### **State Pharmaceutical Manufacturing Corporation - 2021**

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1. Financial Statements

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### 1.1 Opinion

The audit of the financial statements of the State Pharmaceutical Manufacturing Corporation for the year ended 31 December 2021 comprising the statement of financial position as at 31 December 2021 and the statement of comprehensive income, statement of changes in equity and cash flow statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, 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 and Finance Act No. 38 of 1971. My comments and observations which I consider should be report to Parliament appear in this report.

In my opinion, the accompanying financial statements give a true and fair view of the financial position of the corporation as at 31 December 2021 and its financial performance and its cash flows for the year then ended in accordance with Sri Lanka Accounting Standards.

1.2 Basis for Opinion

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I conducted my audit in accordance with Sri Lanka Auditing Standards (SLAuSs). My responsibilities under those standards are further described in the Auditor's Responsibility for the audit of the financial statements section of my report. 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 Management and those charged with Governance for the Financial Statements

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Management is responsible for the preparation of financial statements that give a true and fair view in accordance with Sri Lanka Accounting Standards and for such internal control as management determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the corporation's ability to continue as a going concern, disclosing, as applicable matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the corporation or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the corporation's financial reporting process.

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

### 1.4 Auditor's Responsibility 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 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, they could reasonably be expected to influence the economic decisions of users taken 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 scepticism throughout the audit. I also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my 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.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the corporation's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the management.
- Conclude on the appropriateness of the management's use of the going concern basis of accounting and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the corporation's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my auditor's report. However, future events or conditions may cause the corporation to cease to continue as a going concern.
- Evaluate the overall presentation, 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.

The scope of the audit also extended to examine as far as possible and as far as necessary the following;

• Whether the organization, systems, procedures, books, records and other documents have been properly and adequately designed from the point of view of the presentation of information to enable a continuous evaluation of the activities of the corporation, and whether such systems, procedures, books, records and other documents are in effective operation;

- Whether the corporation has complied with applicable written law, or other general or special directions issued by the governing body of the corporation.
- Whether the corporation has performed according to its powers, functions and duties; and
- Whether the resources of the corporation had been procured and utilized economically, efficiently and effectively within the time frames and in compliance with the applicable laws.

### 1.5 Receivable and Payable Accounts

1.5.1 Receivables

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Audit Observation	Comment of the Management	Recommendation
Rs.4,162,500 to be received for the drugs	Only Rs.4,162,500 related to 02	Action should be
supplied to the State Pharmaceutical	invoices will be charged at this time	taken action to
Corporation had failed to be recovered by	due to sometime taken to settle the	follow-up regularly to
27 May 2022.	performance bond issue with the State	collect the arrears
	Pharmaceutical Corporation.	money.
1.5.2 Payables		
Audit Observation	Comment of the Management	Recommendation
Out of the trade creditor balance of	This has been difficult to make	Creditors should

Rs.556,216,467 as at 31 December 2021, Rs.11,223,744 had exceeded the period from year 01 to year 04, but had not been settled by 25 March 2022.

This has been difficult to make payments due to non-receiving of necessary documents, incompleteness of received documents, incompleteness of relevant confirmations and incompleteness of some tasks.

Creditors should arrange formal settlement within the stipulated period.

1.6 Non-compliance with Laws, Rules, Regulations and management decisions etc.

	rence to the Laws, s and Regulations	Non-compliance	Comment of the Management	Recommendation
(a)		Although employee gratuity allocations are to be made on the basis of the employee's half month's salary or remuneration for each year of full service of the employee,	Labour Commissioner have been obtained in writing regarding the provisions of the Labour Act in this	taken in accordance with the provisions of the relevant

