State Pharmaceutical Manufacturing Corporation of Sri Lanka - 2020

1. Financial Statements

1.1 Opinion

The audit of the financial statements of the State Pharmaceutical Manufacturing Corporation of Sri Lanka for the year ended 31 December 2020 comprising the statement of financial position as at 31 December 2020 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 reported to the Parliament appear in this report.

The financial statements give a true and fair view of the financial position of the Corporation as at 31 December 2020 and of its financial performance and its cash flows for the year then ended in accordance with Sri Lanka Accounting Standards.

1.2 Basis for Opinion

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 Management and Those Charged with Governance for the Financial Statements

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 Institute.

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 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 Institute.
- 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 Non - compliances with Laws Rules and regulations

Laws Rules etc.	and Regulations	Non - compliance	Comment of the Management	Recommendation
(a) Section Payme	n 06(2)(a) of the ent of Gratuity Act of 1983.	gratuity should be allocated based on the employee's half a month's, wage or salary for each year of completed service, instead,	The gratuity allowance is paid with the approval of the Board of Directors and action will be taken to obtain permission from the Department of Management Services in future.	payment of gratuity should be made according to the provisions of the

(b) Public Finance Circular No.438 dated 13 November 2009 and Financial Regulations 103,104 and 105.

No action had been taken to dispose of stock of unusable raw material worth Rs. 5,959,483 as 31 at December 2020, unfinished material worth 6,030,600, finished material costing Rs. 3,383 and 346 units of fixed assets costing 59,259,389 and Rs. determine the responsible persons after conducting

year under review.

The appointed Board of Surveys has identified all the relevant items and with the approval of the Board of Directors and action is being taken to dispose of them expeditiously.

Action should be taken to dispose of assets in accordance with the circular provisions and Action should be taken conduct inquiries in accordance with the financial regulations regarding unusable

inquiries according to the Financial Regulations on unusable stocks and to recover the loss as applicably.

stocks and to determine those responsible and accordingly, the loss should be recovered.

(c) Letter of the Department of Public Enterprises bearing No. PED / A / Surplus / 1/11 (i) dated 23 July 2020

Although the treasury funds investments of Rs. 24,632,603 which had been taken over by the Treasury during the year review had been accounted for as Treasury tax expenditure, other no provisions had been made for Treasury contributions for the year under review.

It has been corrected by revised accounts and accounted for as a special tax expense.

Adequate provisions should be made for Treasury contributions.

(d) Public Enterprise
Circular No. PED
03/2020 dated 18
December 2020

Although Rs. 13,500 only can be paid as bonus per employee annually as per the circular provisions, in addition, the Corporation had paid one employee's monthly salary as a special bonus for the year under review and a Chairman's bonus of Rs. 5,000 or Rs. 10,000 per employee. Accordingly, an additional amount of Rs. 16,577,284 had been paid as bonus without the formal approval during the year under review exceeding the limit approved by the Circular.

All the employees continued to work to meet the essential medicines required of the government hospitals in the midst of the Covid epidemic that affected the whole of Sri Lanka in the year 2020. Accordingly, the relevant Special **Bonus** and Chairman's Bonus were paid with the approval of the Board of Directors of the Institute to admire that service and further encourage the employees.

Action should be taken in accordance with circular provisions. Formal approval of the department that issued the circular is required deviate from the relevant circular provisions.

(e) Paragraph 2 of Public Administration Circular No. 6/97 dated 03 February 1997 Although the term of acting in a post should be subject to a maximum of 3 months, an officer had been recruited for the post of Deputy General Manager Formula and Research on an acting basis for a continuous period of more than 03 years.

Due to the resignation of the officer who served in this post, an officer who had served as the manager of that division was appointed to act; that he is performing the duty in his best in that position; that applications were called for the post on several

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occasions but no qualified candidates had applied; applications have been called for again and arrangements are being made to conduct interviews; a Board of Paper has been prepared to present the matter to the Board of Directors again and that action will be taken to implement decisions the given by the Board in this regard.

