

State Pharmaceutical Manufacturing Corporation - 2024

1. Financial Statements

1.1 Opinion

The audit of the financial statements of the State Pharmaceutical Manufacturing Corporation for the year ended 31 December 2024 comprising the statement of financial position as at 31 December 2024 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 information of the 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 2024 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

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 intend 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 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 Audit Scope

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 skepticism 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 Accounts Receivable and Payable

1.5.1 Amounts Payable

Audit Issue	Management Comment	Recommendation
Although the creditor balance arising on purchases from joint ventures should be settled within 60 days as per the agreements, a balance of Rs. 1,662 million, which was overdue for 60 days had not been settled.	According to the amount of funds released from the General Treasury, the relevant funds will be managed based on the entity's requirements, and steps will be taken to distribute the relevant payments among the joint ventures in the maximum possible manner.	Internal control systems should be established to enable settlement in accordance with the agreements.

1.6 Non-compliance with Laws, Rules, Regulations and Management Decisions etc.

Reference to Laws, Rules and Regulations etc.	Non-compliance	Management Comment	Recommendation
(a) Financial Regulations of the Democratic Socialist Republic of Sri Lanka			
(i) Financial Regulations 3 (2) (iii)	A pre-feasibility study had not been conducted for the Lotus Pharma project, which was initiated with the objective of establishing 05 manufacturing plants covering the basic pharmaceutical needs of the country, and a total of Rs. 377.99 million had been incurred from 2021 to the year under review, comprising Rs. 55.58 million for procurement activities and payment of staff salaries, and Rs.	Due to being engaged pharmaceutical manufacturing, only a financial feasibility study was submitted for approval when the project was initially proposed.	Actions should be taken in accordance with Financial Regulations.

322.41 million for purchasing the relevant land, respectively, and the project had been abandoned midway.

(ii) Financial
Regulations 110

A register of loss and damages had not been maintained.

Actions has already been taken to maintain a loss and damage register for the year 2025. It was stated that action has now been taken to maintain a Loss Register for the year 2025.

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(b) Paragraph 2.10 of Chapter VI of the Establishments Code of the Democratic Socialist Republic of Sri Lanka

Although it is required to report full details of all the appointments including acting and probationary appointments, changes in salary increments, dismissals from service, resignations and retirements, reinstatements and deaths should be reported to the Auditor General from time to time, actions had not been taken accordingly.

It has been scheduled to take necessary action to submit information on all the appointments made in the future to the Auditor General through the Head of the Department.

Actions should be taken in accordance with the provisions of the Establishments Code.

(c) National Medicines Regulatory Authority Act, No. 05 of 2015

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| (i) Section 64 (1) | The renewal of the registration pertaining to 08 pharmaceuticals had been delayed for a period ranging from 107 days to 219 days, due to the failure to submit the required documents relating to those pharmaceuticals, which were due for renewal during the year under review, to the National Medicines Regulatory Authority within the stipulated time frame. | Steps will be taken to manage in a manner that prevents such delays. | Action should be taken in accordance with the provisions of the Act. |
| (ii) Section 64 (2) | Even though the relevant fees had been paid for the renewal of registration of 07 Pharmaceuticals, the renewal of registration for those Pharmaceuticals had been delayed by the Medicines Regulatory Authority due to the non-submission of the required documents. | Actions will be taken to manage and prevent such delays. | -do- |
| (d) Paragraph 5.3 of the Operations Manual for State Owned Enterprises as published by Public Enterprises Circular No. 01/2021 dated 16 November 2021 | Although it had been expected, as stated in the Companies Act, No. 7 of 2007, that at least thirty percent of the profit after tax would be credited to the Consolidated Fund after the reviewing of solvency test, and although the portion corresponding to thirty percent of the profit after tax for the year 2023 amounted to Rs.455,566,592, only Rs.300,000,000 had been credited to the Consolidated Fund. | Action has been taken to transfer to the Consolidated Fund the maximum amount that could be made available to the General Treasury while managing the financial requirements of the institution. | Action should be taken in compliance with the provisions of the relevant circular. |

(e) Guidelines on Corporate Governance for State Owned Enterprises as published by Circular No. 01/2021 dated 16 November 2021

(i) Paragraph 2.6	Although there should have been a Board Secretary possessing the qualifications relevant to the senior management level within the approved cadre, action had not been taken to recruit a qualified Board Secretary.	The necessary specifications for recruiting to this position have been prepared and referred for the approval of the Procurement Board for inviting bids.	-do-
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(ii) Part 2 (a) of Annexure 01 in Section 3.2	Although the financial estimate for each activity should have been specified in the annual action plan, such action had not been taken in respect of the activities of the Human Resources Division.	It has been scheduled to take necessary steps in future to indicate the financial estimated value for each activity of the action plan.	-do-
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(iii) Paragraph 4.3	Although the Risk Committee meetings should have been held at least once in every 03 months, only 02 meetings had been held during the year under review.	Two Risk Committee meetings have been held during the year under review, and as the Board of Directors had not been appointed during the relevant period, it was not possible to hold the Risk Committee meeting in the last quarter.	-do-
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(f) Paragraph 02 of Public Administration Circular No. 6/97 dated 03 February 1997.	Although the period of acting should be limited to a maximum of three months, an officer had	Although applications had been called for the posts of Deputy	Immediate action should be taken to fill the relevant vacant positions.
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been continuously employed on an acting basis for over nine years in the post of Deputy General Manager - Formulation and Research and a sum of Rs.1,541,368 had been paid as acting allowance. Furthermore, with effect from 31 December 2022, two female officers had been appointed on an acting basis to the posts of Deputy General Manager - Human Resources and Deputy General Manager - Marketing.