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		instead, employee gratuity allocations were made on the basis of the employee's full month's salary. As a result, an excess of Rs.1.33 million was paid as gratuity to two officers who retired in the year under review.	directors has been authorized to approve the financial manual in accordance with chapter 2.3 of the operational manual issued by the Department of Public Enterprises and the financial manual including these payments has been approved by the board of directors.	should be complied.
(b)	Financial Regulations 570 and 571(2) of the Code of Financial Regulations of the Democratic Socialist Republic of Sri Lanka	The sum of Rs.1,870,504, which exceeded 02 years from the date of deposit, had not been settled or credited to the government revenue.	Inform the concerned parties and proceed to settle the deposits.	Should be act in accordance with Financial Regulations.
(c)	Public Finance Circular No. 438 dated 13 November 2009 and Finance Regulations 103,104 and 105.	1,841 kg of pharmaceutical raw materials and 865,376 units of packaging materials with a total cost of Rs.3,837,426 were rejected during the year under review due to various reasons, but investigations as per the Financial Regulations were not carried out to identify those responsible and recover the loss. In addition to this, action was not taken action to dispose raw material stocks that cannot be used worth Rs.1,705,675, work in progress stocks worth Rs.1,886,980 and finished goods worth Rs.152,142 properly as at 31 December 2021 and conduct investigations in accordance with the financial regulations and determine the responsible persons in accordance with financial regulations regarding the loss incurred by the corporation due to the cut- off of the rejected and	The approval of the board of directors has been received for the destruction of stocks of work in progress stocks costing Rs.1,693,902, that the arrangements are being made for the destruction of those items and that the stocks of packing materials have been disposed on the approval of the board of directors	accordance with

damaged raw materials from the stock books of the cost of Rs.3,855,964 to recover.

Although the term of acting in

(d)

Paragraph 2 of public

Administration a post shall be subject to a the position of Deputy No maximum of 03 months, an Circular 6/97 General Manager of officer had been recruited for research dated 03 February formulas and 1997 the post of Deputy General resigned, so the officer who worked as the manager of Manager formulas and research on the basis of acting the same department was for the continuous period of appointed to acting, in the more than 04 years. even though meantime, applications were called for recruitment for that position in several occasions, no qualified applicant had applied, that there was no application, recruitment has been temporarily suspended as per National Budget Circular 03/2022 dated 26 April 2022 and recruitment will be carried out as soon the recruitment ie as approved. (e) Public Although the maximum The board of directors is Should Administration amount of distress loan that empowered to approve the complied with the Circular No. 30/2008 can be disbursed per officer financial manual as per dated 31 December should be limited chapter 2.3 of Code to the 2008 Rs.250,000, а total operations manual issued by of Rs.13,656,100 had been paid the Department of Public to 107 officers as distress Enterprises and that the loans exceeding that limit in financial manual containing the the year under review. these payments has been approved by the board of directors. The committee will (f) Paragraph 4.3 of the Although the corporation be guidelines on appointed for the year 2022. shall appoint а risk management committee corporate governance to the of the Department of calculate impact the of Public Enterprises business. operational, Circular No. 01/2021 financial and non-financial dated 16 November risks and to take appropriate 2021 measures to mitigate the risks

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The officer who worked in

Establishment of the Democratic Socialist Republic of Sri Lanka and Public Administration circulars.

be

Should be act in accordance with circular provisions.

the

said

affecting the functioning of

institution.

the

committee had not been appointed until 30 May 2022.

- Public Enterprises Although only a bonus of That the board of directors (g) Circular No. PED Rs.13,500 per annum is is empowered to approve 03/2021 dated 15 payable, in addition to that, a the financial manual as per December 2021 bonus special of chapter 2.3 of the Rs.14,720,810 was paid as a operations manual issued by one the Department of Public monthly salary of employee for the year under Enterprises and the review, and a chairman's financial manual containing bonus of Rs.3,017,229 was these payments has been paid as Rs.5,000 or Rs.10,000 approved by the board of per employee. Accordingly, directors. Rs.17,738,039 had been paid as bonuses in excess of the limit approved by the above circular and without formal approval during the year under review.
- (h) Letter No DMS/F4/10/4/090/2 dated 09 March 2009 of the Department of Management Services addressed to the Secretary. Ministry of Health Nutrition and Indigenous Medicine

(i)

Paragraph 02-01

transportation Although allowances are payable to executive and non-executive officers considering the distance. transport а allowance of Rs.4,700 and Rs.3,000 respectively was paid monthly since the year 2009 regardless of the distance. According to the decision of the board of the monthly directors. allowance was increased to Rs.11,500 and Rs.6,000 respectively from the year 2019.

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The approval of the Management Services Department shall be obtained where the relevant occasions before implementing the decisions of the board of directors. Arrangements should be made to obtain coverage approval for allowances already paid.

