

**Auditor General's Special Report on Procedures taken to avoid the Shortage of
Pharmaceuticals in Government Hospitals by 13 May 2022**

SN -----	Description -----	Page No. -----
1.	Background and Nature of the Report	2
2.	Purpose of the Audit	3
3.	Method of Report Preparation	3
3.1	Document Checking	3
3.2	Other Inspections	3
4.	Scope of Audit	4
5.	Limitations of the Scope	4
6.	Introduction to the process of formulating Medical Supply Requirements	4-7
7.	Information on shortage of medical supplies and information on stock availability due to exchange crisis.	7-14
8.	Observations	14-18
9.	Procedures taken to procure the deficit drugs identified as at 13 May 2022	18-19
10.	Recommendations	20-21
11.	Annexures	

1. **Background and Nature of the Report**

The Mission of the State Ministry of Production, Supply and Regulation of Pharmaceuticals is to create a healthy nation through the production, supply and regulation of high quality pharmaceuticals and to formulate policies and plans to promote the production and supply of pharmaceuticals as well as to regulate the quality of pharmaceuticals and achieve a higher level of health by providing pharmaceuticals timely to institutions in the health sector.

The supply of pharmaceuticals, surgical items, radioactive items and laboratory items required for patient care services provided by all hospitals and other institutions in the health sector under the Ministry of Health and the Provincial Councils are mentioned as Medical Supplies.

Medical supplies Division established under the Ministry of Health to implement, control, direct and supervise the entire process of procuring, ordering, accepting, paying, storing and issuing medical suppliers to get the overall demand for medical supplies was placed under the State Ministry of Production, Supply and Regulation of Pharmaceuticals from 01 September 2020.

The total net allocation to the State Ministry of Production, Supply and Regulation of Pharmaceuticals for the years 2020 and 2021 was Rs. 85,950 million and Rs. 151,980 million respectively. 99 percent and 50 percent or Rs. 85,205 million and Rs. 76,504 million respectively from that was for medical supplies. Accordingly, it was observed that the total net provision for medical supplies in the year 2021 had decreased from 99 percent to 50 percent compared to the year 2020. The actual expenditure on medical supplies during the year 2020 and year 2021 was Rs.. 83,545 million and Rs.. 73,638 million respectively. Accordingly, although the actual quarterly average expenditure on medical supplies in 2020 and 2021 was Rs. 20,886 million and Rs. 18,409 million respectively, according to the information submitted for the audit, the actual expenditure on medical supplies in the first quarter of 2022 was only Rs. 12,454 million. It was also observed that Rs. 25,561 obligations for liabilities had been incurred with the State Pharmaceutical Corporation of Sri Lanka and State Pharmaceutical Manufacturing Corporation for the medical supplies as at 31 December 2021. (Details are given in Annexure 01.)

The number of pharmaceutical items used in hospitals as Vital, Essential and Non-essential was 1,146, the number of surgical items was 8,648, the number of laboratory items was 3,900 and the X-ray items were 44. Out of these, the number of out of stock items of Vital and Essential drugs in the Medical Supplies Division and hospitals were 190 and 51 respectively. In addition, there were 2,724 and 2,156 out of stock Vital and Essential surgical items in the Medical Supplies Division and hospitals respectively at that time. Also, the number of out of stock laboratory items and X-ray items in the Medical Supplies Division and hospitals was 850 and 18 respectively on that day. This Special Audit Report is issued on the basis of above mentioned information on out of stock medical supplies and the stock of medical supplies in stock for a period of less than 03 months and the list of drugs in out of stock obtained from 14 major hospitals. (Details are given in Annexure 02)

2. Purpose of the Audit

The purpose of this special audit was investigate into the timely and adequate supply of pharmaceutical supplies to provide quality patient care and prevention services during the crisis period arising out of the exchange deficit and other factors as at 13 May 2022 and the action to be taken in relation to the shortage of pharmaceuticals. This special audit was carried out under my direction in accordance with the provisions contained in Article 154 of the Constitution of the Democratic Socialist Republic of Sri Lanka.

3. Method of Report Preparation

The following methods were followed in preparing this report.

3.1 Document Inspection

- (a) National Medicine Regulatory Authority Act No. 5 of 2015.
- (b) Code of Government Procurement Guidelines on Pharmaceuticals and Medical equipment.
- (c) Code of Financial Regulations of the Democratic Socialist Republic of Sri Lanka.
- (d) Manual on Management of Drugs revised in 2008 and issued in 1987 with guidelines on drug management.
- (e) Circular No. 02-133/2013 dated 02 September 2013 issued by the Secretary to the Ministry to implement the steps included in the Action Plan for Drug Procurement.
- (f) Information obtained from the PRONTO computer system used to administer the process of medical supplies.

3.2 Other Inspections

- (a) Analytical analysis of various information obtained from government hospitals in relation to the above process.
- (b) Discussions with the top management of the State Ministry of Production , Supply and Regulation of the Pharmaceuticals, Medical Supplies Division and the State Pharmaceutical Corporation.

