State Pharmaceutical Manufacturing Corporation of Sri Lanka – 2019

1.1 Qualified Opinion

The audit of the financial statements of the State Pharmaceutical Manufacturing Corporation of Sri Lanka for the year ended 31 December 2019 comprising the statement of financial position as at 31 December 2019and 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 the Finance Act No. 38 of 1971. My comments and observations which I consider should be reported to the Parliament appear in this report.

In my opinion, except for the effects of the matters described in the paragraph 1.5 of this report, the financial statements give a true and fair view of the financial position of the Corporation as at 31 December 2019, 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 Qualified Opinion

My opinion is qualified based on the matters described in the paragraphs 1.5 of this report.
I conducted my audit in accordance with Sri Lanka Auditing Standards (SLAuSs). My responsibilities, under those standards are further described in the Auditor's Responsibilities 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 qualified 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 Section 16(1) of the National Audit Act No. 19 of 2018, the Corporation is required to maintain proper books and records of all its income, expenditure, assets and liabilities, to enable annual and periodic financial statements to be prepared of the Corporation.

1.4 Auditor's Responsibility for the Audit of Financial Statements

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

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

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Corporation's internal control.

- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the management.

- Conclude on the appropriateness of the management's use of the going concern basis of accounting and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Corporation's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my auditor's report. However, future events or conditions may cause the Corporation to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

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

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

- Whether the Corporation has complied with applicable written law, or other general or special directions issued by the governing body of the Corporation*;*

- Whether the Corporation has performed according to its powers, functions and duties; and

- Whether the resources of the Corporation had been procured and utilized economically, efficiently and effectively within the time frames and in compliance with the applicable laws.

1.5 Financial Statements

1.5.1 Non-Compliance with Sri Lanka Accounting Standard

	Non - compliance with reference to the Standard	Management Comment	Recommendation
(a)	According to the paragraph 110 of the Sri Lanka Financial Reporting Standard 15, policies for recognition of revenue generated from agreements entered into with customers should be disclosed. However the policies for recognition of revenue generated from the agreement entered into with joint ventures of which the Corporation was a party and with pharmaceutical distributers had not been disclosed adequately.	Actions will be taken to disclose the revenue recognition policy in detail and adequately in the financial statements for the next year	Actions should be taken as per the Sri Lanka Financial Reporting Standard
(b)	According to the paragraph 22 of the Sri Lanka Financial Reporting Standard 16, the right of use of asset and the lease liability should be recognized at the commencement date of the lessee. Further according to the paragraph 26 of the said standard, at the commencement date, a lessee shall measure the lease liability at the present value of the lease payments that are not	Actions will be taken as per the Standard in preparing financial statements in the next year.	Actions should be taken as per the Sri Lanka Financial Reporting Standard

	paid at that date. Also in terms of paragraphs 47 (a) and (b) of that standard, right of use assets should be either present in the statement of financial position, or disclose in the notes by the lessee. Nevertheless, actions had not been taken as per the standard to disclose the leased land of Rs.4.92 million which is being used by the Corporation.		
(c)	According to the paragraph 51 of the Sri Lanka Accounting Standard 16, residual value and the useful lifetime of non- current assets should be reviewed annually. However actions had not been taken to revise the estimated error as per the Sri Lanka Accounting Standard 8 in connection with fixed assets valued at Rs.294.82 million which were fully depreciated but in use.	Actions will be taken to take new estimated values of assets in preparing financial statements in the next year.	Actions should be taken as per the Sri Lanka Accounting Standard.

1.5.2 Accounting Deficiencies

	Audit Issue	Management Comment	Recommendation
(a)	Although only a sum of Rs.150,397 should be debited to the spare parts account and credited to the profit and loss account for correcting an accounting error taken place in the previous year, the same accounting treatment had been done for a sum of Rs.2.95 million instead.	Actions will be taken to rectify in preparing accounts for the next year after estimating the proper value of the relevant item.	Financial statements should be submitted to audit after rectifying those errors.
(b)	Expenditure capital in nature incurred during the year under review amounting to Rs.1.28 million had been written off against the profit considering as recurrent expenditure.	Action will be taken to rectify in preparing accounts for the next year.	- Do -
(c)	A cost of expired and quality failed stock amounting to Rs.3.34 million which had been included	Actions will be taken for necessary steps in the next year after obtaining the	- Do -

in the stock remained as at 31 December 2019, had been written off against the profit.	approval of Quality Control Section, Audit Committee and Board of Directors.	

