on past track pathway procedure for WOR issuance approved by CEO to minimize the delays of issuing WOR procurement related to the funds from Indian credit line, Asian Development Bank (ADB), World Bank (WB) and Asian Infrastructure Investment Bank (AIIB).

To minimize delays of issuing WOR procurement related to the funds from Indian credit line, Asian Development Bank (ADB), World Bank (WB) and Asian Infrastructure Investment Bank (AIIB)

4. Financial Implications: Payment for clarifiention letter 10 USD is applicable

5. Risk Analysis

Identified Risk	Risk Likelihood (H, M, L)	Impact (H, M, L)	Strategy to Manage Risk

6. Corporate Governance and Compliance

7. Certification and Recommendation

"This is to certify that the proposal herein before described in this board paper has been prepared having considered all the relevant provisions in the governing Act, regulations, circulars, procurement procedures etc and as such I recommend the aforesaid proposal to notify the board on fast track pathway to issue the WOR the members of the Board of NMRA for consideration and approval"

Name and Signature of HOD- Medicines Regulatory Division P18 12/09/2022

Name and Signature of Focal Point/WOR -- Medical Devices Regulatory Division 12/9/22

A. S. Abeywickrama

(1106)

(82)

8. Submission to Board Approval

"I recommend the aforesaid proposal submitted by Head of Medicines Regulatory Division/ Medical Device Regulatory Division with his/her recommendations to notify the board on **fast track pathway to issue the WOR** for the members of the Board of NMRA for consideration/determination and approval"

Name and Signature of CEO

Dr. Vijith Gunasekera
MBBS, MSc, MEcon, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

(1105)

(81)

From: Medicines Regulatory Division & Medical Device Regulatory Division

12.09.2022

Approval for the procedure for internal fast track pathway for WOR issurance (Medicines and Medical Devices) for procurements from Indian credit line, Asian Development Bank (ADB), World Bank (WB) and Asian Infrastructure Investment Bank (AIIB) as per the instruction of CEO/NMRA

Conditions:

1) All applications should come through the ministry of health.
2) WOR applications for procurements refated to the Indian credit line, ADB , WB and AIIB eligible for this special pathway
3) This special pathway valid only for 06 months from CEO's approval
4) Applications which are not fall in to mentioned categories in (2) should proceed through the WOR committee
5) Payments applicable as per the payment gazette No. 2052/33-05/01/2018 (Attachment 01)
6) Applications should come from SPC/above mentioned other government procurement institution or from a local agent with documents (indent/ purchase order/ quotation document) to prove that they are supplying to the government.
7) All approved / not approved applications through this pathway should table to the MEC/MDEC and board/NMRA
8) CEO/NMRA decision will be the final decision.

Involvement:

Medicines Regulatory Division (MRD)

Ms. Amila Ekanayaka- Head of Division/MRD

Ms. R.W.Nimali Tanuja- Pharmacist/MRD

Ms. Prabashi de Silva- Assistant Pharmaceutical Assessor

(104)
(80)

Ms. Himanshi Rathnasekara- Assistant Pharaemaceytical Assessor

Ms. M.A.C Kumari- Management Assistant/MRD

All pharmacists/ Assistant Pharmaceuticals Assessors in the division responsible for checking the approvals

Medical Device Regulatory Division (MDRD)

Ms. B. Sivanathan- Head of Division/MDRD

Mr. A.S. Abaywickrama- Focal Point WOR/MDRD

Ms. N.B.Ayesha- MA/MDRD

Mandatory documents of the application

Request letter addressed to CEO/NMRA by the applicant

Completed WOR application published on the website (Attachment 02)

Purchase Order/Indent/ Commercial Invoice/ Proforma Invoice

In addition to above mandatory documents NMRA will request additional documents via email when required.(eg: quotation document, wholesale license)

Procedure:

- WOR applications related to this pathway will receive from the CEO's officer/NMRA
- Received applications will be handed over to Pharmacist/NMRA (P18/P38/P25)
- Pharmacist will obtain the approval from CEO/NMRA for process further
- MA-MRD/MDRD will issue the payment note via an email to the applicant.
- Once payment receipt is received MA-MRD/MDRD draft the WOR letter (Attachment 03)
- MA of the relevant division is responsible for the maintenance of database and register.
- Checking of the WOR letter will be done by pharmacists/ Assistant Pharmaceuticals Assessors in the division
- Final checked draft of the WOR letter will be handed over to CEO's signature.
- Letters will be copied to relevant responsible parties.

(1103)

(79)

- Approved and signed WORs will be handed over to MA or DO of the CEO's office for issuance process.
- All approved /not approved applications through this pathway is table in the MEC/MDEC and board

Dr. Vijith Gunasekera.
MBBS, MSc, MEcon, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

Approval of Chief Executive Officer (CEO)/NMRA

Special Pathway ක්‍රමය යටතේ වෛද්‍ය සැපයීම් අංශය වෙත නිකුත් කරන ලද ලියාපදි
කිරීමේ ලිපි අතුරින් ඖෂධ ඇගයීම් කමිටුව විසින් අනුමත නොකරන ලද ඇණවුම්

ඇමුණුම 129

	ලියාපදිංචි යෙන් නිදහස් කිරීමේ ලිපි නිකුත් කළ දිනය	ඖෂධ යේ නම	ඇණවුම් අංකය	ප්‍රමාණ ය	නිෂ්පාදක	සැපයුම්ක රු	දේශීය නියෝජිත	ඖෂධ ඇගයීම් කමිටුවේ තීරණය
1	30-Nov-22	Cefotaxime for Inj. 1g vial	2022/MSD/Q/R/P/00063	250,000 Vials	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved buy from registered supplier
2	30-Nov-22	Ceftriaxone for Inj. 1g Vial	2022/MSD/Q/R/P/00063	437,500 Vials	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved buy from registered supplier
3	30-Nov-22	Itraconazole Cap.100 mg	2022/MSD/Q/C/P/00062	360,000 Caps	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved buy from registered supplier
4	30-Nov-22	Verapamil Inj. 5mg/2ml Amp	2022/MSD/Q/R/P/00080	3,750 Amp	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved as non essential
5	30-Nov-22	Olanzapine Tab 5mg	2022/MSD/Q/R/P/00068	1,875,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved earlier requaet & oredr after checking the quantity required
6	30-Nov-22	Co-Careldopa Tab. 25mg/250mg	2022/MSD/Q/R/P/00068	1400,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved earlier requaet & oredr after checking the quantity required
7	30-Nov-22	Phytomenadione Inj. 1mg/0.5 ml	2022/MSD/Q/R/P/00060	75,000 Amp	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved earlier request & order after checking the quantity required
8	30-Nov-22	Montelukast Sodium Tab 10mg	2022/MSD/Q/R/P/00061	450,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry	N/A	not approved as non essential

						of Health		
9	30-Nov-22	Propylthiouracil Tab 50mg	2022/MSD/Q/R/P/00090	62,500 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved as non essential & price is very high
10	30-Nov-22	Finasteride Tab 5mg	2022/MSD/Q/R/P/00090	112,500 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved at this price
11	30-Nov-22	Metoclopramide Inj.10mg /2ml	2022/MSD/Q/R/P/00061	450,000 Amp	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
12	30-Nov-22	Atropine Sulphate Eye Drops 1% 5ml	2022/MSD/Q/R/P/00089	2,500 Vial	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
13	30-Nov-22	Tropicamide Eye Drop 1%	2022/MSD/Q/R/P/00089	1,250 Vial	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
14	30-Nov-22	Mometasone Furoate Cream 0.1% 5mg	2022/MSD/Q/R/P/00089	12,500 Tube	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
15	30-Nov-22	Meropenem Inj.1g Vial	2022/MSD/Q/C/P/00070	450,000 Vial	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved as there are 10 valid registrations
16	30-Nov-22	Tamsulosin Cap. 0.4 mg	2022/MSD/Q/R/P/00090	1,500,000 Cap	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
17	30-Nov-22	Aciclovir Tab. 200mg	2022/MSD/Q/R/P/00065	525,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted & if the price is below approved MRP
18	30-Nov-22	Levofloxacin	2022/MSD/Q/C/P/00062	45,000 Tab	Savorite Pharmace	DDG/ Medical	N/A	not approved buy from

		Tab. 500mg			uticals Pvt Ltd	Supplies Division, Ministry of Health		registered supplier
19	30-Nov-22	Nifedipine ER Tab.20mg	2022/MSD/Q/R/P/00080	22,500,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
20	30-Nov-22	Mometasone Furoate Cream/Oint.	2022/MSD/Q/R/P/00089	10,000 Tube	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved buy from registered supplier
21	30-Nov-22	Enoxaparin Inj.6000IU/0.6ml	2022/MSD/Q/R/P/00080	250,000 Pesy	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
22	30-Nov-22	Pregabalin Cap.75mg	2022/MSD/Q/C/P/00071	625,000 Cap	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved as there are 17 registered products and non essential
23	30-Nov-22	Labetalol HCL Inj. 100mg/20mg	2022/MSD/Q/R/P/00080	7,000 Amp	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted & if the price is below MRP
24	30-Nov-22	Digoxin Tab 0.25mg	2022/MSD/Q/R/P/00080	550,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted & if the price is below approved MRP
25	30-Nov-22	Montelukast Sodium Chewable Tab. 5mg	2022/MSD/Q/R/P/00061	300,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved
26	30-Nov-22	Carvedilol Tab.12.5 mg	2022/MSD/Q/R/P/00080	750,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted & if the price is below approved MRP
27	30-Nov-22	Ranitidine Inj. 50mg/	2022/MSD/Q/R/P/00061	300,000 Amp	Savorite Pharmaceuticals Pvt	DDG/ Medical Supplies	N/A	approved if the company profile is

966

		2ml Amp			Ltd	Division, Ministry of Health		accepted
28	30-Nov-22	Noradrenaline Inj. 4mg/2ml Amp	2022/MSD/Q/R/P/00080	300,000 Amp	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
29	08-12-2022	Risperidone Tabletsw USP 2mg	ICL/EOI/PI/25/2022	6,250,000 Tablets	Bafna Phamraceuticals Ltd, India	Bafna Phamraceuticals Ltd, India	Pharma Associates	approved earlier check the quantity
30	20-12-2022	Phytomenadione Injection 10mg/ml	ICL/EOI/P2/22/2022	30,000 Ampoules	Nandani Medical Laboratories Pvt. Ltd, India	Nandani Medical Laboratories Pvt. Ltd, India	Novachem Lanka (Pvt) Ltd	approved earlier check the quantity
31	15/12/2022	Digoxin Injection BP 250 mcg/ml	ICL/EOI/PI/15/2022	1 200 Ampoules (2 mL)	Divine Laboratories (Pvt) Ltd, India	Divine Laboratories (Pvt) Ltd, India	Slim Pharmaceuticals (Pvt) Ltd	not approved as non essential

Special Pathway ක්‍රමය යටතේ රාජ්‍ය ඖෂධ නීති ගත සංස්ථාව වෙත නිකුත් කරන ලද ලියාපදිංචියෙන් නිදහස් කිරීමේ ලිපි අතුරින් ඖෂධ ඇගයීම් කමිටුව විසින් අනුමත නොකරන ලද ඇණවුම්