4. **Scope of the Audit**

A sample audit was conducted on the methodology adopted to achieve the medical supply requirements of the Medical Supplies Division, the progress of the orders submitted for the medical supplies, the assistance received from external parties to overcome the shortage of pharmaceuticals in the hospitals and the intervention of the ministry.

5. **Limitations of the Scope**

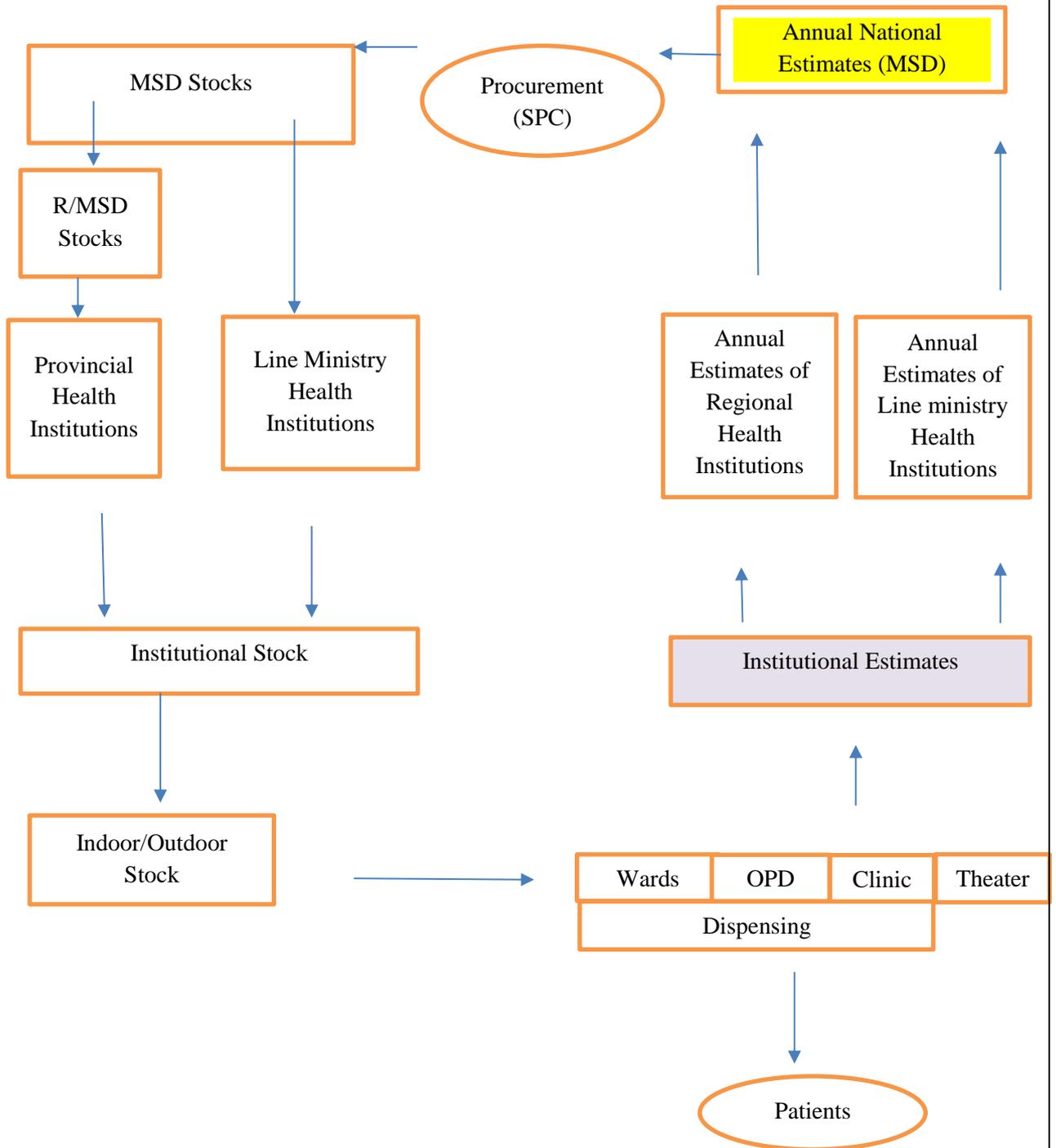
The observations made in this report emphasize that my scope was subject to the following restrictions in reaching conclusions.

The State Ministry had identified 616 items in out of stock (Details are given in Annexure 03) as at 22 April 2022, but did not submit all the details and only a list of uncertified pharmaceuticals in out of stock by an Additional Secretary to the State Ministry had been submitted to the audit and postponement till 24 May 2022 to submit the information about the out of stocks and the availability of sufficient stocks for less than 03 months only as at 13 May 2022 to the audit.