(f) Public Administration Circular No. 30/2008 dated 31 December 2008 Although the maximum amount of distress loan that could be paid to one officer should be limited to Rs.250,000, a total of Rs.12,429,500 had been paid to 101 officers as distress loans exceeding that limit during the year under review.

This Public Administration Circular is especially applicable public institutions such as departments government Management and that Circulars Service are applicable to corporations the State such as Pharmaceutical Manufacturing Corporation

The Establishments Code of the Democratic Socialist Republic of Sri Lanka and **Public** the Administration Circulars should be applied until the Establishment Code for the Corporation itself is prepared and approved by the Treasury.

- (g) Letter of the Department of Management Services addressed to the Secretary, Ministry of Health, Nutrition and Indigenous Medicine, DMS / E4 / 10/4/090/2 dated 09 March 2009
 - (i) Paragraph 02-01

Although transport allowances are payable to the executive and non-executive officers of the Corporation, depending on the distance, a transport allowance of Rs. 4,700 and Rs. 3,000 monthly had been

Action will be taken to send a letter to the Department of Management Services again regarding this matter and obtain approval. Before
implementing the
decisions of the
Board of Directors,
approval of the
Department of
Management
Services should be

paid since 2009 irrespective of the distance. That monthly allowance had been increased to Rs. 8,000 and Rs. 6,000 respectively as per a decision of the Board of Directors from the year 2019.

obtained in the relevant instances. Action should be taken to obtain covering approval for allowances so far paid.

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(ii) Paragraph 02-02

Although a sum of Rs. 4,000 only could be paid to the staff members as a monthly production incentive, contrary to that production incentives had been paid to the entire staff subject to a maximum of Rs. 12,000 per month from 01 July 2011. Accordingly, the total amount overpaid as Product Incentives Rs.121,234,241 during the period from 01 July 2011 to December 2020 including overpayments of Rs. 18,999,486 made during the year under review.

The production incentive was Rs. 4,000 when it was approved by the Department of Management Services in 2009, but the production incentive was increased to Rs. 12,000 in 2019 with the approval of the Board of **Directors** in view inflation. Action will be taken to send a letter to the Department of Management Services again regarding this matter and obtain approval.

(iii) Paragraph 02-03 (i) Although approval had been received to pay only Rs. 2,000 per employee as attendance incentive, it had been increased to Rs. 3,500.

Attendance incentive was increased to Rs. 3,500 in 2019 with the approval of the Board of Directors in view of inflation. Action will be taken to send a letter to the Department of Management Services again regarding this matter and obtain approval.

(ii) If Attendance incentives are paid, payment cannot be made for the unavailed leave at the end of the year, whereas employees who had paid the

Action will be taken to send a letter to the Department of Management Services again regarding this matter and obtain approval. - Do -

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attendance incentive were paid Rs. 12,475,703 for the remaining leave at the end of the year under review.

(iii)Although an employee can be given only the gift vouchers worth Rs. 6,000 once a year for New Year and Christmas, gift vouchers worth Rs. 25,000 each for permanent employees and Rs. 12,500 each for trainees with a total value of Rs. 7,325,000 and in addition, Rs. 12,500 per employee permanent and Rs. 6,250 per other employee with a total value of Rs.4,712,500

> had been paid during the year under review to purchase school books

and equipment

With the approval of the Board of Directors, New Year allowance has increased been to Rs. 25,000 and the Christmas allowance to Rs. 12,500 in 2019, taking into account inflation. Action will be taken to send a letter to the Department of Management Services again regarding matter and obtain this approval

(iv) Paragraph 02-06

Although monthly allowance of Rs. 1,000 can be paid only if an employee attends all the scheduled a sum of Rs. 6,981,100 had been paid as service shift allowance the year during under review as Rs.400, Rs.300 and Rs.200 respectively for executive, trainee executive and non-executive employees for each shift of service attended and the overpayment of service shift allowance had been Rs. 3,549,100.

All these allowances are being paid with the approval of the Board of Directors at present and action is being taken to obtain the written approval of the Department of Management Services for this purpose.

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(h) Decision of the Board of Directors No. BP / 30/15 dated 04th June 2015.

