

பார்லிமென்තු ப்ருகாஸன ஡ாலா ஂக - 164

஡ூஸ஡ நிஷீபா஡ஸ, ஂபுப஡ி஡ி ஡ா நியா஡ன ராப்ய ஂ஡ாஸா஡ஸ

பார்லிமென்துவெ ரபஸே ஡ிஂ஡ூ஡ி பிஂ஡ி஡ெ காரக ஂ஡ால விஂ஡ி ஂ஡ா஡ெ கரன ஡ெ
வார்஡ா ஂ஡ி஡ன்஡ஸென் ஂபாலர நியே஡ 119(4) ஂ஡னே ஡ரு ஂ஡ாஸாவரஸா஡ே
நிரீக்ஂஂஂ

஡ா ஡஡ு ஡஡ன பிஸவர பார்லிமென்துவ வென ஓ஡ிரீபன் கிரீ஡

பாரா஡்ரு஡ன்ற வெளியீ஡ு ஡ொ஡ர் ஡ில - 164

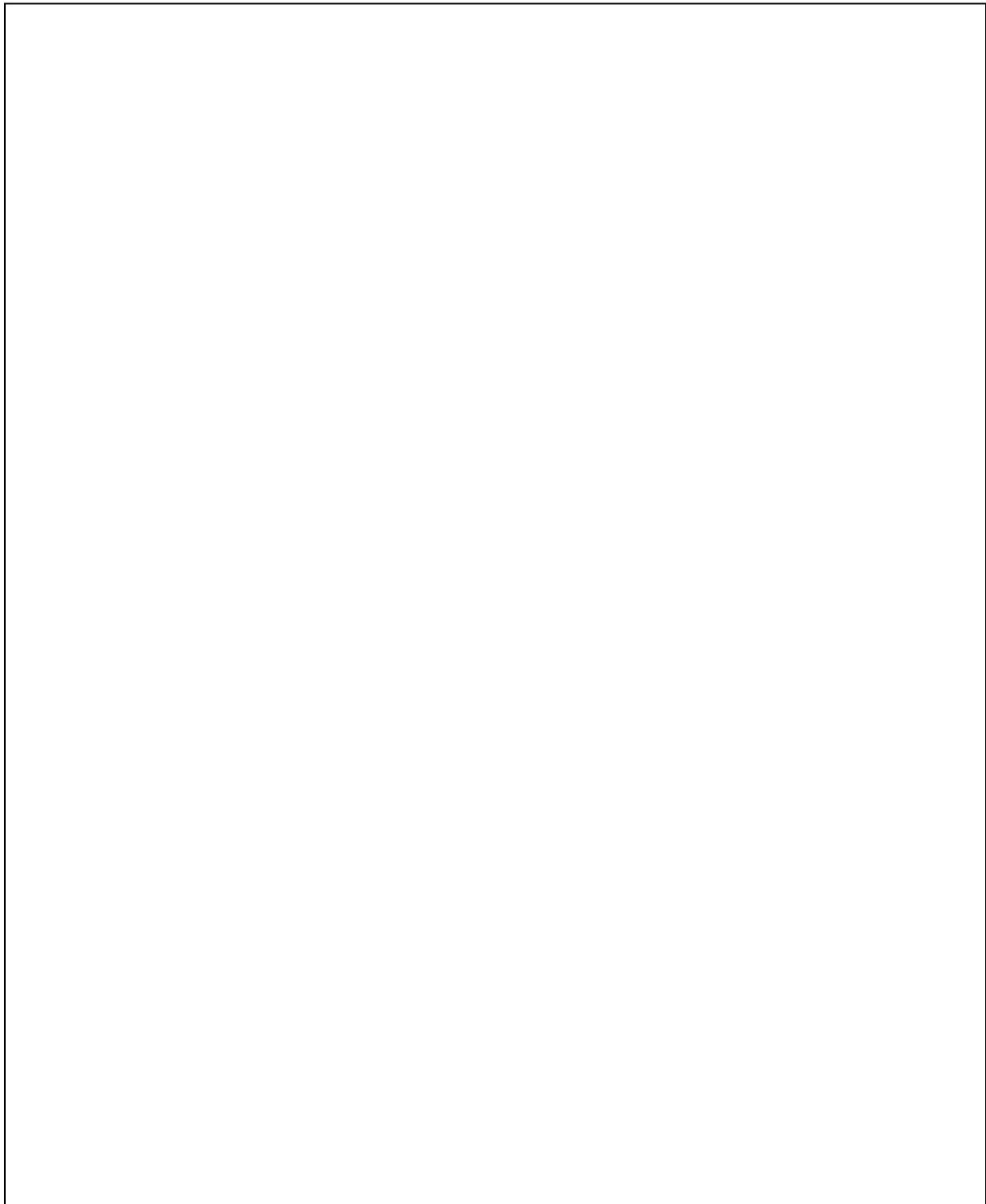
**ஓள஡த ஂ஡்பத்திகள்,வழங்கல்கள் ஡ற்ற஡ும் ஓ஡்ருங்குப஡ுத்தல் ஡ிரா஡ாங்க
ஂ஡ைஂஂஂ**