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(ii)	Paragraph 02- 02	Although only Rs.4,000 can be paid as monthly production incentive to staff members, in contravention of this, production incentives were paid to the entire staff subject to a maximum of Rs.12,000 per month from 01 July 2011. Accordingly, the total sum of Rs.137,490,554 was overpaid as production incentives during the period from 01 July 2011 to 31 December 2021 including Rs.16,256,313 which was overpaid during the year under review.	-do	-do-
(iii)	Paragraph 02- 03	(i) Although approval was obtained to pay only Rs.2,000 per employee per month as attendance incentive, it was increased to Rs.3,500.	-do-	-do-
		(ii) If attendance incentives are paid, the remaining leave may not be paid at the end of the year, Rs.14,359,173 was paid for the remaining leave at the end of the year under review for the employees who had paid the attendance incentive.	-do-	-do-
(iv)	Paragraph 02- 04	Although gift vouchers of Rs.6,000 can be given only once per person for new year and Christmas, gift vouchers worth Rs.25,000 each to permanent employees and Rs.12,500 to trainee employees totaling Rs.7,179,875, in addition, gift vouchers with a total cost of	-do-	-do-
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		Rs.5,037,500 each were also given as Rs.12,500 to permanent employees and Rs.6,250 to other employees to purchase school books and equipment during the year under review.		
	(v) Paragraph 02- 06	Although a monthly allowance of Rs.1,000 can be paid to an employee only if he attends all the scheduled shifts, a sum of Rs.4,891,000 was paid as service shift allowance to executive, trainee executive and non- executive employees for each staff attended by Rs.400, Rs.300 and Rs.200 respectively during the year under review and the overpaid service allowances were Rs.2,575,000.	-do-	-do-
(i)	Decision No. BP/30/15 dated 04 June 2015 of the Board of Directors	Bicycle loans paid to the employees of the corporation were increased from Rs.3,000 to Rs.20,000 form 04 June 2015, but treasury approval for that purpose had not been obtained by the date of audit.	-do-	Treasury approval should be obtained as per Board of Directors decision.

#### Non-compliance with Tax Regulations 1.7

Audit Observation	Comment of the Management	Recommendation
According to the tax report submitted online	This happened due to an error in	Differences accor
by the corporation to the Inland Revenue	the Inland Revenue Department's	to the tax report of

by the corporation to the Inland Revenue Department on 30 December 2021 in relation to the assessment year 2021/2020, it was stated that Rs.166,941,903 was paid as selfassessment but the actual selftax, assessment tax payment was only Rs.166,351,979 according to the tax audit reports and payment vouchers in the corporation and due to that the difference was Rs.589,924. Reasons for the difference were not disclosed.

the Inland Revenue Department's computer system, there is no mistake in tax calculation or accounting and that will be discussed with the Inland revenue Department to get a correct report in this regard.

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\_\_\_\_ ording to the tax report of the Inland revenue Department and tax audit report of the corporation should be

compared.

### 2. Financial Review

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### 2.1 Financial Result

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The operating result of the year under review amounted to a profit of Rs.1,006,185,465 and the corresponding profit in the preceding year amounted to Rs.1,017,364,317. Therefore, a deterioration amounting to Rs.11,178,852 of the financial result was observed. The main reasons for the deterioration were increasing selling and distribution expenses by 122 percent and tax expenses by 59 percent.

### 2.2 Trend Analysis of Major Expenditure Subjects

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The selling and distribution expenses of the previous year and the year under review were Rs.49,137,643 and Rs.109,186,789 respectively and the expenditure had increased by 122 percent in the year under review compared to the previous year. It included sales promotion discounts and a 101 percent increase in expenses.

### 2.3 Ratio Analysis

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The gross profit ratio and net profit ratio of the year under review had decreased by 1.1 percent and 0.7 percent respectively compared to the previous year and there was an increase of 21.4 times in debtor turnover ratio and a decrease of 42 days in debt recovery time.

- 3. Operational Review
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- 3.1 Management Inefficiencies

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Audit Observation

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- A building which had been purchased and (a) expenditure renovated at an of Rs.133,767,599 for the purpose of establishing a public testing laboratory and a training school was closed and idle from 20 August 2019 to 27 May 2022 and this situation was due to that the corporation had no prior planning or preparation to complete any of the other requirements to be fulfilled for the establishment of the laboratory and training school. This had been pointed out in the audit reports on several occasions, but the corporation authorities had not taken proper measures for it.
- (b) Due to non-annual review of residual value and useful life for non-current assets, fixed assets costing Rs.667,436,317 were fully depreciated, but continue to be utilized.