	ලියාපදිංචියෙන් නිදහස් කිරීමේ ලිපි නිකුත් කළ දිනය	ඖෂධයේ නම	ඇණවුම් අංකය	ප්‍රමාණය	නිෂ්පාදක	සැපයුම් කරු	දේශීය නියෝජිත	ඖෂධ ඇගයීම් කමිටුවේ තීරණය
1	17/09/2022	Ofloxacin vialEye/Ear Drops, 5ml	DHS/ICL/X/003/2022	3000 vials	Belco Pharma, India	Belco Pharma, India	Pharmatec Pvt Ltd	Not approved as non-essential
2	17/09/2022	Flucloxacillin Syrup 125mg/5ml, 100 ml bottles	DHS/ICL/X/003/22	75,000 BOTTLES	Sparsh Bio -Tech Pvt Ltd, India	Centurion Healthcare Pvt Ltd, India	Yaden International Pvt Ltd	Not Approved
3	17/09/2022	Dextrose Injection USP 50% W/V	LP/DHS/EP/SA/3508/22 Tender No; DHS/RP/EP/86/2022	66,000 Vials	Mercury Laboratories Ltd, India	Mercury Laboratories Ltd, India	Yaden	Not Approved as there is local manufacturing
4	17/09/2022	Thiamine Tablet 10mg	DHS/ICL/X/001/2022	12,000,000 Tablets	Innova Captab, India	Innova Captab, India	Slim Pharmaceuticals	not approved as the strength is too low
5	17/09/2022	Metronidazole Inj. BP 500mg/100 ml Bottle	LP/DHS/EP/NV/3531/22	220,000 Bottles	Opsonin Pharma Ltd, Bangladesh	Opsonin Pharma Ltd, Bangladesh	Yaden International pvt ltd	Not approved as there is a local manufacturer at LKR 101
6	17/09/2022	Montelukast Chewable Tablet 5mg	DHS/ICL/X/007/2022	1,200,000 Tablets	Innova Captab, India	Innova Captab, India	Slim Pharmaceuticals	Not approved as not essential & there are 16 valid registrations
7	17/09/2022	Rifaximin Tablets 550mg (Rifaliv 550)	DHS/ICL/X/007/2022	70,000 Tablets	RV Life Sciences Ltd, India	RV Life Sciences Ltd, India	Tabrane Healthcare	Not approved as non essential
8	17/09/202	Mosapride	RES/ICL/17/	3,000,00	Micro	Micro	Kamazu	not for

	2	Citrate Tablets 5mg	2022	0	Labs Ltd, India	Labs Ltd, India	Pvt Ltd	MSD. Not approved & purchase from registered suppliers. Non essential
9	17/09/2022	Salbutamol Oral Solution BP 2mg/5ml in 500ml	PFI/ICL/2022-3/2022-23/016	48,000 Packs	Innova Captab Ltd, India	Innova Captab Ltd, India	Slim Pharmaceuticals	Not approved
10	17/09/2022	Pazopanib Tablets 200mg	DHS/ICL/X/008/2022	54,000 Tablets	SP Accure Labs Pvt Ltd, India	SP Accure Labs Pvt Ltd, India	Pharma associates	Non essential. Not approved
11	17/09/2022	Mebeverine Hydrochloride Tablets BP 135mg	DHS/ICL/X/007/2022	120,000	Treffer Pharmaceuticals, India	Centurion Healthcare Pvt Ltd, India	Yaden International Pvt Ltd	Not approved as non essential
12	17/09/2022	Cinnarizine Tablets BP 25mg	RES/ICL/07/2022	8,400,000	Mercury Laboratories Ltd, India	Centurion Healthcare Pvt Ltd, India	Yaden	Not approved as non essential. buy from registered products
13	17/09/2022	Midazolam Maleate Tablets 7.5mg	DHS/ICL/X/007/2022	5000 Tablets	Mercury Laboratories Ltd, India	Centurion Healthcare Pvt Ltd, India	Yaden	Not approved. Buy from a regsitered product.
14	17/09/2022	Terbinafine Tablets USP 250mg	DHS/ICL/X/001/2022	60, 000 tablets	Cian Healthcare Limited, India	Cian Healthcare Limited, India	Slim Pharmaceuticals	not approved as non essential
15	17/09/2022	Recombinant Human Interferon Alfa 2b Injection IP 3MIU/0.5ml	DHS/ICL/X/004/2022	1000 vials	Reliance Life Sciences Private Limited	Reliance Life Sciences Private Limited	ABC Pharma Services Limited	Not approved as non essential
16	21/09/2022	Famotidine Tablets USP 40mg	RES/ICL/08/2022	12,000,000 Tablets(120,000 Packs*10*10's)	Dagon Pharmaceuticals Pvt Ltd-India	Centurion Healthcare Pvt Ltd-India	Yaden Laboratories Pvt Ltd	not approved as non essential
17	21/09/2022	Ketotifen Tablets 1mg	RES/ICL/15/2022	36,000 Packs*10*10's	Innova Captab Ltd- India	M/s Innova Captab-India	M/s Slim Pharmaceuticals Pvt Ltd	not approved

18	21/09/2022	Linagliptin Tablets 5mg	RES/ICL/15/2022	48,000 Packs*3*10's	Innova Captab Ltd- India	M/s Innova Captab-India	M/s Slim Pharmaceuticals Pvt Ltd	Not approved as non essential
19	21/09/2022	Pioglitazone Hydrochloride Tablets 15mg	RES/ICL/06/2022	12,000 Packs*10*10's	Innova Captab Ltd_india	M/s Innova Captab-India	M/s Slim Pharmaceuticals Pvt Ltd-Colombo	Not approved as non essential
20	21/09/2022	Methyl Salicylate Compound Gel.	SPC/WM/246/2022	240,000 Packs*30 g Tube	Centurion Healthcare Private Ltd	M/s Centurion Healthcare Pvt Ltd-India	M/s Yaden International-Colombo	Not approved as non essential
21	21/09/2022	Paracetamol Tablets BP 500mg	SPC/EF/250/2022	18,000 Packs of 100*10's in Pack	Innova Captab Ltd- India	M/s Innova Captab-India	M/s Slim Pharmaceuticals Pvt Ltd	Not approved
22	21/09/2022	Ketaconazole Scalp Solution 2% w/v	SPC/NN/198/2022	18,000 Packs of 60ml	Belco Pharma-India	M/s Belco Pharma - India	M/s Pharmatec Pvt Ltd-Nugegoda	Not approved. Buy from registered suppliers/ products
23	21/09/2022	Aceclofenac Contrlled Release Tablets 200mg	SPC/NDB/296/2022	4,500 Packs *10*10's	Innova Captab Ltd- India	M/s Innova Captab-India	Slim Pharmaceuticals Ltd Colombo	not approved as non essential
24	21/09/2022	Glimepiride Tablets 4mg	SPC/DM/266/2022	48,000 Packs *10*10's	M/s Belco Pharma-India	M/s Belco Pharma - India	M/s Pharmatec Pvt Ltd-Colombo	not approved buy from registered supplier
25	22/09/2022	Chlorphenamine Maleate Syrup USP 2mg/5ml	SPC/SBK/230/2022	30,000 Bottle of 450ml	Innova Captab Limited	M/s Innova Captab-India	M/s Slim Pharmaceuticals Ltd-Colombo	not approved buy from registered supplier
26	22/09/2022	Clindamycin Hydrochloride Capsules USP 300mg	SPC/SBK/231/2022	15,000 Packs*3*10's	Innova Captab Limited	M/s Innova Captab-India	M/s Slim Pharmaceuticals Ltd-Colombo	not approved buy from registered supplier
27	22/09/2022	Clindamycin Hydrochloride Capsules USP 300mg	SPC/SBK/261/2022	10,000 Packs*3*10's	Centurion Healthcare Private Limited	M/s Centurion Healthcare Private Limited - India	M/s Yaden International-Colombo	not approved buy from registered supplier
28	22/09/2022	Mefanamic Acid Tablets 250 mg	SPC/WM/185/2022	20,000 Packs *1000 Tablets	Belco Pharma-India	M/s Belco Pharma - India	M/s Pharmatec Pvt Ltd	not accepted . buy from registered supplier

962

29	22/09/2022	Triamcinolone Acetonide Injection BP 40mg/ml	DHS/ICL/X/002/2022	2000 Vials	Belco Pharma, India		Pharmatec Pvt Ltd	not approved as high price
30	23-09-2022	Sodium Acid Phosphate Effervescent Tablets	SDHS/ICL/X/001/2022	120,000 Tablets	Vovantis Laboratories Pvt Ltd -India	Centurion Healthcare Pvt Ltd-India	Yaden International Pvt Ltd-Colombo	not approved
31	27/09/2022	Amoxicilin Dispersible Tablets125 mg	SPC/NDB/208/2022	3,000,000 Tablets	Sparsh Bio-Tech Pvt Ltd-India	Centurion Healthcare Pvt Ltd-India	State Pharmaceuticals Corporation of Sri Lanka	not approved
32	28-09-2022	Etoposide Capsules USP 50 mg	DHS/ICL/X/002/2022	1,200 Capsules	M/s BDH Industries Ltd -India	M/s BDH Industries Ltd - India	M/s Ravilux Company Pvt Ltd-Colombo	not approved as the dose is 100 mg
33	28-09-2022	Levoflocin Tablets 500mg USP	DHS/ICL/X/001/2022	180,000 Tablets	M/s Cian Healthcare Pvt Ltd - India	M/s Cian Healthcare Pvt Ltd - India	M/s Slim Pharmaceuticals Pvt Ltd-Colombo	not approved as there are valid registered products
34	28-09-2022	Trypan blue Opthalmic Solution 0.06%-0.08% 1ml	DHS/ICL/X/004/2022	11,500 vials	M/s Contacare Ophthalmic & Diagnostic Pvt Ltd -India	M/s cContacare Ophthalmic & Diagnostic Pvt Ltd - India	M/s Lenstech Innovations Pvt Ltd-India	not approved as non essential
35	28-09-2022	Pantoprazole for IV Injection 40mg	SPC/AD/025/2021	17,000 Vials	Cadila Healthcare Ltd - India		Sunshine Healthcare Lanka Ltd	Not approved. Buy from a regsitered product.
36	28-09-202	Pantoprazole for IV Injection 40mg	DHS/IG/711/20	40,000 vials	Cadila Healthcare Ltd - India		Sunshine Healthcare Lanka Ltd	Not approved. Buy from a regsitered product.
37	04/10/2022	Duloxetine Hydrochloride Capsules 20mg	DHS/ICL/X/007/2022	1,000,000 Capsules	Comed Chemicals Ltd, India	Comed Chemicals Ltd, India	PTC Medical Pvt Ltd	not approved as nonnessential & buy from registered supplier
38	07/10/2022	Ruxolitnib Tablets	DHS/ICL/X/004/2022	14,000 Tablets	Aeon Formulati	Aeon Formul	Lanka Therapeut	not approved

		20mg		(500packs x 28's)	on Pvt Ltd, India	ation Pvt Ltd, India	ics Pvt Ltd	as non essential
39	07/10/2022	Ruxolitnib Tablets 15mg	DHS/ICL/X/004/2022	7,476 Tablets (267 packs x 28's)	Aeon Formulation Pvt Ltd, India	Aeon Formulation Pvt Ltd, India	Lanka Therapeutics Pvt Ltd	not approved as non essential
40	12/10/2022	Melatonin Tablets 3 mg	DHS/ICL/X/011/22	200,000 Tablets(1000's)	M/s Zee laboratories-India	M/s Zee laboratories-India	N/A	not approved
41	12/10/2022	Pantoprazole Injection 40 mg	DHS/ICL/X/011/2022	120,000 vial (1's)	Zee Laboratories- India	Zee Laboratories-India	ABC Pharma Pvt Ltd	not approved
42	17/10/2022	Methyl Salicylate Compoound Gel	RES/ICL2/04/2022	138,000 tubes	Belco Pharma - India	Belco Pharma -India	Pharmatech Pvt Ltd-Nugegoda	not approved as non essential
43	18/10/2022	Aminophylline Injection 250mg in 10ml	DHS/RP/ICL/023/2022	7,500 Amp	Systochem Laboratories Ltd-India	Indues Life Sciences Pvt Ltd-India	Care Ring Pharma Pvt Ltd-Watala	not approved as both manufacturer & local agent are not registered with concerns
44	18/10/2022	Misoprostol Tablets USP IP 200mg	DHS/ICL/PS/384/2022	150,000 Tablets	Sterilgene Life Science Pvt Ltd-India	Sterilgene Life Science Pvt Ltd-India	Pharma Associates -Colombo	not approved
45	18/10/2022	Moxifloxacin HCL Eye Drop 0.5% W/V	DHS/ICL/X/004/2022	20,000 Dropper Bottle	Ajantha Pharma Ltd-India	Ajantha Pharma Ltd-India	A.Baur & Co. (Pvt)Ltd	not approved. already given
46	18/10/2022	Risperideone Tablets 2mg	DHS/ICL/SA/389/22	12,000,000 Tablets	Zee Laborstories -India	Zee Laborstories - India	ABC Pharma Services-Colombo	not approved. already given
47	18/10/2022	Carboplatin Injection BP 450 mg/45kml	DHS/ICL/NV/386/2022	11,000 vials	Celon Laboratories Pvt Ltd- India	Celon Laboratories Pvt Ltd-India	Medmart Pharma - Dehiwala	not approved get from a registered product
48	19-Oct-2022	Meropenem Injection USP 500mg	DHS/M/ICL/PM/409/2022	400,000 vial	Swiss Parenterals Ltd-India	Swiss Parenterals Ltd-India		not approved as histtory of quality failures
49	20-10-2022	Duloxitine DR Capsules	DHs/ICL/IN/201/22	1,000,000 Capsules	Comed Chemicals Ltd,		PTC Medicals (Pvt) Ltd	not approved as non