Although the bicycle loan paid to the employees of the Corporation had been increased from Rs. 3,000 to Rs. 20,000 from 04 June 2015, the Treasury approval had not been obtained for that purpose.

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2. Financial Review

2.1 Financial Results

The operations of the Corporation for the year under review had resulted in a profit of Rs. 1,017,364,317 as compared with the corresponding profit of Rs. 434,777,878 for the preceding year, thus resulting in an increase of Rs. 582,586,439 in the financial results. This increase was mainly due to increase in the sales income by 35 per cent.

2.2 Trend analysis of the key expenditure items

Sales and distribution expenses during the year under review were Rs.99,189,983 and Rs.49,137,643 and that expenses had decrease by 50 per cent in the year under review compared to the preceding year. This was mainly due to the 86 per cent decrease in sales promotion expenditure included in it.

2.3 Ratio Analysis

The gross profit ratio and net profit ratio for the year under review had increased by 1.9 percent and 4.7 percent respectively in the year under review compared to the preceding year while the debtors turnover ratio had increased by 3.6 times and the recovering period of debt had decreased by 64 days.

3. Operating Review

3.1 Identified Losses

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Audit Observation

During the year under review, 3,105.25 kilograms of pharmaceutical raw materials and 292,938 units of packaging materials had been rejected due to various reasons, resulting in a loss of Rs. 3,429,299.

Comment of the Management

These stocks had been rejected due to expiration, mechanical rejection, rejection due to packaging damage and removal of stocks due to the introduction of new products.

Recommendation

A formal investigation should be conducted into the quality failure and expiration of the raw material and packaging material and action should be taken to identify the parties responsible for the

loss and recover the loss

3.2 Operating Inefficiencies

Audit Observation

- (a) A building which had been purchased and renovated at a total cost of Rs. 133,767,599 with a view to establishing a general testing laboratory and a training school was closed from 20 August 2019 to 31 October 2021 and this situation had arisen due to the lack any prior plan or preparation for any other requirements to be met for setting up a laboratory and a training school.
- commenced (b) Having construction 06 August on 2017, the Cephalexin manufactory was modernized at a cost of Rs.89,898,864 and completed by 09 August 2019. But no action had been taken to obtain the necessary approvals or purchase of the necessary machinery for the manufacture drug. of the Cephalexin Thereafter, plans had been drawn to start production of Levothyroxine tablets IP 50mg therein and a sum of Rs. 3,798,296 had been spent for the opening ceremony of the factory premises 23 on December 2020. But no pharmaceuticals whatsoever been manufactured commercially in this factory even as of 31 October 2021.

Comment of the Management

This property was purchased in 2017 with the decision to establish a Proposed Pharma zone in the Kalutara, Welipenna and Bulathsinhala areas. It was expected to establish a training center for the employees of the factories that start joint venture with the Corporation and a general testing laboratory here to maintain the quality of the manufactured drugs and that due to failure carry out these activities, the matter was referred to the Board of Directors for taking a decision on the sale of the property.

The Cephalosporin manufactory was started due to high demand for the drug Cephalexin capsules from both the public and private sectors, but when manufactory was completed, there was not adequate demand for the drug. Accordingly, it was later decided to replace the Cephalexin capsules with Levothyroxine tablets and Flucloxacillin capsules, but approval of the Drug Regulatory Authority has not so far been given for the production of those drugs. After a preliminary supervision, several changes had been proposed and on completion of the work it is ready for a second monitoring.

Recommendation

Steps should be taken according to a specific plan to utilize the building.

Plans should be made to meet other relevant requirements to gain the maximum benefits from the investments. (c) The residual value and useful life of non-current assets at a total cost of Rs.328,849,588 had not been reviewed annually.

Our institute has appointed a Fixed Assets Committee to deal with all matters relating to fixed assets. That committee identifies the status of fixed assets, their useful life and ineffective assets and takes action to remove such ineffective assets. Similarly, action has been taken to estimate fixed assets in accordance with Sri Lanka Accounting Standards since 2020. However, in the face of the ongoing epidemic in the country, it has become impossible to do this work and this work will definitely be carried out in the year 2021.

