

## **Head 423 - State Ministry of Production, Supply and Regulation of Pharmaceuticals**

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### **1. Financial Statement**

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#### **1.1 Qualified Opinion**

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The audit of the financial statements of the State Ministry of Production, Supply and Regulation of Pharmaceuticals for the year ended 31 December 2020 comprising the statement of financial position as at 31 December 2020 and the statement of financial performance, and cash flow statement for the year then ended, was carried out under my direction in pursuance of provisions in Article 154 (1) of the Constitution of the Democratic Socialist Republic of Sri Lanka read in conjunction with provisions of the National Audit Act No. 19 of 2018. The Summary Report containing my comments and observations on the financial statements of the State Ministry of Production, Supply and Regulation of Pharmaceuticals was issued to the Accounting Officer on 06 August 2021 in terms of Section 11 (1) of the National Audit Act No. 19 of 2018. The Annual Detailed Management Audit Report of the Ministry was issued to the Accounting Officer on 21 September 2021 in terms of Section 11 (2) of the Audit Act. This report is presented to Parliament in terms of Section 10 of the National Audit Act No. 19 of 2018 which is read in conjunction with Article 154 (6) of the Constitution of the Democratic Socialist Republic of Sri Lanka.

In my opinion, except for the effects of the matters described in Paragraph 1.6 of this report, the financial statements prepared give a true and fair view of the financial position of the State Ministry of Production, Supply and Regulation of Pharmaceuticals as at 31 December 2020 and its financial performance and cash flow for the year then ended in accordance with Generally Accepted Accounting Principles.

#### **1.2 Basis for Qualified Opinion**

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My opinion is qualified based on the matters appear in Paragraph 1.6 of this report. I conducted my audit in accordance with Sri Lanka Auditing Standards (SLAuSs). My responsibility for the financial statements are further described in the Auditor's Responsibilities Section. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

#### **1.3 Responsibilities of the Chief Accounting Officer and the Accounting Officer for the Financial Statement**

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The Accounting Officer is responsible for the preparation of financial statements that give a true and fair view in accordance with Generally Accepted Accounting Principles and provisions in Section 38 of the National Audit Act, No.19 of 2018 and for the determination of the internal control that is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

As per Section 16(1) of the National Audit Act, No.19 of 2018, the Ministry is required to maintain proper books and records of all its income, expenditure, assets and liabilities to enable the preparation of annual and periodic financial statements.

In terms of Sub-section 38(1)(c) of the National Audit Act, the Accounting Officer shall ensure that an effective internal control system for the financial control exists in the Ministry and carry out periodic reviews to monitor the effectiveness of such systems and accordingly make any alterations as required for such systems to be effectively carried out.

#### **1.4 Auditor's Responsibilities for the Audit of the Financial Statements**

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My objective is to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error and to issue an auditor's summary report that includes my opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with Sri Lanka Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate and its materiality depends on the influence on economic decisions taken by users on the basis of these financial statements.

As part of an audit in accordance with Sri Lanka Auditing Standards, I exercise professional judgment and maintain professional skepticism throughout the audit. I also furthermore;

- Appropriate audit procedures were designed and performed to identify and assess the risk of material misstatement in financial statements whether due to fraud or errors in providing a basis for the expressed audit opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- An understanding of internal control relevant to the audit was obtained in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Ministry's internal control.
- Evaluate the structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Evaluate the overall presentation, structure and content of the financial statements including disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

I communicate with the Accounting Officer regarding, among other matters significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

## 1.5 Report on Other Legal Requirements

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I express the following matters in terms of Section 6 (1) (d) of the National Audit Act No. 19 of 2018 .

As the Ministry has been established in the year 2020, there was no need to issue financial statements for the preceding .

## 1.6 Comments on Financial Statements

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### 1.6.1 Presentation of Accounts

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The following observations are made.

<b>Audit Observation</b>	<b>Comments of the Accounting Officer</b>	<b>Recommendation</b>
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<b>(a) Annual Financial Statements</b> Although the Annual Financial Statements should be submitted to the Auditor General on or before 28 February 2021, in terms of the Guideline No. 06 with the State Accounts Circular No. 250/2016 (i) dated 03 August 2016 issued by the Department of State Accounts, the Sinhala version on 10 March 2021, the English version on 06 June, 2021 and the Tamil version on 17 September 2021 were submitted for audit with delays.	Agree with the observation. Lack of adequate staff and the Covid 19 epidemic caused the delay and the Tamil version would be submitted on or before 31 July 2021 .	Annual financial statements should be submitted for audit on the due date in accordance with the Guidelines issued by the Department of State Accounts.
<b>(b) Reconciliation Statement of Advances to Public Officers' Account</b>		
Even though the Reconciliation Statement on Advances to Public Officers' Account No. 42301 should	Agree with the observation. Lack of adequate staff and the Covid 19 epidemic	Reconciliation Statement of Advances to Public Officers' Account should be

have been submitted to the Auditor General on or before 28 February 2021 in terms of the Guideline No. 04 of the Department of State Accounts , it had been submitted for audit on 11 May 2021 with a delay of 02 months and 11 days.

caused the delay and the actions would be taken to recruit the required staff in future.

submitted for audit on the due date in accordance with the Guidelines issued by the Department of State Accounts.

(c) Losses occurred due to shortages of drugs, expirations, failures in quality and damages to drugs in the Medical Supplies Division during the year under review were not calculated or disclosed in Note (ii) submitted with the financial statements and instead, the loss occurred during the previous year amounting to Rs. 417.02 Million had been included in the Note.

Actions has not been taken in the year 2020 on disposals and expirations due to the existing Covid 19 epidemic, actions will be taken to calculate the figures and included in the financial statements 2021 and as the Ministry of Finance has not given its approval to write off the losses of Rs. 417.02 Million identified during the preceding years, it has been further included in the financial statements.

The losses occurred due to drug shortages, expiration, failure in qualities and damages to drugs occurred during the year under review should be calculated and disclosed in Note (ii) of the financial statements.

(d) Although the maximum expenditure limit of the advances to public officers account No. 42301 was Rs. 13.8 Million as per the Appropriation Act, it had been entered as Rs. 60 Million and though the maximum debit balance limit was Rs. 20 Million it was stated as Rs.130 Million in the Advance Account , Form ACA-5

Agree with the observation and it is ensured that such omissions do not occur in future .

Correct information should be accurately disclosed in the financial statements.

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| <p>(e) Due to non-maintenance of register of advances by the Medical Supplies Division the value of the advances paid for the work contracts could not be ascertained and the value had not been recorded in the Formats ACA-5 (a) and ACA-5 (b).</p> | <p>Relevant officers have been instructed to maintain the register of advances as per the State Accounts Circular No. 250/2016 (i) dated 03 August 2016</p> | <p>Arrangements should be made to maintain and update the register of advances using the prescribed forms.</p> |
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**1.6.2 Statement of Financial Performance**

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The following deficiencies were observed in the accounting of non-revenue receipts related to financial statements.

Audit Observation	Comments of the Accounting Officer	Recommendation
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<p>(a) Even though the total of the Treasury imprest receipts as at 31 December 2020 was Rs. 39,179.44 Million as per the imprest account prepared according to the ACA-3 Format, thus the figure was Rs. 39,279.44 Million as per the statement of financial performance, the difference was Rs. 100 Million. The reasons for the difference had not been identified and necessary adjustments had not been made.</p>	<p>Agree with the observation and look for reasons for the change and submit later.</p>	<p>Treasury imprests receipts and other receipts should be properly accounted for. As soon as such a change occurs, the cause should be investigated and necessary adjustments should be made.</p>
<p>(b) As a result of receipts of Rs. 166.04 Million received from other sources as at 31 December 2020 were not included in the statement of financial performance as per the imprest account prepared according to the ACA-3 Format, non-revenue receipts had been understated by the same amount.</p>	<p>-do-</p>	<p>-do-</p>

### 1.6.3 Property , Plant and Equipment

#### Audit Observation

Although the cost of assets acquired during the year under review was Rs. 66.35 Million as per the statement of non-financial assets in Format No. ACA-6, thus the assets purchased during the year under review was Rs. 128.46 Million as per the expenditure statement according to the programmes in the Format ACA-2 (ii) , the difference was Rs. 62.11 Million. The reasons for the difference had not been ascertained and necessary adjustments had not been made.