General Manager Human Resources, Formulation, Research and Development respectively, it had not been possible to select a qualified candidate for those positions up to date. Further, applications had been called for the post of Deputy General Manager - Finance on 16 March 2025.

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| (g) Paragraph VI of the Management Services Circular No. 02/2020 dated 26 October 2020 | Although a formal succession plan should have been prepared to fill the relevant vacancies arising from the retirement of employees in the approved cadre, action had not been taken accordingly. | A written request had been made to the Department of Human Resource Management of the University of Sri Jayewardenepura for obtaining guidance. | Action should be taken in accordance with the provisions of the circular. |
| (h) Paragraph 3 (a) of the Circular No. F.M. 01/2015/01 dated 15 May 2015 and the letter of the Senior Assistant Secretary (Administration) of the Ministry of Health dated 14 March 2023 | A sum of Rs. 1,689,108, which had been paid in excess as Incidental allowances and combined allowances by deviating from prescribed instructions, had not been recovered even by the end of the year under review. | Action has been taken to recover the amount from several officers, while the remaining officers have submitted an appeal to the Secretary of the Ministry. | Action should be taken to recover the overpaid amounts, and disciplinary action should be taken against the parties involved in this irregularity. |

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| (i) 4.2.1 and 4.2.2 of the Government Procurement Guidelines | A procurement plan expected for a period of at least 03 years and a procurement schedule that chronologically describes the steps of each procurement process from the beginning to the end of each procurement activity had not been prepared. | The procurement plan and the procurement time schedule are being prepared for the procurements currently being carried out. | Action should be taken in accordance with the provisions of the Procurement Guidelines. |
| (j) The decisions of the Board of Directors bearing No. BP/30/15 dated 04 June, 2015 and No. BP/62/22 dated 22 September 2022 | Even though the bicycle loan paid to the employees of the Corporation had been increased from Rs. 20,000 to Rs. 75,000, the approval of the Director General of the Department of Public Enterprises had not been obtained for this. | A written request for approval has been submitted to the Director General of the Department of Public Enterprises, and it has been informed that approval is expected to be granted in due course. | Action should be taken in a manner that ensures consistency between Board of Directors' decisions and applicable laws, rules, and regulations. |
| (k) Agreement for joint ventures between the Corporation and other pharmaceutical manufacturers | | | |
| (i) Section 5.2.4 | Although investors were required to commence construction of their manufacturing plants within 03 months of signing the agreements, relevant information regarding 07 investors had not been examined. | The construction activities of the manufacturing facilities of the investors who have established joint ventures were being monitored, and the construction activities at the Greenthrough companies were also being supervised. | Action should be taken to inspect the manufacturing facilities of the remaining investors, in accordance with the agreements for the joint venture. |

(ii) Section 3.16	Although the Medicom Joint Venture was supposed to manufacture 16 pharmaceutical items and supply them to the State Pharmaceutical Manufacturing Corporation, no Pharmaceuticals had been supplied during the year under review.	In the year 2022, Medicom was unable to supply the required Pharmaceuticals to the Medical Supplies Division, resulting in a very low supply performance level, consequently, Pharmaceuticals were not procured from them.	Action should be taken in accordance with the agreement for the joint venture, and appropriate measures should be taken in relation to any breach of the agreement.
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2. Financial Review

2.1 Financial Results

The operating result of the year under review amounted to a profit of Rs. 2,156 million and the respective profit in the preceding year amounted to Rs. 1,518 million. Accordingly, a growth of Rs.638 million, representing 42 percent of the financial results, was observed. This growth was primarily due to the reduction of the provision for doubtful debts from Rs.800.9 million in the previous year to Rs.4.8 million during the year under review, the decrease in sales discounts from Rs.132 million to Rs.78 million, resulting in a 90.72 percent reduction in sales and distribution expenses, and the reduction in foreign exchange losses, which led to a 56.48 percent decrease in financial expenses.

2.2 Ratio Analysis

The gross profit and net profit ratios in the year under review were increased by 0.50 percent and 3.52 percent, respectively, compared to the previous year. The debt turnover ratio, which was 16 percent in the previous year, had increased to 17 percent in the year under review, while the debt collection period decreased by 01 day.