1.5.3 Unreconciled Control Accounts or Records

Item	Amount as per the financial statements Rs. million	Amount as per the subsidiary records Rs. million	Difference Rs. million	Management Comment	Recommendation
Cost of sales of 13 pharmaceutical items which had been manufactured by the Corporation	34.66	35.07	0.41	Work orders which were not completely updated at the instance of closing accounts are updated to the standard cost and the difference will be balanced through Journal entries.	Reasons for differences should be recognize and actions should be taken to make rectification.

1.5.4 Documentary Evidences not made available for Audit

Item	Amount	Audit evidence not submitted	Management Comment	Recommendation
	Rs. million			
Cost of sales	10.44	Subsidiary records relating to correct work orders and journal entries.	Actions will be taken to check manually in order to confirm the accuracy of analysis obtain from the computer system.	Correct work orders for confirming the amount of cost of sales and subsidiary records relating to journal entries should be submitted to audit.

1.6 Non Compliance with Laws, Rules, Regulations and Management Decision etc.

	Reference to Laws, Rules, Regulations and Management Decisions etc.	Non - compliance	Management Comment	Recommendation
(a)	Section 06 (2) (a) of the Gratuity Act No.12 of 1983.	Although provision for gratuity should be done based on the half a month salary for each completed year of the service of the employee, gratuity provision had been made based on full month salary of each employee. As a result, a sum of Rs.3.85 million had been overpaid for 5 officers retired during the year under review as gratuity payments.	Actions were taken to pay based on the approval of Board of Directors.	Provisions for gratuity should be made as per the sections of the Act.
(b)	Financial regulations 102,103,104 and 105 of the Financial Regulations of the Democratic Socialist Republic of Sri Lanka	Although the loss occurred from quality failed 178 kilograms of raw materials and 448 kilograms of working progress drugs was Rs.781,553 during the year under review, actions had not been taken to carry out a proper investigation to recognize responsible parties, to recover the loss, to dispose properly and to write off the stock from the books.	Stocks which had not a market value was written off from the books as per the accounting standards.	Actions should be taken as per the Financial regulations.
(c)	Public Finance Circular No. 438 dated 13 November 2009.	Proper actions had not been taken to dispose unusable raw materials at a cost of Rs.5.89 million, working progress stock at a cost of Rs.6.03 million and 309 units of fixed assets at the total cost of Rs.54.10 million but zero book value.	Raw materials which were not disposed are due to be properly disposed, initial steps for destroying working progress stocks will be reported to the Audit Committee and will be submitted to the approval of the Board of Directors. A committee was appointed to dispose the fixed assets with zero book value properly.	Actions should be taken as per the Circular.
(d)	Treasury Circular	A fixed assets register had not been maintained in	Actions will be taken since next year to	Actions should be taken as per the