6. **Introduction to the Process of formulating Medical Supply Requirements**

- 6.1 A medical supply should not be purchased without the recommendation of the Formulary Review Committee as per the Cabinet Decision No. AMP/12/1602/509/005-11 dated 13 December 2012 regarding the Action Plan for Drug Procurement.
- 6.2 The Therapeutic Committees of each hospital were held regularly on a monthly basis with a view to promoting proper drug management and drug use in accordance with the provisions in paragraph 01 of Circular No. 02-133/2013 dated 02 September 2013 issued by the Secretary to the Ministry to implement the steps included in the Action Plan for Drug Procurement approved by the Cabinet.
- 6.3 Frequently consumed items are identified as Estimated Items and their annual requirement is estimated and orders are sent to the State Pharmaceutical Corporation of Sri Lanka for procurement from worldwide suppliers and Non-Estimated items are not required when the annual requirement arises was the purchasing methodology followed by the State Ministry.
- 6.4 The future annual requirement is estimated by the respective hospital authorities based on the consumption pattern of the medical supplies and the remaining stocks and sent to the Medical Supplies Division 13 months prior to the month in which the supply is required. It is the responsibility of the Medical Supplies Division to consolidate the annual requirements

sent and identify the total requirement. The process from identifying the need for medical supplies to delivering medical supplies to patients is given below.



- 6.5 In the process of procuring the national demand for medical supplies, the Medical Supplies Division had to issue orders to the State Pharmaceutical Corporation for the procurement of estimated items with a supply period of 11 months as per paragraph 02 of Annexure III of the Chapter 05 in Manual of Management of Drugs.
- 6.6 The National Medicine Regulatory Authority (NMRA) incorporated by the National Medicine Regulatory Authority Act No. 05 of 2015 with the aim of improving access to quality assured medicines and healthcare products only to the country at reasonable prices to register those suppliers and their supplies after checking the conditions of the medical supplies provided by the suppliers. Any medical supply will not be cleared by the Sri Lanka Customs without a certificate of registration from the National Medicine Regulatory Authority.
- 6.7 Imported medical supplies which are not registered in the National Medicine Regulatory Authority as proclaimed in above paragraph 6.6 are procured from suppliers in the local market and it was implemented a process of issuing Waiver of Registration Letter (WOR) by the National Medicine Regulatory Authority on behalf of the Medical Supplies Division, the State Pharmaceutical Corporation of Sri Lanka and the private sector importers of medical supplies to have such purchases cleared by the Sri Lanka Customs. Medical supplies will be cleared by the Sri Lanka Customs only after the submission of the Waiver of Registration Letter
- 6.8 The National Drug Quality Assurance Laboratory was established under the National Medicine Regulatory Authority to assist in the process of verifying the standards of procured medical supplies. The Cabinet approval was given on 15 October 2009 for the five years Development Plan for the year from 2010 to 2015 which was prepared at a total estimated cost of Rs. 410 million to develop the infrastructure and human resources of the National Pharmaceutical Quality Control Laboratory with a view to increasing the number of laboratory tests to test the quality of medical supplies.
- 6.9 According to the Manual on Management of Drugs, pharmaceuticals should be stored in a well-ventilated place to maintain the quality and storage and storage should be maintained at a specified temperature. Also, the Medical Supplies Division should maintain a secure stock for 03 months and in addition to periodically inspecting drug stores by a staff officer, sample testing should be done for the confirmation of the accuracy of drug storage and accounting.
- 6.10 Circular provisions issued from time to time on drug management by the Ministry of Health were to be followed.
- 6.11 Efforts are being made supplied the demand for medical supplies from global suppliers as well as local markets with utilizing various procurement methods such as open competitive procurement, limited competitive procurement and quoting on the recommendations of the

Cabinet Procurement Committees, Ministry Procurement Committees, Departmental Procurement Committees and Regional Procurement Committees.

- 6.12 The Medical Supplies Division as well as Government Hospitals procures imported medical supplies from the local purchase to avoid shortage of medical supplies in case of delays in stock receipts for orders submitted to the State Pharmaceutical Corporation of Sri Lanka.
- 6.13 The Medical Supplies Division had to be recover the additional cost incurred in purchasing medical supplies from local market from the State Pharmaceutical Corporation as per agreements entered with the State Pharmaceutical Corporation of Sri Lanka, due to the delays mentioned in the previous paragraph,
- 6.14 Rs. 191.7 million had been spent on the project launched in 2008 to maintain the Medical Supply Management Information System ((MSMIS) required for better organization of the medical supply management process and continuous supply of essential medicines to government hospitals as at 31 December 2016. This information system was linked to 55 hospitals and institutions under the Ministry, 26 Regional drug stores, the National Medicine Regulatory Authority, the National Drug Quality Control Laboratory and the State Pharmaceutical Corporation. This entire process from ordering to issuing medical supplies was expected to be managed through a computer system.