3. Operational Review

3.1 Uneconomic transactions

Audit Issue	Management Comment	Recommendation
A sum of Rs.27,550,136 incurred for a four-storied administrative building, which has not been constructed since 2018, had remained idle within the balance of Rs.73,582,498 in the work-in-progress account for more than 07 years, constituting an uneconomic expenditure.	A sum of Rs.27,550,136 has been incurred to date for the administrative building included under the work-in-progress account. Since no definitive decision has yet been taken by top management regarding its construction, there remains a possibility of constructing the building in the future. Therefore,	A formal investigation and evaluation should be carried out regarding the past process related to the construction of the four-storied building.

the administrative building should continue to be maintained under the work-in-progress account.

3.2 Management Inefficiencies

Audit Issue	Management Comment	Recommendation
(a) Although a sum of Rs.1,106,420,551 had been charged by the Medical Supplies Division from the Corporation as price variations and penalty charges pertaining to the medicines of the joint ventures supplied to the Medical Supplies Division from 2018 to 2024, action had not been taken to recover that amount from the respective joint ventures, and it had been shown in the Trade Debtors accounts of the Medical Supplies Division for a long period.	The main reason for this situation was that the Medical Supplies Division has not yet settled the relevant payment vouchers for the past several years. For example, invoices amounting to around Rs.19 billion for the year 2023 still remain unsettled, and due to such non-settlement, recovery without verification has been difficult. However, letters specifying the outstanding recoverable amounts have already been sent. Furthermore, 96 percent of the payment vouchers for the year 2024 have been settled.	Control mechanisms necessary for a formal reconciliation process between the information of the Medical Supplies Division and the Corporation should be introduced, and action should be taken to recover the outstanding balances from the respective joint ventures that remain unsettled to date.
(b) 135 items with a cost of Rs. 119,158,776 included in non-current assets as at 31 December 2024 had not been physically verified.	Fixed assets that were not physically available during the fixed asset verification in the year 2024 should be re-examined to confirm whether they actually do not exist, and that in some instances, this situation had mainly arisen due to the detachment of asset identification numbers and the failure to update the proper transfer of assets. Plans are being made to introduce a new mechanism to ensure that asset identification numbers will not be removed and that necessary measures will be taken to minimize this issue in the future.	Action should be taken to physically verify all assets without omissions prior to the preparation of final accounts and in accordance with Financial Regulations.

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| <p>(c) Although a batch of raw materials valued at Rs.13,557,223 had been issued by the Corporation to the Joint Venture on 03 March 2023 under the pharmaceutical raw material exchange system, action had not been taken to recover the relevant amount more than two years.</p> | <p>Action will be taken in the future to recover either the money or the pharmaceutical raw materials.</p> | <p>Action should be taken to recover the money or obtain the pharmaceutical raw materials.</p> |
| <p>(d) Rs.25,780.89 million received from the Department of Treasury Operations on 16 instances during the year under review for pharmaceuticals supplied by the Corporation to the Medical Supplies Division had been credited to the debtors account without proper identification by reconciling with the relevant supply invoices.</p> | <p>The settlement of bills pertaining to supply invoices amounting to Rs.25,780,890,000 received from the General Treasury for Medical Supplies in the year 2024 had been correctly accounted for. Approximately 96 percent of the bill settlements in the year 2024 had been identified, and bill settlements had not been received for only a small remaining amount. Invoices amounting to Rs.19,452,851,018 relating to the year 2023 have still not been settled, and continuous efforts are being made in coordination with the Medical Supplies Division to settle these bills.</p> | <p>Action should be taken to reconcile with supply invoices and identify them correctly. A proper mechanism should be established to expedite the reconciliation process.</p> |
| <p>(e) Although 08 types of pharmaceuticals with high demand in the local market developed by the Research and Development Division had been submitted to the National Medicines Regulatory Authority in the year 2023 for approval as commercial products, the approval for those commercial products had not been received for more</p> | <p>Approval had been received by the National Medicines Regulatory Authority in the year 2025 for one pharmaceutical out of the 08 pharmaceuticals. The required documents for the registration of several pharmaceuticals out of the remaining 07 had been submitted, while the documents required for the registration of the rest are still</p> | <p>A proper mechanism should be introduced to ensure that the process for renewing registrations is carried out correctly and in a timely manner, and disciplinary action should be taken against the responsible officers for any delays.</p> |

than 1½ years due to the failure to properly submit the required documents that should be submitted along with them.

being prepared by the Corporation.

(f) The registration certificates for Mebendazole Tab USP 100 mg and Flucloxacillin Capsule BP 500 mg had expired on 16 December 2024 and 17 December 2024, respectively, and the Corporation had not taken action to renew these certificates on the due dates. As a result, following the renewal of registration by the National Medicines Regulatory Authority for Flucloxacillin Capsule BP 500 mg on 29 January 2025 and Mebendazole Tab USP 100 mg on 01 February 2025, the Corporation was unable to supply the relevant medicines for the orders requested by the Medical Supplies Division. Accordingly, medicines with a cost of Rs.26,177,276 as at 31 December 2024 remained in the Medical Supplies Division warehouse of the Corporation.