	No.IAI/2002/02 dated 28 November 2002	connection with computer, accessories and software at the total cost of Rs.42.34 million as at 31 December 2019.	maintain a fixed assets registers per the Circular.	Circular.
(e)	Public Enterprises Circular No.PED 12 dated 02 June 2003.	Although 04 Audit Committee Meetings should be conducted annually, at least a one meeting had not been conducted for the year under review.	A director representing the General Treasury was not appointed for the year 2019. As the Chairman of the Audit Committee is appointed representing the Treasury, the Audit Committee could not be appointed.	Actions should be taken as per the Circular.
(f)	Public Administration Circular No.30/2008 dated 31 December 2008 and the section 10 of chapter xxiv of the Establishment Code.	Although the maximum amount of the distress loan payable to an officer should be limited to Rs.250,000, a sum of Rs.3.42 million had been paid during the year under review to 45 officers exceeding the said limit.	Payments were made on the approval of the board of directors.	Payments should be made according to the Establishment Code of the Democratic socialist Republic of Sri Lanka and the Public administration Circulars until preparing of an Establishment Code including administration regulations inherent in the Corporation and obtaining approval of the General Treasury.
(g)	Paragraph No. 02- 01 of the Letter of the Department of Management Services No. DMS/E4/10/4/090/2 dated 09 March 2009 addressed to the Secretary, Ministry of Health, Nutrition and	(i) Although transport allowances should be paid considering the distance to the executive and non-executive staff of the Corporation, a transport allowances of Rs.4,700 and Rs.3,000 respectively had been paid monthly since the year 2009 without considering the distance. According to a decision of Board of Directors,	A letter was sent to the Department of Management Services requesting a discussion in connection with the transport allowance and production incentive allowance of which the employees of the Corporation were paid and as a reply, it was informed to prepare and submit an incentive scheme together with	Such allowances should be paid in relevant instances after obtaining the approval of the Department of Management Services and actions should be taken to obtain the covering approval for the payments already paid.

Indigenous Medicine	this monthly allowance had been increased and paid as Rs.8,000 and Rs.6,000 since the year under review.	recommendation. Actions are being taken accordingly.	
	(ii) Although a sum of Rs.4,000 can be paid to the staff as a monthly production incentive allowance, contrary to that requirement production incentive allowances had been paid to the entire staff since 01 July 2011 Subject to a maximum of Rs.12,000 per month. Accordingly total sum of Rs.102.23 million including a sum of Rs.21.49 million which had been overpaid during the year under review had been paid as production incentive allowance since July 2011 to 31 December 2019 exceeding the said limit.	-do-	-do-

2. Operational Review

2.1 Management Inefficiencies

	Audit Issue	Management Comment	Recommendation
(a)	A cost control unit had not been established in the Corporation even though almost 2000 million units of 45 pharmaceutical items are being manufactured in the Corporation and even a post of cost accountant had not been got approved. As a result, cost relating to products manufactured by the Corporation and purchased from local manufacturers as per the agreements of joint ventures could not be controlled.	Although a post of cost accountant is not available, the cost of the productions of the Corporation is examined by officers who held executive posts. Actions will be taken to recruit an officer in this regard in future.	An appropriate post for operations and control of the cost relating to the productions of the Corporation should get approved and should be recruited.

(b)	Although 200 kilograms of Clopidogrel Bisulphate had been purchased at a cost of Rs.1.91 million during the year 2018 , the production license and the registration certificate which should be needed to manufacture Clopidogrel Bisulphate Tab 75mg using the said raw material had not been obtained from the National Drug Regulatory Authority even up to 10 June 2020. As a result, 38 million tablets of the said drug which had been ordered by the Medical Supplies Division had been purchased from joint ventures by incurring a sum of Rs.75.56 million. However the standard production cost of the Corporation relating to the said drug was Rs.66.72 million. Accordingly an additional cost of Rs.8.84 million had to be incurred by the Corporation due to purchasing of said drug from joint ventures without manufacturing by the Corporation.	Development activities could not be completed within the expected period of time due to technical issues occurred in the research stage of this drug. This drug was referred to registration at the time and actions were taken to carry out research in first step of commercial level using 200 kilograms of raw material purchased.	A cost benefit analysis should be carried out to recognize items which can be supplied to the Medical Supplies Division under a situation of low cost and more benefits to the Corporation and an analytical evaluation should be done to determine the which purchase or product is most beneficial to the corporation and to the national economy in general and the production mix should be determined and the production should be designed accordingly.
(c)	When packing after production of drugs and surgical items, labels for each item including the trade name of the Corporation and the state emblem had been printed by other external institutes. However a proper supervision or control had not been done by the Corporation in this regard. As a result law quality drugs and surgical items could be entered to the market damaging the trade name and good will of the Corporation. Actions had not been taken to keep such access closed.	Such investigation had not been done by the Corporation up to now and it will be tested from now on. Actions will be taken to enter the condition of "issuing labels in any way to a third party as a serious offense" into agreements entered into with printers.	A proper investigation and control should be carried out to close the possibility of access of law quality drugs and surgical consumables into the market damaging the trade name and the goodwill of the Corporation
(d)	The Corporation had failed to determine the items which can	The total number of orders received to the	Items which can be supplied to the Medical