7. Information on shortage of medical supplies and information on stock availability due to exchange crisis

- 7.1 The details of out of stock and stocks were sufficient for less than 03 months only medical supply items as on 22 April 2022 and 13 May 2022 are given below.
- 7.1.1 The list of Vital and Essential Medical Supplies items identified as at 31 May 2022 is given below.

Type of Medical Supplies Item -----	Number of items out of stock -----		
	In the Medical Supplies Division -----	In hospitals -----	
Vital and Essential Drugs	190	51	
Vital and Essential Surgical items	2,724	2,156	
Regular and Complementary items		850	
X-ray		18	
Total	<u>2,914</u>	<u>868</u>	<u>2,207</u>

7.1.2 The total number of out of stock drug items was 306 and 311 respectively as at 22 April 2022 and 13 May 2022.

Type of Drug Item	No. of drug items used in hospitals	No. of out of stock drug items as at 22 April 2022	No. of out of stock drug items as at 13 May 2022
(i) Vital items	14	03	02
(ii) Essential items	646	176	188
(iii) Non-essential items	486	127	121
	<u>1,146</u>	<u>306</u>	<u>311</u>

7.1.3 The list of pharmaceutical items that have been in sufficient stock for less than 03 months only as at 22 April 2022 are given below..

Type of Drug Item	Adequate No. of drug items for less than 01 month only	Adequate No. of drug items for a period of 01 to 02 months only	Adequate No. of drug items for a period of 02 to 03 months only	Total
Vital out of 14 items	05	02	01	08
Essential out of 646 items	116	57	46	219
Non-essential out of 486 items	<u>47</u>	<u>19</u>	<u>17</u>	<u>83</u>
Total	<u>168</u>	<u>78</u>	<u>64</u>	<u>310</u>

7.1.4 The list of pharmaceutical items that will be in sufficient stock for less than 03 months as at 13 May 2022 is given below.

Type of Drug Item	Adequate No. of drug items for less than 01 month only	Adequate No. of drug items for a period of 01 to 02 months only	Adequate No. of drug items for a period of 02 to 03 months only	Total
Vital out of 14 items	06	01	01	08
Essential out of 646 items	104	52	51	207
Non-essential out of 486 items	<u>45</u>	<u>27</u>	<u>15</u>	<u>87</u>
Total	<u>155</u>	<u>80</u>	<u>67</u>	<u>302</u>

7.2 It was observed that Vital and Essential drugs which were out of stock in the Medical Supplies Division and Health Institutions are being used for the following categories of diseases.

Disease Category	No. of items out of stock in the Medical Supplies Division	No of items out of stock in institutions
(i) Narcotics out of 13 items	05	01
(ii) Drugs used in the treatment of infections out of 67 items	16	04
(iii) Drugs used in the treatment of Cardiovascular system out of 63 items	12	02

(iv)	Drugs acting on the treatment of Central Nervous system out of 68 items	15	04
(v)	Drugs affecting nutrition & blood out of 54 items	24	06
(vi)	Drugs used in the treatment of disease of the Respiratory system out of 34 items	02	-
(vii)	Immunological products & vaccines out of 14 items	06	02
(viii)	Drugs used in the treatment of Endocrine system out of 37 items	09	-
(ix)	Drugs acting on the treatment of Gastrointestinal system out of 14 items	03	01
(x)	Drugs acting on the eye, ear, nose & oropharynx & skin out of 74 items	33	06
(xi)	Drugs used in the treatment of malignant diseases & for immunosuppression out of 85 items	31	10
(xii)	Drugs used in obstetrics, gynaecology & urinary tract diseases out of 13 items	06	02
(xiii)	Drugs used in the treatment of musculoskeletal & joint diseases out of 11 items	03	-
(xiv)	Drugs used in anaesthesia out of 30 items	07	-
(xv)	Antidotes out of 09 items	07	05
		----	---
		179	43
		====	===

7.3 A list of out of stock surgical items and surgical items in stock for a period of less than 03 months as at 13 May 2022 is given below.

7.3.1 Details of out of stock surgical items as at 13 May 2022 are given below.

Surgical -----	Out of stock surgical items as at 13 May 2022 -----	
	In the Medical Supplies Division -----	In hospitals -----
Vital items	03	03
Essential items	2,721	2,153
Non-essential items	2,330	1,459
Total	<u>5,054</u>	<u>3,615</u>

7.3.2 Details of the surgical items that will be in sufficient stock for less than 03 months as at 13 May 2022 are given below.

As at 13 May 2022	Adequate No. of drug items for less than 01 month only -----	Adequate No. of drug items for a period of 01 to 02 months only -----	Adequate No. of drug items for a period of 02 to 03 months only -----	Total -----
Vital items	-	-	-	-
Essential items	540	18	22	580
Non-essential items	<u>562</u>	<u>35</u>	<u>31</u>	<u>628</u>
Total	<u>1,102</u>	<u>53</u>	<u>53</u>	<u>1,208</u>

- 7.4 List of out of stock laboratory items and the number of laboratory items in stock sufficient for less than 03 months as at 13 May 2022 is given below.