Due to the delay in the registration of these pharmaceuticals, the orders that could not be supplied in December 2024 were able to be fulfilled by January 2025.

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(g) Although Clopidogrel Tablets USP 75 mg (500 Pack Size) had been introduced in the Corporation in 2020 as a new pharmaceutical for in-house production, its manufacturing had been unsuccessful due to weaknesses in the production formula. If the production formula had been properly developed and the medicine manufactured within the Corporation to meet the requirements of the Medical Supplies Division, there would

Action is being taken to develop the production formula for Clopidogrel Tablets USP 75 mg.

Action should be taken to address the existing weaknesses in the production formula and to manufacture the pharmaceutical.

have been an opportunity to achieve a profit of 10 percent. However, the Corporation did not act accordingly and instead supplied only about 1,700 packs through a Joint Venture, achieving a profit of 6 percent.

(h) A sum of Rs. 438,146,336 had been received in year 2023 under World Bank Grant for the expansion, renovation, and purchase of pharmaceutical equipment for the penicillin zone, and the Corporation had also incurred a cost of Rs. 24,895,256 for the same purpose. By purchasing high-speed capsule filling machines and other pharmaceutical machinery for the penicillin zone, it was expected to increase the plant's production capacity and develop a new low-humidity area for new products such as Co-amoxiclav tablets. Although it was planned to produce 261 million capsules of the five types of penicillin capsules currently being produced in the penicillin zone in the year under review, only 191 million capsules were actually produced, compared to 275 million capsules produced in 2019. Accordingly, although the penicillin zone was improved, significant progress had not been achieved.

(i) Although it had been planned to produce 84 million units of Metformin BP 500 mg according to the production plan in the year under review, only about 9.28 million units

Further studies are required on the production of new antibiotics within the penicillin zone, and action will be taken in the future to produce the medicine Co-amoxiclav.

Action is being taken to recover the penalty charges for the year 2024 from the respective entities.

A post-evaluation should be carried out regarding the failure to achieve the expected objectives of the project, and necessary corrective actions should be taken.

The production plan should be prepared with proper feasibility studies, and action should be taken to follow more advantageous alternative methods.

had been produced and released to the private market. Although there was an opportunity to earn a profit margin of 12 percent by manufacturing this medicine within the Corporation, an order of Rs. 50 million received from the Medical Supplies Division under purchase order number 2024/SPM/N/R/P/00015 had been given to the Sands Active Joint Venture, from which only a profit margin of 6 percent had been earned. Furthermore, the purchase order No. 2024/SPM/N/R/P/00015 of the Medical Supplies Division for the procurement of 250 million units of medicine had been given to the Corporation, as well as to its joint ventures, Celogen Lanka (Pvt) Ltd and Sands Active (Pvt) Ltd. However, due to the failure of Celogen Lanka (Pvt) Ltd to supply the medicine within the stipulated delivery schedule, the Corporation had to pay a penalty of Rs. 12,311,005 to the Medical Supplies Division. Nevertheless, the Corporation had not taken action to recover the said penalty from Celogen Lanka (Pvt) Ltd.

- (j) The sales plan, production plan, and procurement plan had not included the production, sale, or purchase of raw materials for the medicine Rosuvastatin Tablets IP 10 mg, which has a high market demand. Furthermore, 75 kg of pharmaceutical raw materials with a cost of Rs.12,991,560 received on 21 March 2023

The supplier has agreed to replace the batch, and the necessary actions are currently being carried out. As the final stage of this process, approvals related to customs clearance in the supplier's country are being obtained.

Raw materials should be procured according to the sales, production, and procurement plans prepared taking into consideration factors such as demand, production timeframe and capacity, and the existing technical feasibility for the manufacture of medicines.

pertaining to that medicine had not been used for production until June 2024. Although the Quality Control Division of the Corporation had confirmed that these raw materials did not conform to IP specifications, this test had been carried out only after one year, on 24 June 2024. However, action had not been taken to return the relevant batch and obtain suitable raw materials from the supplier instead of that stock.

- (k) Although there had been technical defects in the Aspirin AR Tablets 75 mg medicine, raw materials amounting to 641 kg valued at Rs.1,786,398 had been purchased in the years 2022 and 2023 without considering those defects, and they had remained underutilized in the warehouse. 300 kg of Aspirin AR Tablets raw materials were procured in September 2022 and 500 kg in April 2023. Three production lots were produced in 2023; however, due to low demand for bulk packs, production activities were temporarily halted until the start of blister packing. Subsequent tests revealed that the 2024 lot did not conform to BP specifications, causing delays in production. Currently, efforts are being made to explore the possibility of providing the remaining Aspirin raw materials to a pharmaceutical manufacturer. Action should be taken to use the pharmaceutical raw materials before their expiration.
- (l) Although 600 kg of Pharmaceutical raw material of Chloroquine Phosphate BP costed at Rs. 6,698,610, which had been purchased in the year 2020 with the intention of using it for the Covid – 19 pandemics, and to be expired on 31 March 2025 had been remained idly in the warehouse premises during the year under review. However, no action had been taken to re-export the raw material to the supplier or Chloroquine Phosphate BP 250 mg was recommended for use during the COVID-19 pandemic, and it was possible to manufacture five million Chloroquine Phosphate BP 250mg tablets within a very short period utilizing the raw material stock available at that time, and to supply them to the Medical Supplies Division to meet the country's requirements. However, this raw material stock remained Action should be taken to re-test the raw materials for possible use, or to re-export them to the supplier, or to re-export them to another party.

sell it to another party.

unused as the medicine was not utilized as expected.