	be supplied to the Medical Supplies Division at a low cost and more beneficial to the Corporation and the production mix after having a cost benefit analysis	Corporation for its production for the year 2019 was 2,045.80 million units and out of that, 456.59 million units could not be supplied to the Medical Supplies Division as at the end of the year. Orders were obtained for the maximum capacity of the Corporation during the year under review and the rest was purchased from local manufacturers through joint ventures. Hence a huge amount of money can be saved to the Government.	Supplies Division at a low cost and more beneficial to the Corporation and the production mix should be determined after having a cost benefit analysis
(e)	The following observations are made in connection with the building purchased and renovated in order to establish a general test lab and a training school.		
	(i) A sum of Rs.131.39 million had been incurred to purchase the land with said building and to renovate the building in the years 2017 and 2018 and the building had been taken over by the Corporation on 18 August 2019 after renovations. However the building had been remained idle and closed even by 20 May 2020 the date of audit without using for any purpose. Further the Certificate of Compliance which should be obtained from the Institute of Local Government for this building had not been obtained as well.	Actions are being taken to obtain the certificate of compliance for this building.	Actions should be taken to utilize the building in maximum according to a specific plan after obtaining the Certificate of Compliance.

	(ii) It was not observed that the Corporation has any pre plan or preparation for other requirements which are needed to be established the laboratory or training school after renovations of the building.	Approval of the Department of Management Services was obtained for the staff which is necessary to open the laboratory and the training school. Approval for registration was requested from the Tertiary and Vocational Education Commission. In addition to that, a report was called about the other methods of which the building can be used. However the personal idea is that the building should not have been bought. Nevertheless a Committee was appointed to check whether the building can be used effectively because the building is a property of the Corporation at present and actions will be taken according to the recommendation made by the Committee.	Actions should be taken to utilize the building in maximum according to a specific plan
(f)	Cephalexin plant had been renovated by incurring a sum of Rs.88.42 million during the year under review and it had been handed over to the Corporation by the contractor on 09 August 2019. However the Certificate of Good Manufacturing Practice had not been obtained for Cephalexin Capsules USP 250 mg which was proposed to be manufactured in this factory and the registration of the National	Although the renovated building was handed over to the Corporation, machinery which is necessary for the production was not installed. Hence it could not be applied for the Certificate of Good Manufacturing Practice	Operational activities should be carried out according to a specific plan as to be obtained the maximum benefit for the cost incurred for the renovation.

	Drug Regulatory Authority had not been obtained. As a result, productions could not be commenced even up to 16 July 2020.		
(g)	The stock of 1,000 kilograms out of the raw material Phenoxymethyl penicillin Potassium BP2015 which had been purchased at a cost of Rs.5.12 million in the year 2017 had been failed the quality due to the stock not being adhered to the British Pharmacopeia Standard. Out of the value of that quality failed stock, a sum of Rs.1.67 million which should be further recovered from the supplier had not been recovered even up to the date of this report.	A sum of Rs.2.5 million was set off from the retention money after the said raw material failed the quality. The local agent had agreed to pay the rest of the money and follow up actions are being taken by the procurement section in this regard.	Actions should be taken to recover the due amount without delay.

2.2 Operational Inefficiencies

	Audit Issue	Management comment	Recommendation
(a)	The following observations are made in connection with the production efficiency and the effectiveness of the Corporation.		
	(i) According to the monthly production and packaging plan of the Corporation, the expected production of 25 drugs out of 45 could not be completed during the year under review.	Certain pharmaceuticals which was planned to be manufactured annually could not be manufactured in due amount due to a lot of reasons such as due specifications not being available in the air of the factory, lack of staff for manufacturing and packaging, technical issues being occurred in manufacturing, technical issues occurred as raw material being changed due to changes	Realistic plans for production and packaging should be prepared as to be achieved maximum efficiency and effectiveness in manufacturing process.