Type of Laboratory Item	No. of items used in hospitals	No. of out of stock items as at 13 May 2022	No. of items in stock only for less than 03 months as at 13 May 2022
-----	-----	-----	-----
Regular items	800	250	85
Complementary items	3,100	600	300
	-----	-----	-----
	3,900	850	385
	=====	=====	=====

- 7.5 List of out of stock X-ray items and X-ray items in stock for less than 03 months as at 13 May 2022 is given below.

Type of X-ray Item	No. of items used in hospitals	No. of out of stock items as at 13 May 2022	No. of items in stock only for less than 03 months as at 13 May 2022
-----	-----	-----	-----
Regular items	44	18	06

- 7.6 The ordered medical supplies were not received properly due to the Covid 19 epidemic in the country during the first quarter of 2020, 2021 and 2022 and the deficit of exchange due to the economic and political crisis. Details of the cases where foreign letters of credit could not be opened on 22 April 2022 due to exchange deficit are given below according to the information provided by the State Ministry to the audit.

Current level of letters of credit applications	Value for medical supplies required by the Medical Supplies Division	Value for SPC medical supplies
-----	-----	-----
	US \$ million	US \$ million
For letters of credit pending at the banks	3.0	3.0
For letters of credit to be submitted to the bank	7.0	0.2
	---	---
	<u>10</u>	<u>3.2</u>

- 7.7 According to the information submitted for audit by the State Pharmaceutical Corporation, foreign letters of credit could not be opened as US \$ 4,005,381, Euro 344,552 and Danish krone 2,570,625 for 33 indents related to 24 items as at 22 April 2022 due to the exchange deficit (Details are given in Annexure 04).
- 7.8 The total amount payable to suppliers, Peoples' Bank and Bank of Ceylon by 20 April 2022 for medical supplies ordered by the State Pharmaceutical Corporation from the local market was Rs. 4,278.83 million. Details are given below.

The party to be paid -----	Amount ----- Rs.
To suppliers	3,113,733,700
To Peoples' Bank	917,949,778
To Bank of Ceylon	<u>247,141,647</u>
Total	<u>4,278,825,125</u>

- 7.9 The Corporation had provided information that there was a total financial requirement of Rs. 23,123 million as at 25 May 2022 as the State Pharmaceutical Corporation has disbursed Rs. 7,135 million for issuing letters of credit, payments to suppliers and imports and clearances for orders in the Medical Supplies Division and Rs. 15,988 million for settling bank overdraft facilities for medical supplies.

8. Observations

- 8.1 Although the immediate cause of the shortage of medical supplies mentioned in No. 7 above is the exchange deficit, due to the following factors and among them are the fact that the computer system has not been properly updated and it is not being used properly, lack of proper coordination and coordination between the Medical Supplies Division, the Ministry of Health, the State Pharmaceutical Corporation of Sri Lanka and the State Pharmaceutical Manufacturing Corporation of Sri Lanka, lack of regular monitoring of the activity and progress of orders issued to the State Pharmaceutical Corporation of Sri Lanka and non-compliance with the procurement schedule were the main reasons for the shortage of drugs and these factors had contributed to the pharmaceutical shortage according to the audit about the orders issued to the State Pharmaceutical Corporation for the years of 2019,2020,2021 and 2022 by the Medical Supplies Division for 81 items out of 406 items identified as Vital and Essential by the State Ministry as on 22 April 2022.
- 8.1.1 The Medical Supply Management Information System (MSMIS) was established for the medical supply management and it has facilitated 82 institutions including the Medical Supplies Division, State Pharmaceutical Corporation of Sri Lanka, National Medicine Regulatory Authority and the hospitals under the Ministry of Health from the year 2015. The system was expended to base hospitals and used for ordering, distribution and stock management of medical supplies. The system should carry out stock receipts and annual inventory surveys of all the hospitals where the system was set up and that the computer system should be allowed to be used for auditing purposes by circular No. 03/2015 dated 27 November 2015 by the Secretary of Health. But, this computer system had not been properly updated and used. Details are given below.
- (i) The Medical Supplies Division submit the relevant lists of orders for the respective year to the State Pharmaceutical Corporation of Sri Lanka through this MSMIS or PRONTO computer system with a lead time of 11 months, but the corporation had not immediately commenced procurement for those orders and the procurement was delayed until written copies of the order list were received by the corporation. It was taken more than 18 days to send the written copies of the orders issued to the corporation through the computer system to the Import Division of the corporation and since procurement had only begun after that, a significant amount of time had elapsed from supply period of 11 months to the process of placing orders and receiving orders. Pharmacists and senior officials in the Medical Supplies Division issued the order through the computer system, but the written documents were delayed. Although lists of 41 orders out of 90 orders for 08 vital items and essential items were issued by the computer system to the State Pharmaceutical Corporation of Sri Lanka in the first two months of the year, it had taken between 18 days and 06 months for the Import Division of the State Pharmaceutical Corporation to receive the written copies of the order lists. (Details are given in Annexure 05.)