#### Comments of the Accounting Officer

Agree with the observation and necessary adjustments will be made in preparation of accounts for the year 2021.

#### Recommendation

The cost of assets acquired during the year under review should be accurately identified and as soon as such a difference occurs, the cause should be investigated and necessary adjustments should be made.

### 1.6.4 Failure to Maintain Documents and Registers

It was observed in audit test checks that the State Ministry had not maintained below mentioned certain registers and some documents in an updated manner .

#### Audit Observation

- (a) A Register of Securities containing the details of the officers and employees to be kept securities had not been prepared in accordance with Financial Regulation 891 (1) .

#### Comments of the Accounting Officer

Because it is a newly started Ministry, this document could not be opened for the year 2020 and that it has already been opened.

#### Recommendation

A Register of Securities should be maintained for the officers who had to keep securities so that the information mentioned in the Financial Regulation is included.

(b)	A Register of Damages had not been maintained as per the Financial Regulation 110 .	-do-	A Register of Damages should be maintained in accordance with the Format stated in the Financial Regulation.
(c)	A Register of Liabilities had not been maintained as per the Financial Regulation 214 .	-do-	Liabilities should be recorded in a document so that they can be checked regularly.
(d)	A Register of Vehicles had not been maintained as per the Financial Regulation 1647 (e) .	-do-	A Register of Vehicle should be maintained in accordance with Financial Regulation.

**1.6.5 Lack of Evidence for Audit**

----- <b>Audit Observation</b> -----	<b>Comments of the Accounting Officer</b> -----	<b>Recommendation</b> -----
Answers had not been submitted even by 15 August 2021 for the 19 audit queries submitted to the State Ministry during the year under review and the value of countable transactions related to those queries was Rs. 41,091 Million.	Due to the limitation of reporting of officers to duties because of the prevailing Covid epidemic, this delay had occurred and arrangements are being made to submit the answers to the audit expeditiously in future without any delay.	After reviewing the Register of Audit Queries referred to in Financial Regulation 452 (1) after a period of time, by the Accounting Officer , actions should be taken to rectify the deficiencies pointed out in the audit queries in accordance with Financial Regulation 155 and those queries should be answered immediately. If answering for such inquiries may be delayed, actions should be taken to send an interim report for that.

### 1.6.6 Certifications to be made by the Accounting Officer

Even though the Accounting Officer is required to certify in the following matters in accordance with the provisions of Section 38 of the National Audit Act No. 19 of 2018, actions had not been taken accordingly.

<b>Audit Observation</b>	<b>Comments of the Accounting Officer</b>	<b>Recommendation</b>
<p>(a) The Chief Accounting Officer and Accounting Officer should ensure that an effective internal control system for the financial control of the Department is being carried out and to conduct periodic reviews to monitor the effectiveness of such systems and accordingly make any alterations as required for such systems to be effectively carried out and even though such reviews should be made in writing and submit a copy to the Auditor General, the statements that such reviews were made had not been furnished to audit.</p>	<p>Since this State Ministry was established on 09 August 2020 , failure to recruit adequate staff and formulate an effective internal control system for financial control, an internal control system is currently in place and conduct previous reviews on its effectiveness.</p>	<p>Actions should be taken in accordance with the Provisions of Section 38 of the National Audit Act No. 19 of 2018 .</p>
<p>(b) Although the Chief Accounting Officer and the Accounting Officer shall ensure that all audit queries are answered within the specified time period as required by the Auditor General, the answers for the audit queries had not been given in terms of Paragraph 1.5.2 (f) of the Report.</p>	<p>Due to the limitation of reporting of officers to duties because of the prevailing Covid epidemic this delay had occurred and actions will be taken without delay in future .</p>	<p>- do -</p>



**2. Financial Review**

**2.1 Entered into Liabilities and Commitments**

The following observations are made.

<b>Audit Observation</b>	<b>Comments of the Accounting Officer</b>	<b>Recommendation</b>
<p>(a) The liabilities amounted to Rs. 128.63 Million relating to 17 expenditure objects as at 31 December 2020 had not been included in the Statement of Treasury Liabilities and the relevant expenditure object had not been mentioned with regard to the liabilities amounted to Rs. 1.56 Million included in the statement of commitments and liabilities shown in Note (iii) submitted with the financial statement .</p>	<p>It is agreed with the audit observation and that the answers will be submitted later.</p>	<p>The statement of Liabilities and Commitments shown in Note (iii) should be prepared in a manner of reconciling with the statement of commitments issued by the Treasury.</p>
<p>(b) As per the statement of liabilities shown in Note (iii), although the liabilities to be paid to the private sector suppliers for the procurement of medical supplies on that day and the liabilities to the State Pharmaceutical Corporation of Sri Lanka were Rs. 5,056.64 Million and Rs. 133,885 respectively, thus those figures were shown as Rs. 49.93 Million and Rs.6.16 Million respectively in the statement of liabilities prepared by the Treasury, the difference was Rs. 5,006.71 Million and Rs. 6.03 Million respectively. Nevertheless, the necessary adjustments had not been</p>	<p>-do-</p>	<p>-do-</p>

made finding the reasons for the difference.

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| (c) | The liabilities entered into amounting to Rs. 2,601.28 Million had not been included in the Note (iv) of the statement of liabilities in terms of Financial Regulation 94 (2) and (3). | -do-   | All the liabilities should be included in the statement of liabilities. |
| (d) | Liabilities amounted to Rs. 108.41 Million had been entered into exceeding the savings of the provisions made for 07 expenditure objects in contrary to Financial Regulations 94 (1).  | Every effort is made to enter into commitments based on the provisions received, it has to enter into commitments with essential functions as per nature of the health service and the steps will be taken to minimize such commitments in future. | Actions should be taken in accordance with Financial Regulations.       |

**2.2. Reconciliation Statement on Advances to Public Officers' Account**

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 The following observations are made in this regard.

<b>Audit Observation</b>	<b>Comments of the Accounting Officer</b>	<b>Recommendation</b>
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(a) Although the debt balances of the officers who had transferred out should be settled within three months in accordance with Financial Regulations 485 (4) and Public Enterprise Circular No. 89 of 22 October 1993, the total of	It had tried to recover the debts and actions are being taken furthermore to do so.	Arrangements should be made in terms of Financial Regulations and circular provisions.

unpaid debt balance of 15 officers who had Transferred from the Medical Supplies Division for more than 05 years as at 31 December 2020 was Rs. 384,981 .

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| (b) | Actions had not been taken to recover the loan balances of Rs.1.56 Million due from 30 officers who had left the service from the borrowers or guarantors even by 31 December 2020 . | Necessary steps have been taken to recover these loan balances from the borrower or guarantor. | Actions should be taken to recover the debts from the debtors or guarantors or to take legal action against it. |
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### 2.3 Exceeding of Limits

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**Audit Observation**  
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Although the maximum debit balance limit of the advances to public officers account No. 42301 was Rs. 20 Million, thus the actual debit balance was Rs. 41.64 Million, the maximum debit balance limit had exceeded by Rs. 21.64 Million . The Ministry had not taken actions to revise the maximum debit limit.

**Comments of the Accounting Officer**  
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This has happened on taking over the loan balances of the officers of the Medical Supplies Division which had been under the Ministry of Health, to the State Ministry and a request has been made to the Cabinet of Ministers in terms of Section 8 of the Appropriation Act to amend the limits.

**Recommendation**  
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Arrangements should be made to act within approved limits and to act to amend approved limits before exceeding limits.

## 2.4 Non-compliance with Laws, Rules and Regulations

The instances of non-compliance with the provisions of the Laws, Rules and Regulations observed during the audit test checks are analyzed below.