	occurred time to time in the tender process, raw materials not being received in due time.	
(ii) Twenty out of 38 pharmaceuticals manufactured by the Corporation and supplied to the Medical Supplies Division during the year under review, it had been failed to exceed 80 per cent of the entire annual requirement which had been ordered by the Medical supplies Division. Further it had been failed to supply even 50 per cent of the entire annual requirement of 13 other pharmaceuticals which had been ordered by the Medical Supplies Division.	The entire requirement could not be supplied because Manufacturing had to be suspended as due specifications not being available in the air of the factory and lack of staff for manufacturing. All stocks manufactured by the Production Section and hand over to the Marketing Section are supplied to the Medical Supplies Division for the orders of the Medical Supplies Division.	The market share of the Corporation should be protected having maximum effort to complete the orders of the Medical Supplies Division.
(iii) The demand of annual requirement of Medical Supplies Division of 2 million units could not be supplied due to the Tolbutamide Tablets BP 500 mg which had been introduced in the year 2016 not being manufactured during the year under review.	The amount of 2 million units of the said drug was manufactured in the year 2018 and was packed in early 2019. However at present, purchasing of said drug was suspended by the Medical Supplies Division.	- Do-
(iv) Out of the stock of pharmaceuticals ordered by the Medical Supplies Division for the year under review, 408.23 million units of 18 drug items for the sales price of Rs.528.86 million could not be supplied even up to 12 February 2020 due to the reasons such as due	The observation is correct and pharmaceuticals were supplied to the Medical Supplies Division on due time at present by increasing manufacturing in the year 2020.	The market share of the Corporation should be protected having maximum effort to complete the orders of the Medical Supplies Division

	specifications not being available in the air of the factory, lack of staff for manufacturing and packaging, scarcity of necessary raw materials for manufacturing and delays in getting supplied and lack of required packs.		
(v)	An additional cost of Rs.21.64 million had to be incurred as a result of suspension of production halfway and reproduce due to ability of braking pills in to small parts of drugs manufactured being increased during the year under review, variations of the weight of pills, bad appearance and difficulties of braking pills. Actions had not been taken to minimize these unfavorable situations which had been occurred in the production process in every year.	Pharmaceuticals has to be reproduced due to the technical issues occurred in the production process. The main reason affected to this situation is frequent variations of the quality of raw materials. The Corporation has to be faced such issues frequently and an additional cost has to be incurred thereon.	Actions should be taken to minimize the decreasing of quality of pharmaceuticals and production issues.
(vi)	During the year under review 224 kilograms of raw materials at a cost of Rs.2.50 million had been purchased for 4 pharmaceuticals which were in the research stage. However the Corporation had failed to manufacture the said pharmaceuticals in commercial level even up to 13 July 2020. Details relating to the dates of research activities commenced, completed, information relating to the registration in the National	Two items of pharmaceuticals were submitted to the National Drug Regulatory Authority for registration and other two items were still in the research stage which needs for registration. Actions is being taken for registration of Flucloxacillin Sodium BP.	Actions should be taken to purchase raw materials according to the Purchasing Plan for Raw Materials prepared on the basis of Marketing Plan and the Production Plan. Further the research activities for new pharmaceuticals should be accelerated.

	Drug Regulatory Authority and reasons for the production could not be commenced had not been submitted to audit. A stock of 200 kilograms of raw materials of Flucloxaullin Sodium BP purchased for research activities in the previous year at a cost of Rs.1.70 million had been remained in the pharmaceutical raw material stores even up to 16 July 2020 without utilizing.		
(vii)	It was observed in the physical audit verification carried out on 23 October 2019 that 5,466 kilograms of finished drugs of which the production process had been completed, for the approval of Quality Control Section and 2,355 kilograms of finished drugs for packing had been piled up in the factory due to lack of capacity of the Quality Control Section and Packing Section respectively.	Quality Control Section takes 2-3 days for checking finished drugs usually after finishing the production process and it has to be rechecked for instances. Such analytical activities also have to carry out in the Quality Control Section and such drugs are approved by the Quality Control Section once the testing activities completed.	In order to complete the production process in maximum capacity and efficiency, capacity of the Quality Control Section and the packing Section should be improved.
(viii)	The approved cadre for the Quality Control Department which is primarily be responsible for the quality of productions of the Corporation was 30 as at 31 December 2019. However actions had not been taken to fill the vacancies of the Deputy General Manager (quality	Although applications were called to fill those vacancies on 08 September 2019 through newspaper notices, it had to be postponed due to the general election and actions will be taken to recruit for the said posts after the general election.	Actions should be taken to fill the vacancies as soon as possible.