- (ii) It was observed that, there was a lack of proper relationship and coordination from many years between the Medical Supplies Division, Ministry of Health, State Pharmaceutical Corporation of Sri Lanka and State Pharmaceutical Manufacturing Corporation, which are mainly involved in the management of medical supplies and those agencies were carrying out the work related to the order in isolation. Although the computer system has provided all the above institutions with the facility to updated the progress of the relevant order by entering the status of each step from ordering the medicine to the time of stock delivery, it was observed that the officials of the State Pharmaceutical Corporation of Sri Lanka did not enter the information related to the order into the system from 07 years due to technical problem. The relevant officials had not taken action to rectify the technical probelm. Also, the corporation had stored the information related to the order through other computer Excel sheet without updating it through this system. Therefore, information such as the date of technical evaluation of the relevant tender, the date on which the procurement committee made its decision, the date on which the letters of credit were opened could not be obtained instantly. As a result, it was taken more time to inquire and make decisions was to who is responsible for the delay in procurement as well as to get instant information about the current progress of the order.
- (iii) Although some orders submitted by the Medical Supplies Division through the computer system to the State Pharmaceutical Corporation of Sri Lanka and the State Pharmaceutical Manufacturing Corporation of Sri Lanka had been canceled, the change request feature in the computer system was not used to cancel orders.
- (iv) As the computer system does not represent the bulk conditions in the ward of the hospitals, the hospitals could not fetch the necessary information to analyze what are the essential medical supplies at the moment.

8.1.2 The Medical Supplies Division had not taken any steps to monitor the progress of the approximately 13,000 medical supplies orders for the next year from several years.

8.1.3 Although the Medical Supplies Division had issued orders to the State Pharmaceutical Corporation of Sri Lanka with a supply period of 11 months for the years 2021 and 2022, but the relevant officials had failed to complete the procurement of 27 orders by the date of this report. (Details are given in Annexure 06 and 07)

8.1.4 19 Orders were issued to the State Pharmaceutical Corporation of Sri Lanka in the year 2020 for the year 2021 and in the year 2021 for the year 2022 in related to 11 Vital pharmaceutical items and from that, only small quantities of 04 orders were received by the Medical Supplies Division. All other orders did not arrive in stock due to procurement issues or procurement delays. (Details are given in Annexure 07.)

- 8.1.5 Although it was the policy to issue orders with a supply period of 11 months for the purchase of estimated items, more than a time out of 11 months or more than 11 months of time had been spent on procurement due to non-compliance with the procurement schedule. It was taken 12 to 27 months to complete the procurement of some orders issued by the Medical Supplies Division. (Details are given in Annexure 06 and 07.)
- 8.1.6 Out of the 11 items of Vital drugs used in hospitals, 02 items were out of stock in the Medical Supplies Division and hospitals due to the following reasons.
- (i) It was observed that the bulk of the stock of anti-rabies serum items given to patients exposed to rabies, which is a vital drug was zero in the Medical Supplies Division and the stock remained in the hospitals for less than a month due to planning problems and not an exchange deficit. 07 months after submitting the order for the year 2020, the Medical Supplies Division had cancelled the order and had not placed the order for the years 2021 and 2022. The order issued on 28 March 2018 for the year 2019 was amended 21 months later on 06 January 2022. The order was delivered to the supplier on 19 January 2022 and the letters of credit were opened on 07 April 2022. Accordingly, improper planning of annual orders was the main reason for the shortage of these pharmaceutical items.
 - (ii) The order to purchase Anti Rabies (TC) vaccine for the year 2022 required for the treatment of rabies was received by the State Pharmaceutical Corporation of Sri Lanka on 17 March 2021, but the relevant purchase order was awarded to the supplier on 24 March 2022 after 12 months later. It was observed that although the stock level of this item in the Medical Supplies Division was sufficient for less than a month, the existing stock levels in the hospitals remained manageable.
 - (iii) Order for the year 2022 of the Streptokinase vaccine which is out of stock vital drug for heart disease was issued to the State Pharmaceutical Corporation of Sri Lanka in January 2021. Tender was cancelled twice and called back due to lack of suppliers. There was a stock shortage as on March 2022 due to the tender was still in the evaluation stage. However, action has been taken to purchase these 250 vaccines for Rs. 559,782 with the assistance of the Asian Development Bank (ADB), it was observed that the stocks will be sufficient for 03 months after receiving the aforesaid stock.
 - (iv) Tenecteplase 40mg vaccine was purchased to replace the Streptokinase vaccine due to side effects. The Medical Supplies Division had decided on 14 September 2021 to cancel the Tenecteplase 40 mg vaccine for the year 2022 due to there are enough stocks to be received for orders issued in previous years. However, the Ministry identified the drug as a shortage, as it had stocks in the Medical Supplies Division for less than 02 months as at 22 April 2022.