Action should be taken in accordance with paragraph 51 of the Sri Lanka Accounting Standards 16. The financial statements for the year 2021 should be properly prepared and submitted.

3.3 Operating Inefficiencies

Audit Observation

Comment of the Management

Recommendation

(a) The following observations are made on the production efficiency and the effectiveness of the Corporation.

(i) An annual production plan had not been prepared for the year under review and monthly production plans had been prepared instead. Action will be taken to prepare an annual production plan from 2022.

An annual production plan should be prepared.

(ii) There was a difference of 350 million units of 47 types of drugs between the total production demand identified according to the sales plan and the monthly production plan.

Although there was a market demand for some of the products mentioned here, they were not produced in 2020. This was due to actual order received was less / more than the estimated quantity; problems with maximum capacity of production machinery; product requirements prepared on the basis of monthly demand, i.e. lack of manufacturing facilities to produce all the products in the sales plan within the stipulated period; that some items were manufactured more or less than the planned quantities due to shortage of raw materials and technical problems in manufacturing certain products.

A realistic annual sales plan as well as a realistic annual production plan should be prepared and every possible effort should be made to achieve the targets set in those plans.

(iii) Although the total production requirement identified according to the sales plan was 2,077 million units for 28 types of drugs, the actual production was only 1,535 million units for 24 types of drugs.

Due to the reasons such as actual order received was less / more than estimated quantity, maximum capacity of production machinery, product requirements prepared on the basis of monthly demand i.e. lack of manufacturing facilities to produce all the products in the sales plan within the stipulated period, shortage of materials and technical problems in manufacturing certain products, the production of some items remained less than the planned quantities.

Realistic production and marketing plans should be prepared for maximum production efficiency and effectiveness

(iv)According to the sales plan, by exceeding the total production requirement of 17 types of drugs by 163 million units 1,206 million units had been produced. However, only 999 million units had been sold during the year under review. Out of the remaining 207 million units, 3.07 million units of 03 pharmaceutical items could not be sold due to non-receipt of orders from the Medical Supplies Division even for the year 2021.

Although the actual production unit was higher than the estimated number of units, other than the surplus stock of 3 product items out of those products, other products can be supplied based on the order for the year 2021. Nevertheless, due to non-receipt of orders from the Medical Supplies Division for 3 items for the year 2021, the sale of those stocks has become problematic.

Realistic production and marketing plans should be prepared for maximum production efficiency and effectiveness necessary changes in those plans should made keeping with the timely needs and changes and maximum effort should be made to achieve the desired goals.

(v) Due to increase in the possibility break up the tablets manufactured during the year under review into small pieces, variations in the weight of the pills, bad looks and difficulty in breaking the pill, the production had to be halted and additional cost that had to be incurred to resume the production was Rs. 2,563,069. Measures had not been taken to minimize these adverse effects production process experienced every year.

That the fact of the tablets being breaking up into small pieces and variations in the weight of the pills are the practical issues in the production of drugs; there is no readdition of the active ingredient in the reproducing of those drugs; that only the auxiliary raw material is added instead, and that only the cost of auxiliary raw materials, the additional labour costs incurred in reproduction, and the overhead cost are added to the total production cost again.

Action should be taken to improve the quality of medicines and minimize production problems. (vi)An amount of 213 kg of pharmaceutical raw material purchased at a total cost of Rs. 2,042,844 for research activities during the last two years and the year under review remained unused even as at 17 February 2021. It was also confirmed that 175 kilograms of drug raw material was not of the required standard.

That the raw material purchased for research purposes will be used in accordance with the introduction of new products to the market and the supplier has agreed to replace 175 kg of substandard raw material.

Raw materials purchasing plan should be prepared based on the sales plan and production plan and action should be taken to procure the raw material accordingly and research for new drugs should be expedited.

(vii) The production of Clarithromycin Tablets **USP** 500mg introduced last year and Clopidogrel 75mg tablets, Nimodipine tablets 30mg, Tramadol Capsule 50mg, Flucloxacillin capsules 500mg and Prednisolone tablets 1mg introduced during the year under review had not been commenced and it was not even included in the production plan. Accordingly, it was observed that no adequate attention had been paid to the continuous production and promotion of products new introduced annually and as a result. innovations had not adequately contributed to the product mix.