### Comment of the Management

The approval of the board of directors has been granted to price quotes for the sale or lease of the Horana Bulathsinhala building where the laboratory and training school were to be established and that advertisements have been published in the newspapers on 13 February 2022.

Recommendation The building should be utilized according to a specific plan.

Although fully depreciated in the year 2021, the depreciation process has been completed and the draft report has now been received for the fixed assets to

Actionshouldbetakenasperparagraph51ofStankaAccountingStandard16.

be further utilized and the necessary provisions in the accounts will be made during the year 2022 after the receiving of the final revaluation report.

(c) 101 items with a cost of Rs.8,302,287 included in non-current assets had not been subjected to the physical survey conducted for the year under review as at 31 December 2021 and those items were also not identified as deficiencies. That reasons for not being physically surveyed are being monitored by a fixed assets committee and that relevant information will be submitted for audit in future. All non-current assets of the corporation should undergo physical survey and deficiencies and excesses should be identified and reported.

### 3.2 Operational Inefficiencies

# Audit Observation

(a) There was a difference of 120 million units of 81 types of drugs between the total production requirement identified according to the sales plan and the monthly production plan.

- (b) According to the marketing plan, the total production requirement identified was 1,877 million units of 58 types of drugs, but actual production was only 1,127 million units of 25 drugs.
- (c) Due to the increase in the ability of tablets to be break into small pieces during the reviewed year, variations in the weight of the tablets, bad appearance and difficulty in breaking the tablets, the production had to be stopped and remanufactured and due to that, the additional cost of Rs.2,749,960

### Comment of the Management

The production requirement of the marketing department is prepared base on the existing stock levels and market demand, the monthly production plan is prepared with considering the types of raw materials available in the warehouses and their quantities, the existing machines and their capacities and the product formulas etc. approved by the National Drug Regulatory Authority and such changes may occur in such cases.

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The quality assurance system is important to reduce the need to reproduce in an institute, confirm that the final product is in the right condition from the raw materials of the same standard for this, the production of the same method, but due to the tender system, the

#### Recommendation

The full effort should be made to reach the targets of the annual sales plan and the monthly production plans should also be adhered.

Realistic production and marketing plans should be prepared to produce products with maximum efficiency and effectiveness.

Action should be taken to improve the quality of drugs and reduce production problems. was spent. Action was not made to reduce these bad conditions that occur in the production process every year.

- (d) 07 types of drugs produced by the corporation that exceeded the maximum selling price determined by the National Drugs Regulatory Authority were priced lower that the cost of production and a loss of Rs.38,593,701 had to be incurred during the year under review due to the sale of 03 drug items below their production cost.
- (e) Out of the 72 types of drugs with a sales value of Rs.2,714,300,224 to be planned sell to the medical supplies division in the year under review, it had not been able to achieve the supply target of 1,202 million units. Out of that, the corporation had failed to achieve the total supply of 18 drug items, which had expected a supply target of 375.7 million units with sales value a of Rs.558,481,531 and 50 percent supply of 6 pharmaceutical items that expected a target of 465.4 million units with a total supply and sales value of Rs.666,007,940.
- (f) The corporation had failed to supply 785 million units of drugs with a sales value of Rs.1,927,233,717 from the drugs ordered by the medical supplies division for the year under review due to various reasons such as non-availability of raw materials, insufficient machine capacity, technical defects in production process etc.

price of raw materials purchased varies by several times, therefore, the quality assurance system cannot be maintained properly and re-productions can occur in such an environment.

Although both Cloxacillin capsule BP 500 mg (Blister) and Diltiazem tablets 60 mg (Blister) have received requests for open market sales among the product items mentioned here, the products could not be sold in the open market due to the lack of facilities to provide them as blister packs and the price will be determined on the basis of cost and market prices in future when those products are introduced in the open market.

The marketing plan guides the company's planning activities for the next year and it is only a rough estimate, that there are instances when a marketing plan cannot be achieved as same and that these values may increase or decrease by a certain percentage. The price should be decided as not to cause loss to the corporation and at least covers the cost of production.