- 8.1.7 Due to the order for 70,000 Suxamethonium Chloride vaccines used for anesthetic purposes for the year 2021 was issued to the State pharmaceutical Corporation of Sri Lanka on 28 February 2020 and letters of credit were opened on 11 March 2022 after 24 months later, the stock had not been received as at 22 April 2022. Also, the order for 90,000 vaccines for the year 2022 had been issued to the Corporation on 31 January 2021, but the stock receipt date of 08 March 2022 has been revised up to the year 2023 by the Medical Supplies Division. Therefore, this item was in stock for less than 02 weeks in the Medical Supplies Division and less than 02 months in hospitals by 22 April 2022.
- 8.1.8 The order for an essential drug of 220,000 bottles of Cetirizine HCL syrup used for allergies for the year 2019 was issued by the Medical Supplies Division on 07 February 2018, but letters of credit were issued on 31 May 2020, more than 27 months after that date. During this period, the Medical Supplies Division had issued an order for 340,000 bottles on 15 November 2019 for the year 2020 and the order for the year 2019 had been rejected by the Medical Supplies division on 29 July 2020 as the order had been placed by a local manufacturer. Subsequently, an order for 260,000 bottles was issued to the State Pharmaceutical Manufacturing Corporation of Sri Lanka for the year 2021 on 23 February 2021, but after receiving 21 percent or 55,872 bottles of that order, the Medical Supplies Division had canceled the order on 12 August 2021. Also, the Medical Supplies Division had not placed any order for the year 2022 until 12 May 2022. The drug, which is mostly used for young children, was estimated to have a monthly requirement of 21,664 bottles by the Medical Supplies Division, but the supply was nil and the hospitals had only enough stock for about 05 weeks as at 22 April 2022. The stock levels of Castle Street Women's Hospital, Kurunegala Teaching Hospital and Badulla General Hospital were zero as at 22 April 2022.
- 8.1.9 It was taken nearly 02 years to receive the stock of essential vaccine of Meropenem 1g vaccine as the result of transfer from cabinet standing committee to ministry procurement committee level due to incorrect decisions and improper planning in the procurement process of the order issued by the Medical Supplies Division to the State Pharmaceutical Corporation on 06 February 2020 for purchases for the year 2021, changes of order level from time to time, transfer from the procurement committees of the Ministry of Health to the procurement committees of the State Ministry of Health due to change in scope of the Ministry, transfer from State Ministry procurement committee level to Cabinet standing procurement committees again due to increase the contract value. The bidder, who had been selected for a procurement period of 20 months, was awarded the tender for only 50 percent of the required stock as a new supplier. The remaining 50 percent had taken more than 04 months to award the tender. It was observed that, this drug was in stock for less than a month in the Medical Supplies Division and hospitals as at 22 April 2022 due to that the order issued on 23 February 2021 for the year 2022 is also at the evaluation level. Also, due to this delay, the drug which could have been purchased at Rs. 481 per unit was purchased at Rs. 49.52 million by the government hospitals in the year 2021 at various price ranges from Rs. 1,956 to Rs. 4,697 at a high price from the local market.

8.1.10 It was further observed that, there was a shortage of pharmaceuticals due to regularly revised the stock schedules for 23 stocks of drugs mentioned in the list of drugs in out of stock submitted by the State Ministry for audit, suspension of orders by the Medical Supplies Division and the Procurement Committee, cancellation of orders and decline in demand due to the spread of Covid 19 disease. (Details are given in Annexure 08)

8.1.11 The Medical Supplies Division was placed an order for the years of 2020/2021 to Nitrofurantoin tab. 50 mg, which is a non-manufactured pharmaceutical item by the State Pharmaceutical Manufacturing Corporation and subsequently it was canceled. Accordingly, the Medical Supplies Division had placed an order without confirming whether the drug items were manufactured by the Corporation and the order was later canceled and time was taken for another order.

9. Procedures taken to procure the deficit drugs identified as at 13 May 2022

9.1 It is being taken action to make payments to pharmaceutical suppliers identified by the State Ministry of Production, Supply and Regulation of Pharmaceuticals, Supplies and Regulation, Medical Supplies Division, State Pharmaceutical Corporation of Sri Lanka and State Pharmaceutical Manufacturing Corporation and arrangements were being made to prioritize the purchase of medical supplies items which could not be procured due to exchange deficits and to utilize the assistance schemes described below.