An order has been received for the Clarithromycin **Tablets USP** 500mg from Medical Supplies Division for the year 2020. Since the other items were introduced in late 2020 and orders have been received from the Medical Supplies Division for the year 2021, it will be possible manufacture and promote these items in 2021.

Adequate attention should be focused to the continuous production and promotion of new products introduced annually.

- (b) The following observations are made regarding the sale and distribution of drugs by the Corporation.
 - (i) Due to various reasons such as lack of raw material, insufficient machinery capacity, existing technical defects in the manufacturing process etc., the Corporation had failed to supply 570.78 million units of 26 types of drugs with sales value of Rs.

The Medical Supplies Division made request to delay several drugs, including Theophylline ER Tab 125mg and the demand for some drugs was not up to the expected level due to the prevailing situation in the country.

The market share of the medical supplies sector should be protected by making maximum effort to complete orders.

1,003 million out of the drugs ordered by the Medical Supplies Division for the year under review. Out of that the Corporation had failed to meet the entire requirement of 30 million units of the Theophy.ER Tab 125mg drug with a sales value of Rs. 44.10 million.

(ii) The local market sales target of 549 million units of 28 drugs with sales value of Rs. 616 million could not be met during the year under review. Out of that, any quantity of 02 items of drugs with a sales target of 5.21 Million Unit with a sales value of Rs.3.92 million could not be sold.

Due to the reasons such as lack of production of certain products throughout the year 2020, decrease in demand for certain products due to the Covid 19 epidemic in the country, receiving orders for less than the estimated order volume from the Medical **Supplies** Division, failure to procure raw material on time, delays in the supply of raw materials in the world market in the face of the existing Covid 19, abnormal rise in raw material prices and technical defects in the manufacturing process, the sales targets could not be achieved.

Maximum effort should be made to reach the targets of the annual sales plan.

(iii) Drugs consisting of 115 million units with sales value of Rs.854 million and 30 other items not included in the sales plan had been sold during the year under review.

Although these products are not included in the sales plan, as it is the policy of the present government to develop the local pharmaceutical industry, most of the pharmaceutical products purchased through imports have started to be produced locally.

Realistic annual sales plans should be prepared and revised as per the requirements.

(c) A quantity of 20,200 plastic bottles of 60ml costing Rs. 314,716 included in the stock of packaging materials as at 31 December 2020 had not been used since December 2013.

These bottles have not been used due to no longer packaging in the bottles the products that were intended to be packaged in these bottles and they are to be properly disposed of as it is now decaying.

Those should be disposed of properly

(d) No action had been taken to recover 736,000 deposited in clearing companies during the period from 2017 to the year under review.

That some deposits have already been withdrawn and that steps are being taken to recover the deposits that are found unable to withdraw. Many clearing companies were shut down and restricted to essential activities due to the Corona epidemic and they started working online, thus making it difficult to withdraw deposits.

Deposits should be recovered as soon as the clearances are completed

3.4 **Procurement Management**

Audit Observation Comment of the Management _____

Recommendation _____

The following observations are made with regard to the procurement process implemented during the procurement of pharmaceutical raw materials and packaging materials during the year under review.

(a) Orders had been issued to the supplier before approval of the Technical Evaluation Committee and the Procurement Committee was granted and signing the agreements.

That on the basis of the stock level of certain items to be obtained expeditiously, order has been issued to the supplier subject to the covering approval of the Technical Evaluation Committee and the Procurement Committee, taking into account the time taken to obtain approval of those committees and that covering approval of the Technical Evaluation Committee and the Procurement Committee was subsequently obtained.

Action should be taken accordance with guidelines of the Government Procurement Guidelines.

Bid opening committees had not been (b) appointed in accordance with Guideline 6.3.3 (a) of the Government Procurement Guidelines and bid opening activities had not been reported in the prescribed form as per Guideline 6.3.6.