	<b>Observation</b> -----	<b>Comments of the Accounting Officer</b> -----	<b>Recommendation</b> -----
<b>Reference to Laws, Rules and Regulations</b> -----	<b>Non-compliance</b> -----	<b>-----</b>	<b>-----</b>
(a)	Public Finance Circular No. 05/2016 dated 31 March 2016	The Annual Board of Survey Report for the year under review had not been submitted for audit by the Medical Supplies Division even by 10 May 2021 .	These duties were delayed due to the prevailing Covid epidemic and some warehouse officers suffering from Covid disease, the survey regarding the common goods that have been commenced is currently being done and actions will be taken to provide such reports expeditiously.
(b)	Section 8.12.3 of the Government Procurement Guidelines	Although the assets relevant to 02 completed contracts whereas the cost was not calculated and taken over by the Medical Supplies Division, had not been duly inventoried.	The assets purchased should be properly inventoried.

### 3. Operating Review

#### 3.1 Failure to Perform Duties

Any medical supply should not procure without a recommendation from Formulary Revision Committee in accordance with the Decision of Cabinet of Ministers No. 403 /12/1602/509/005/-11 dated 13 December 2012 regarding the Action Plan for Drug Procurement. The following observations are made as per the audit test checks carried out on the conduct of Formulary Revision Committee and about the purchase of drugs by the Medical Supplies Division during the year under review.

Audit Observation	Comments of the Accounting Officer	Recommendation
(a) Although the Formulary Revision Committee should be held annually as per the Decision of the Cabinet of Ministers, arrangements had been made to hold such committees only once in 03 years. If the Formulary Revision Committee cannot be held annually, the approval of the Cabinet of Ministers should be obtained to hold it every 03 years, as per the Directive of the Public Accounts Committee held on 06 June 2019 , the approval had not been obtained even by 10 May 2021 .	A Cabinet Memorandum has been prepared for the approval of the Cabinet of Ministers recommending that it was appropriate to hold Formulary Revision Committee once in 03 years, it has been sent to a further feasibility study to be conducted before obtaining approval for it and thereafter, actions will be taken to refer to the Cabinet of Ministers with necessary amendments.	Action should be taken in accordance with the Decision of the Cabinet of Ministers and the Directive of the Committee on Public Accounts.
(b) As a result of the matters such as appointment of Members of Formulary Revision Committee and Sub -Committees for the year 2019/2020 until the end of the year 2020, only 10 sub-committees were held until the first quarter of 2021, issuing the final	The Formulary Revision Committee were held as scheduled and 10 Formulary Revision Committee Meetings have been held for the year 2020 .	-do-

report of the Formulary Revision Committee Meetings which were commenced for the year 2016/2017 on 17 January 2019, failure to specify the dates on which the recommendations are to be implemented, it was observed that the actions had not been taken to appoint, activate and to issue reports of Formulary Revision Committee within a specific time frame.

(c) Although the Therapeutic Committee meetings of the respective hospitals should be held regularly on a monthly basis in accordance with the Decision of the Cabinet of Ministers to promote proper drug management and drug use, it was observed that no such action had been taken even by 31 December 2020 .

(d) It was observed that out of the 20,850 items of medical supplies in use, the number of items which were not recommended by the Formulary Revision Committee during the year under review was 7,394 or 35 per cent and there are some drugs still in use that have been deleted from the recommendations of Formulary Revision Committee..

Fifty one Therapeutic Committees have been held for the year 2020 and future arrangements have been made to hold Therapeutic Committees for the year 2021.

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Comments have not been given.

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(e) The Medical Supplies Division had placed orders for the purchase of 258 items of drugs which were not approved by the Formulary Revision Committee for the year under review for Rs. 3,507.29 million by 29 June 2020 . Seven items including 03 items cost at Rs. 285 Million mentioned in the computer system, as items not approved by the Formulary Revision Committee had been purchased by the Medical Supplies Division for the year 2020 .

Due to the reasons such as changing the strength of the drug as capsules and tablets, changing the volume or strength of the injections and obtaining stock reference numbers as items of the raw material used to prepare the Formulary items , certain drugs recommended by the Formulary Revision Committee are used through other reference numbers in accordance with the drugs approved by the Revision Committee, even though other stock reference numbers are used, the items are similar in functionality as those of the items approved by the Formulary Revision Committee, these items are not shown in the computer system as Formulary Approved items, certain items are still used for specific diseases even after being removed by the Formulary Revision Committee, such items have to be re-submitted to the next Formulary Revision Committee for approval and it is necessary to do so in order to save the lives of the patients.

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(f) The Lady Ridgeway Children's Hospital and Peradeniya Teaching Hospital had purchased 49 pharmaceutical items valued at Rs. 9.07 Million and 6 liters of Uirusolve + EDS valued at Rs. 200,400 from the local market respectively had not

These drugs were purchased for residential and clinical patients at the request of specialist physicians and if these drugs have to be purchased frequently in future, actions will be taken to obtain the approval of the Formulary Revision Committee.

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received the approval of the Formulary Revision Committee during the year under review .

### 3.2 Other Observations

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 The following observations are made.

<b>Audit Observation</b> -----	<b>Comments of the Accounting Officer</b> -----	<b>Recommendation</b> -----
<p>(a) It was observed that the storage space and the required infrastructure were not sufficient as more than 1/3 of the space of the Head Office premises where the Medical Supplies Division is located was used for office activities and 15 items including 09 stock items of medical supplies valued at Rs. 284.27 Million which was not received by the store keeper had been kept outside the storage premises for a period of 03 days to 71 days.</p> <p>It was observed at the physical audit test check carried out on 17 March 2021 that 05 drug items which should be stored at a temperature of 30 degrees Celsius and below valued at Rs. 120.29 Million, had been kept in the corridor and in stores with temperatures above 30 degrees Celsius. The time when the specified temperature was not kept, had ranged from 02 days to 71 days. It was also observed that these drugs consisted of drugs used for allergies,</p>	<p>The stocks of drugs be stored in the corridor and received by the warehouses as soon as the spaces are available in the warehouse to prevent demurrages for the containers in case the stocks are returned to the State Pharmaceutical Corporation due to the lack of space in the Storage Division, when the stocks of the warehouses are in the corridor, the undertaking of the above stocks would be delayed when the stocks remained in the corridor due to the priority given to receive the shortage stocks of medicines of the medical supplies section. there are such problems in accepting stocks due to the non-issuance of medicines because of the reduction in the number of patients coming to the hospitals due to the Covid 19 epidemic and measures have been taken to avoid</p>	<p>Actions should be taken to store the medical supplies up to standard, fire extinguishers to be serviced on due dates and to complete the relevant contract works expeditiously.</p>



diabetes, and antibiotics.

Further, the Fire extinguishers in the warehouse where medicines, surgical and chemical substances are stored had expired since 2018.

Similarly, although the contract for installation and repair of air conditioning system which was contracted out in 2013 valued at Rs. 119.3 Million, should have been completed by 31 October 2016 as per the agreement, as a result of payment of 99.78 per cent of the contract value or Rs. 119.03 Million to the contractor even by 17 March 2021, the works had not been completed by the contractor even by 30 June 2021 and there was no interest in that.

these situations .

- (b) The following observations are made regarding the recovery of additional costs incurred due to purchase of medical supplies from the local market to avoid shortage of medical supplies due to delays in the procurement process late delivery or other reasons from responsible parties, including suppliers.

- (i) Although the Medical Supplies Division had identified that an additional cost of Rs. 5,166 Million had to be incurred during the period of 10 years from 2007 to 2016, the additional cost identified

The Medical Supplies Division has instructed the State Pharmaceutical Corporation to forward to the Medical Supplies Division the additional cost incurred due to the purchase of medical supplies from the local market in order to avoid the shortage of medical supplies due to delays in the procurement process,

It should act in accordance with the agreements entered into with suppliers in respect of additional costs which they are directly responsible and a mechanism should be introduced to recover those additional costs from the officials

by the State Pharmaceutical Corporation had been Rs. 4,941 Million. The reasons for the difference of Rs. 225 Million had not been identified.

that those charges have not been made, however, since local purchases are not being made by the Medical Supplies Division at present, this situation will not arise because of the local purchases have been transferred from the year 2017 to the State Pharmaceutical Corporation.

responsible for the additional costs when suppliers are not liable.