	control) post and 6 vacancies in the quality control assistant post.		
	(ix) The approved number of Drugs Complete Assistants as at 31 December 2019 was 29 and it had been failed to fill 2 vacancies out of the above said posts.	Applications were called to fill those 02 vacancies on 20 February 2020 through newspaper notices and recruitments had to be suspended due to the general election.	- Do -
(b)	A sales target of Rs.353.95 million consisted with 41 items of drugs could not be achieved during the year under review and the percentage of failure to reach expected targets was in a range of 06 to 92 percent.	Manufacturing is being carried out giving priority to the orders of the Medical Supplies Division. Sales targets could not be achieved due to scarcity of raw materials and technical issues and necessary steps are being taken to expand the sales network in order to supply the production of the Corporations to the open market continuously in future.	Maximum effort should be taken to achieve the targets of the annual sales plan.

3. Management of Joint Ventures

Audit Issue	Management Comment	Recommendation
Under the proposal for opening joint ventures between the State Pharmaceutical Corporation and appropriate private investors in order to expand the drug production process locally, the Corporation had entered in to agreements with 17 potential investors for supplying of drugs in the years 2018 and 2019. The following observations are made in connection with the way that had been followed by the Corporation in carrying out transactions with such joint ventures during the year 2019.		
(i) Although it had been recommended by the official	The tripartite agreement which	Actions should be

	Committee for establishment of joint ventures appointed by the Cabinet Ministers that the Corporation should enter into agreements with producers for relevant pharmaceuticals, contrary to that recommendation, the Chairman of the Corporation had entered in to a tripartite agreement with a local manufacturer and an interim institute for manufacturing and supplying of surgical consumables.	had been signed with those institutes was cancelled on 30 May 2020. From now on, agreements will be signed only with pharmaceutical producers for joint ventures and a methodology will be prepared as possible as to manage joint ventures properly.	taken as per the recommendation of the Official Committee appointed by the Cabinet Ministers.
(ii)	According to the recommendation of the Official Committee appointed by the Cabinet Ministers, quality control, management and technical assistance of the production process of the investor who had contracted for the joint venture should be provided by the Corporation and 10 per cent of shares of the business of the said investor should be issued to the Corporation in this regard. However 15 drug items for Rs.2,172.65 million and 05 items of surgical consumables for Rs.42.41 million had been purchased from two private companies of which shares had not been issued and sold to the Medical supplies Division during the year under review. Further an adequate quality control or management had not been provided by the Corporation for the said two private companies.	It was informed investors that 10 per cent of shares of the business should be issued to the Corporation. Quality controls testing for the products manufactured by joint ventures are done by the Corporation or the Industrial Technology Institute. It is expected to take necessary actions having a discussion with the panel of lawyers of the Corporation in connection with the management assistance.	Actions should be taken as per the recommendation of the Official Committee appointed by the Cabinet Ministers.
(iii)	The sale price should be decided adding 20 per cent profit margin to the production cost of the pharmaceuticals manufactured by the investor who had contracted for the joint venture. The total	Actions will be taken as not to be exceeded the relevant profit margin in future. A special investigation is carried out by the Director General of the Ministry of Health (finance) whoa key	Actions should be taken as per the recommendation of the Official Committee appointed by the