A realistic annual marketing plan should be prepared and it should be revised with a formal approval with necessary and full efforts should be given to achieve the targets.

There were no comments.

The corporation should try its best to fulfill the orders of the medical supplies division while minimizing the existing disruptions and protect its market share.

- (g) Out of the 2,076 million units of medicine supplied to the medical supplies division for the year under review, the sales value of which was Rs.5,300,782,520, only 1,338 million units of drugs with a sales value of Rs.2,140,206,445 were provided from the corporation's products due to that the corporation has not worked as its maximum capacity and the remaining sales value of 738 million units of drugs amounting to Rs.3,160,576,075 were provided by joint venture supplies.
- (h) The corporation had failed to supply 136,964 units of drug packaging with a sales revenue of Rs.85,707,417 related to 50 orders taken form the selected distributors as a sample for medicines manufactured by the corporation only during the period of 03 weeks from 11 November 2021 to 30 November 2021.

entire demand of the the distributors during the year under review to insufficient due production capacity and the marketing department is able to reach higher sales targets further through increasing the production capacity of the corporation.

The corporation could not achieve

The most of the products produced

relatively low-volume and high

cost items and we are currently

focusing on the production of

expensive imported drugs in the

processed Lotus Pharma Project.

ventures

are

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through

- (i) The corporation had failed to supply 988,283 drug packaging units with a sales value of Rs.444,538,751, which ordered by the State Pharmaceuticals Corporation, during the year under review and it was possible to provide less than 30 percent
- (j) Board of Directors approval was not obtained for the current sales process system (Sales process) in the sales division and the gate pass numbers were not recorded in the invoices issued by the department. Some other invoices were not approved and some invoices were not signed as checked but that were approved.

The lack of sufficient production capacity of the corporation, the lack of sufficient stocks of the corporation's products due to periodic changes in the orders given by the SPC and the inability to provide emergency demand quantities have mainly affected the failure to reach the monthly sales targets of the State Pharmaceuticals Corporation.

There is currently no sales process system in the sales division, only the rough layout of the sales process currently in practice was given at the request of the audit division, the approval of 03 invoices has been avoided, it will not happen again and that all these deficiencies will be avoided in the year 2022. The corporation should work at its maximum production efficiency to select the most profitable product mix.

The production capacity of the corporation should be increased to be able to provide a supply that according to the demand and orders should be completed with consent monitoring of existing stock.

Action should be taken to increase the production capacity to be able to provide the supply that according to the demand.

A sales process system should be developed, approved and implemented.

- (k) Rs.853,500 deposited in 24 clearing companies had failed to be recovered even though the clearing activities had been completed during the period from the year 2017 to the year under review.
- Although the total of material cost, (1)employee cost and absorption cost in relation to a sample of 04 sales orders in the sales cost schedule created by the computer system in relation to the sales made to the medical supplies division reviewed during the year was Rs.38,182,618, it was Rs.52,400,228 according to the sales order value and the difference was Rs.14.217.610. Reasons for the difference were not disclosed.
- 3.3 Procurement Management Audit Observation

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- It was not followed the guidelines 4.2.1 and (a) 4.2.3 of the code of procurement guidelines in 04 cases of purchase of pharmaceutical raw materials and packaging materials at an expenditure of Rs.127,517,807 during the year under review. Also, bid opening committees were not appointed as per guideline 6.3.3 (a) and the opening of bids was not recorded in a prescribed form as per the guideline 6.3.6. Orders had been placed with the supplier before the approval of the procurement committee and the contract registration certificate under the Public Contracts Act had not been obtained from the supplier. As per the guideline 5.4.10 (b), performance security was not obtained.
- (b) 6,000 kg of raw material Paracetamol DC 90 at a cost of Rs.11,068,650 had been purchased from three suppliers. The procurement committee had recommended that the tender samples of the suppliers should be approved by the corporation's laboratory, but the samples had not been

Relevant parties will be informed and action will be done to settle these deposits.

A separate module is maintained in the computer system for cost of sales, in some cases, the cost of sales is not recorded correctly in the system even though the sales returns are recorded correctly in the ledger and in some cases; the necessary steps are taken after notifying the relevant computer company.

Deposits should be recovered as soon as the clearances are completed.

Regular inspections and comparisons should be made in the numerical differences between the reports and documents related to each division maintained as control strategies.