		USP 200mg			India			essential
50	25/10/2022	Atorvastatin Tablets 20mg	RES/ICL/01/2022	220,000 Packs	Emcure Pharmaceuticals Ltd-India		Emcure Pharmaceuticals Ltd-India	not approved as there are 21 registered products
51	25/10/2022	Calcium 500mg+Vitamin D3 250IU Tablets	DHS/ICL/SA/423/22	3,000,000 Tablets	Magbro Healthcare -India	Magbro Healthcare - India	ABC Pharma Services - Colombo	not approved as non essential
52	25/10/2022	Olanzapine tablets USP 5mg	DHS/ICL/ED/364/22	6,700,000 Tablets	Stallion Laboratories Pvt Ltd-India	Stallion Laboratories Pvt Ltd-India	Siba Holdings Pvt Ltd-Colombo 13	not approved buy from registered supplier
53	26/10/2022	Colecalciferol Tablets USP 5000IU	DHS/ICL/X/009/2022	150,000 Tablets	Gelnova Laboratories India Pvt Ltd-India	Gelnova Laboratories India Pvt Ltd-India	Tabrane Pharmaceuticals Pvt Ltd-Colombo	not approved as non essential
54	26/10/2022	Montelucast Tablets 5mg	DHS/UD/625/2022	698,550 Tablets	Cadila Healthcare Ltd - India	Cadila Healthcare Ltd -India	Sunshine Healthcare Lanka Pvt Ltd-Colombo 10	not approved as non essential
55	27-10-2022	Norfloxacin Tablets BP/USP/IP/400mg	DHS/ICL/X/001/2022 (DHS/ICL/HD/001/420/2022)	280,000 Tablets	Jakson Laboratories Pvt Ltd- India	Infugen Pharma Pvt Ltd-INDIA	Junaht International Pvt Ltd-Sri Lanka	not approved as the manufacturer is black listed in India
56	28-10-2022	Diclofenac Potasium Tablets 50mg	RES/ICL/06/2022	78,000 Packs	Stallion Laboratories Pvt Ltd-India	Stallion Laboratories Pvt Ltd-India	Siba Holdings Pvt Ltd	not approved buy from registered supplier
57	28-10-2022	Loratadine Syrup USP 5mg/5ml 60ml	RES/ICL2/02/2022	91,000 Bottles	Magbro Healthcare Pvt ltd-India	Magbro Healthcare Pvt ltd-India	ABC Pharma Services Pvt Ltd-Colombo 10	not approved buy from registered supplier
58	28-10-2022	Pentoxifylline 400mg modified release Tablets	DHS/RP/200/2021	12,500 Tablets	Solitaire Pharma Pvt Ltd-India	Orexo Bio Pharma Pvt Ltd-Sri Lanka	N/A	not approved as non essential

Special Pathway ක්‍රමය යටතේ රාජ්‍ය ඖෂධ නීති ගත සංස්ථාව වෙත නිකුත් කරන ලද ලියාපදිංචියෙන් නිදහස් කිරීමේ ලිපි අතුරින් ඖෂධ ඇගයීම් කමිටුව විසින් කොන්දේසි සහිතව අනුමත කරන ලද ඇණවුම්

	ලියාපදිංචියෙන් නිදහස් කිරීමේ ලිපි නිකුත් කළ දිනය	ඖෂධයේ නම	ඇණවුම් අංකය	ප්‍රමාණය	නිෂ්පාදක	සැපයුම් කරු	දේශීය නියෝජිත	ඖෂධ ඇගයීම් කමිටුවේ තීරණය
1	17/09/2022	Hydroxyurea Capsules 500mg	DHS/ICL/X/002/2022	300,00apsules	Samarth Life Sciences Pvt Ltd, India	Samarth Life Sciences Pvt Ltd, India	Pharma Associates	Approved if it is below Approved MRP
2	17/09/2022	Cardioplegia Infusion Bulb (st. Thomas solution) (PLEGICARD)	DHS/ICL/X/006/2022	1,750 Ampoules	Smarth Life Sciences Pvt Ltd, India	Smarth Life Sciences Pvt Ltd, India	Pharma Associates	Approved subject to price
3	17/09/2022	Azathioprine Tablet BP 50mg	DHS/RR/EP/109/2022 (Indent No: LP/DHS/EP/UD/3524/2022)	208,000 Tablets	Mercury Laboratories Ltd, India	Yaden International PVT LTD	Yaden International pvt ltd	Approve if the price is below approved MRP
4	17/09/2022	Morphine Sulphate Syrup BP 2mg/ml, 100ml bottles	DHS/ICL/X/003/2022	2,400 Bottles	Belco Pharma, India	Belco Pharma, India	Pharmatec Pvt Ltd	Approved if it is below approved MRP
5	17/09/2022	Fluconazole injection 200mg in 100ml	DHS/ICL/X/001/2022	42,000 vials	Bruder Life Sciences, India	Bruder Life Sciences, India	Advitec International Ltd	Approved if it is below approved MRP
6	17/09/2022	Acyclovir Eye Ointment BP 3% W/W, 5g	DHS/ICL/X/003/2022	2,750 Tubes	Sunway Rohoto Pharmaceutical Pvt Ltd, INDIA	Centurion Healthcare Pvt Ltd, India	Yaden International PVT Ltd	Approved if it is below approved MRP
7	17/09/2022	Sunitinib	DHS/ICL/X/008/2022	10,000 Capsules	Accure Labs Pvt	Accure Labs	Softcare Internatio	Approved if it is

		Maleate 50mg			Ltd, India	Pvt Ltd, India	nal	below approved MRP
8	17/09/2022	Lidocaine Topical Aerosol USP 10% W/V 50ml	DHS/RR/EP/108/2022 (Purchase order No: LP/DHS/EP/DA/3513/2022)	330 Bottles	Opsonin Pharma Ltd, Bangladesh	Opsonin Pharma Ltd, Bangladesh	Yaden	Approved if it is below approved MRP
9	17/09/2022	Actinomycin for Injection 500mcg (Actinomycin D injection. 500mcg)	DHS/ICL/X/002/2022	750 Vials	Bruck Pharma Pvt Ltd, India	Centurian Healthcare Pvt Ltd	Yaden International pvt ltd	Approved if below the approved MRP
10	17/09/2022	Leucovorin Calcium injection USP 50mg/5ml	DHS/RP/EP/125/2022 (Indent No: LP/DHS/EP/PM/3545/2022)	4,600 vials	Bruck Pharma Pvt Ltd, India	Bruck Pharma Pvt Ltd, India	Yaden International pvt ltd	Approved if below the approved MRP
11	17/09/2022	Metoprolol Tartrate Injection 1mg/ml, 5ml	DHS/ICL/MM/122/2022	800 Ampoules	Belco Pharma , India	Belco Pharma , India	Pharmatec Pvt Ltd	Approved if below approved MRP
12	22/09/2022	Cefixime Dispersible Tablets USP 100mg	SPC/SBK/262/2022	12,000 Packs*10*10's	Innova Captab Limited	M/s Innova Captab Ltd-India	M/s Slim Pharmaceuticals Ltd-Colombo	Approved if below below approved MRP

Special Pathway ක්‍රමය යටතේ වෛද්‍ය සැපයීම් අංශය වෙත නිකුත් කරන ලද ලියාපදිංචියෙන් නිදහස් කිරීමේ ලිපි අනුරින් ඖෂධ ඇගයීම් කමිටුව විසින් කොන්දේසි සහිතව අනුමත කරන ලද ඇණවුම්

	ලියාපදිංචියෙන් නිදහස් කිරීමේ ලිපි නිකුත් කළ දිනය	ඖෂධයේ නම	ඇණවුම් අංකය	ප්‍රමාණය	නිෂ්පාදක	සැපයුම් කරු	දේශීය නියෝජිත	ඖෂධ ඇගයීම් කමිටුවේ තීරණය
1	30-Nov-22	Metoclopramide Inj.10mg/2ml	2022/MSD/Q/R/P/00061	450,000 Amp	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
2	30-Nov-22	Atropine Sulphate Eye Drops 1% 5ml	2022/MSD/Q/R/P/00089	2,500 Vial	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
3	30-Nov-22	Tropicamide Eye Drop 1%	2022/MSD/Q/R/P/00089	1,250 Vial	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
4	30-Nov-22	Mometasone Furoate Cream 0.1% 5mg	2022/MSD/Q/R/P/00089	12,500 Tube	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
5	30-Nov-22	Tamsulosin Cap. 0.4 mg	2022/MSD/Q/R/P/00090	1,500,000 Cap	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted
6	30-Nov-22	Aciclovir Tab. 200mg	2022/MSD/Q/R/P/00065	525,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division	N/A	approved if the company profile is

						, Ministry of Health		accepted & if the price is below approved MRP
7	30-Nov-22	Nifedipine ER Tab.20mg	2022/MSD/Q/R/P/00080	22,500,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division , Ministry of Health	N/A	approved if the company profile is accepted
8	30-Nov-22	Enoxaparin Inj.6000IU/0.6ml	2022/MSD/Q/R/P/00080	250,000 Pesy	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division , Ministry of Health	N/A	approved if the company profile is accepted
9	30-Nov-22	Labetalol HCL Inj. 100mg/20mg	2022/MSD/Q/R/P/00080	7,000 Amp	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division , Ministry of Health	N/A	approved if the company profile is accepted & if the price is below MRP
10	30-Nov-22	Digoxin Tab 0.25mg	2022/MSD/Q/R/P/00080	550,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division , Ministry of Health	N/A	approved if the company profile is accepted & if the price is below approved MRP
11	30-Nov-22	Carvedilol Tab.12.5mg	2022/MSD/Q/R/P/00080	750,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division , Ministry of Health	N/A	approved if the company profile is accepted & if the price is below approved MRP
12	30-Nov-22	Ranitidine Inj. 50mg/2ml Amp	2022/MSD/Q/R/P/00061	300,000 Amp	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division , Ministry of Health	N/A	approved if the company profile is accepted

13	30-Nov-22	Noradrenaline Inj. 4mg/2ml Amp	2022/MSD/Q/R/P/00080	300,000 Amp	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	approved if the company profile is accepted

අධිකාරිය යටතේ වලංගු ලියාපදිංචිය පැවතීම හේතුවෙන් Special Pathway ක්‍රමය හරහා ලබා දුන් ලියාපදිංචියෙන් නිදහස් කිරීම් සඳහා ඖෂධ ඇගයීම් අනුකමිටුව විසින් අපරාණුමැතිය ලබා නොදුන් අවස්ථා

	ලියාපදිංචියෙන් නිදහස් කිරීමේ ලිපි නිකුත් කළ දිනය	ඖෂධයේ නම	ඇණවුම් අංකය	ප්‍රමාණය	නිෂ්පාදක	සැපයුම් කරු	දේශීය නියෝජිත	පවතින ලියාපදිංචිය වලංගු ඖෂධ ගණන	ඖෂධ ඇගයීම් කමිටුවේ තීරණය
1	17/09/2022	Montelukast Chewable Tablet 5mg	DHS/ICL/X/007/2022	1,200,000 Tablets	Innova Captab , India	Innova Captab , India	Slim Pharmaceuticals	16	Not approved as not essential & there are 16 valid registrations
2	17/09/2022	Mosapride Citrate Tablets 5mg	RES/ICL/17/2022	3,000,000	Micro Labs Ltd, India	Micro Labs Ltd, India	Kamazu Pvt Ltd	2	not for MSD. Not approved & purchase from registered suppliers. Non essential
3	17/09/2022	Cinnarizine Tablets BP25mg	RES/ICL/07/2022	8,400,000	Mercury Laboratories Ltd, India	Centurion Healthcare Pvt Ltd, India	Yaden	1	Not approved as non essential. buy from registered products
4	17/09/2022	Midazolam Maleate Tablets 7.5mg	DHS/ICL/X/007/2022	5000 Tablets	Mercury Laboratories Ltd, India	Centurion Healthcare Pvt Ltd, India	Yaden	2	Not approved. Buy from a regsitered product.
5	21/09/2022	Ketaconazole Scalp Solution 2% w/v	SPC/NN/198/2022	18,000 Packs of 60ml	Belco Pharma-India	M/s Belco Pharma-India	M/s Pharmatec Pvt Ltd-Nugegoda	6	Not approved. Buy from registered suppliers/ products
6	21/09/2022	Glimepiride Tablets 4mg	SPC/DM/266/2022	48,000 Packs *10*10's	M/s Belco Pharma-India	M/s Belco Pharma-India	M/s Pharmatec Pvt Ltd-Colombo	4	not approved buy from registered supplier
7	22/09/202	Chlorphe	SPC/SB	30,000	Innova	M/s	M/s Slim	5	not