(m) Although approximately 29 new types of pharmaceuticals were introduced during the period from 2018 to 2024, those introductions had not made a sufficient contribution to the Corporation's product mix, as insufficient attention was given to the continuous production and promotion of the newly introduced medicines, except for a few high-demand drugs.

Among the new pharmaceuticals introduced during this period, some have been produced solely to meet the requirements of the Medical Supplies Division, and there is no demand for these medicines in the private market. The private market demand for medicines such as Rosuvastatin Tablets 5 mg, Sitagliptin Tablets 50 mg, Loratadine Tablets 10 mg, Cetirizine Tablets 10 mg, Losartan Potassium Tablets BP 25 mg, and Mefenamic Acid Tablets BP 500 mg is limited to blister packaging. However, due to the inadequacy of the current blister packing machines, it has not been possible to meet the existing market demand for these products.

New medicines that have demand from both the Medical Supplies Division and the private market should be incorporated into the product mix.

(n) Although only the ground floor of about 3,762 square feet of the four-storied building with an area of approximately 18,439 square feet located in Bulathsinhala owned by the Corporation, had been utilized for the Corporation's warehouse activities, the remaining 3 floors covering around 10,837 square feet had remained idle without being put to effective use. Furthermore, 30 auditorium chairs and 10 lobby chairs procured with the objective of establishing a common testing laboratory and a training school in the building had not

All the matters were taken into consideration. It has also been decided to provide those chairs to a government university, and the necessary actions are currently being carried out for that purpose. This building is currently being used temporarily as a warehouse.

Action should be taken to obtain maximum benefits relative to the money expended for the purchase of the building.

been utilized for a period of 05 years, and those items were observed to be deteriorating.

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| <p>(o) 9000 kg of Amoxicillin (AA003) pharmaceutical raw material valued at Rs.104,844,337 had been rejected on 01 March 2024, and although replacement batches had been received on two instances as 4500 kg on 27 February 2025 and 4500 kg on 18 December 2024, the rejected stock had retained in the relevant warehouse, resulting in additional storage costs.</p> | <p>Action has been taken to recover the storage charges paid for the warehouse from the supplier and the bond.</p> | <p>The quality testing process should be formalized and expedited, and measures should be taken to return rejected batches to suppliers immediately in order to minimize additional storage costs.</p> |
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3.3 Operational Inefficiencies

Audit Issue	Management Comment	Recommendation
<p>(a) An order (2024/SPM/N/R/P/00029) had been placed by the Medical Supplies Division to the State Pharmaceuticals Manufacturing Corporation on 06 September 2023 for the purchase of 7.5 million capsules of Tramadol Hydrochloride 50 mg pharmaceutical. Accordingly, although 4 million capsules and 3.5 million capsules were scheduled to be supplied by 06 January 2024 and 06 May 2024, respectively, only 5.256 million capsules were supplied for the relevant order during the year 2024. Due to late supply of medicines, the Corporation had to pay a late fee of Rs. 1.298 million for 05 bills to the Medical Supplies Division. Furthermore, although it was expected to generate sales revenue of Rs. 118.57 million by selling 7.5 million units of the</p>	<p>Even though it is true that the Corporation having to pay penalties due to delayed supply is unfavourable to the Corporation, However, the Medical Supplies Division has been requested to provide the delivery schedule on a monthly and reasonable basis when placing orders. It is expected to supply these orders within the relevant delivery schedule by considering it as a collective responsibility of all divisions of the Corporation.</p>	<p>Action should be taken to establish necessary control mechanisms to ensure that pharmaceuticals are supplied within the stipulated time frame.</p>

pharmaceutical according to the marketing plan of the Corporation, only Rs. 60.175 million was earned during the year under review.

(b) According to the production plan for the year under review, the budgeted production was 4,020 million units of pharmaceuticals, while the actual production was 3,146.54 million units, resulting in an adverse variance of 874.3 million units. This was a decrease in production of medicines by 381.08 million of pharmaceutical units compared to the previous year.