(ii) The additional cost identified by the State Pharmaceutical Corporation to be recovered so far was Rs. 320 Million and neither the Medical Supplies Division nor the State Pharmaceutical Corporation had taken actions to recover the remaining Rs. 4,621 Million.

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(iii) Out of the total additional costs identified by the State Pharmaceutical Corporation so far, only Rs. 83 Million out of the Rs. 194 Million directly responsible by the suppliers had been recovered. Those responsible in respect of Rs. 104 Million and another Rs. 21.8 Million incurred due to deficiencies in supplier ordering and procurement process where the supplier was

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not responsible, had not been identified so far.

(iv) The additional cost of Rs. 558 Million occurred at the local purchases made by the State Pharmaceuticals Corporation on 57 occasions to avoid the shortage of medical supplies created due to delays in the procurement process during the period from 2018 to 2020 had not been recovered even by the date of this report. -do- -do-

(v) A methodology had not been identified to recover the additional cost which was incurred by each hospital for medical supplies purchased from the local market, from the suppliers. Although 35 government hospitals and health institutions under the Line Ministry had purchased medical supplies from the local market at a cost of Rs. 2,219,148,518 during the year under review, the additional costs involved in it had not been calculated or recovered. -do- -do-

(c) Medical supplies cost at Rs.1,136.64 Million out of the medical supplies issued by the Medical Supplies Division to Government Eighty circulars were issued regarding quality failures during the year 2020, because of the entire category of drugs A system should be introduced and implemented so that the quality of a sample can be

Hospitals had failed the quality. The remaining amount of medical supplies had not been identified by the time the hospitals were notified of the failure of the quality.

that fail the quality are charged since 2015, the remaining stocks in hospitals are not being computed, the computer system is decentralized only up to the basic hospital level and the stocks could not be calculated by the computer system once they were issued from the warehouse of those hospitals to the each units.

checked as soon as medical supplies are received and adequate facilities and staff should be maintained for this purpose. The cost and administrative fees for quality failed medical supplies should be recovered from the relevant suppliers and If there is an inability to do so, the reasons should be ascertained and actions should be taken to recover from the responsible officers.

(d) There were glass fragments, visible particles, a dead cockroach, broken tablets, discoloration, non-compliance with British pharmacological specifications (BP Specification), 03 deaths due to adverse reactions , Microbial Contamination etc. had been identified in many of the failed medical supplies and as a result, those were discarded from use or discontinued of use. There were Antibiotics (Meropenem /Flucloxacillin / Vancomycin), and also the drugs used for allergies, asthma and

It is impractical to prevent only by increasing the number of quality tests in errors observed, only GMP Certified products (GMP Certificates) should be provided to minimize the issue of substandard drugs to patients, only the defects in the product from production to supply can identify from quality inspection , damages caused by defects in warehousing, transportation and handling cannot be detected by quality inspections, although a methodology to check the quality of the drugs before the release of the drug in

-do-

cancers had consisted among the medical supplies which were discarded for unsuitable use during the year under review.

the period before June 2020 was not implemented after that, a methodology was started as soon as the drugs were received by the Medical Supplies Division, the samples were taken from several batches and sent to the laboratory of the State Pharmaceutical Corporation for testing, these test reports are issued within 07 days and the batch would not be released until then, if the quality fails, a sample from the same category will be sent back to the National Drug Quality Laboratory to be ascertained if the quality fails, the report will be submitted to the National Medicines Regulatory Authority and actions will be taken to withhold or withdraw from use, since June 2020, a number of 193 samples have been sent to the State Pharmaceutical Corporation, Out of these, since 45 samples had failed, then were sent to the National Drug Quality Laboratory for re-verification as and 28 batches were found to be failed and discarded and because the State Pharmaceutical Corporation has the facilities to test only 316

types of drugs the National Medicines Regulatory Authority is planning to test more drugs.

(e) Although it had been revealed in the audit reports continuously about reporting of failure of the quality after issuing drugs to hospitals, at the time of issuance of circulars on quality failed drugs, 100 per cent of them have been issued to patients or have been completed, about the spontaneous expiration of those items before being withdrawn or revoked the items ordered withholding should be further tested, losing the ability to recover relevant losses from suppliers for expired items due to delays in testing, it was observed that , there was no system in place to check the quality of the drugs before they were issued to the hospitals to avoid such situations even by the date of this report.

It is impractical and sometimes inefficient to put the samples of all stock of drugs received by the Medical Supplies Division to chemical, physical and biological quality tests due to inadequacy of existing quality laboratory testing facilities and the capacity, however, a system has been introduced to test drug samples before issuing them to hospitals.

Actions should be taken to procure quality medical supplies, issue them only to hospitals after testing the quality, and to eliminate the risk of issuing substandard drugs to patients. Further, a system should be put in place to expedite the testing of drugs that have been withheld due to quality failure.

(f) Although it was reported to the audit that the withholding orders for the use of medical supplies are communicated to the relevant hospitals and institutions by the computer system from 2020 with a view of preventing the provide of drugs which had failed quality to the patients due to the delay in issuing notification circulars on drugs that fail in quality, as the

Plans have been prepared and approved to provide the connectivity to computer systems (MSMIS) for 570 Regional Hospitals by 31 December 2021 .

The PRONTO computer system should be used to issue orders regarding drugs that fail the quality.

computer system was not installed in 1,381 hospitals out of the total number of 1,521 hospitals, that purpose could not be achieved.

- (g) The Polonnaruwa District General Hospital had received 609,561 units out of 13 types of quality failed drugs at a cost of Rs. 14.38 Million during the year under review and out of these, 529,443 units, or 86.85 per cent, had been issued to patients. Nevertheless, no tests or inquiries whatsoever had been made in respect of the patients who had used the drugs and the measures to be taken only in respect of drugs which have failed the quality and remained in the stores had been informed by the respective circulars.
- A methodology for testing system so far for patients who have used substandard drugs has not been introduced and the methodology mentioned in the answer (e) has been introduced to check the condition before issuing the drugs received to the Medical Supplies Division.
- Arrangements should be made to identify quality failed drugs before issuing them to patients.
- (h) From the drug called Peritoneal Dialysis Solution 1.5% that is issued for Kidney Patients, 7,100 units cost at Rs. 6.47 Million units under 5 categories had remained at the Polonnaruwa General Hospital warehouse at the time of the inspection and it was observed that the 08 packages of this medicine had emptied due to leaks and also there were complaints that the drugs issued to patients often leaked out of the packing.
- It will be reported to you later conducting a Departmental inquiry in this regard and taking further actions .
- Actions should be taken to procure the medicines of proper quality.

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|--|---|---|
| <p>(i) Actions had not been taken in respect of 34 quality failed surgical consumable materials and laboratory material items that had been stored in drug warehouses at the Peradeniya Teaching Hospital for a long time to be removed from the warehouse in accordance with the Circular of the Secretary to the Ministry of Health No. WMS-01/13/2009 dated 21 May 2009 even by 04 September 2020, the date of audit .</p>  | <p>The observation is correct, the disposal had been delayed due to problems faced by the Sri Lanka Pharmaceuticals Corporation in dealing with the disposal of quality failed drugs in the recent past and necessary instructions have been given to expedite the disposal activities.</p>   | <p>Actions should be taken in accordance with the circular.</p>   |
| <p>(j) The Auditor General's report revealed a shortage of Rs. 10 Million in medical supplies handed over by the State Pharmaceutical Corporation to the Medical Supplies Division in 2004 and 2005. Although actions should be taken to recover Rs. 9.37 Million from the parties involved in the loss or to reimburse the loss as per Recommendation No. 4.2 of the Committee appointed in this regard, even though nearly 08 years had elapsed since the investigation report was issued, the State Pharmaceutical Corporation had recovered only Rs. 3.18 Million out of Rs. 9.24 Million to be recovered from the relevant parties. The amount of Rs. 6.06 Million which was not recovered was about 65 per cent of the total loss. Of that, it could not be recovered due to the fact that</p> | <p>The Secretary of Health has instructed to charge Rs. 133,084 from Mr. S.J Lokunarangoda, a warehouse keeper of the Medical Supplies Division as per the recommendations of the Committee appointed on the instructions of the Parliamentary Public Accounts Committee to inspect for the loss of Rs. 10 Million identified in the delivery of drugs from the State Pharmaceutical Corporation to the Medical Supplies Division in the years 2004 and 2005 and to determine those responsible, the State Pharmaceutical Corporation has been given the responsibility of recovery of the remaining Rs. 9.87 Million and hat the relevant amount has</p> | <p>Actions should be taken to recover the loss from the relevant parties and if there is an inability to do so, to find out the reasons and recover from the responsible officials.</p> |



the case on Rs. 3.20 Million due from the Transport Contractor had expired, Rs.1.71 Million stock to be charged from the local agent who supplied the items could not be supplied by the supplier, delays in the Medical Supplies Division regarding the loss of Rs.1.05 Million, negligence of the officials such as destruction and misplacement of files.

not been charged since Mr. S. J Lokunarangoda was later acquitted and released.