That action will be taken to update existing approvals in keeping with the needs.

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Performance security had not been obtained in accordance with Guideline 5.4.10 (b) of the Government Procurement Guidelines.

In cases where suppliers do not provide performance security, action will be taken to withhold 10 per cent of the amount

Action should be taken accordance with guidelines of the Government

payable in lieu of performance security and that the Corporation will take a loan period of 30 to 60 days for the full amount when making payments to local suppliers.

Procurement Guidelines.

(d) As per Guideline 8.9.1 (b) of the Government Procurement Guidelines, no formal agreement was entered into for contracts of goods or services exceeding 500,000 and the certificate registration of the contract under the Public Contract Act had not been obtained from the supplier.

In case where most of the supplier institutions were closed due to the Corona epidemic and the Corporation was maintained with a very limited number of employees, action was taken to maintain stocks which were the objective ultimate without relying the contract on agreements and Contract Registration Certificate (Form PCA(4) under the **Public** Contract Act and that the supplier constantly was monitored to minimize possible risk.

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3.5 **Joint Venture Management**

Audit Observation

Under the proposal to initiate joint ventures between the State Pharmaceutical Manufacturing Corporation and the appropriate private investors to expand the pharmaceutical manufacturing process, Corporation had entered into agreements with 15 potential investors in 2018 and 2019. The following observations are made regarding the manner in which the Corporation had carried out transactions with those joint ventures during the year under review.

(a) Although agreements had been reached with 15 investors to supply the drugs, drugs had been purchased only from three investors as at 31 December 2020.

Comment of the Management

Recommendation

Only two investors had fulfilled manufacturing facilities and qualifications required to supply drugs to the Medical **Supplies** Division.

Action should be taken as recommended by the official committee appointed by the Cabinet of

Ministers and constant follow up should be carried out on the status of other contracted investors.

(b) As per the recommendation of the official committee appointed by the Cabinet of Ministers to set up joint ventures, the Corporation should have entered into an agreement with the Drug Producer to supply the drugs. Nevertheless, the Corporation had entered into an agreement with an investor who was only an intermediate supplier and not a manufacturer and received the supplies.

That the tripartite agreement signed with this institution had expired on 30 May 2020. If the Glosante Pvt. Ltd. enters into agreements with the Corporation for joint ventures in the future, they will only be required to supply drugs manufactured through their factory. In this connection the **GMP** Certificate, Manufacturing License and National Drug Regulatory Authority (NMRA) Registration Certificate should be obtained in the name of that company and they have already informed that they have submitted the documents to the NMRA for registration

Action should be taken as recommended by the official committee appointed by the Cabinet of Ministers

(d) According to the joint venture agreement, the investor should determine the selling price by adding a profit margin of 20 per cent to the production cost of the drugs and surgical consumables produced. The total production cost of 06 pharmaceutical items procured from one such investor and sold to the Medical Supplies Division during the year under review was Rs.823,010,169. Adding a profit of Rs.129,898,488, they had provided to the Corporation at an invoice value of Rs.952,908,657. The Corporation had added another service charge Rs.66,692,327 to that invoice value and sold them to the Medical Supplies Division for Rs. 1,019,600,983. The investor had earned a profit margin of 16 per cent of the total cost of the above 06 drugs and the Corporation had earned a service charge of 7 per cent of the invoice price. Accordingly, the selling price had been determined by adding 23 per cent of

As a government entity, the tender process should be followed when purchasing raw materials, but private investors have the ability to purchase raw materials in a way that reduces their unit cost, so the Corporation's service charges show higher amount when determining the selling price.

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the total production cost as profit and service charge.

(d) The Corporation had tested quality only for 36 items out of 43 items procured from the joint venture and supplied to the Medical Supplies Division during the year under review. Although 03 items of surgical consumables had been procured and supplied to the Medical Supplies Division during the year under review, due to lack of the facilities with the Corporation to test the quality of the materials, the samples had been sent to the Industrial Technology Institute (ITI) by the suppliers themselves. The quality of the drugs had been confirmed only according to the test reports issued by that institute. Accordingly, there had been no insufficient independent confirmation of the quality of the drugs supplied to the Medical Supplies Division under the joint venture.