956

	2	namine Maleate Syrup USP 2mg/5ml	K/230/2022	Bottle of 450ml	Captab Limited	Innova Captab-India	Pharmaceuticals Ltd-Colombo		approved buy from registered supplier
8	22/09/2022	Clindamycin Hydrochloride Capsules USP 300mg	SPC/SBK/231/2022	15,000 Packs*3*10's	Innova Captab Limited	M/s Innova Captab-India	M/s Slim Pharmaceuticals Ltd-Colombo	8	not approved buy from registered supplier
9	22/09/2022	Clindamycin Hydrochloride Capsules USP 300mg	SPC/SBK/261/2022	10,000 Packs*3*10's	Centurion Healthcare Private Limited	M/s Centurion Healthcare Private Limited-India	M/s Yaden International-Colombo	8	not approved buy from registered supplier
10	22/09/2022	Mefanamic Acid Tablets 250 mg	SPC/WM/185/2022	20,000 Packs *1000 Tablets	Belco Pharma-India	M/s Belco Pharma-India	M/s Pharmatec Pvt Ltd	3	not accepted . buy from registered supplier
11	28-09-2022	Levofloxacin Tablets 500mg USP	DHS/ICL/X/001/2022	180,000 Tablets	M/s Cian Healthcare Pvt Ltd - India	M/s Cian Healthcare Pvt Ltd - India	M/s Slim Pharmaceuticals Pvt Ltd-Colombo	11	not approved as there are valid registered products
12	28-09-2022	Pantoprazole for IV Injection 40mg	SPC/AD/025/2021	17,000 Vials	Cadila Healthcare Ltd - India		Sunshine Healthcare Lanka Ltd	6	Not approved. Buy from a regsitered product.
13	28-09-202	Pantoprazole for IV Injection 40mg	DHS/IG/711/20	40,000 vials	Cadila Healthcare Ltd - India		Sunshine Healthcare Lanka Ltd	6	Not approved. Buy from a regsitered produc
14	04/10/2022	Duloxetine Hydrochloride Capsules 20mg	DHS/ICL/X/007/2022	1,000,000 Capsules	Comed Chemicals Ltd, India	Comed Chemicals Ltd, India	PTC Medical Pvt Ltd	6	not approved as nonnessential & buy from registered supplier
15	18/10/2022	Carboplatin Injection BP 450 mg/45kml	DHS/ICL/NV/386/2022	11,000 vials	Celon Laboratories Pvt Ltd-India	Celon Laboratories Pvt Ltd-India	Medmart Pharma - Dehiwala	7	not approved get from a registered product
16	25/10/2022	Atorvastatin Tablets 20mg	RES/ICL/01/2022	220,000 Packs	Emcure Pharmaceuticals Ltd-India		Emcure Pharmaceuticals Ltd-India	21	Not approved as there are 21

									registered products
17	25/10/2022	Olanzapine tablets USP 5mg	DHS/ICL/ED/364/22	6,700,000 Tablets	Stallion Laboratories Pvt Ltd-India	Stallion Laboratories Pvt Ltd-India	Siba Holdings Pvt Ltd-Colombo 13	6	not approved buy from registered supplier
18	28-10-2022	Diclofenac Potasium Tablets 50mg	RES/ICL/06/2022	78,000 Packs	Stallion Laboratories Pvt Ltd-India	Stallion Laboratories Pvt Ltd-India	Siba Holdings Pvt Ltd	6	not approved buy from registered supplier
19	28-10-2022	Loratadine Syrup USP 5mg/5ml 60ml	RES/ICL/02/2022	91,000 Bottles	Magbro Healthcare Pvt ltd-India	Magbro Healthcare Pvt ltd-India	ABC Pharma Services Pvt Ltd-Colombo 10	6	not approved buy from registered supplier
20	30-Nov-22	Cefotaxime for Inj. 1g vial	2022/MSD/Q/R/P/00063	250,000 Vials	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	5	not approved buy from registered supplier
21	30-Nov-22	Ceftriaxone for Inj. 1g Vial	2022/MSD/Q/R/P/00063	437,500 Vials	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	7	not approved buy from registered supplier
22	30-Nov-22	Itraconazole Cap.100 mg	2022/MSD/Q/C/P/00062	360,000 Caps	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	9	not approved buy from registered supplier
23	30-Nov-22	Meropenem Inj.1g Vial	2022/MSD/Q/C/P/00070	450,000 Vial	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	10	not approved as there are 10 valid registrations
24	30-Nov-22	Levofloxacin Tab. 500mg	2022/MSD/Q/C/P/00062	45,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	11	not approved buy from registered supplier
25	30-Nov-22	Mometasone Furoate Cream/Oint.	2022/MSD/Q/R/P/00089	10,000 Tube	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	9	not approved buy from registered supplier
26	30-Nov-22	Pregabalin Cap.75mg	2022/MSD/Q/C/P/00071	625,000 Cap	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry	N/A	17	not approved as there are 17 registered

						of Health			products and non essential

නිෂ්පාදකයන්ගේ ඖෂධ තත්ත්වයෙන් අසමත් වීම් පිළිබඳ වාර්තා වී ඇති ඖෂධ සඳහා ලියාපදිංචියෙන් නිදහස් කිරීම් ලබා දුන් අවස්ථා

	ලියාපදිංචියෙන් නිදහස් කිරීමේ ලිපි නිකුත් කළ දිනය	ඖෂධයේ නම	ඇණවුම් අංකය	ප්‍රමාණය	නිෂ්පාදක	සැපයුම් කරු	දේශීය නියෝජිත	ගුණාත්මය පිළිබඳව ගැටලු ඇති වූ අවස්ථා
1	17/09/2022	Dextrose Injection USP 50% W/V	LP/DHS/EP/SA/3508/22 Tender No; DHS/RP/EP/86/2022	66,000 Vials	Mercury Laboratories Ltd, India	Mercury Laboratories Ltd, India	Yaden	one batch of Dextrose Injection USP 50%w/v has been **withdrawn**, three batches of Dobutamine Injection USP 250mg/20ml were withdrawn, one batch of Flumazenil Injection USP 0.5mg/5ml has been withdrawn, one batch Metaraminol Injection BP 10mg/ml was withdrawn
2	17/09/2022	Mosapride Citrate Tablets 5mg	RES/ICL/17/2022	3,000,000	Micro Labs Ltd, India	Micro Labs Ltd, India	Kamazu Pvt Ltd	one batch of Metformin Tablets BP 500mg was withheld
3	17/09/2022	Cinnarizine Tablets BP 25mg	RES/ICL/07/2022	8,400,000	Mercury Laboratories Ltd, India	Centurion Healthcare Pvt Ltd, India	Yaden	one batch of Amlodipine Besylate Tablets USP 2.5mg was withheld, one batch of Disulfiram Tablets BP 250mg was wirhdrawn, one batch of Isoniazid Tablets BP 100mg was withdrwan, one batch of Pyrazinamide Tablets BP 500mg was withdrawn

952

4	17/09/2022	Midazolam Maleate Tablets 7.5mg	DHS/ICL/X/007/2022	5000 Tablets	Mercury Laboratories Ltd, India	Centurion Healthcare Pvt Ltd, India	Yaden	one batch of Amlodipine Besylate Tablets USP 2.5mg was withheld, one batch of Disulfiram Tablets BP 250mg was wirhdrawn, one batch of Isoniazid Tablets BP 100mg was withdrwan, one batch of Pyrazinamide Tablets BP 500mg was withdrawn
5	21/09/2022	Glimepiride Tablets 4mg	SPC/DM/266/2022	48,000 Packs *10*10's	M/s Belco Pharma-India	M/s Belco Pharma-India	M/s Pharmatec Pvt Ltd-Colombo	Batch withdrawal for Morphine tablets BP 30mg has reported
6	22/09/2022	Mefanamic Acid Tablets 250 mg	SPC/WM/185/2022	20,000 Packs *1000 Tablets	Belco Pharma-India	M/s Belco Pharma-India	M/s Pharmatec Pvt Ltd	Batch withdrawal has reported for Morphine tablets BP 30mg
7	12/10/2022	Melatonin Tablets 3 mg	DHS/ICL/X/011/22	200,000 Tablets(1000's)	M/s Zee laboratories-India	M/s Zee laboratories-India	N/A	03 batches of Azithromycin tablets have been withdrawn
8	18/10/2022	Risperidone Tablets 2mg	DHS/ICL/SA/389/22	12,000,000 Tablets	Zee Laborstories -India	Zee Laborstories -India	ABC Pharma Services-Colombo	three batches of Azithromycin Tablets USP 250mg withdrawn
9	18/10/2022	Carboplatin Injection BP 450 mg/45kml	DHS/ICL/NV/386/2022	11,000 vials	Celon Laboratories Pvt Ltd-India	Celon Laboratories Pvt Ltd-India	Medmart Pharma - Dehiwala	No quality failures, Docetaxel Injection 100mg and 500mg were withheld due to ADR
10	19-Oct-2022	Meropenem Injection USP 500mg	DHS/M/ICL/PM/409/2022	400,000 vial	Swiss Parenterals Ltd-India	Swiss Parenterals Ltd-India		one batch withdrawn fromImipenem and Cilastatin for Injection USP 500mg, one batch withdrawn from Vancomycin hydrochloride for Injection USP 500mg, one batch

								withdrawn from Cefuroxime for injection USP 750mg
11	25/10/2022	Calcium 500mg+ Vitamin D3 250IU Tablets	DHS/ICL/SA/423/22	3,000,000 Tablets	Magbro Healthcare -India	Magbro Healthcare -India	ABC Pharma Services - Colombo	one batch withdrawn from Metformin Tablets BP 500mg
12	08-12-2022	Risperidone Tabletsw USP 2mg	ICL/EOI/PI/25/2022	6,250,000 Tablets	Bafna Phamraceuticals Ltd, India	Bafna Phamraceuticals Ltd, India	Pharma Associates	no quality failures for this product. Metformin Tablets BP 500mg one batch withheld, Albendazole Tablets 400mg one batch withheld, Dexamethasone Tablets BP 4mg one batch withdrawn, Chlorpheniramine Tablets BP 4mg product withdrawn
13	17/09/2022	Cardioplegia Infusion Bulb (st. Thomas solution) (PLEGIOCARD)	DHS/ICL/X/006/2022	1,750 Ampoules	Smarth Life Sciences Pvt Ltd, India	Smarthh Life Sciences Pvt Ltd, India	Pharma Associates	one batch of Verapamil Injection BP 5mg/2ml was withdrawn
14	17/09/2022	Azathioprine Tablet BP 50mg	DHS/RR/EP/109/2022 (Indent No: LP/DHS/EP/UD/3524/2022)	208,000 Tablets	Mercury Laboratories Ltd, India	Yaden International PVT LTD	Yaden International pvt ltd	one batch of Amlodipine Besylate Tablets USP 2.5mg was withheld, one batch of Disulfiram Tablets BP 250mg was wirhdrawn, one batch of Isoniazid Tablets BP 100mg was withdrwan, one batch of Pyrazinamide Tablets BP 500mg was withdrawn
15	17/09/2022	Acyclovir Eye Ointment	DHS/ICL/X/003/2022	2,750 Tubes	Sunway Rohoto Pharmac	Centurion Healthcar	Yaden International	one batch of Chondroithin sulphate sodium

950

		BP 3% W/W , 5g			eutical Pvt Ltd, INDIA	e Pvt Ltd, India	PVT Ltd	4%w/v and sodium hyaluronate 3% w/v Ophthalmic Solution was withdrawn
16	17/09/2022	Metoprolol Tartrate Injection 1mg/ml, 5ml	DHS/ICL/MM/122/2022	800 Ampoules	Belco Pharma , India	Belco Pharma , India	Pharmatec Pvt Ltd	Batch withdrawal had reported for Gentamicin Injection BP 80mg/2ml, Irinotecan hydrochloride trihydrate Injection USP 1000mg/5ml, Irinotecan hydrochloride trihydrate Injection USP 40mg/2ml