- (k) It was decided at the review committee meetings held on 09 and 17 April 2020 under the chairmanship of the Minister of Health to provide medical supplies to government hospitals without any shortage, to ensure a continuous supply of drugs, the entire annual requirement including the buffer stock for all medical supplies should be ordered when placing an order with the State Pharmaceutical Corporation for the year 2021, the stocks due in previous years for each order should not be deducted. All the orders submitted for the year 2021 had been revised again on or closer to 20 April 2020 after this decision and as a result of these revisions, orders in the year 2021 had increased by 25 per cent to 112 per cent as compared to 2020. Although the need for each medical supplies should be

Although the total annual requirement, including buffer stocks, should be ordered for all medical supplies when placing an order to the State Pharmaceutical Corporation for the year 2021, as the Ministry of Health has decided not to make orders which should have received for each order due in previous years, the orders sent by the Medical Supplies Division Orders for the year 2021 were revised again, however, excess of stock due to stockpiling because of receiving of the stock due in previous years and the setting of timetable for receipt of stocks ordered for the year 2021 in two installments, cancellation of orders due to sharp decline in consumption of items due to the Covid epidemic in

Arrangements should be made to prepare realistic estimates in a way that minimizes the variance between the estimate and the actual consumption and place orders based on the that.

systematically analyzed and forecast instead of that, it was observed that due to acting in accordance with the above decision that there may be an excess of medical supplies and a trend to expire in future.

(l) Although the Medical Supply Containers supplied by the State Pharmaceutical Corporation should have the State Logo printed on them was an internal control tactic that was introduced to prevent misuse as well as condition of the order, 03 items cost at Rs. 156.28 Million whereas the cost of the State Logo was not printed had remained in the warehouses of the Medical Supplies Division on 17 March 2021.

(m) The Polonnaruwa General Hospital is maintained 06 warehouses for storing drugs and 2,062,522 units of drugs containing 82 items valued at Rs. 44.18 Million had been piled up insecurely outside the warehouses due to non-increase of drug storage facilities as compared to the expansion of the hospital and insufficient space for existing drugs in the warehouses. There were a large number of boxes with disposable gloves that were informal and unsafe on and around the stairs of the main warehouse and it was observed that the drugs which were in the air-conditioned

2020 and 2021 and to temporarily withhold, necessary steps are being taken to prevent stock excesses and expiration in collaboration with the State Pharmaceutical Corporation.

Although the printing of State Logo is mentioned as a condition of the order, there may be occasions when stocks of items have to be accepted without the State Logo considering the urgent need for medical supplies or the inconvenience caused by the Covid epidemic in some cases and if not, the State Pharmaceutical Corporation is notified to charge from the suppliers for these items.

Due to insufficient space in the warehouse of the drugs of the Polonnaruwa General Hospital thus, these drugs are stored outside the main warehouse and the necessary plans have been prepared to build a new warehouse for drugs..

The State Logo should be printed on it , the terms of the order should be included in and instructed to act accordingly.

Actions should be taken to store all medical supplies up to standard and to fulfill the infrastructure need for that.

storage were at a temperature higher than the required temperature due to the storage of drugs without a proper gap in such a way that they do not get ventilation.

(n) Even though the approval of the Cabinet of Ministers had had been obtained in the year 2017 for the construction of a warehouse for drugs at Peradeniya Teaching Hospital with an estimated of Rs. 463 Million, the future arrangements had not been made due to non-availability of funds for the construction. Due to the inadequacy of storage facilities, 44 items of medicines and surgical consumables had been piled up in various places in the hospital corridors, part of the Director's quarters and part of the medical officer's dormitory basement and kitchen and there were 14 items of medicine that should be stored in a temperature range from 25 to 30 degrees Celsius.

(o) Local market prices of medical supplies purchased by the Lady Ridgeway Children's Hospital had taken an extraordinarily higher than the prices of the State Pharmaceutical Corporation during the year under review and within that, there were 16 drug items cost at Rs.1.37 Million with a shelf life

The approval of the Department of National Planning has been obtained for the construction of the proposed drug store, construction could not be commenced due to lack of funds and relevant officers have been instructed to obtain the necessary funds and commence the construction in future.

Wherever possible, the drugs are purchased from the State Pharmaceutical Corporation, when the drugs are not available at State Pharmaceutical Corporation small portions are purchased and therein, it has to buy at a relatively high price as compared to wholesale

Steps should be taken to expand the storage facilities in hospitals.

Arrangements should be made to minimize the local purchases ,in case of absolutely essential, measures should be taken to purchase with transparency and at a reasonable price and to maintain a thorough

period of 03 months and 11 months. In comparing the price of the items purchased under the emergency purchases at the Peradeniya Teaching Hospital with the average purchases of those items from the Medical Supplies Division of the Ministry of Health, a higher range variation from 26 per cent to 2016 per cent was observed .

(p) Four hundred patients had been registered for the cancer clinic at Polonnaruwa Hospital by 31 January 2021 and out of many of the estimated drugs needed for this clinic have been in out of stock for a considerable period of time. During a period of more than 05 years from 01 January 2016 to 18 February 2021,

Twelve items of pharmaceuticals for more than 50 per cent of those number of days , 25 items of pharmaceuticals in between 25-50 per cent of those number of days and 49 items of pharmaceuticals in between 0-25 per cent of those number of days had remained out of stock . Actions had not been taken to provide drugs by giving priority to the patients who are suffering from a life-threat disease such as cancers, without a shortage.

prices.

There are cancer centers in every part of the island to treat the growing number of cancer patients and the daily requirement of drugs for these patients is increasing day by day, however, due to non-registration of certain cancer drugs with the National Medicines Regulatory Authority, the continuous supply of drugs has been interrupted, similarly, because of failure to supply delivery of orders on time, or delivery in late by some drug suppliers the supply of drugs has been disrupted, there have also been reported that the disruptions to supplies because of to inability to issue letters of credit on time due to financial constraints at certain times or delays in payments to suppliers, however, under the prevailing

supervision on this.

A database should be built so that it can be maintained free of a shortage of essential medicines and accordingly, actions should be taken to supply those drugs and there, the priority should be given to the drugs for the life-threatening patients such as those for cancers .

(q) The payments which should be made for surgeries of patients sent to Sri Jayewardenepura Hospital by the Ministry of Health, had been set off for a Rs. 553.28 Million to be received for medical supplies issued to that Hospital from 2014 to March 2021 without formal approval and concurrence and the values had also not been properly accounted for .

circumstances, the Medical Supplies Division, in collaboration with the State Pharmaceutical Corporation, take steps to provide the maximum possible supply of medicines for the needs of cancer patients and actions will be taken in future to provide all medicines to all patients whenever possible.

Without charging for medical supplies issued to Sri Jayewardenepura Hospital, setting off the bills for the patients sent to the Sri Jayewardenepura Hospital from the Sri Lanka National Hospital and other hospitals for cardiac surgeries with the approval of the Ministry of Health instead, accordingly, although the Medical Supplies Division and the Sri Jayewardenepura Hospital have agreed on the amount to be set off by July 2019 the settlement had not been made as payments by now, however, arrangements will be made to provide medicines for cash to the Sri Jayewardenepura Hospital and to pay for the cardiac surgeries performed by the hospital through the Ministry of Health in

A formal approval and concurrence should be obtained from the Treasury for such set offs and the transaction should be properly accounted for.

future.