Three items of surgical consumables were procured and supplied to the Medical Supplies Division during the year under review on the basis of the quality assurance issued by the Institute of Industrial Technology (ITI) after quality inspection. There is no facility to inspect the relevant surgical instruments in the existing system.

The Corporation shall adequate make independent assurance of the quality of the drugs supplied to the Medical Supplies Division under the joint venture.

3.6 Deficiencies in the Contract Administration

Audit Observation

Due to the reasons such as selection of (a) construction consultants and contractors without transparency and without following certain guidelines in the Government Procurement Guidelines, failure to include terms and conditions on contract termination dates and late payment in the agreements, constantly changing basic plans without proper approval, carrying out constructions without complying with the plans and bill of quantities, failure of Corporation to complete the work within the contract period due to exceeding the contract value as well as due to insufficient oversight by the responsible parties of the Corporation during the contract period, construction of four storey building, construction of flyover,

Comment of the Management

That there is no a Civil Engineer for civil engineering activities including supervision of construction projects the of Corporation. The Engineering Division of the corporation carries out all the related duties while carrying out all the engineering work required maintaining the institution with the assistance of consulting firms. Considering these matters, a new post of Civil Engineer has been approved for the Corporation on the need to construct and maintain buildings and that recruitments for the post will be made in the future and thereby, action will be taken to avoid these shortcomings in the

Recommendation

Action should be taken to carry out contract administration in accordance with the Government Procurement Guidelines and to properly manage and supervise those activities.

construction of steel structure warehouse, conversion of Penicillin Zone warehouse into Cephalosporin Production division and modernization of Bulathsinhala building, it observed that the administration of the Corporation's contracts was at a poor level.

supervision and administration.

(b) Although the total contract value for the construction of Zone G, converting the Penicillin Zone warehouse Cephalosporin Production Division was Rs.80,510,608, works had been carried out in excess of the total contract value by Rs.11,918,835 without obtaining the approval of the Departmental Procurement Committee as at February 2020.

That the construction of this factory building was commenced on the Design & Build basis under the supervision of the then Project Manager of the Corporation. However, it was later found that construction of such pharmaceutical factory was special task during the construction process and that there was very little experience in consulting and supervising such construction in Sri Lanka. Although the construction company had taken steps to complete the construction work within the scope of the tender and hand it over to the Corporation on August 2019, additional construction work modifications (Extra works variations) had to be done to commence production with the approval of the Drug Regulatory Authority. The final bill quoting contract value for additional works has been submitted to the Corporation and it has been submitted to the Technical Evaluation Committee of the Department to obtain the approval of the Departmental Procurement **Board** for the construction work which has been done exceeding the contract value.

Formal approval should be obtained for work done in excess of the contract value.

Although Rs. 6,016,902 had been spent (c) at 18 February 2021 for the It was decided to temporarily suspend this project as it was be taken to identify the

Necessary steps should

construction of proposed flyover to connect two buildings, the governing authority had decided to stop the relevant construction. Accordingly, the cost incurred thereon had become a fruitless expenditure. uneconomical to further continue the project and the matter has been referred for recommendations and approval of the Board of Directors for further action of the project. parties that should be held responsible for contributing to launch this project without proper feasibility study and to recover the money.

(d) Although piling work for the construction of four-storied administration building had been completed at a cost of Rs. 28,952,527 by 07 March 2018, no constructions of the building had been commenced even as at 31 July 2021.

Although piling work for the construction of this administration building had been completed by 08 March 2018, the construction contract had not been awarded by then. Bids relating to this construction were called for in the year 2019 and the bids presented were referred to the Technical Evaluation Committee of Ministry for technical evaluation. been Having considered construction plans again based on experience the on the constructions carried out during the recent past and obtained a piling condition analysis report from the Central Engineering Consultancy Bureau, attention has been drawn on replanning the construction and the building is to be constructed in the future.

Construction administration should be duly carried out in accordance with the Government Procurement Guidelines and action should be taken to ensure proper management and supervision on those activities.