Comment of the Management

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The procurement plan and procurement schedule prepared in accordance with guidelines 4.2.1 and 4.2.3 of the procurement guidelines are hereby resubmitted, a committee will be appointed to correct the deficiencies and open the bids and sign the reports and signature as according required to guidelines 6.3.3 and 6.3.6., 10 percent of the total payment will be retained as per board approval in lieu of performance security.

The manufacturers who currently supply Paracetamol DC 90 ingredients are doing the necessary work for registration with the National Drug Regulatory Authority, the interpretation given here Recommendation

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Government procurement guidelines should be followed in accordance with the code of procurements.

Government procurement guidelines for medicines and medical equipment should be done in accordance with the tested for that purpose. Further, all these three suppliers were not previous suppliers of the relevant raw materials and all three were not registered with the National Drug Regulatory Authority. The raw materials provided by two suppliers had failed the terms of requirements of disintegration time, less moisture content, less flow ability, friability and compressibility which had to be passed during the machine trial test conducted by the formula development and production department of the corporation and one supplier's machine trial test reports were not submitted for audit. Samples of raw materials were not checked and quality verified before tender evaluation. Instead, based on the analysis reports submitted by the supplier, the quality control division of corporation had released the those ingredients for the production of materials.

(c) 50 kg of Levothyroxine sodium DC granules (Manufacturing of pilot batches) had been purchased at an expenditure of Rs.689,648 and although according to the relevant order conditions, the raw materials should have a life time of 2 1/2 years from the date of receive to the island, the life time of the raw materials received was only 05 months from the date of received. It was noted that the life time of the Levothyroxine tablets 1P 50 mcg medicine produced using this raw materials is 02 years based on a declaration (Declaration letter) obtained from the supplier without asking the supplier about this or retrieving the raw material.

 (d) Although 3,000 kg of Flucloxacillin Sodium BP 2000 raw material purchased during the reviewed year costing Rs.23,331,831 was not in the required standard, it was rejected by the quality control division of the

about the quality of medicines is not correct, the quality of a drug is the standard that a drug should have at the time it reaches a patient, that problems arising in machine testing are bottlenecks in the production process and considering the high demand paracetamol of in the situation of prevailed Covid epidemic, the quality control department released the raw materials for the production medicine the of after confirming the condition of the raw materials by 100 percent.

Although basically 06 months life time is given, it can be manufactured up to 02 years by checking the quality, it is determined by the drug manufacturer that the drugs are manufactured under the full supervision and approval of the quality control division, the manufacturer has given a Quality Assurance Certificate for two years, although it is true that the life time of the relevant ingredient is 05 months from the date of received to Sri Lanka, it is possible to produce pills with a life time of two years using these ingredients and the life time of two years has been determined after conducting accelerated stability studies.

The supplier has basically agreed to pay the value related to the stock of rejected raw materials to the corporation and that the Code of government procurement guidelines for drugs and medical equipment should be

procurement should also be done in accordance with the recommendations of the procurement committee as well as the terms of order.

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guidelines

subsequent

corporation on 25 June 2021, but the corporation has not taken action to replace the stock of raw materials or recover money from the supplier or take any other action against the supplier until 27 May 2022. Also, the performance bond of Rs.6,999,549 related to this procurement had expired on 30 September 2021 and it had not been monetized or updated before.

necessary arrangements are being made for that. The performance bond has not been updated and that the stock will be replaced as soon as possible or the relevant cost covered. followed and subsequent

procurement should be done in accordance with the recommendations of the procurement committee as well as the terms of order.

### 3.4 Management of Joint Ventures

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Audit Observation

- (a) The corporation had entered into agreements with 17 potential investors for the supply of drugs under the proposal to start joint ventures between the State Pharmaceutical Manufacturing Corporation and appropriate private investors to expand the process of manufacturing drugs locally, but drugs had been purchased from only 04 investors as at 31 December 2021.
- The corporation had conducted quality (b) checks for only 21 items out of 56 items of drugs and surgical consumables purchased from joint venture and supplied to the medical supplies division during the year under review. Accordingly, the corporation had provided 35 items to the medical supplies division without taking any steps to check their condition. Among them, although 03 items of surgical consumables were purchased from one investor and supplied to the medical supplies division, the supplier had directly sent the samples to the Industrial Technology Institute (ITI) and purchased based on the quality test reports obtained due to the corporation did not have the necessary facilities to check the quality of the materials. Accordingly, it was observed that there was no sufficient independent verification of the quality of the drugs supplied to the medical supplies division under the joint ventures.