- (r) A cost of Rs. 2,364.70 Million in medical supplies which had failed the quality during the period from 2011 to 2020, had not been recovered from the relevant suppliers. Within that, there were Rs 2,111.46 Million of purchases from State Pharmaceuticals Corporation, Rs. 60.61 Million of local purchases, purchases from local manufacturers amounting to Rs. 109.96 Million, purchases from State Pharmaceutical Manufacturing Corporation amounted to Rs. 81.95 Million and also purchases of surgical gauzes amounting to Rs. 732,330. Due to the expiration at the time of issuing the circular that some medical supplies had failed the quality, the loss caused by the failure of the quality could not be recovered. As an example for that, it can be mentioned that the expirations of a number of 108,000 Cefuroxime sodium for injection BP 750 mg cost at Rs. 5.80 Million before the issuance of the quality failure circular occurred on 30 September 2017 and 31 January 2018.
- A sum of Rs. 779,648,623 have been charged from suppliers for quality failed medical supplies during the period from 2016 to 2020 and that the Secretary to the Ministry of Pharmaceuticals, Supplies and Regulatory State Ministry has decided not to charge from the suppliers for failed surgical gauzes.
- The cost and administrative fees of quality failed medical supplies should be recovered from the relevant suppliers and if there is an incapable, arrangements should be made to charge from responsible officers after finding the reasons.

### 3.3 Projects Implemented with Local Funds

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Prior to 2012, the Medical Supplies Division managed medical supplies using a computer system called Oracle and the first phase of the Medical Supply Management Information System (MSMIS) has been established since 2012 combining 82 institutions under the Ministry of Health. The project on expansion of the system to the level of Divisional Hospitals (MSMIS

Expansion Project) was launched in 2017 and is scheduled to be completed in 2020 on a decision of the Cabinet of Ministers and the total estimated cost was Rs. 954 Million. As the actual expenditure as at 31 March 2021 was only Rs. 309.88 Million, the financial progress had remained at as low as 32 per cent. The following observations are made in this regard .

	<b>Audit Observation</b> -----	<b>Comments of the Accounting Officer</b> -----	<b>Recommendation</b> -----
<b>(a)</b>	Even though this information system had been planned to be installed in 571 health institutions, the establishment had only been completed in 140 institutions by 31 March 2021 and it was observed that another 337 institutions were establishing the system. Accordingly, the number of institutions that had not yet begun the installation of the system was 94 . Further, although the estimated number of computers required for the system was 1,550, only 863 computers had been supplied by 31 March 2021 .	It has been planned to provide MSMIS system connectivity to 571 Institutions such as all Provincial General Hospitals, Base Hospitals and all the Divisional Hospitals as per the approval of the Cabinet of Ministers received, At though about 1550 computers are needed , since the budget allocation received in 2018 was only Rs. 200 Million, the provisions were not sufficient to procure computers, printers, UPS machines for 571 Institutions, therefore, actions were taken to purchase equipment including 650 computers for 258 institutions, although the number of institutions that have set up the information system was only 140, about 55 per cent of the information system installation work of another 337 institutions and about 15 per cent of the information system installation work of the remaining 90 institutions have been completed and additional time has been requested until 30 June 2022 to complete the remaining work.	Responsibilities for planning, implementing and monitoring the achieving of performance of the project should be specifically assigned to the officers and arrangements should be made to utilize the provisions made available within the relevant period and to follow up on that.

<b>(b)</b>	<p>A specific programme for training which is needed to maintain the system had not been identified and a prior identification on the information, reports and forms required for management had also not been carried out. Although the assistance of a programmer had been sought for such needs had been made, a long-term solutions for that had not been identified.</p>	<p>About 650 officers have already been trained on the use of MSMIS, estimates have been prepared for the training of another 950 officers and submitted for approval and the approval has been obtained for a part of it , further, about 120 officers have been trained and completed from the approved part , everyday computer reports requested by the users in each section have already been prepared and incorporated into the system for their own use and actions will be taken to prepare the specialized computer records required for the analysis of information required by the Accounts Division, Management, Audit Division and other divisions occasionally by a programmer and to be provided in future.</p>	-do-
<b>(c)</b>	<p>The local purchases made by institutions affiliated with the Medical Supply Management System (MSMIS) from 06 June 2019 had to be done only through that system as per the letter dated 08 July 2019 MSD/ICT/MSMIS-LP / 2019 of the Deputy Director General of Medical Supplies. However, granting the approval for the request made from that system by the Peradeniya Teaching Hospital (LP Request ) to the Medical Supplies Division was delayed due to various reasons. Until that</p>	<p>Because of some changes had to make in the computer system while performing this task through the computer system this was properly implemented from 01 August 2019 and after that the necessary arrangements will be made to purchase the items in the Drug Formulary Register locally through the computer system.</p>	-do-



<p>approval is received, bids were being made manually and orders were being placed for the selected supplier and after receiving the approval, the manual process was being incorporated into the computer management system. Accordingly, it was observed that the transactions related to unapproved medical supplies are not entered into the computer system.</p>		
<p>(d) The approval of the Cabinet of Ministers had received on 29 March 2017 for the project of Strengthening Drug Storage Facilities in Government Hospitals and Health Institutions at the estimated cost of Rs. 712.08 Million with the aim to increase the space for storage of medicines, modernization of old pharmacies, providing of storage shelves systems and necessary equipment, improvement of communication, cold storage and transport facilities in 866 units of hospitals under the Ministry of Health, Divisional Medical Supplies Divisions (RMSD), Base Hospitals, Divisional Hospitals and Primary Care Units.</p>	<p>A sum of Rs. 86.23 Million was received for the project of modernizing the drug storage facilities of 866 Hospitals, Divisional Medical Supplies Division (RMSD), Base Hospitals, Divisional Hospitals and Primary Care Units under the Ministry of Health and from that amount, provisions have been made for 31 institutions, to carry out the work, supervision and follow up should be made by the relevant Director of Divisional Health Services or Heads of Institutions, under this, some health institutions have totally completed the works , provisions made for the year 2021 have been provided to 91 health institutions, the officers above should complete this work before 31 December 2021 and inform the Medical Supplies Division and even though the work had not been completed by May 2021 the works are expected to be</p>	<p>Responsibilities for planning, implementing and monitoring the achieving of performance of the project should be specifically assigned to the officers and arrangements should be made to utilize the provisions made available within the relevant period and to follow up on that.</p>

completed by 31 December 2021 .

### 3.4 Procurements

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 The following observations are made.

<b>Audit Observation</b>	<b>Comments of the Accounting Officer</b>	<b>Recommendation</b>
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<p>(a) Although it was the policy of the Medical Supplies Division to issue orders to the State Pharmaceutical Corporation with a supply period of 11 months for the purchase of the estimated medical supplies, the State Pharmaceutical Corporation had failed to provide medical supplies without delay. About 80 per cent of the orders submitted to the State Pharmaceutical Corporation for the year 2020 had not been delivered on time. A period of 9 to 21 months had been spent for the procurement of 09 pharmaceutical items for which the State Pharmaceutical Corporation had commenced procurement activities in the year 2019 and this Ministry had spent between 04 months and 13 months to provide the Decision of the Procurement Committee on the procurement of 16 drug items which had been sent to the Ministry of Health for the Ministry Appointed Procurement Committee after commencing the</p>	<p>The Medical Supplies Division will prepare estimates on time and deliver the required orders to the State Pharmaceutical Corporation on time, the procurement process may take a long time as a result of delays in Technical Evaluation Committee Reports, challenging to procurement decisions, submission of appeals and deficiencies of suppliers, taking actions for regularly reviewing the progress to avoid that situation as much as possible, appointing separate standing procurement committees for pharmaceuticals and surgical materials to minimize delays in coordinating procurement activities, to review monthly procurement Standing Cabinet appointed Procurement Committee in collaboration with the Ministry of Finance .</p>	<p>Actions should be taken to make remedies to minimize the delay in reviewing the reasons for the delay in providing of medical supplies, to draw the attention of the State Pharmaceutical Corporation and the Procurement Committees and Technical Evaluation Committees of the Ministry and to identify and implement strategies as required and purchases from the local market should be kept at a minimum.</p>

procurement activities in the year 2019 . Appropriate actions had not been taken to minimize the spending more time in different layers than planned for the procurement process and though the delays of the supplier cause delays in medical supplies to identify those causes and to minimize delays. Due to this delay, very expensive medical supplies were procured from the local market every year. The total cost of medical supplies purchased from the local market during the year under review alone was Rs. 6,265 Million.