අත්‍යාවශ්‍ය නොවන ඖෂධ වීම හේතුවෙන් ඖෂධ ඇගයීම් කමිටුවේ අපරාණුමැතිය හිමි නොවූ ඖෂධ

	ලියාපදිංචියෙන් නිදහස් කිරීමේ ලිපි නිකුත් කළ දිනය	ඖෂධයේ නම	ඇණවුම් අංකය	ප්‍රමාණය	නිෂ්පාදක	සැපයුම් කරු	දේශීය නියෝජිත	ඖෂධ ඇගයීම් කමිටුවේ තීරණය
1	17/09/2022	Ofloxacin vialEye/ Ear Drops, 5ml	DHS/ICL/X/003/2022	3000 vials	Belco Pharma, India	Belco Pharma, India	Pharmatec Pvt Ltd	Not approved as non-essential
2	17/09/2022	Montelukast Chewable Tablet 5mg	DHS/ICL/X/007/2022	1,200,000 Tablets	Innova Captab , India	Innova Captab , India	Slim Pharmaceuticals	Not approved as not essential & there are 16 valid registrations
3	17/09/2022	Rifaximin Tablets 550mg (Rifaliv 550)	DHS/ICL/X/007/2022	70,000 Tablets	RV Life Sciences Ltd, India	RV Life Sciences Ltd, India	Tabrane Healthcare	Not approved as non-essential
4	17/09/2022	Mosapride Citrate Tablets 5mg	RES/ICL/17/2022	3,000,000	Micro Labs Ltd, India	Micro Labs Ltd, India	Kamazu Pvt Ltd	Not for MSD. Not approved & purchase from registered suppliers. Non-essential
5	17/09/2022	Pazopanib Tablets 200mg	DHS/ICL/X/008/2022	54,000 Tablets	SP Accure Labs Pvt Ltd, India	SP Accure Labs Pvt Ltd, India	Pharma associates	Non-essential. Not approved
6	17/09/2022	Mebeverine Hydrochloride Tablets BP 135mg	DHS/ICL/X/007/2022	120,000	Treffer Pharmaceuticals, India	Centurion Healthcare Pvt Ltd, India	Yaden International Pvt Ltd	Not approved as non-essential
7	17/09/2022	Cinnarizine Tablets BP 25mg	RES/ICL/07/2022	8,400,000	Mercury Laboratories Ltd, India	Centurion Healthcare Pvt Ltd, India	Yaden	Not approved as non-essential. buy from registered products
8	17/09/2022	Terbinafine Tablets USP	DHS/ICL/X/001/2022	60, 000 tablets	Cian Healthcare Limited, India	Cian Healthcare Limited,	Slim Pharmaceuticals	not approved as non-essential

		250mg				India		
9	17/09/2022	Recombinant Human Interferon Alfa 2b Injection IP 3MIU/0.5ml	DHS/ICL/X/004/2022	1000 vials	Reliance Life Sciences Private Limited	Reliance Life Sciences Private Limited	ABC Pharma Services Limited	Not approved as non-essential
10	21/09/2022	Famotidine Tablets USP 40mg	RES/ICL/08/2022	12,000,000 Tablets(120,000 Packs*10*10's)	Dagon Pharmaceuticals Pvt Ltd- India	Centurion Healthcare Pvt Ltd-India	Yaden Laboratories Pvt Ltd	not approved as non-essential
11	21/09/2022	Linagliptin Tablets 5mg	RES/ICL/15/2022	48,000 Packs*3*10's	Innova Captab Ltd- India	M/s Innova Captab-India	M/s Slim Pharmaceuticals Pvt Ltd	Not approved as non-essential
12	21/09/2022	Pioglitazone Hydrochloride Tablets 15mg	RES/ICL/06/2022	12,000 Packs*10*10's	Innova Captab Ltd_india	M/s Innova Captab-India	M/s Slim Pharmaceuticals Pvt Ltd-Colombo	Not approved as non-essential
13	21/09/2022	Methyl Salicylate Compound Gel.	SPC/WM/246/2022	240,000 Packs*30 g Tube	Centurion Healthcare Private Ltd	M/s Centurion Healthcare Pvt Ltd-India	M/s Yaden International-Colombo	Not approved as non-essential
14	21/09/2022	Aceclofenac Contrlled Release Tablets 200mg	SPC/NDB/296/2022	4,500 Packs *10*10's	Innova Captab Ltd- India	M/s Innova Captab-India	Slim Pharmaceuticals Ltd Colombo	not approved as non-essential
15	28-09-2022	Trypan blue Opthalmic Solution 0.06%-0.08% 1ml	DHS/ICL/X/004/2022	11,500 vials	M/s Contacare Ophthalmic & Diagnostic Pvt Ltd - India	M/s cContacare Ophthalmic & Diagnostic Pvt Ltd - India	M/s Lenstech Innovations Pvt Ltd-India	not approved as non-essential
16	04/10/2022	Duloxetine Hydrochloride Capsules 20mg	DHS/ICL/X/007/2022	1,000,000 Capsules	Comed Chemicals Ltd, India	Comed Chemicals Ltd, India	PTC Medical Pvt Ltd	not approved as non-essential & buy from registered supplier
17	07/10/2022	Ruxolitnib Tablets 20mg	DHS/ICL/X/004/2022	14,000 Tablets (500packs	Aeon Formulation Pvt	Aeon Formulation Pvt	Lanka Therapeutics Pvt Ltd	not approved as non-

				x 28's)	Ltd, India	Ltd, India		essential
18	07/10/2022	Ruxolitnib Tablets 15mg	DHS/ICL/X/004/2022	7,476 Tablets (267 packs x 28's)	Aeon Formulation Pvt Ltd, India	Aeon Formulation Pvt Ltd, India	Lanka Therapeutics Pvt Ltd	not approved as non-essential
19	17/10/2022	Methyl Salicylate Compoound Gel	RES/ICL2/04/2022	138,000 tubes	Belco Pharma - India	Belco Pharma - India	Pharmatech Pvt Ltd-Nugegoda	not approved as non-essential
20	20-10-2022	Duloxitine DR Capsules USP 200mg	DHs/ICL/IN/201/22	1,000,000 Capsules	Comed Chemicals Ltd, India		PTC Medicals (Pvt) Ltd	not approved as non-essential
21	25/10/2022	Calcium 500mg+ Vitamin D3 250IU Tablets	DHS/ICL/SA/423/22	3,000,000 Tablets	Magbro Healthcare -India	Magbro Healthcare -India	ABC Pharma Services - Colombo	not approved as non-essential
22	26/10/2022	Colecalciferol Tablets USP 5000IU	DHS/ICL/X/009/2022	150,000 Tablets	Gelnova Laboratories India Pvt Ltd-India	Gelnova Laboratories India Pvt Ltd-India	Tabrane Pharmaceuticals Pvt Ltd-Colombo	not approved as non-essential
23	26/10/2022	Montelucast Tablets 5mg	DHS/UD/625/2022	698,550 Tablets	Cadila Healthcare Ltd -India	Cadila Healthcare Ltd - India	Sunshine Healthcare Lanka Pvt Ltd-Colombo 10	not approved as non-essential
24	28-10-2022	Pentoxifylline 400mg modified release Tablets	DHS/RP/200/2021	12,500 Tablets	Solitaire Pharma Pvt Ltd-India	Orexo Bio Pharma Pvt Ltd-Sri Lanka	N/A	not approved as non-essential
25	30-Nov-22	Verapamil Inj. 5mg/2ml Amp	2022/MSD/Q/R/P/00080	3,750 Amp	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved as non-essential
26	30-Nov-22	Montelukast Sodium Tab 10mg	2022/MSD/Q/R/P/00061	450,000 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved as non-essential
27	30-Nov-22	Propylthiouracil Tab 50mg	2022/MSD/Q/R/P/00090	62,500 Tab	Savorite Pharmaceuticals Pvt Ltd	DDG/ Medical Supplies Division, Ministry of Health	N/A	not approved as non-essential & price is very high
28	30-Nov-22	Pregabali	2022/MS	625,000	Savorite	DDG/	N/A	not

		n Cap.75m g	D/Q/C/P/ 00071	Cap	Pharmace uticals Pvt Ltd	Medical Supplies Division, Ministry of Health		approved as there are 17 registered products and non-essential
29	15/12/2022	Digoxin Injection BP 250 mcg/ml	ICL/EOI/ PI/15/202 2	1 200 Ampoules (2 mL)	Divine Laboratori es (Pvt) Ltd, India	Divine Laborato ries (Pvt) Ltd, India	Slim Pharmace uticals (Pvt) Ltd	not approved as non-essential

Annexure 134

Non-preparation of Average Annual Orders in the year 2022 by the Medical Supply Division

SRNumber	Generic Name
00304202	Clobazam Tablet 10mg
00103002	Clarithromycin for Infusion 500 mg vial
00000301	Fentanyl Citrate Injection 100mcg in 2ml ampoule
00204001	Dopamine Hydrochloride Injection BP 200mg/5ml

Non-preparation of average annual orders in the year 2023 by the Medical Supply Division

SR Number	Generic Name
00304004	Sodium Valproate Syrup 200mg/5ml, 100ml
01205102	Trastuzumab Injection 440mg
00206101	Dried,Factor VIII fraction200-350 IU
00600204	Anti Rabies (TC) Vaccine

Non-preparation of Average Annual Orders in the year 2024 by the Medical Supply Division

SR Number	Generic Name
01205102	Trastuzumab Injection 440mg
00107403	Liposomal Amphotericin B Injection 50mg
00206101	Dried,Factor VIII fraction200-350 IU
00204001	Dopamine Hydrochloride Injection BP 200mg/5ml
00300201	Chlordiazepoxide Tab 10mg
00101403	Cefuroxime Tablet 500mg
00102102	Meropenem Injection 1g

Annexure 135

Delaying of Submission of Average Annual Order of 2022

SR number	Generic name	Date of submission to the State Pharmaceutical Corporation	Number of delayed months
00406202	Calcium Polystyrene Sulphonate 15g-17g powder sachet	22 february 2021	01
00107101	Fluconazole Capsule 50mg	24 February2021	01
00405401	Calcium 500mg+ Vitamin D3 250IU Tab	22 February 2021	01
01205102	Trastuzumab Injection 440mg	17 June 2021	05
00107901	Aciclovir Tab 200mg	25 February 2021	01

Delaying of Submission of Average Annual Order of 2023

SR number	Generic name	Date of Submission to the State Pharmaceutical Corporation	Number of delayed months
00304202	Clobazam Tablet 10mg	10 November 2022	10
00406202	Calcium Polystyrene Sulphonate 15g-17g powder sachet	10 November 2022	10
00203002	Glyceryl Trinitrate Inj.50mg/10ml	17 November 2022	10
00405401	Calcium 500mg+ Vitamin D3 250IU Tab	10 November 2022	10
00103002	Clarithromycin for Infusion 500 mg vial	15 November 2022	10
00200102	Digoxin injection BP 500 mcg/2ml	17 November 2022	10
00000301	Fentanyl Citrate Injection 100mcg in 2ml ampoule	08 November 2022	07
00402201	Protein hydrolysate Injection 100ml (Amino Acid for Intravenous Nutrtion 65.3g/L Injection)	17 November 2022	10
00305901	Levetiracetam Tablet 500 mg	22 November 2022	10
00304001	Sodium Valproate Tab. 100mg	21 September 2022	11
		03 February 2023	10
00107901	Aciclovir Tab. 200mg	15 November 2022	09
00402702	Thiamine Hydrochloride	01 November 2022	10

	Injection 100 mg/ 2ml Ampoule		
00303704	Phenytoin Sodium Inj. 250mg/5ml	02 November 2022	09
00302001	Risperidone Tab 2mg	2022.11.24	10

Annexure 136

Non-initiation of procurement activities until information on the orders is communicated in writing to the Corporation