(e) Construction of a two-storied building had been commenced on 21 September 2018 and a sum of Rs. 36,045,249 had been spent by 19 February 2021 for that purpose. Although the constructions should have been completed by 21 August 2019 as per the original estimate, constructions had not been completed even by 19 February 2021. However, a building with a structure sufficient enough to the planned capacity had not been constructed and therefore, the Central Engineering Consultancy Bureau had been informed on 06 October 2020 to re-examine the structure of the building.

Payments were delayed due to the delay in the receipt of money due from the Government to the Corporation. Covid epidemic and the changes in the original plan had contributed to the delay in the construction of the building. The Central Engineering Consultancy Bureau (CECB) analysed the steel structure design of this building. A recommendation had been made to carry out re- verification of the foundation. Accordingly, a report was obtained again from the M/S Soil Matter Pvt Ltd that carried out the soil investigation. The

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final plan reviewing report of the CECB was given on 25 February 2021 and accordingly, the construction company is carrying out the project at present while implementing the recommendations in the plan reviewing report.

3.7 Human Resource Management

Audit Observation Comment of the Management Recommendation

The following observations are made on the human resource management of the Corporation.

The approved cadre of the Corporation (a) as at 31 December 2020 was 353 and the actual cadre, number of vacancies and the excess cadre as at that date stood at 302, 67 and 16 respectively. No action had been taken to obtained approval Department of the Management Services for making recruitments to the essential posts including 06 vacant posts of the executive grade and for the excess cadre.

According to the scheme of recruitment approved by the Department of Management Services and the Circulars issued by the Department of Management Services, applications have been called for the vacant posts and recruitments have been made for a number of posts.

Action should be taken to fill vacancies of the essential posts in accordance with the scheme of recruitment.

(b) Although qualified officers should be recruited to the post of Drugs Manufacturing Assistant of the Corporation in accordance with the scheme of recruitment by calling for applications through the publication of a public notice newspaper or advertisement and conducting an interview, contrary to the above scheme, 17 officers had been recruited on contract basis from the applications sent to the Corporation by the Coordinating Secretary to the Ministry of Health and Indigenous Medicine

The necessity for the Drugs Manufacturing Assistant has been informed to the Department of Management Services and sought approval and these employees were recruited with the approval of the Secretary to the Ministry as a remedial measure to the problematic situation arisen regarding the drugs packaging process due to the employees shortage resulting from the Covid 19 epidemic situation.

All recruitments should be made in accordance with the approved scheme of recruitment.

4. Accountability and Good Governance

4.1 Annual Action Plan

Audit Observation

Comment of the Management

Recommendation

The following observations are made on the progress of the accomplishment of activities included in the Action Plan prepared for the year 2020.

(a) In terms of Public Enterprises Circular PED12 dated 02 June 2003, the Action Plan should be prepared including the Key Performance Indicators to evaluate the performance of the activities to be carried out within the prescribed timeframe. Nevertheless, the Action Plan prepared by the Corporation for the year 2020 had not included the Performance Indicators specifically and adequately in a measurable level. As a result, the progress of the accomplishment of activities included in the Action Plan for the year under review could not be precisely evaluated.

Although it was the usual practice of the Corporation to prepare Action Plan in accordance with the Circular No.12 of the Public Enterprises Circular dated 02 June 2003, it had to be prepared as per the format sent by the Ministry of Health in the year 2020.

Action should be taken in accordance with Public Enterprises Circular PED12 dated 02 June 2003.

(b) Out of 91 activities costing Rs. 875.8 million included in the Action Plan, 51 activities valued at Rs. 735.9 million had not been even started during the year under review and 14 activities initiated during the year under review had not been completed. The physical progress achieved relating to any activities of three departments had not been disclosed.

the preparation Action Plan according to the format given by the Ministry of Health, the financial progress can be measured according to the that indicates column "Physical Progress as a percentage" in the relevant format and accordingly, the value of the financial progress achieved can be by the measured percentage of the physical progress.

Action should be taken in accordance with the Public Enterprises

Circular PED12 dated 02 June 2003.