# Comment of the Management

Although signed joint venture agreements with 17 investors, two of them have not built factories and out of the remaining 15 investors, only 4 investors have the necessary manufacturing facilities and qualifications to supply drugs to the medical supplies division.

It was not possible due to the covid 19 epidemic situation throughout the year 2021 to get the consumables spare parts required for the chemical substances required to carry out the quality inspection work on behalf of those material items and the scientific equipment used for the analytical work, that they went to the ITI institute and did a study for the surgical consumables and after purchasing the necessary equipment for that, the above mentioned quality checks will be carried out in the laboratory of the State Pharmaceutical Manufacturing Corporation from the year 2022.

Recommendation

Arrangements should be made to start joint ventures by encouraging other investors who have signed agreements.

corporation The should be carried out adequate independent verification of the quality of drugs supplied to the medical supplies division under the joint ventures.

- The selling price was to be decided by (c) adding a profit margin of 20 percent to the cost of production of drugs and surgical consumables manufactured by the joint cost venture investor. The total of production of 01 drug item purchased from one investor and sold to the medical supplies division during the year under review was Rs.6,262,252. The investor had supplied the item to the corporation for Rs.6,112,800. The corporation had added service charges of Rs.2,235,696 to the invoice value and sold it to the medical supplies division for Rs.8,348,496. The profit margin of 33 percent of the production cost of the drug item was charged by the investor and 37 percent of the profit and service charge by the corporation.
- (d) Although the accounting policy of providing drugs to the medical supplies division with a profit margin of 6 percent on the purchase price for joint venture supplies was disclosed in the financial statements, the corporation had earned profit from 17 percent to 37 percent of the purchase price on the drugs purchased from the joint ventures and supplied to the medical supplies division.
- (e) The quality control, management and technical support of the investor's production process should be provided by the corporation as recommended by the official committee appointed by the cabinet for the implementation of the joint venture proposal and 10 percent of the investor's shares in the business had to be issued to the corporation for that. However, only two investors who are currently dealing with the corporation had issued shares to the corporation and the remaining two investors had not issued their shares to the corporation by 30 May 2022.

That price committee meetings are held once in 06 months to determine the price of drugs supplied to the medical supplies division by the corporation and associated businesses, the price of this drug was decided in the price committee meeting held on 05 April 2021, although the price of a pack unit was Rs.173,927, due to the decrease in the price of raw materials of this drug, the joint venture reduced the price of a pack unit Rs.127,350 and there to was no time to get approval of the price committee again for the reduced price.

Their invoices had not been changed as per the cost sheets given by them in relation to the price change of the respective drugs in the price committee meeting held on 05 October 2021.

The directors for those investment companies will be appointed in future and those institutions are also preparing the document related to the issuance of share certificates. A profit margin of 20 percent should be added to the production cost of drugs and surgical consumables and the selling price should be decided as recommended by the official committee appointed by the Cabinet of ministers.

related The transactions should be done as recommended bv the official committee appointed by the cabinet as well as according to the accounting policies disclosed in the financial statements.

Action should be taken as recommended by the official committee appointed by the cabinet.

### 3.5 Deficiencies in Contract Administration

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### Audit Observation

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- Although Rs.6,016,902 had been spent (a) by 27 May 2022 for the construction of the proposed flyover connecting two buildings, 03 years after signing the contract with the contractor and construction, starting the the controlling authority had decided to stop the construction work after deciding that the construction was not feasible and due that, the amount spent had become an idle expenditure.
- Rs.27,550,136 were spent and (b) the initial underground filling work was done for the construction of a fourstorey administrative building and although the filling work was completed on 07 March 2018, almost 04 years had passed up to 31 March 2022, but the corporation had failed to select a qualified contractor for the construction of this building and to start the construction work.
- The construction work had started on (c) 21 September 2018 for the construction of a two-storey warehouse building to finished store medicines and Rs.36,943,060 had been spent on this construction as at 31 March 2022. The construction was supposed to be completed by 21 August 2019 according to the initial agreement, but the construction continued to be delayed and it was proposed to finish the work on 17 May 2022 according to the project performance schedule provided by the construction company,

# Comment of the Management

As a product expansion project, this project was started with the aim of carrying out the exchange of goods between two regions in efficient and standard an manner, but later. the construction of this bridge was not useful as the exchange of goods between these two regions was unnecessary and it was not correct the decision of it as an idle expense and this construction had to be stopped based on the practical decision.