SR Number	Generic name	Order	Date of receiving the Order to the SPC		Delay (months)
			By MSMIS system	In writing	
00406202	Calcium Polystyrene Sulphonate 15g-17g powder sachet	2022/SPC/N/R/P/00042	2021.02.22	2021.12.23	10
00107101	Fluconazole Capsule 50mg	2022/SPC/N/C/P/00046	2021.02.24	2021.03.25	01
00304004	Sodium Valproate Syrup 200mg/5ml, 100ml	2022/SPC/N/R/P/00003	2021.01.08	2021.03.17	More than 02
00203002	Glyceryl Trinitrate Inj.50mg/10ml	2022/SPC/N/R/P/00016	2021.01.31	2021.03.18	More than 01 ½
00405401	Calcium 500mg+ Vitamin D3 250IU Tab	2022/SPC/N/R/P/0042	2021.02.22	2021.12.22	10 months
00200102	Digoxin injection BP 500 mcg/2ml	2022/SPC/N/R/P/00016	2021.01.31	2021.02.27	Nearly 1 month

Annexure 137

Reasons that led to the shortage of medicines

SR Number	Generic name	Number of months under shortage	Reasons for the shortage to continue
00304202	Clobazam Tablet 10mg	8 months (from July to February 2023)	• Non preparation and implementation of average annual order for the year 2022. • Failure of the State Pharmaceutical Corporation to obtain 7,500,000 units of the Order 2021/SPC/N/R/P/00001. • Receiving by the Medical Supplies Division with a delay of more than 5 months, of the first stock containing 3,000,000 units of the order 2022/SPC/X/R/P/00294 for 4,300,000 units • Although the first stock containing1,250,000 units related to the average order of the year 2023 was to deliver on 11 July 2023 and the second stock containing1,250,000 units was to deliver on 11 September 2023,the State Pharmaceutical Corporation had failed to obtain those stocks even by 30 November 2023.
00406202	Calcium Polystyrene Sulphonate 15g-17g powder sachet	09 months (from 01 Januay 2022 to 27 July 2022, From 01 January 2023 to 08 March 2023)	• Although it had been planned to obtain on15 June 2021, 47,500 units of the average order of the year 2021, obtaining of those units had been extended till 01 February 2022 by the Director of the Medical Supplies Division, stating that the demand for this medicine has decreased owing to Covid epidemic. 2021 • Receiving by Medical Supplies Division on 28 July 2022 with a delay of more than 05 months, 47,280 units of the above 47,500 units. Delaying by 10 months the commencement of procurement activities related to the average annual order 2022,

			received by the State Pharmaceutical Corporation through MSMIS computer system. • Having taken the procurement decision following the receipt of the recommendation of the Technical Evaluation Committee, delaying to inform the Procurement Unit of the State Pharmaceutical Division by a period of time close to three months. • Delaying to issue the indenture by a period of time close to three months following the selection of the supplier. • Making the average annual order 2022 with a delay of more than 14 months.
00107101	Fluconazole Capsule 50mg	06 Months (From December 2022 to 11 May 2023)	• Failure of the State Pharmaceutical Corporation to obtain 500,000 units of the average order No 2021/SPC/N/R/P/00062 containing 2,250,000 units, the indenture of which having been issued only for 1,100,000 units and 444,300 units of the order No 2020/MSD/E/C/P/00053. • Rejection by the bidder to accept the supply since 21 months had been spent for procurement activities of the average annual order of the year 2022. 04 months of idle time period had been spent to select a supplier from the Evaluation Form submitted to the Departmental Procurement Committee and the fact that further 10 months of idle time period being spent for the verification of the acceptability of the shelf life of 80 per cent of the stock of medicines delivered by the selected supplier.
00304004	Sodium Valproate Syrup 200mg/5ml, 100ml	7 months (from August 2021 to 09 March 2022 20)	• Delaying by the State Pharmaceutical Corporation for a period close to 24 months till 02 November 202, to issue the indenture of the order No 2021/SPC/N/R/P/00001 for purchasing 81,250 units. • Although the procurement activities related to the average annual order No

			2022/SPC/N/R/P/00003 had been commenced on 22 April 2021, 17 long months till 21 September 2022, had been spent to select as the supplier the only bidder that had come forward and due to the weak communication existed between the State Pharmaceutical Corporation and the Medical Supplies Division, the opinion of the Medical Supplies Division could not be obtained of the only bidder presented although 11 months had been spent to obtain the opinion of the Medical Supplies Division, such opinion had not been received.
00203002	Glyceryl Trinitrate Inj.50mg/10ml	4 months (From August 2022 to 25 November 2022)	• Cancellation on 20 July 2021 of the average order of the year 2022 without calculating how much of the demand for this medicine has declined owing to Covid 19 pandemic and without presuming the amount needed for the period to follow and temporary cancellation on 29 June 2021 of a stock of 50,000 units of the average annual order bearing No 2021/SPC/N/R/P/00048. • Although the State Pharmaceutical Corporation had been informed on 12 March 2022 by the Medical Supplies Division to obtain the remaining 50,000 units of the temporarily suspended average order of the year 2021, delaying by a period close to four months till 07 July 2022 and taking another 21 days to inform this decision to the supplier.
00405401	Calcium 500mg+ Vitamin D3 250IU Tab	35 ½ months (from 15 December 2020 to 30 November 2023)	• Expiration of the NMRA certificate of the only supplier who had obtained the said certificate for this medicine. • Non-registration with the National Medicine Regulatory Authority, of a supplier who satisfied the specifications of Medical Supplies Division regarding this medicine during the period from

			2021 to 30 November 2023. • Accordingly, cancellation of the orders following spending unnecessarily too long a time period for procurement activities of this medicine in the years 2021, 2022 and 2023 without registrtion of new suppliers or in case of non-availability of suppliers, without suitably revising the specifications of the Medical Supplies Division in accordance with alternative medicines available in the market.
00103002	Clarithromycin for Infusion 500 mg vial	14 months (From September 2022 to 30 November 2023)	• At the start of the year 2022, only 44,000 medicine units related to the average order of the year 2020 were available with the Medical Supplies Division and in the backdrop of this entire stock was to expire by September 2022, the average order of the year 2022 had not been prepared. • Failure of the State Pharmaceutical Corporation to obtain the 70,000 medicine units of the average order of the year 2021. • As the medicine stocks available with the Medical Supplies Division were nearing expiration, the order bearing No 2022/SPC/X/R/P/00583 for purchasing 25,000 units under Indian Credi Line in respect of the year 2022, had been referred on 15 September 2022 to the State Pharmaceutical Corporation and although the indenture had been issued on 18 October 2022 by the Corporation upon the WOR certificate, the Corporation had failed to obtain the medicine stocks till 30 November 2023.
00200102	Digoxin injection BP 500 mcg/2ml	19 months (from October 2021 to April 2022)=7 (from 21 August 2022 to	• Delaying by 2 months of commencement of procurement activities for the average order of the year 2022, spending 7 long months for procurement and delaying by 02 months for obtaining medicines from the supplier. • Taking into consideration 8,750 units of the

		12 February 2023)=6 (From March 2023 to the end of August 2023)=6	average annual order of the year 2021 in respect of which no indenture had been issued when deciding on the average units required for the years 2022, 2023 and 2024, as a result of underestimating the required amounts in those years, 2,750 medicine units of the avaerage order of 2022 were sufficient for 4 months from 22 April 2022 to 20 August 2022. • When this medicine with a monthly forecast requirement of 583 units was fully exhausted, although the indenture of the order bearing No 2022/SPC/X/R/P/00582 for purchasing 2,400 units sufficient for 4 months, was referred on 14 October 2022 to the supplier, the supplier had delayed supplying the medicine stock by 08 months till 29 August 2023. • Since receiving of stocks of the X order had been delayed, although a supplier had been selected by the order bearing No 2022/MSD/V/R/P/00066, upon the WOR certificate under Indian credit line for purchasing 1,200 units using the Emergency Procurement Procedure, 740 units that had been provided to the Medical Supplies Division by him on 13 February 2023 were sufficient only for 20 days • Idle time period of 02 months till 30 January 2023, had been spent for calling bids for the average order bearing No 2023/SPC/N/R/P/00120 of the year 2023, referred to State Pharmaceutical Corporation for purchasing 2,400 medicines sufficient for 4 months, Although a supplier had been selected by the Divisional Procurement Committee of the Corporation upon WOR certificate following spending of further 04 months from that day, the indenture had not been issued to the supplier till 30 November 2023.
00402201	Protein hydrolysate Injection 100ml	19 months (From	• Failure of the State Pharmaceutical Corporation to obtain 2,860 units at Rs.895 per unit even by

	(Amino Acid for Intravenous Nutrtion 65.3g/L Injection)	November 2021 to May 2023)	30 November 2023 out of the 6000 units of the average order of the year 2021. • Having spent 30 long months till 05 July 2023 for procurement activities of the average order of the year 2022, submitted to the Corporation on 31 January 2021, such order had been cancelled on 05 July 2023. • Having spent more than 6 months for procurement activities of the order bearing No2022/SPC/X/C/P/00283 for purchasing 12.000 units, this order had been cancelled on 11 October 2022. • Following referring the order bearing No2022/SPC/E/C/P/00480 for purchasing 1000 units of this medicine through Emergency Procurement Procedure, which is similar to a month's requirement, as per a decision of the health sector Emergency Procurement Committee and after referring the indenture on 07 September 2022 by the State Pharmaceutical Corporation, the medicine stock which received on 16 September 2022, was sufficient only for the month of September. • Following a delay of 10 months by the State Medical Corporation, a period of more than 04 months till 21 March 2023 had been spent for calling bids for the order bearing No 2023/SPC/N/C/P /00086 for purchasing 6000 units for the State Medical Corporation and although the decision of the Technical Evaluation Committee had been given on 18 May 2023,the committee decision had not been given even by 30 November 2023 by the Divisional Procure-emnt Committee of the State Pharmaceutical Corporation • Order bearing No 2023/SPC/E/C/P/00160 for purchasing 3000 units under Emergency Procurement, had been submitted on 28 February 2023. Although a supplier had been selected on

			01 November 2023 by the Emergency Procurement Committee, the indenture related thereto had not been referred to the supplier even by 30 November 2023. • Only one supplier had come forward for all orders above and it was observed that the said supplier had forwarded a unit price which is 85 per cent higher than the unit price of Rs.895 submitted for the average order of the year 2021.
00300201	Chlordiazepoxide Tab. 10mg	May 2021 February 2023 October 2023	• In accordance with the indenture issued on 01 January 2021 for 1,800,000 pills of the 2,300,000 pills of the annual forecast order of the year 2021, of the order of 2021, although supplies should be made available as early as possible, the supplier had spent a period of 5 months and 16 days. • 600,000 pills were ordered under Indian credit line in 2022, and although importation certificate under Poisons, opium and dangerous drugs Act No 17 of 1929 had been obtained by 31 December 2022, the supplies had been provided on 12 July 2023 after a delay of 6 months. • Following the issuance of the purchase order to the supplier on 24 November 2022 for obtaining 300,000 pills related to the order bearing No 2022/MSD/V/R/P/00099 of the Medical Supplies Division, although the supplies were to be provided on 15 January 2023, such supplies were not delivered even after spending 11 months. • Although supplies were to be provided on 09 October 2023 as per the indenture issued on 07 July 2023 for obtaining 600,000 pills through the annual medicine requirement of the year 2023, such supplies had not been provided. Although the order bearing No 2022/MSD/V/R/P/00099 was given to the local agent of the supplier to whom this procurement was granted, such supply

			had not been provided as at the audited date. .(MSU/A/SPC/A/2023/AQ/23)
01201701	Cytarabine inj. 100mg/5ml	From 2020 to October 2023	• Cancellation of the tender after spending 01 year and 06 months for the procurement process of the order bearing No2020/SPC/N/R/P/00003 01 year and 06 months. Upon the failure of the supplier to provide medicine stocks during the period when the letter of credit is in force and due to the suspension of orders for items having slow issued stocks and additional stocks, temporary suspension of these orders on 20 May 2021. • Cancellation of the tender due to the sole bidder making bids for the order bearing No 2020/SPC/A/R/P/00168, has resubmitted a higher price after cancelling the tender owing to change of specifications. • Cancellation of the tender due to the non submission of bid security by the bidder who submitted the lowest bid for the order baring No 2021/SPC/N/R/P/00020 and the other bidder submitting higher bid. • Since the termination has been occurred of the registration period issued by the National Medicines Regulatory Authority, of the supplier selected as per the decision of the Procurement Committee dated 23 March 2021, although payment had been made on 16 November 2021 for renewing the registration, National Medicines Regulatory Authority had failed to issue the certificate even by 19 October 2023 even though the relevant documents related to renewing the registration had been submitted 220 days ago. • In the context of the tender No 2022/SPC/E/R/P/00744 was withdrawn on 16 January 2023 due to the issue of obtaining raw materials by the supplier with whom the tender was placed, the procurement Committee, without

			exploring the possibility whether it is possible to obtain medicines in the event of recalling bids, has acted irresponsibly and no final decision had been taken thereon even after elapsing of 92 days as at 06 September 2023. • In the context of the supplier to whom two contracts had been awarded in the year 2022, related to purchasing 1,500 injection vials under the order bearing No 2023/SPC/N/R/P/00081, being unable to provide medicines due to non-availability of raw materials and non-availability of the dose that was ordered by the Corporation, awarding of the order No 2023/SPC/N/R/P/00081 also to the same supplier. (MSU/A/SPC/C/2023/AQ/20)
00101403	Cefuroxime Tablet 500mg	November, December 2022 November	• Awarding the tender to the second lowest bidder who offered to provide a unit at USA dollar 0.118 (11.80/100) due to the difference between the offered trade name of the lowest bidder under order bearing No 2022/SPC/X/R/P/00272 and his trade name appearing in the NMRA certificate. • Although the approval of the Indian Credit Line related to the order was received on 28 December 2022, stocks had not been received by the Medical Supplies Division even after a lapse of 9 months and 12 days. • 1,125,000 units at the rate of Rs. 51.25 of which the total value amounting to Rs. 57,656,250 had to be purchased under Emergency Procurement. Further, owing to a scarcity started prevailing in hospitals, 3000 units at the rate of Rs. 135 per unit had been purchased on 26 November 2022 by the Castle Hospital and 200 units at the rate of Rs.46 per unit had been purchased by the Kandy National Hospital. (MSU/A/SPC/B/2023/AQ/26)