பாரா஡்ரு஡ன்ற ஂரச கணக்குகள் கு஡்ருவினால ஡ுன் வைக்கப்பட்ட ஂ஡ிக்கை
஡ொ஡ர்பாக நிலையியல் க஡்டளை ஡ிலக்க஡் 119(4)஡ின் கீழ் கௌரவ
ஂ஡ைஂஂ஡ரின் ஂவதா஡ிப்புக்கள஡் ஡ற்ற஡ும் ஂது ஡ொ஡ர்பாக ஡஡ுக்கப்பட஡்
஡஡வ஡ிக்கைகள஡் பாரா஡்ரு஡ன்றத்திற்கு ஂ஡ர்ப்பித்தல்

Parliamentary Series Number – 164

**State Ministry of Production, Supply and Regulation of
Pharmaceuticals**

**Submission of observations of Hon. Minister and steps taken with
regard to the reports tabled by the Committee on Public Accounts in
terms of Standing Order No. 119(4)**



	Shortcomings identified by the Committee/directives given by the Committee	Action taken by the Committee to rectify the shortcomings/implement the recommendations/current status
01	Failure to comply with the Action plan for procurement of drugs. As per the Action Plan approved by the Cabinet, the Drugs Review	Since it was impractical to hold the Prescription Review Committee Meetings annually and, Directives of the Committee on Public Accounts,

	<p>Committee should annually meet to review matters related to the varieties of drugs purchased, the quantities to be purchased, drugs to be removed from use and issues related to Drug specifications. However, the said committee had not conducted its meetings after the year 2011 and therefore, 4619 medical supply items with a value of Rs.10,193 million had been purchased from the year 2011 to 2016.</p> <p>The Committee has ordered to submit the Cabinet paper on holding Prescription Review Committee meetings to the Cabinet of ministers and to obtain approval.</p>	<ul style="list-style-type: none"> • Conducting Prescription Review Committees every two (02) years • Conducting Prescription Review Committees on operation theaters and laboratories every three (03) years <p>Approval of the Cabinet of Ministers has been obtained for this on 01.02.2022. (Annexure 01)</p>												
02	<p>Weaknesses in the Medical Supply Estimation Process.</p> <p>The Medical Supply and Management Information System (MSMIS) has disclosed that 19,844 medical supply items have been utilized by the year 2017.</p> <p>The Committee which observed that the information of the drugs which have been removed from use had not been deleted from the Medical Supply and Management Information System, committee has directed to take measures to remove the information of the drugs that are not in use anymore from the database and to insert information when new drugs are added for use and to take measures to update the system accordingly.</p>	<p>Discontinued drug items cannot be completely removed from the medical supply system as they are required for follow-up. But getting estimates and ordering for these items is restricted by the system. As of 2022.10.19, the number of Active Items in the system is 12754 and it is as follows.</p> <table style="margin-left: 20px;"> <tr> <td>Medicines</td> <td>-</td> <td>1,151</td> </tr> <tr> <td>Surgical</td> <td>-</td> <td>8,134</td> </tr> <tr> <td>Laboratories</td> <td>-</td> <td>3,469</td> </tr> <tr> <td>Total</td> <td>-</td> <td>12,754</td> </tr> </table>	Medicines	-	1,151	Surgical	-	8,134	Laboratories	-	3,469	Total	-	12,754
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03.	<p>Purchasing drugs by the Brand Name.</p> <p>When a sample of ten estimated items was examined, it was disclosed that Name Patient drugs have been purchased on 243 occasions spending Rs. 168 million from the year 2014 to June, 2016 related to 7 items. Similarly, it was disclosed that the</p>	<p>Medicines are ordered to the State Pharmaceutical Corporation only in the Generic Name of the medicine. However, the doctors recommend the Original Product to the cancer patients who have reached to the second stage since it is difficult to quantify the quality of bio-medicines (Eg.-Trastuzumab) which are the anti-cancer medicines issue in the name of the patients.</p>												