The building and machinery in the Penicillin zone were closed for several months for renovation work carried out under World Bank Grant in the year 2024. During the same year, 12 trained employees of the Production Division resigned from service, in addition, the shortage of raw materials, certain technical issues and the decrease in orders received for Levothyroxine Tablets 50 mcg had also affected production. However, some medicines with high demand were produced in larger quantities compared to the year 2023. The production of 3,559.92 million tablets in 2023 was the highest annual production in the history of the Corporation. When the factory was upgraded in 2018 under JICA assistance, the annual production capacity was estimated to be around 3,200 million units. Therefore, the target of 4,020 million units is a highly challenging goal under the prevailing conditions and it had been determined based on the situation that existed at the end of the year 2023.

Production plans should be prepared based on achievable targets, and necessary measures should be taken to carry out operations in a manner that enables reaching higher targets.

(c) Paracetamol medicine was introduced to the market in 2016 under the brand name Pacidol, and it had been planned to sell 720,000 packaging units of this medicine during the year under

Based on the market demand for the SPMC Pacidol item, it had been estimated to sell 720,000 packaging units for the year 2024. However, as the blister packaging machine used

Although the active contribution of all divisions of the Corporation is essential to achieve the expected targets, the Corporation had achieved

review, with an expected revenue of Rs. 178,200,000. Although promotional expenses had also been incurred to promote the brand name of this medicine, which has high market demand and does not require a medical prescription, only 114,150 packaging units of Pacidol had been sold during the year under review as production had not taken place as planned, generating a revenue of only Rs. 30,513,176.

- (d) Although 32.81 million units of Ciprofloxacin Tablets USP 500 mg had been requested for the local market from January to October 2024, only a very small quantity of 2.36 million units of medicine had been supplied. According to the sales plan of the Corporation for the year under review, it had been planned to sell 13.5 million and 13.2 million units of that medicine respectively, however, no units had been produced during the year under review. Although large quantities of Ciprofloxacin HCL USP pharmaceutical raw material were available in the warehouse for the production of Ciprofloxacin Tablets USP 250 mg and 500 mg medicines, which have high demand in the local market, the Corporation had lost substantial revenue due to the inability to produce them within the scheduled timeframe.

for this item is also utilized to package about 08 other products, only 114,150 packaging units of Pacidol were packaged and made available for market sale during the year 2024. The entire quantity had been sold within the year. In the promotional activities of the State Pharmaceuticals Manufacturing Corporation, the Pacidol brand name, which is one of the OTC medicines in the SPMC product mix, is frequently used, not solely for the promotion of Pacidol, also for the promotion of the SPMC name (Image).

The raw materials were used during the first two months of 2025 to produce 7.5 million units of Ciprofloxacin 250 mg and 3.6 million units of Ciprofloxacin 500 mg. The production of these medicines is technically very difficult, and only a few experienced employees were involved in that task. Otherwise, due to issues such as tablet sticking and breakage during the manufacturing process, a considerable amount of time and labour is required, and the possibility of rework is also high. Furthermore, as 12 trained employees resigned from service during the year 2024, a decision had to be made on prioritizing which medicines should be produced.

only a very small percentage of approximately 16 percent of the estimated value, which is not adequate in any way. Therefore, the attention of the divisions of the Corporation should always be focused on prioritizing production based on market demand.

As this medicine has a demand in both the private market and the Medical Supplies Division, priority should be given to increase medicine production. Immediate action should be taken to resolve the related human resource issues.

3.4 Procurement Management

Audit Issue	Management Comment	Recommendation
(a) The following observations are made regarding the procurement of supply and installation of the ceiling of the Quality Control Laboratory of the Corporation.		
(i) Although it is stated in Section 4.3 of the Procurement Guidelines that a total cost estimate relevant to the procurement should be prepared, and Section 4.3.2 stipulates that the total cost estimate should be approved by the Departmental Procurement Committee, a total cost estimate had not been prepared.	It was difficult to carry out the sub-projects including them in one scope in addition to the main project and each service provider was different. Accordingly, it was practically not an easy task to prepare a total cost estimate for the different services within a short period of time.	Actions should be taken in accordance with the Procurement Guidelines.
(ii) Although a procurement process should not be initiated without a firm commitment that the funds required for the procurement have been allocated in accordance with 4.1.1 (c) of the Procurement Guidelines, out of the Rs. 5 million required for the procurement, only Rs. 3 million had been allocated from the 2024 annual budget, and approval from the Finance Division to obtain the remaining Rs. 2 million had not been obtained even by 02 February 2024, when the contract was awarded.	This centralized air conditioning system which was valued about Rs. 35 million at that time, consisting of the most modern components available at present, and that it was a grant made entirely free of charge based on the mutual goodwill and understanding of all parties. That taking the sub-projects carried out in addition to the main project as a single subject matter was a difficult task, and that each service provider was different. Accordingly, that preparing a total cost estimate for the varied services herein on a short-term basis is not a practically easy task.	-do-
(iii) Even though a performance security of five percent valid up to 28 days beyond the completion of the work under the contract should have been obtained from the contractor as per Section 5.4.8 of the Procurement Guidelines no such performance security had been obtained.	Since these sub-projects were carried out as an emergency work, the approval of the Finance Division for the financial shortfall and the awarding of the contract had been done simultaneously.	-do-