00703701	Zoledronic Acid Injection	February 2023	• Delays of the supplier
00600601	Yellow Fever Vaccine 0.5ml	From August 2022 to October 2023	• Medicines of only one order had been received out of 07 orders given to the Project for improving the health systems for 2022 and 2023. • Since it has been informed that there is an excess stock and slow movement of the order bearing No 2022/SPC/N/C/P/00021 containing 1500 units, action has been taken to temporarily suspend for 14 days. • Cancellation of the order bearing No 2022/SPC/X/C/P/00283 for 3000 units. • Since no bid was received in response to the bid invitation made on 13/03/2023 for the order bearing No 2023/SPC/N/C/P/00088 for 2500 units, bids were reinvited on 13/03/2023. • Delay of granting the order related to the indenture bearing No DHS/AMS/460/2022 due to the reasons such as a balance of USD 1,876.45 is remaining to be paid to the supplier and the delay being caused in obtaining NMRA approval for obtaining medicines with 69% shelf life, not signing the relevant agreement even though the indenture has been issued, tthat he relevant agency has informed that changes be made in the letter of credit, non-mentioning of HS Code correctly in Air waybill, and non-availability of MSE reference and SR number in the bill. • Cancellation of the bids following no bidder submitting bids for the two bids invitations for supplying 3000 vaccinations under the order bearing No 2022/SPC/X/C/P/00283
00701103	Thyroxin tablets BP 25mcg	From October 2022 to October 2023	• Cancellation on 18.10.2021 of the order bearing No 2020/SPC/N/R/P/00001 owing to the failure of the supplier to forward the Submission Test Report to the effect that his product agrees to the

			BP specification. • Withholding on 25.10.2021 of 8,000,000 units of the order bearing No 2020/SPC/A/R/P/00278 • Cancellation on.18.08, 2021 of the order bearing No 2021/SPC/N/R/P/00093. • Cancellation on 2022.10.19 of the order bearing No 2022/SPC/X/R/P/00285. • Non-receipt of stocks so far related to the order bearing No 2023/SPC/N/R/P/00084. • Cancellation of 03 orders from 2020 to 2022 and lack of attention by the officers in charge of procurement towards full exhaustion of stocks at the Medical Supplies Division. • Not taking action by the State Pharmaceutical Corporation to carry out procurement activities in accordance with the related time frame, and the failure of the Medical Supplies Division to maintain a sufficient stock level in respect of thyroxine medicine due to cancellation and withholding of orders, thus preventing the distribution amongst hospital net-work.
00305901	Levetiracetam Tablet 500 mg	March 2023 May 2023	• The reasons for creating a scarcity for this medicine are detailed in Volume II.
00203702	Verapamil HCL Injection 5mg/ 2ml	January – December 2022	• The reasons for creating a scarcity for this medicine are detailed in Volume II.
00304001	Sodium Valproate Tab. 100mg	May 2022 January 2023	• The reasons for creating a scarcity for this medicine are detailed in Volume II.
00402702	Thiamine Hydrochloride Injection 100 mg/ 2ml Ampoule	October 2021 September 2022	• The reasons for creating a scarcity for this medicine are detailed in Volume II.
00107901	Aciclovir Tab. 200mg	November 2022	• The reasons for creating a scarcity for this medicine are detailed in Volume II.

		July 2023	
00303704	Phenytoin Sodium Injection 250mg/5ml	during the period from December 2021 to June 2023	• The reasons for creating a scarcity for this medicine are detailed in Volume II.
00302001	Risperidone Tab 2mg	June-October 2022	• The reasons for creating a scarecity for this medicine are detailed in Volume II.
01000601	Betamethasone Eye/Ear/Nasaldrops 0.1%,5ml -7.5 ml Dropper Bot.	No receipts or issuances at the Medical Supplies Division from 2019 to 31 May 2023	• The reasons for creating a scarcity for this medicine are detailed in Volume II.
01601001	Pralidoxime chloride injection 1g in 20ml ampoule	Receipts for the period from 2019 to 2023 is nil and no issuances reported after 2921.	• The reasons for creating a scarcity for this medicine are detailed in Volume II.
00903201	Nepafenac ophthalmic suspension 0.1% w/v ,3ml	No receipts or issuances at the Medical Supplies Division from 2019 to 15 May 2023	• The reasons for creating a scarcity for this medicine are detailed in Volume II.

Annexure 138

Instances of Occurrence of Issues on the Accuracy of Estimates

- **Omeprazole Sodium Inj. 40mg (SR- 00800803)**

Year	Estimated Amount Units	Number of Units received at the Medical Supplies Division
2019	1,211,391	1,000,000
2020	1,470,109	900,000
2021	1,693,892	1,500,000
2022	1,649,908	1,200,000
2023	1,891,693	320,994

- **Anti-Rabies human 1g 300I.U. (SR - 00602501)**

Year	Estimated Amount	Amount received at the Medical Supplies Division
2019	8,186	3,000
2020	2,253	3,000
2021	2,720	2,900
2022	8,401	400
2023	5,552	1,250

- **Hydrocortisone Tab. 10mg (SR - 00701502)**

Year	Estimated Amount	Amount received at the Medical Supplies Division
2019	1,199,255	1,347,000
2020	1,751,700	1,200,000
2021	1,879,400	1,187,500
2022	1,936,240	1,171,200
2023	1,968,140	1,034,620

- **Salbutamol Respiratory Sol 0.5% 15ml Vial (SR-00500109)**

Year	Estimated Amount Units	Amount received at the Medical Supplies Division
2019	386,768	10,000
2020	538,707	282,000
2021	464,519	140,000

2022	307,882	141,100
2023	479,715	140,000

- **Yellow Fever Vaccine 0.5ml (SR 00600601)**

Year	Estimated Amount (Injection vials)	Amount received at the Medical Supplies Division (Injection vials)	Variance between the estimates and receipts
2019	8,090	4,300	3,790
2020	8,637	7,300	1,337
2021	8,876	0	8,876
2022	9,452	50	9,402
2023	8,723	3,500	5,223

- **Thyroxin tablets BP 25mcg (SR - 00701103)**

Year	Estimated Amount Units	Number of units received at the Medical Supplies Division	Variance
2019	2,827,130	3,934,000	-1,106,870
2020	13,130,350	3,200,080	9,930,270
2021	8,388,270	4,941,500	3,446,770
2022	8,803,410	449,000	8,354,410
2023	11,989,350	Order not received	11,989,350

- **Thyroxin tablets BP 25mcg (SR00701103)**

  Number of Requested Medicine Units and the number of Medicine Units issued to Hospitals by the Medical Supplies Division

Year	Description	Ragama	Kalubovila	Jaffna
2019	The estimated number of medicine units sent to the Medical Supplies Division by the hospitals.	-	60,000	100,000

	Number of medicine units requested by the Hospitals	368,001	210,000	290,000
	Number of medicine units issued to the Hospitals.	304,000	202,000	161,500
2020	The estimated number of medicine units sent to the Medical Supplies Division by the hospitals.	4,800,000	1,800, 000	1,800,00
	Number of medicine units requested by the Hospitals	1,200,000	1,050,000	450,000
	Number of medicine units issued to the Hospitals.	432,060	715,510	165,060
2021	The estimated number of medicine units sent to the Medical Supplies Division by the hospitals	600,000	1,000,000	960,000
	Number of medicine units requested by the Hospitals	-	360,000	240,000
	Number of medicine units issued to the Hospitals	-	360,000	480,000

Annexure 139

Action had not been taken to obtain a performance Security

SR Number	Order	Orders	Value	Value of the Performance Security
00206901	2023/SPC/E/R/P/00162	1,500	225,225,000	22,522,500
00206901	2023/SPC/E/R/P/00187	4,500	655,404,750	65,540,475
00107403	2022/SPC/E/C/P/00741	6,250	232,812,500	23,281,250
00206101	2023/SPC/E/C/P/00166	13,500	335,238,750	33,523,875
00204001	2023/SPC/E/R/P/00187	37,500	13,297,500	1,329,750
00300201	2023/SPC/N/R/P/00069	600,000	USD.. 13,200	USD. 1,320
00103501	2022/SPC/E/C/P/00731	48,000	Rs.27,600,000	Rs.2,760,000
00103501	2023/SPC/N/C/P/00080	96,000	USD.. 51,360	USD.. 5,136
00204702	2022/SPC/X/R/P/00264	1,000,000	USD.. 4,100,000	USD.. 410,000
00204702	2022/SPC/E/R/P/00739	225,000	Rs. 310,500,000	Rs. 31,050,000
	2023/SPC/N/R/P/00062	2,250,000	USD. 261,750	USD. 26,175

Annexure 140

Non-charging of fines

SR Number	Order	Quantity of Orders	Period of delay	Value of the Fine
00206901	2023/SPC/E/R/P/00187	4,500	44 days	Rs.65,540,475
00206101	2023/SPC/E/C/P/00166	13,500	47 days	Rs.33, 523,875
00101703	2022/SPC/E/R/P/00703	27,500	02 months	USD. 7,040
00204001	2023/SPC/E/R/P/00187	37,479	21 days	Rs. 1,329,005
00103501	2022/SPC/E/C/P/00731	48,000	30 days and 64 days	Rs. 4,237,750
00204702	2022/SPC/E/R/P/00739	225,000	25 days	Rs. 38,812,500
00204702	2022/MSD/V/R/P/00066	250,000	07, 9, 10 months	USD.57,249.77
00602501	2022/SPC/E/R/P/00492	400	02 months 23 days	Rs. 8,232,000
00304001	2022/SPC/E/R/P/00488	1,000,000	03 months 20 days	Rs. 3,920,000

Annexure 141

Non-submission of Performance Bonds

SR Number	Order	Value Rs.	Value of the performance Bond Rs.
00107403	2022/SPC/E/C/P/00476	76,875,000	7,687,500
00101403	2022/SPC/X/R/P/00272	239,740,000	23,974,000
Total			**31,661,500**

Annexure 142

Rather than Placing Orders in Bulk at Once, Issuing Several Orders

SR Number	Order Number	Date of Order	Quantity(Onits)
00300201	2022/MSD/V/R/P/00099	2022/11/23	300,000
00300201	2023/SPC/N/R/P/00069	2022/11/24	600,000
00103501	2022/MSD/V/C/P/00073	2022.11.01	48,000
00103501	2022/SPC/E/C/P/00731	2022.11.02	48,000
00103501	2023/SPC/N/C/P/00080	2022.11.15	96,000
00102102	2022/MSD/Q/C/P/00070	2022.11.01	450,000
00102102	2022/SPC/E/C/P/00724	2022.11.02	450,000
00102102	2023/SPC/N/C/P/00119	2022.11.17	900,000

2018 මාර්තු 14
2018 மார்ச் 14
14th March 2018

AGDSL

විගණකාධිපති දෙපාර්තමේන්තුව
கணக்காய்வாளர் தலைமை அதிபதி திணைக்களம்
Auditor General's Department

සෞඛ්‍ය, පෝෂණ හා දේශීය වෛද්‍ය අමාත්‍යාංශයේ වෛද්‍ය සැපයීම් අංශය විසින් සිදු කරනු ලබන වෛද්‍ය සැපයීම්, සැපයීමේ ක්‍රියාවලිය පිළිබඳ විගණකාධිපති විශේෂ විගණන වාර්තාව

சுகாதார, போசணை மற்றும் சுதேச மருத்துவ அமைச்சின மருத்துவ வழங்கல் பிரிவினால மேற்கொள்ளப்பட்ட மருத்துவ வழங்கல், வழங்கல் செயற்பாடு தொடர்பான கணக்காய்வாளர் தலைமை அதிபதியின் விசேட கணக்காய்வு அறிக்கை

Special Audit Report of the Auditor General on Process of Supplying Medical Supplies carried out by the Medical Supplies Division of the Ministry of Health, Nutrition and Indigenous Medicine

8. Recommendations

The deficiencies and weaknesses pointed out by the observations in Paragraph 6 of this report may be avoided by the implementation of following recommendations. Further, it will pave the way for purchasing the standard medical supplies at minimum cost and storing them and distribution of sufficient quantities to the hospitals within the due period.