**(b)** Twenty one institutions, including hospitals and universities, have performed PCR tests to detect the COVID-19 virus and Medical Supplies Division had spent a sum of Rs. 762.96 Million to purchase of 1,482 PCR Kit required for these tests at various prices by the State Pharmaceutical Corporation, Hospitals and Health Institutions on behalf of the Medical Supplies Division. The following observations are made based on an audit test check carried out.

**(i)** Although the type of PCR machine available in each hospital and health institutions and the type of PCR Kit

The emergency purchases were made based on the then-existing specifications on the emergency situation at the beginning of the

Technical specifications should be prepared and approved properly studying and

suitable for that type of machine should be analyzed and the accurate specifications should be prepared, due to failure to act accordingly in the procurement made in April 2020, the bids had been called without including the main factors to be included in the specification such as approved CE IVD or equivalent, should have 2 SARS CoV 2 RNA targets, should have an extraction control preferably an endogenous human gene target, compatible with a wide range of thermal cyclers.

Covid epidemic, however, the requirement specifications have been prepared by May 2020 .

identifying the type of PCR Kit suitable for PCR machines in hospitals and their requirements and procurements should be carried out accordingly.

(ii) The technical evaluation was done to the advantage of one company based on the urgency, past experience and the type used by the Medical Research Institute (MRI), by making notes as the types of PCR Kit suggested for procurement by bidders who submitted the lowest responsive bids were incompatible with existing PCR machines or could not be tested in parallel. Similarly, it had been decided to award the contract to the bidder who had submitted the

The Medical Supplies Division has called for bids for the PCR Kit on two occasions and submitted the bids to the Technical Evaluation Committee and then submitted to the Procurement Committee on the recommendation of the Technical Evaluation Committee and made purchases with the approval of the Procurement Committee.

Actions should be taken in accordance with Government Procurement Guidelines and responsive minimum bidder should be selected with transparency.

highest price for a PCR kit justifying that the PCR kits of the bidder recommended by the Special Procurement Committee of the Ministry for technical evaluation were being used by the institutions under the Ministry of Health.

(iii) The financial loss occurred due to the fact that the purchasing of 328 PCR Kit by State Pharmaceuticals Corporation on 03 occasions at higher prices on behalf of the Medical Supplies Division and by the Medical Supplies Division was Rs. 125 million without considering the market price of Rs. 1,850 for a PCR Kit .

-do-

Necessary steps should be taken to recover the financial loss caused by violating the Government Procurement Guidelines by the responsible officials.

(c) Even though it was authorized to purchase drugs amounting to Rs.75,000 with the approval of the Head of the Institution subject to bids after confirming that there were no drugs in the Medical Supplies Division in terms of Section 19.4 of the letter No. HS / FR / 135/2020 dated 28 February 2020 of the Secretary to the Ministry of Health

Officers have been instructed not to buy drugs in excess of the limit.

Purchases should not exceed the financial limits set out in the letter of delegation of financial control.

authorizing financial control for the financial year 2020, without taking actions accordingly, 07 items of drugs and Surgical Consumables with a total cost of Rs. 1.82 Million had been purchased by the Peradeniya Teaching Hospital exceeding that limit.

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| (d) | Due to all the procurement activities related to the emergency purchases of the Peradeniya Teaching Hospital, including the evaluation and recommendation, were done by the Chief Pharmacist of the Hospital, formal internal control systems had not been put in place for those procurement activities. Therefore, it was observed that there may be an inherent risk of occurring error and fraud. | Internal control systems had not strengthened due to lack of adequate staff and the relevant officers have been instructed to recruit the required officers and to act in accordance with a formal internal control system. | A formal internal control system for procurement should be introduced in accordance with Government Procurement Guidelines. |
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### 3.5 Improper Transactions

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 The following observations are made.

<b>Audit Observation</b>	<b>Comments of the Accounting Officer</b>	<b>Recommendation</b>
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(a) The VAT amounting to Rs.398,663 had been paid to the contractor who had not registered for VAT and had been entrusted	Since it has been prepared and submitted including VAT in issuing certificates of payment by the Central Engineering Consultancy Bureau which was	Actions should be taken to recover the overpaid amount from the contractor or responsible officers .

with the repair work of the Digana sub-warehouse of the Medical Supplies Division.

the institution for Consultancy Services, VAT has been paid to the contractor due to the negligence of the officer in charge of the building and the officer in charge of the accounts and actions will be taken to re-charge the amount from the retention of the contract amounting to Rs. 303,882 and the final bills and actions will be taken not to occur such an omission in future.

(b) Liquidated damages amounting to Rs.307,884 had not been levied in terms of the agreement regarding the delay of 306 days in the completion of the construction work of the Accounts Unit of the Medical Supplies Division and a sum of Rs. 3.93 million had been paid for three unapproved variations.

Although the total variance was Rs. 3.93 Million on the changes in the bills of quantities on requirements, and for the additional works, the total variance was only Rs. 1.43 Million after deducting the value for that item on the original bills of quantities as savings from the value of the variance in bills of quantities.

Actions should be taken to recover the liquidated damages and to obtain approval for unapproved variations or to re-charge the amount.

### 3.6 Assets Management

#### Audit Observation

The total number of vehicles used by the Medical Supplies Division was 51, the registered ownership of any of these vehicles had not been transferred to the State Ministry. Fuel tests had not been done as per the Paragraph 3.1 of Public Administration Circular

#### Comments of the Accounting Officer

Necessary arrangements are being made to take over 51 vehicles from the Ministry of Health to the State Ministry which are being used by the Medical Supplies Division, actions are being taken to carry out fuel tests of vehicles belonging to the Medical Supplies Division, delays in repair works of lorries due to

#### Recommendation

Actions should be taken to transfer the ownership to the State Ministry and to carry out fuel consumption tests and to carry out repairs as scheduled.

No. 30/2016 dated 29 December 2016. Likewise, although 1 ½ year had elapsed after having approval for 04 lorries cost at Rs. 2.51 Million for repairs, those repairs had not been made.

curfew, travel restrictions and closures of the institutions due to the spread of Covid-19 virus and 02 lorries have been repaired and put into operation by now.

### 3.7 Losses and Damages

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The following observations are made.

<b>Audit Observation</b>	<b>Comments of the Accounting Officer</b>	<b>Recommendation</b>
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<p>(a) Even though the details of losses as 60 cases of Rs. 253.39 Million less than 05 years, 209 cases of Rs. 162.83 Million in between 05 to 10 years and 01 case of Rs. 813,400 over 10 years had been entered into the age analysis of further recoverable or writing off losses outlined under Note (i) of the financial statements, actions had not been taken to recover or write off those losses.</p>	<p>The loss of Rs. 4,479.59 Million relating to 05 incidents out of the losses with regard to 269 incidents were further to be recovered or deducted for less than 10 years amounting to Rs. 416.22 Million have been submitted to the Verification Branch of the Ministry of Health for further action to be taken from the relevant parties and write off from the book, preliminary investigation reports on a loss of Rs. 813,400 for a case of more than 10 years were submitted to the Verification Branch of the Ministry of Health, flood damages Rs. 199.26 Million has been submitted to the Treasury for approval to be written off from the book and at the instance of the remaining 264 cases, the activities of writing off from the book have been commenced and being processed.</p>	<p>Actions should be taken to recover the relevant losses and damages in accordance with Regulations 103 to 108 of the Financial Regulations.</p>