(iv) Although Section 3.12.2 of the Procurement Guidelines stipulates that information regarding the experience and past performance of the bidders in similar contracts should be obtained from the bidders, such information had not been obtained from the selected bidder and only the details of a bank account maintained by the company for a period of about one year from 24 December 2022, the date of commencement of the business, had been submitted. The letter for awarding the contract was sent on 02 February 2024, and the entire project was scheduled to be completed before 08 February 2024, and as this occurred as an emergency work, obtaining a performance security had been avoided. Accordingly, it is expected that necessary steps will be taken in the future to obtain a performance security. -do-

(v) Although Section 8.9.1 of the Procurement Guidelines stipulates that a formal letter of acceptance should be issued and a formal contract agreement should be signed with the selected bidder for contracts exceeding Rs. 250,000 in terms of Section 8.9.1 of the Procurement Guidelines, the entity had not taken the necessary steps to sign a formal contract agreement for the contract. Since this occurred as a very emergency matter, there was not sufficient time to prepare and sign a formal contract agreement. Accordingly, it is expected to carry out the necessary actions to prepare and sign a contract agreement when obtaining such services in the future. -do-

(b) The following observations were made regarding the procurement of transportation facilities.

(i) Although, a formal letter of acceptance should be issued, and for contracts exceeding Rs. 500,000 a formal contract agreement should be signed in terms of Section 8.9.1 of the Procurement Guidelines, the Corporation had not signed agreements with suppliers regarding the transportation services, which had been obtained for over four years and covered about ten destinations. It is expected to sign a contract agreement when awarding the transportation tender to suppliers in the following year. Necessary actions should be taken in line with the Procurement Guidelines.

- (ii) Although the supplier who submitted the lowest price for each destination was selected from among the 09 suppliers who submitted bids, and the physical inspection of the vehicles of those suppliers had been carried out on 29 August 2024, members of the Technical Evaluation Committee had not participated in that inspection, and it had been assigned to the Transport Division.
- The weaknesses have been identified, and action will be taken to ensure the participation of Technical Committee members in the future.
- do-

3.5 Joint Venture Management

Audit Issue	Management Comment	Recommendation
<p>Although the Medical Supplies Division had informed the conditions to be followed when supplying pharmaceuticals to the Division through its letter No. MSD/SB11/SPMC/ORD/PO/2017 dated 04 April 2017, the Corporation had not taken action to include those conditions in the agreements entered into with the joint ventures. Accordingly, although the effective shelf life of the relevant pharmaceutical should be at least 85 percent at the time of distribution to the Medical Supplies Division, it had been stated as 75 percent in the agreements with the joint ventures. Further, although the Medical Supplies Division charged the total invoice value of the relevant batch and an administrative fee of 25 percent of that value for the proper destruction of the pharmaceutical in cases where the pharmaceuticals are not in conformity with standards, such conditions had not been included in the agreements with the joint ventures. Moreover, even though it had been stated that penalties would be charged for delayed supplies, the relevant</p>	<p>Necessary action is being taken to include in the joint venture agreement the conditions relating to maintaining a minimum effective shelf life of 85 percent, and the recovery of a 25 percent administrative fee and penalties.</p>	<p>An internal circular should be issued including the relevant matters, and necessary action should be taken to amend the agreements entered into with the joint ventures accordingly.</p>

conditions had not been included in the related business agreements, resulting in the Corporation having to bear responsibilities and losses alone.

3.6 Deficiencies in Contract Administration

Audit Issue	Management Comment	Recommendation
<p>Although the Board of Directors of the Corporation had approved the proposal to install an efficient cooling system that would meet the cooling demand prepared in accordance with the recommendations of the detailed energy audit conducted in 2019 on the adequacy of the cooling system currently used by the Corporation, it had not been implemented by the end of the year under review.</p>	<p>Technical and financial bids were called for the installation of a new cooling system subject to the approval of the Procurement Committee. The technical bids and financial bids were opened on 23 April 2025. The Technical Evaluation Committee will conduct the evaluation and refer to the Procurement Committee for awarding the tender.</p>	<p>Action should be taken to investigate the abnormal delay and implement prompt corrective measures.</p>

3.7 Delays in Projects or capital works

Audit Issue	Management Comment	Recommendation
<p>It had been planned to establish 05 manufacturing plants to cover the basic pharmaceutical needs of the country under the proposed Lotus Pharma new manufacturing facility, and after 03 years, a cost of Rs. 4,349.2 million equivalents to US\$ 13.1 million had been estimated for establishing a plant for the production of general oral solid drugs as the first phase. Although it was stated in Board Paper No. BP/44/22 dated 20 October 2022 and the Board decision dated 07 October that an area of 20 acres was sufficient to construct the 03 expected manufacturing plants under this project, Rs. 322.4 million had been spent to purchase 65 acres. Furthermore, although the Procurement Committee appointed by the Cabinet on 02 February 2024 had instructed that a feasibility</p>	<p>All relevant factors have been taken into consideration, and it is expected that project activities will be initiated in the future. A committee has been appointed by the Ministerial Advisory Committee to conduct the feasibility study, and it is expected to conduct a feasibility study and prepare a report in the future in accordance with the recommendations and guidance of the appointed committee.</p>	<p>Action should be taken to expedite the implementation of the project.</p>

study covering all areas relevant to the project should be conducted, no action had been taken. Although it was expected to complete this project within 03 years according to the five-year plan from 2022 to 2026, as at the date of audit on 27 May 2025, although 03 years and 05 months had elapsed, the physical progress was Zero.