	<p>drug Trastuzumab, a very expensive name patient drug given for cancer patients had been purchased from a local supplier incurring an expense of Rs. 891 million on 14 occasions under its brand name Herticad rejecting the original drug by the name of Herceptin in the years 2018 and 2019. Here an additional cost of Rs.230.9 million had to be borne due to the purchase of this particular drug, rejecting the lower rates which were available.</p> <p>The Committee has ordered to take measures to purchase the Name Patient drugs only in extremely essential instances.</p>	<p>Accordingly, medicines given in the name of the patient are purchased under the Brand Name only in case of emergency.</p> <p>However, the approval for this should be taken through this State Ministry, the State Pharmaceutical Corporation of Sri Lanka (SPC) and the National Medicine Regulatory Authority (NMRA) in addition to the recommendation of specialist doctors.</p>
04.	<p>Hospitals purchasing drugs from the local market without the recommendation of the Drugs Review Committee.</p> <p>The Lady Ridgeway Children's Hospital has purchased drugs with a value of Rs.9 million in the year 2020 without the recommendation of the Drugs Review Committee.</p>	<p>Only if recommended by specialist doctors, the purchase of prescribed medicines will be done with the recommendation of the Director General of Health Service and the approval of the Secretary of Health.</p> <p>But the purchase of medicines in this way is at a minimum level and a large amount of frequently purchased medicines have been prescribed and procured through the State Pharmaceuticals Corporation.</p>
05.	<p>Not maintaining the Medical Supply Stores as per the appropriate condition.</p> <p>It was observed that the temperature of the warehouses belonging to the Medical Supply Division has not properly been maintained and that the medical supplies had been stored in the central medical stores and in the corridors of the hospitals. As a result of improper storage of drugs, drugs with a value of Rs.6259 million have failed the quality from the year 2011 to 2020, It was observed that 99% of these drugs had by that time been issued to patients when they were identified to have failed the quality. It has not been possible to recover the</p>	<p>A 28,000 sq. ft. temperature controllable warehouse has been procured from Veyangoda and a 49,000 sq. ft. Warehouse has been procured from Shavasthipura by now.</p> <p>In addition, the Pharmaceutical Storage Facility Upgrading Project has spent Rs.65.37 million in the year 2020 and Rs.233.37 million in the year 2021 to improve the regional storage facilities of 81 institutions.</p>

	<p>cost of the drugs that fail the quality from the suppliers.</p> <p>The committee has ordered to finish the work for storing medicines so as to preserve the safety of the medicines.</p>	
06.	<ul style="list-style-type: none"> There had been very expensive estimable items among the items which were not estimated. This factor had been ignored and had been purchased locally at an exorbitant price without making competition. <p>It was observed that when a certain drug is estimated, it is purchased by the State Pharmaceuticals Corporation following the international bidding procedure and the Name Patient drugs are purchased from the local market without making estimations. Although the drug Trastuzumab is a Name Patient drug it has been estimated and imported incurring a substantial loss and certain other drugs seem to have been purchased from the local market without making estimates.</p> <p>The Committee has ordered to minimize local purchases by taking measures to purchase the said drugs only when needed, considering the excessive cost incurred, when the said drugs are purchased locally.</p> <p>Similarly, the Committee has ordered to prepare a document including the names of drugs locally purchased by the hospitals and to submit it to the Auditor General.</p>	<p>On the recommendation of specialist doctors, these medicines are purchased by the hospitals. but the requests are analyzed by a committee appointed to make recommendations, and medicines are identified (Annexure 02) and bought without estimates and those medicines are selected through adopting an international bidding procedure. Apart from that, National Medicine Authority has been giving the approval is evaluation whether this drug is suitable and necessary for use in this country.</p>
07.	<p>Not Complying with a Procurement Schedule.</p> <p>Although a period from 11-12 months can be spent for the Ministerial Procurement Committee level orders, in the year 2020, a period of 14-48 months has been</p>	<p>The approval of the Cabinet of Ministers was obtained on 19.01.2022 to introduce a new computer system called Swastha to be able to prepare medicine estimates based on the patients' medicine Consumption Base and to be able to follow a proper procurement plan and a procurement time table based on that information (Annexure 03). Accordingly, the</p>