8.1 It is recommended that no medical supply whatsoever should be purchased without a recommendation of the Formulary Revision Committee and the said Committee meetings should be held duly.(Reference – Paragraphs 7.1.1 and 7.2.1)

8.2 It is recommended that meetings of the Therapeutic Committee should be held monthly in a regular manner for the proper drug management and promotion of drug use.
(Reference – Paragraph 7.1.2)

8.3 It is recommended that an Independent Specification Control Unit should be established in the Medical Supplies Division.
(Reference – Paragraph 7.2.1)

8.4 It is recommended that action should be taken to study and identify the items mostly consumed and expensive items that can be estimated but included in the non-estimated items and include them in the list of estimated items.
(Reference – Paragraphs 7.2.1 and 7.2.2)

8.5 It is recommended that action should be taken to develop the specifications in a timely manner for the determination of formulary items.
(Reference – Paragraph 7.2.1)

8.6 It is recommended that action should be taken to maintain the fixed specifications.
(Reference – Paragraph 7.2.1)

8.7 It is recommended that action should be taken for the prevention of including the items to the list by slightly changing the specifications and by introducing as a specified item.
(Reference – Paragraph 7.2.1)

8.8 It is recommended that action should be taken to limit as much as possible the number of items of medical supplies being approximately 20,000 consumed in the island by implementing the recommendations mentioned in the paragraphs from 8.1 to 8.7 above.
(Reference – Paragraph 7.2.1)

8.9 It is recommended that action should be taken to develop the specifications in a timely manner for the determination of formulary items and to avoid the excess of stocks and expiry of stocks due to the changes in specifications.
(Reference – Paragraph 7.2.1)

8.10 It is recommended that action should be taken to estimate the annual requirement by identifying the items that can be estimated but included in the non-estimated items of medical supplies and to purchase from worldwide suppliers and further, to reduce as much as possible the number of non- estimated items of medical supplies.
(Reference – Paragraph 7.2.2)

8.11 It is recommended that action should be taken to avoid the delay in the procurement process by efficiently carrying out the activities pertaining to the files sent by the State Pharmaceuticals Corporation to submit to the Ministry Procurement Committee and Cabinet Appointed Procurement Committee according to a proper procurement plan and procurement time schedule and further, to assign the responsibility thereon to the relevant officers.
(Reference – Paragraphs 7.3.1 , 7.3.2 and 7.3.3)

8.12 It is recommended that a specific methodology should be established to identify whether the delay of the ministerial procurement process which is the delay in the process of stock orders or the delay of the supplier is the reason for the delay in supplying the medical supplies.

(Reference – Paragraph 7.3.3)

8.13 It is recommended that action should be taken to minimize the additional cost in purchasing from the local market by minimizing the purchases of medical supplies from the local market and by implementing the recommendations mentioned in the paragraphs from 8.1 to 8.12 above.

(Reference – Paragraph 7.4.1)

8.14 In case of a purchase from the local market due to a delay of the supplier, it is recommended that action should be taken to submit the relevant information to the State Pharmaceuticals Corporation for the recovery of additional cost from the relevant suppliers before the expiry of the performance bond of the supplier or the payment of retention money of the Letter of Credit.

(Reference – Paragraph 7.4.2)

8.15 It is recommended that action should be taken to establish and implement a methodology for the recovery of additional cost or the loss sustained by the Government due to the delay in the process of stock orders, from the officers responsible.

(Reference – Paragraphs 7.4.3 and 7.4.4)

8.16 In case of controlling the supplies provided without the approval of the Medical Supplies Division and contrary to the Delivery Schedule, it is recommended to the State Pharmaceutical Corporation to consider the recovery of a surcharge for the delays from the Service Charge of 10 per cent paid to them.

(Reference – Paragraph 7.3.2)

8.17 It is recommended that a formal inquiry should be held on the purchase of sterilized surgical rubber gloves at a higher price due to the failure to take action as per the decision taken by the Cabinet of Ministers and the loss sustained should be recovered from the officers responsible.

(Reference – Paragraph 7.5)

8.18 It is recommended to limit as much as possible the purchases of medical supplies not registered at the National Medicines Regulatory Authority.
(Reference – Paragraph 7.6.1)

8.19 It is recommended to reconsider the issue of No Objection Letters for the prevention of entering the quality failed drugs to the country and the damages caused to the patients therefrom and further, to pay the attention on issuing No Objection Letters only in extraordinary instances subject to only an approval of an independent and impartial committee.
(Reference – Paragraphs 7.6.1 and 7.6.2)

8.20 It is recommended that necessary action should be taken to implement the Five Year Development Plan prepared for the development of infrastructure facilities and human resources in the National Drugs Quality Assurance Laboratory so as to test the quality of a sample of any medical supply immediately after the purchase.
(Reference – Paragraphs 7.6.3, 7.7.1 and 7.7.2)

8.21 It is recommended that the Quality Control Reports issued by the National Drug Quality Assurance Laboratory should be issued without delay as the tests on quality of medical supplies begin only after a complaint received and therefore, at the time of receiving relevant quality reports , such medical supplies were almost used or the shelf life of those medical supplies had expired.
(Reference – Paragraphs 7.7.3, 7.7.4, 7.11.1, 7.11.3, 7.11.4 and 7.11.5)

8.22 In case of minimizing the provision of quality failed medical supplies, it is recommended to blacklist those suppliers and to impose strict conditions on the renewals at the National Medicines Regulatory Authority.
(Reference – Paragraph 7.7.5)

8.23 It is recommended that a formal inquiry should be held on the repeat orders placed with the suppliers who provide quality failed medical supplies.
(Reference – Paragraphs 7.7.6 and 7.8)

8.24 It is recommended that action should be taken to control the provision of quality failed medical supplies in large quantities from the countries such as India and the Procurement Committees and Technical Evaluation Committees should take action to

select the suppliers considering the quality and reasonable prices and not the lowest price in the import of drugs.
(Reference – Paragraph 7.8)

8.25 It is recommended that the decision of the Cabinet of Ministers to recover the cost of quality failed medical supplies and 25 per cent of the cost as administrative expenditure from the suppliers, should be implemented properly.
(Reference – Paragraph 7.9)

8.26 It is recommended that the issue of quality failed medical supplies to the patients should be immediately controlled by implementing the recommendations stated in paragraphs from 8.18 to 8.25 above.
(Reference – Paragraphs 7.10.1 and 7.10.2)

8.27 It is recommended that the process up to the withdrawal of quality failed medical supplies, should be carried out through the PRONTO computer system.
(Reference – Paragraphs 7.11.2)

8.28 It is recommended that the State Emblem should be properly stenciled on all the medical supplies.
(Reference – Paragraphs 7.12)

8.29 It is recommended that Lorries up to the standard should be used for the transportation of medical supplies.
(Reference – Paragraphs 7.9 and 7.13.3)

8.30 As the quality of medical supplies is declined due to the failure in storing the medical supplies within the range of relevant temperature, it is recommended that the tender samples and the samples obtained in the purchase of drugs should be stored until the stock is over after issuing to the hospitals.
(Reference – Paragraph 7.9)

8.31 It is recommended to maintain a storing system up to the standard with sufficient capacity to maintain well ventilated, well lighted stores with acceptable temperature limits for the protection of the quality of drugs and to pay the due attention to the security of stocks.
(Reference – Paragraphs 7.13.1, 7.13.2 and 7.13.3)

8.32 It is recommended to issue the Goods Received Notes (GRN) immediately after the receipt of drugs from the State Pharmaceuticals Corporation.

(Reference – Paragraph 7.14)

8.33 It is recommended that the donations from foreign countries should be stored and issued with a proper management for the use in a state of emergency.

(Reference – Paragraphs 7.15.1and 7.15.2)

8.34 A buffer stock of 03 months should be maintained in respect of every medical supply for an efficient stock control. However, as the Procurement Lead Time for medical supplies at present is 11 months, a buffer stock of 06 months should be maintained and due to the lack of adequate storing facilities therefor, a high cost have to be borne. Therefore, it is recommended that the reducing of quantity of the buffer stock by minimizing the Procurement Lead Time should be considered.

(Reference – Paragraphs 7.16.1)

8.35 It is recommended that a methodology of ordering based on the Re-Order Level of stock should be adopted to minimize the lead time for medical supplies.

(Reference – Paragraph 7.16.1)

8.36 It is recommended that attention should be paid to maintain the stock level of suitable items of medical supplies.

(Reference – Paragraph 7.16.2)

8.37 It is recommended that the proper storing and accounting of drugs should be ensured by test checks in addition to the periodical inspection on drug stores by the Managerial staff.

(Reference – Paragraph 7.16.3)

8.38 It is recommended that an insurance coverage should be obtained against the damages from fire and theft in respect of stores belonging to the Medical Supplies Division.

(Reference – Paragraph 7.16.4)

8.39 It is recommended that formal inquiries on stock shortages should be held in terms of Financial Regulations 101,104 and 119.

(Reference – Paragraph 7.17)

8.40 It is recommended to implement the suitable methodologies to identify the actual requirement for minimizing the quantity of expired medical supplies, to purchase only the medical supplies with adequate shelf life, to store them at required temperature levels and for distribution.

(Reference – Paragraph 7.18.1 and 7.18.2)

8.41 When supplying stocks to the Medical Supplies Division by the suppliers, the conditions on the minimum shelf life of the drug should be mentioned in the order while the drugs with short shelf life should not be accepted in respect of items of less consumption. It is recommended that, if the stocks with short shelf life are accepted, attention should be paid to distribute them by following a specific method.

(Reference – Paragraph 7.18.1 and 7.18.2)

8.42 It is recommended that the Medical Supplies Management Information System should be properly established so as to obtain all information until the consumption of medical supplies issued to hospitals.

(Reference – Paragraph 7.19.1)

8.43 It is recommended that the entire process of stock control should be assigned to several officers under the segregation of duties as irregularities may be occurred due to assigning duties to one officer.

(Reference – Paragraph 7.19.2)

8.44 It is recommended that action should be taken to increase the number of approved cadre of the Medical Supplies Division after a proper study and to assign duties in a systematic manner.

(Reference – Paragraph 7.19.2)

8.45 It is recommended to take action to find out the reasons for the difference between the accounting records of the Medical Supplies Division and the accounts of the State Pharmaceuticals Corporation and rectify it and in case of any irregularity, necessary action in terms of Financial Regulations from 101 to 113 should be taken therefor.

(Reference – Paragraph 7.20)

8.46 It is recommended to take necessary prompt action to prepare and implement proper plans for the management of processes such as preparation of estimates on medical supplies, procurement and ordering, to properly maintain the medical supplies stores and the motor vehicles used for transportation of medical supplies up to the standard and to improve adequate infrastructure facilities for the increase of quality tests on medical supplies.

8.47 The main objective of the Medical Supplies Division is to purchase of standard medical supplies at minimum cost required for the inpatients and outpatients in Government hospitals and storing them and further, to distribute those in prescribed quantities on due time to the hospitals and other health institutions. It is recommended that the preparation and implementation of plans and taking follow up action should be done for the achievement of the said main objective reaching the maximum level of economy, efficiency and the productivity of Rs.27,527 million being the average of annual expenditure incurred on medical supplies.