This contract has been canceled due to the price of the responsive bidder who submitted the lowest bid was lower than the engineer's estimate and the fourstorey building constructed by this bidder in the year 2019 had defects and it was not built in accordance with the standards and the plan will have to be reviewed in accordance with the current requirements, the next phases will be implemented and the services of a new consulting firm will be taken.

The corporation was unable to

make the payments due to the

delay of the money to be

charged from the government by

2019

continuously delayed due to the

covid epidemic situation, that the

structure of this building was

company agreed to carry out the

project within the same cost as

by

the

work

the

and

the

was

Central

Consultancy

construction

Recommendation

Necessary steps should be taken to recover the money spent from the responsible parties who contributed to start this project without proper feasibility study.

Contract administration activities should be carried out in a formal manner in accordance with the Code of government procurement guidelines and action should also be taken to properly manage and supervise those tasks. Future activities should be planned without wasting the money spent.

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vear

construction

reanalyzed

Engineering

Bureau,

but no extension of date was made for this.

the tender was awarded by implementing those recommendations, due to the agreements made by the revising the plans as the increase in charges, they have to face a big problem financial and the construction company has agreed to complete the work by 20 April 2022.

### 3.6 Human Resource Management

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Audit Observation

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- (a) The approved number of employees was 423, the actual number of employees was 326 and the number of vacant employees was 97 as at 31 December 2021. But, 95 vacant posts were not filled up or revised the approved staff as 17 executive level posts, 48 non-executive level posts and 30 minor employee posts for the formulas, including 02 main positions of research and development division and quality control division, which are very important areas for the production process by 31 March 2022.
- (b) The recruitment procedures for 07 approved posts had failed to be approved by the Department of Management Services by 27 May 2022.

# Comment of the Management

Applicants are invited on 20 September 2020 for the posts of 02 divisional heads, the qualified applicant for the interview did not participate for the interview held on 01 December 2021, applications were called again for those 02 positions on 12 December 2021 and interviews will be conducted in future.

### Recommendation

Arrangements should be made to fill up the required posts in accordance with the recruitment procedure and in a formal manner.

The recruitment procedures related to 04 posts have been submitted for approval and the recruitment procedures related to the remaining 03 posts are being prepared and inspections are being carried out.

### Recruitment

procedures should be prepared and approved by the Management Services Department.

- 4. Accountability and Good Governance
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4.1 Annual Action Plan

Audit Observation

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 (a) The action plan that had been prepared had not been approved by the board of directors and no financial value was given for the activities related to the production, human resources, Comment of the Management

The action plan for the year 2022 will be prepared and approved by the board of directors including financial values for all activities.

Recommendation

The action plan should be formally prepared and necessary approvals should be obtained. marketing, internal audit and formula, research and development departments that were included in it.

- (b) Although the action plan should be prepared by including the performance criteria (Key performance indicators) in order to be able to evaluate the performance of the activities to be performed in the periods according to the Public Enterprise Circular No. PED 12 dated 02 June 2003, it was not possible to accurately evaluate the progress of the activities included in the action plan due to that the performance criteria of the activities included in the prepared action plan were not specified in a specific, quantitative and measurable level.
- (c) Among the 27 activities included in the action plan with an estimated cost of Rs.515.5 million. 06 activities with an estimated cost of Rs.19 million and 27 activities for which the cost was not estimated were not started during the year under review and 10 activities with an estimated cost of Rs.473 million were initiated. but not completed during the year under review. Also the physical progress achieved during the year under review was not disclosed in any of the activities.

The action plan for the year 2021 was prepared as per PED 12 circular and the performance determinants of the activities of the 2022 action plan be specifically and quantitatively included.

According to the format sent by

the Ministry of Health, while

preparing the action plan, the

progress

column indicated as a percentage

of the physical progress given in

accordingly, the percentage of

physical progress can measure

measured according

relevant

the financial progress.

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Should be act in accordance with the provisions of Public Enterprises circulars.

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