- (i) ICL – Indian Credit Line
- (ii) World Bank loan assistance scheme (WB)
- (iii) World Health Organization assistance (WHO)
- (iv) Asian Development Bank assistance (ADB)
- (v) Receiving the assistance of other donors to the Ministry

9.1.1 The details of the assistance agreed to be provided under each assistance line are given below.

Assistance Line -----	Amount agreed to be given ----- US \$ million
Loan assistance approved by 13 May 2022 -----	
ICL – Indian Credit Line	200
World Bank loan assistance scheme	23
Asian Development Bank assistance (ADB)	<u>21</u>
	<u>244</u>
Loan assistance not approved by 13 May 2022	

World Bank loan assistance scheme	50
Asian Development Bank assistance (ADB)	<u>145</u>
	<u>195</u>
Total	439

9.1.2. Recommendations were made to purchase drugs manufactured in India (Country of origin-India) under the Indian loan facility. The assistance of US \$ 200 million had been provided as US \$ 126 million in loans for orders of Medical Supplies Division and pharmacies, US \$ 4 million for the State Pharmaceutical Manufacturing Corporation, US \$ 25 million for local manufacturers and US \$ 45 million for private suppliers, but the Ministry's Drug Subcommittee had already approved US \$ 55.5 million worth of medical supplies until 22 April 2022. It was only 28 percent of that grant and US \$ 114.6 million or 91 percent from the assistance allocated to State Pharmaceutical Corporation and pharmacies, which placed orders on behalf of the medical supplies division was remained unutilized. (Details are given in Annexure 09)

9.1.3 The list of pharmaceutical, surgical and laboratory items expected to be obtained by the Ministry under each of these assistance scheme is given in the attachments.

Aid/ Funding Agency

-
- (i) Indian Credit Line (ICL) (Annexure 10)
 - (ii) World Health Organization assistance (WHO) (Annexure 11)
 - (iii) Asian Development Bank assistance (ADB) (Annexure 12)

9.1.4 In addition, some hospital Directors have applied for both local and foreign donations for pharmaceutical shortages in their hospitals (Details are given in Annexure 13)

9.1.5 Arrangements have been made to open a separate account under the Health Development Fund for remittances to the Ministry of Health by foreigners as well as foreign workers for medical supplies.

10. Recommendations

Implementing the following recommendations will help to avoid the mistakes and weaknesses presented in the observations made in paragraph 8 of this report and ensure that

quality medical supplies are procured and stored at the lowest possible cost and delivered to hospitals in the proper quantity at the appropriate time.

- 10.1 It is recommended to avoid delays in the procurement process and that responsibility be delegated to the relevant officials by effectively executing the activities related to the files sent by the State Pharmaceutical Corporation of Sri Lanka to be submitted to the Ministry Procurement Committee and the Cabinet Procurement Committee according to a proper procurement plan and procurement schedule.
- 10.2 A safe stock of 03 months should be maintained for each medical supply for effective control. However, the procurement lead time is about 11 months although and although it is necessary to maintain a safe stock of 06 months, it is recommended that consideration be given to reducing the level of secured stock by minimizing procurement time due to the lack of adequate storage facilities and the high cost.
- 10.3 It is recommended that action be taken to implement a re-order stock level based ordering system to reduce the lead time required for medical supplies.
- 10.4 It is recommended that attention be paid to maintaining stock levels for appropriate medical supplies items.
- 10.5 It is recommended that the computer system be properly updated and used.
- 10.6 It is recommended that a proper liaison and coordination be maintained between the Ministry of Health, the State Pharmaceutical Corporation of Sri Lanka and the State Pharmaceutical Manufacturing Corporation of Sri Lanka, which are primary involved in the management of medical supplies.
- 10.7 It is recommended that steps be taken to monitor the progress of medical supply orders submitted by the Medical Supplies Division for the next year and that responsibility be properly assigned to officers.
- 10.8 It is recommended that an easy system be introduced into the system as to be able to update information on drugs in out of stock in hospitals.
- 10.9 It is recommended that steps be taken to minimize the impediments to assistance projects implemented through the Ministry to minimize the shortage of drugs.
- 10.10 It is recommended that the relevant suppliers be selected and referred to the Ministry of Trade within a short period of time to utilize the maximum of the provisions made under the Indian Loan Scheme.
- 10.11 It is recommended that action be taken to identify Indian products that fulfill the conditions of the loan scheme.

- 10.12 It is recommended that orders for essential pharmaceuticals not included in the Indian loan scheme should be processed for assistance from the World Bank, World Health Organization, Asian Development Bank or other donations.
- 10.13 It is recommended that all assistance be managed in maximally.
- 10.14 It is recommended that all orders required for the next 03 months be recommended and submitted to the relevant agencies before the end of May.
- 10.15 It is recommended that action be taken to commence procurement based on the data received by the State Pharmaceutical Corporation of Sri Lanka through the computer system and to avoid delays in receiving written orders.
- 10.16 It is recommended that an action be taken to increase the production capacity of the State Pharmaceutical Manufacturing Corporation and to explore and prioritize the possibility of increasing the number of manufactured drug types.

Auditor General

National Audit Office

May 2022