3.8 Human Resource Management

Audit Issue	Management Comment	Recommendation
(a) The approved cadre of the Corporation as at 30 April 2025 was 449, while the actual cadre stood at 334, resulting in 115 vacancies. Accordingly, 10 positions including 02 key posts in the Human Resources and Finance divisions, 82 positions in non-executive grade and 23 positions of minor employees were remained vacant.	It was agreed with the paragraph.	Necessary action should be taken to fill the vacancies in the essential positions without delay.
(b) Since the recruitment procedure approved by the Department of Management Services on 28 March 2013 for the posts of the Corporation had been revised from time to time with approved amendments and new positions, the recruitment process of the Corporation had become complex, and it had been possible under this to recruit under different qualifications for posts belonging to the same category.	The scheme of recruitment approved prior to the year 2013 is applicable for the posts approved before that year, while for the posts approved after 2013, the Department of Management Services approves the scheme of recruitment according to the new model. The scheme of recruitment according to the new model has been prepared for all posts and referred to the Department of Management Services for approval and the management is currently taking action to equalize the recruitment qualifications for posts falling under same category and eliminate the existing irregularities.	Action should be taken to formalize human resource management.

- (c) Although the applications had been called through newspaper advertisements on 6 instances during the period from 04 October 2018 to 01 December 2024 to recruit an officer for the post of Deputy General Manager (Formulation and Research), action had not been taken to recruit a suitable officer and a manager had been assigned to perform the duties of that post since the year 2016.
- Applications had been called on 06 instances for the post of Deputy General Manager – Formulation, Research, and Development. Qualified applications had not been received on 05 instances, and although an interview was conducted on one instance, the applicant had not appeared for the interview.
- Action should be taken to recruit a suitably qualified officer without delay.
- (d) An officer who had been selected for the Post of Quality Control Officer as an internal applicant was given 25 marks in relation to performance in the interview conducted for the recruitment of officers for 02 Posts of Quality Control Officer in the year under review and other internal applicants were given marks lower as 5 and 7 marks and all the members of the interview board had given marks together in relation to performance. Therefore, it was not observed during the audit that the said interview board had acted independently and impartially without taking action to recruit a targeted candidate.
- According to the interview marking procedure specified in the recruitment scheme, the marks were awarded accordingly. The awarding of marks is decided with the consensus of all other members, based on the views of the representative from the Ministry of Health and Mass Media.
- The interview board should conduct its activities independently, impartially, and in a transparent manner.

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| <p>(e) According to the existing old recruitment scheme (SOR) of the Corporation for the post of Quality Control Manager, a minimum of 03 years of post-qualification experience in Analytical Chemistry or Quality Assurance was required. Although a candidate with expertise in both areas should have been selected, and the recruitment scheme should have been amended accordingly, the Corporation had not taken prompt action to implement these amendments.</p> | <p>An amendment to the recruitment scheme for Manager - Quality Control is not required, and a separate post of Manager – Quality Assurance has been approved, and the recruitment scheme for this post has been referred to the Department of Management Services for approval.</p> | <p>Action should be taken to streamline human resource management.</p> |
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4. Accountability and Good Governance

4.1 Annual Action Plan

Audit Issue	Management Comment	Recommendation
<p>(a) Out of 48 activities included in the Action Plan, progress had not been reported for 23 activities, and therefore it was not possible to obtain confirmation regarding their progress.</p>	<p>Action will be taken to provide the actual status of the relevant activities when providing the progress of the Action Plan in the future.</p>	<p>Action should be taken to report the progress of the Action Plan appropriately.</p>
<p>(b) Although the main objective stated in the Corporate Plan prepared for the 05-year period from 2022 to 2026 was to increase the annual output by 5 percent through expanding resources and increasing production capacity through maximum utilization, the Corporation had failed to achieve that target.</p>	<p>The Corporation plans to increase production capacity in 2025 by identifying the current weaknesses and maximizing the use of existing resources.</p>	<p>Operational efficiency should be improved to achieve the targets specified in the Corporate Plan.</p>
<p>(c) Although introducing 05 new products per year, including a commercially viable medicine and an essential medicine, was stated as an objective in the Corporate Plan, that objective had not been achieved.</p>	<p>The Corporation has identified these shortcomings and expects to take corrective measures during the year 2025.</p>	<p>-do-</p>