	<p>spent for the procurement of certain drugs and a period of 7 to 24 months has been spent to get the approval of the Technical Evaluation Committee and the Procurement Committee for the procurement documents. Due to the delays of these time frames Procurement lead time had expired and the relevant drugs had been consequently purchased from the local market at a higher rate.</p> <p>The Committee has ordered to prepare an electronic system (ERP) enabling to follow a proper procurement plan and a procurement timetable or to take measures to rectify the shortcomings of the prevailing system enabling its further development and to submit a report in this regard to the Committee.</p>	<p>suppliers have been selected and the procurement process has been completed to develop the relevant system and data storage and networking has been initiated in association with Sri Lanka Telecom. With the implementation of this system, delays of procurement can be minimized.</p> <p>According to the order of the Public Accounts Committee, a new electronic system (ERP) can be prepared to be able to work according to a proper procurement plan and procurement schedule or the existing system has been improved and delays can be minimized. A report on that has been provided to the committee.</p>
08.	<ul style="list-style-type: none"> ● Although there is a need to recover the additional cost incurred when purchasing the required medical supply from the local market by the Medical Supply Division due to the delay of the suppliers. ● Lack of a methodology to trace the party which is truly responsible for the delay although it is necessary to recover the loss from the suppliers when items are purchased from the local market due to the delay of the suppliers. <p>The Committee has ordered to formulate a suitable methodology by the Health Ministry to prevent the purchase of drugs from the local market due to the delay of suppliers.</p> <p>The Committee has ordered to provide the Committee with a detailed report having conducted an analysis on the drugs with a delayed supply by the internal audit committee of the Ministry of Health.</p>	<p>During the request for extend of letters of credit, it is done through a committee and a fee is charged for the delay and 70 million late fees have been charged for the last 5 months.</p> <p>After receiving the medical supplies to medical supply division, the stock receipts are entered into a Good Receive Note so that the delay can be identified. If there is a delay due to employees, there is a possibility to detect through this system.</p> <p>The relevant report has been forwarded to the Public Accounts Committee through letter No. CA/AQ/FCC/02/COPA/2019(iii) dated 22.06.2022</p>

	<ul style="list-style-type: none"> • The methodology to recover the additional expenditure borne on the purchase of drugs from the local market by the hospitals. 	
09.	Medical supply that fails the quality have been issued to patients due to the delay of the ministry in issuing circulars.	The new “Swastha” computer system proposed to be introduced has the potential to overcome this shortcoming by extending it to local hospitals.
10.	<p>The progress of recovering the loss incurred on the drugs that fail the quality from the suppliers. The committee has ordered to the provide the committee with a report within one month, including the progress of the money recovered from the suppliers for quality failure drugs.</p> <p>The committee has ordered to take measures to get the Medical Supply Division to recover the cost of the drugs or other medical supply that fail the quality from the relevant suppliers instead of recovering those expenses from the State pharmaceuticals corporation.</p>	<p>The relevant report has been forwarded to the Public Accounts Committee through letter No. SM/PSRP/07/COPA/20(1) dated 28.03.2022. (Annexure 04)</p> <p>Suppliers who have not made the relevant payments are being blacklisted and legal action is being taken.</p>
11.	<p>Not printing the state emblem in certain medical supply containers.</p> <p>The Committee has ordered to provide with a report within one month including the details of drugs which do not carry the state emblem.</p>	<p>in the case of Purchase of very small quantities in case of necessity, acceptance of donated medicines under controlled conditions, purchase of small quantities of essential medicines from pharmacies in certain cases, purchase of generic medicines, purchase of medicines on demand in Covid situation without government logo Had to get. In all other cases, the purchase is made with the state emblem.</p> <p>Report on the supply of pharmaceuticals which have not been printed with the State Emblem has been forwarded to the Public Accounts through letter No. SM/PSRP/07/COPA/20(1) dated 28.03.2022.</p>
12.	Not issuing the Goods receiving Notes (GRN) documents	The relevant report has been forwarded to the Committee on Public Accounts through letter