- (b) Actions had not been taken to remove or to send different sizes of 945 units of Kumtscher Cloverleaf Nail For Femur Accessories and 08 more stock items remained as non-moving items which had been in the operation theater premises of Peradeniya Teaching Hospital for a long time as on 04 September 2020 to other hospitals. Similarly, 706 units of expired Austin Moore Prosthesis (A.M.H. Prosthesis) cost at Rs. 1,863,211 had not been included in the inventory. Further, Lady Ridgeway Children's Hospital had purchased 16 drug items valued at Rs. 1.37 Million during the year under review with a short shelf life of between 3 months and 11 months.
- These devices, which have been imported from time to time for many years are now in decline due to the addition of new devices, these devices are received to the store on orders made by specialist doctors, although the device is the same, due to differences in their sizes, the entire stock is released to the operation theatre, it is essential that these devices be sterilized in all sizes before starting surgery and that keeping them in the main store affect emergency surgeries and as these devices belonging to the consumable category, maintaining of an inventory is not carried out after issuance.
- Steps should be taken to prepare realistic estimates in such a way as to minimize the variance between the actual consumption and the estimated value minimize and to make orders based on that, reduce expirations as much as possible by conducting frequent studies on declining demand for slow moving items. Purchasing items with a short shelf life should be limited as much as possible and if there are parties responsible for the expiration, the loss should be recovered from them.
- (c) Even though the drugs that cannot be used in a District General Hospital should be disposed of on a quarterly basis, according to the Manual on Management of Drugs issued by the Ministry of Health, Safety and Nutrition in 2008, the Polonnaruwa District General Hospital had not carried out such disposal activities from the year 2016 to the year 2021 and actions had not been taken
- Agree with the observation. Due to the problems encountered by the Sri Lanka Pharmaceuticals Corporation in disposing of failed quality drugs in the recent past, the disposals had been delayed and necessary instructions have been given to expedite these disposal activities at present.
- Actions should be taken in accordance with the Manual on Drug Management.

even by 31 January 2021, to dispose of 84 types of expired drugs as at 31 December 2015 at Anuradhapura Teaching Hospital with a cost of Rs. 10.19 Million

### 3.8 Uneconomic Transactions

#### Audit Observation

The Medical Supplies Division had incurred Rs.294.86 Million on 152 occasions for the clearance of donations received from foreign countries for the hospitals and health institutions under the Ministry of Health during the year under review. Because of the matters such as delays in providing approval by the Ministry of Health, delays in submission of documents, delays in receiving the approval of National Medicines Regulatory Authority, delays in receipt of financial allocations, delays in receiving of the approval of the Department of Import and Export Control, a sum of Rs. 16.98 Million had been paid as demurrage charges in clearing of the donations and as a result of failure to proper planning of the role of

#### Comments of the Accounting Officer

Only donations from UNICEF are received with notice in advance, it had not happened to pay a considerable late fee in clearing those donations, clearance is commenced as soon as it is reported that the donated items have arrived at the airport and port without prior notice, a demurrage has to be paid as it takes a considerable amount of time to prepare the documents and obtain the relevant approvals and that there has been an unavoidable delay about 2 weeks for obtaining the approval of the Medicines Regulatory Authority, about one week for obtaining the license of the Controller of Imports and Exports, about one week for obtaining the approval for exchange , about one week for debiting the import license, a considerable time to withdraw the fine which had to be paid due to importing of goods without obtaining the import license and as a result of the limited working hours of the

#### Recommendation

Delays in the clearance of donations from foreign countries should be minimized.

clearance , demurrage charges of Rs. 8.1 Million had to be paid in 04 instances.

Department of Imports and Exports, because of the closure of the country due to the Corona epidemic from March 2020, the offices of airlines, shipping companies and service offices of the Inland Revenue Department were closed, due to the restrictions made by the Customs Department and the Ports Authority.

### 3.9 Management Inefficiencies

#### Audit Observation

The Medical Supplies Division had not taken necessary steps to recover Rs. 395.50 Million of debts which had elapsed for more than 05 years for drugs issued to hospitals and institutions owned by other government agencies.

#### Comments of the Accounting Officer

The Medical Supplies Division has commenced activities to recover the dues from drugs by informing monthly to the companies which provides pharmaceuticals from 2021 and the relevant institutions have also been informed to recover the dues for the previous years.

#### Recommendation

Collection of debts should be expedited.

### 4. Achieving the Sustainable Development Goals

#### Audit Observation

In order to act in accordance with the Sustainable Development Act No. 19 of 2017, it had to manage its resources efficiently in order to achieve the objectives of Sustainable Development Act No. 19, 3.6, 3.9,11 and 11.2 . Nevertheless, the Ministry had not prepared

#### Comments of the Accounting Officer

As it is a new State Ministry established on 09 August 2020 , it took a long time to recruit adequate staff and although it was not possible to act directly according to the Sustainable Development Act No. 19 of 2017,

#### Recommendation

Relevant programmes should be prepared and implemented to achieve the Sustainable Development Goals.

programmes to achieve those objectives

actions have been taken to operate the resources received by the Ministry efficiently.

## 5. Good Governance

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### 5.1 Performing Services to the Public

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#### Audit Observation

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Although an Information Officer had been appointed to deal with information requested by citizens under the Right to Information Act No. 12 of 2016, an officer had not been appointed to deal with the appeals.

#### Comments of the Accounting Officer

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Since it is a new State Ministry established on 09 August 2020, time was taken to recruit adequate staff, that an information officer and an appeals officer could not be appointed and the instructions have been given as such officers should be appointed.

#### Recommendation

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It should act in accordance with the Right to Information Act.

### 5.2 Internal Audit

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#### Audit Observation

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An Internal Audit Division had not been established for the State Ministry of Production, Supply and Regulation of Pharmaceuticals in accordance with the provisions in Section 40 of the National Audit Act No. 19 of 2018 .

#### Comments of the Accounting Officer

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Although the post of Chief Internal Auditor and two Auditors have been approved to the staff of this Ministry, an Internal Audit Division could not be established since officers had not been appointed to those posts and requests have been made to the Ministry of Public Administration to obtain the required officers.

#### Recommendation

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Actions should be taken in accordance with the provisions of Section 40 of the National Audit Act No. 19 of 2018.

### 5.3 Audit and Management Committee

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#### Audit Observation

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Although 04 Audit and Management Committee meetings are required to be held annually on a quarterly basis, according to the Management Audit Circulars No. DMA/2009 (1) dated 09 June 2009, No. DMA / 2009 (1) (i) dated 28 January 2016 and DMA /1-2019 dated 12 January 2019 , though about 10 months had elapsed since the inception of the Ministry, there was not even a single Audit and Management Committee meeting had been held.

#### Comments of the Accounting Officer

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It could not hold the Audit and Management Committee meetings because of the limited officers available due to the current situation of Covid 19 are also busy, and also the absence of a Chief Internal Auditor and arrangements have been made to hold Audit and Management Committee meetings in future.

#### Recommendation

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Actions should be taken in accordance with the provisions of Section 41 (1) of the National Audit Act No. 19 of 2018.

### 6. Human Resources Management

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The following observations are made in this regard.

#### Audit Observation

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- (a) Out of 700 approved posts for the Medical Supplies Division, 209 posts were vacant as at 31 December 2020 and it was observed that the vacancies in 02 posts of Assistant / Deputy Director (Information and Communication Technology), 04 posts of Assistant Director (Medical Supplies), 02 posts of Special Grade Pharmacist, 06 posts of Information and Communication Technology Officer, 45 posts of Medical Supply Assistant, 06 posts of

#### Comments of the Accounting Officer

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These vacancies have been notified when submitting the details of the staff to the Ministry of Health and it has been informed to fill the vacancies as well.

#### Recommendation

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Actions should be taken to fill the vacancies considering the requirements.

Fork Lift Operators, 28 posts of packer and 58 storekeepers for many years have been an impediment to the proper and efficient operation of the medical supply process.

(b) Five employees in 03 approved posts had been deployed in excess.

(c) The State Ministry was established on 09 August 2020 and it was observed that the existing vacancies of about 82 per cent of the total number of employees may be an impediment to the proper and efficient functioning of the Ministry.

Necessary steps will be taken to include the posts of the 05 employees who were deployed in excess into the approved staff.

Actions are being taken to fill the staff vacancies.

Actions should be taken to remove the excess employees or to revise the number of approved posts.

Actions should be taken to fill the vacancies considering the requirements.