	<p>immediately after receiving the medical supply.</p> <p>Here it was revealed that the drugs purchased by the State pharmaceuticals corporation are transported to the Medical Supply Division through the transport suppliers. As the storage facilities are not sufficient in the said stores, medical supply with a substantial value is kept in corridors without accepting them from the suppliers. These stocks are received by the stores once storage facilities are available and the GRN documents are issued only after that.</p> <p>The committee has ordered to provide the committee with a report within one month including the steps that have been taken to issue the GRN documents as soon as the drugs are received from the State pharmaceuticals corporation.</p>	<p>No.SM/PSRP/07/COPA/20(1) dated 28.03.2022</p> <p>To avoid this situation, a new unit called Pricing and Checking Unit has been set up in front of the entrance of the Medical Supplies Division on 25/11/2021. Likewise, 04 officers are currently on duty there under the shift system from 8.00 am to 8.00 pm. This is active on all government working days. Prior to installing this unit, the supplier had to go to different sections to complete the relevant work after receiving the stock to the Medical Supplies Division and with the establishment of this new unit, all those functions can be performed from that unit. This process has become more efficient, avoiding pre-existing problems. At present, undertaking all stocks received by the Medical Supplies Division and GRNs are issued within one day. So far, GRN issuance facilities have been provided for Veyangoda, Shravastipura, Wellawatta Angoda and Digana regional warehouses.</p>
13.	<p>Not taking action as per the financial regulations regarding the shortage of stocks.</p> <p>Action has not been taken with pertinence to the stock deficiencies of Rs.43 million which was available in the stores of the medical supply division as at 2015.12.31.</p>	<p>Deficiency inventory reduction related to 11 store officers are below.</p> <p>Amount recovered as on 31.12.2020 - රු.3,261,404.00</p> <p>Value recovered from 01.01.2021 to 30.09.2022 - රු.179,970.00</p> <p>Value recovered as on 30.09.2022 - රු.3,441,374.00</p>
14.	<p>Tendency of getting expired medical supply.</p> <p>It has been revealed that the cost of expired drugs from the year 2015 to 2017, in the year 2018, in the year 2019 and in the year 2020 is 1,122, 126, 240 and 208 million Rupee respectively.</p>	<p>After implementing the “Swastha” computer system proposed to be introduced at the hospital level, the pattern of drug consumption can be identified. Accordingly, medicines are estimated based on the consumption pattern.</p>

	<p>It was also disclosed that a large quantity of Thyroxin 50mcg expired in the Base Hospital, Homagama in the year 2017-2018 as it had been erroneously calculated as 600,000 although its annual estimate was 600,000. It was also disclosed that the value of the aforesaid drugs was 3.4 million Rupee.</p>	
15.	<ul style="list-style-type: none"> ● A methodology had not been introduced to test the quality of samples of all the medical supply purchased and the manner in which the quality of the drugs is tested currently. ● The developments of the laboratory of the National Drugs Control Authority ● Importing drugs which are not registered in the National Medicines Regulatory Authority. <p>The committee ordered to prepare a set of proposals regarding the methodologies to identify the drugs which fail the quality through a committee appointed by the cabinet and to present them to the committee.</p> <p>As the National Drug Regulatory Authority laboratory located at Narahenpita is currently a land owned by the Ministry of Agriculture, the cabinet of Ministers should submit the paper to the cabinet of Ministers and obtain approval for taking over that land. Since this</p>	<p>There are no facilities in this country to check the condition of certain medical supplies and the National Medicines Regulatory Authority's laboratory is being improved with the support of the World Health Organization to improve those facilities. The work is expected to be completed within 2 years.</p> <p>The State Pharmaceuticals Corporation will not import any drug that is not approved by the National Medicines Regulatory Authority into the country.</p> <p>The National Medicines Regulatory Authority has decided to start the relevant development activities according to the preliminary discussions related to the proposed new land that will be handed over to the National Medicines Regulatory Authority.</p> <p>For statement of facts regarding the Cabinet Paper, a letter has been addressed to the Director General of the Urban Development Authority. (Annexure 05) It has requested an</p>

building complex is proposed to be built on a 2.5-acre land, if there is no technical need, it has been ordered to refer the plan to the National Planning Department for re-review so that it can be built on a 1-acre land.	estimate of the cost of the construction required to resettle the squatters and the occupants of its quarters, and details of the time frame required to remove the squatters and legally take over the land to the National Medicines Regulatory Authority.
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Dr. K. S. Rambukwella

~~Dr. Keheliya Rambukwella,~~

Minister of Health.