	production cost of 11 pharmaceutical items purchased from such investor and sold to the Medical Supplies Division was Rs.614.26 million and it had been supplied to the Corporation for invoice value of Rs.698.57 million adding Rs.84.31 million as the profit. The Corporation had added a sum of Rs.57.87 million to the said invoice value as service charges and had supplied to the Medical Supplies Division for Rs.756.44 million. Out of the total production cost of the said 11 items, 13.73 per cent had been earned by the investor as a profit margin and 8.28 per cent of the invoice value had been earned by the Corporation as service charges. Accordingly the sale price had been decided by adding 23.15 per cent of the total production cost as profit and service charges.	member of the Pricing Committee especially in connection with profit margin and relevant prices. Prices are approved after comparing the proposed prices further with the cost sheet by the Accountant of the Medical Supplies Division.	Cabinet Ministers
(iv)	According to the recommendation made by the Official Committee appointed by the Cabinet Ministers, although the joint venture should be established only with the companies of which the drugs and medical instruments are manufactured, it had been contracted with a private company of which surgical equipment had been distributed only without manufacturing. Five items of surgical consumables had been supplied to the Corporation for Rs.42.41 million by the said investor in 8 instances after purchasing from other suppliers for Rs.35.02 million and adding another sum of Rs.7.39 million as an intermediate profit. Further the Corporation had added	Action will be taken not to occur such instances again, the tripartite agreement was cancelled and such purchasing will not be done from such intermediaries from now on. A Committee had been appointed by the Corporation to study this methodology in future with transparency and it was planned to refer to the pricing Committee after having a rigorous study by the said Committee. There was an opportunity to save a huge amount of money to the country and to create number of new job opportunities because joint ventures are more profitable to the Country.	Actions should be taken as per the recommendation of the Official Committee appointed by the Cabinet Ministers.

	another sum of Rs.2.67 million as service charges and had supplied to the Medical Supplies Division for Rs.45.08 million. This investor had purchased the said item from the actual manufacturer through another intermediary in one instance above. Attention had not been paid by the Corporation in any instance for the production cost of the actual manufacturer. When considering the price of surgical consumables supplied by the said intermediary investor to the Medical Supplies Division in 8 instances during the year under review, it was observed that profit and service charges in a range of 56 to 115 per cent of the sales price of the actual manufacturer had been retained by the Corporation and the intermediary investors.		
(v)	It was confirmed that cost sheets presented to the Corporation by the private company which only the distribution was carried out without manufacturing surgical equipment mentioned in above (iv) were not accurate and they were not prepared including the actual cost of production of the first manufacturer . Actions had not been taken by any responsible officer of the Corporation to get confirmed the accuracy of such cost sheets and to get confirmed the data included in the cost sheets by an independent party.	Action will be taken to appoint a committee consists with officers who can be responsible for the said matter after paying rigorous attention in this regard and to confirm the accuracy of cost sheets since the year 2020.	Actions should be taken as per the recommendation of the Official Committee appointed by the Cabinet Ministers and the accuracy of the cost sheet should be confirmed independently.
(vi)	A joint venture had not been built up because the investor who had contracted to the joint venture had earned profit and in addition the Corporation had earned service charges and the purpose of	The cost sheets of all joint ventures will be referred to the said Committee for a complete check and prices will be referred for the approval after minimizing all deficiencies.	Actions should be taken as per the recommendation of the Official Committee appointed by the Cabinet Ministers

	providing pharmaceuticals in a minimum cost had not been fulfilled as expected. A process of converting public funds incurring by the Government for medical supplies to income of several intermediate companies had been implemented through the said activity. Proper supervision, guidance or administration had not been carried out by the Corporation as the main partner of the joint ventures.		
(vii)	The Certificate of Good Manufacturing Practice (GMP) and the license for manufacturing of surgical consumables had not been obtained from the National Drugs Regulatory Authority by an actual manufacturer of surgical consumables which had been purchased and supplied by the contracted investor to the Medical supplies Division. Further another actual manufacturer had obtained the Certificate of Good Manufacturing Practice on 02 January 2002 and the Production license on 20 November 2010 and however those documents had not been updated from the National Drug Regulatory Authority.	Although actions were taken by an actual production institute to obtain the Certificate of Good Manufacturing Practice (GMP), the National Drugs Regulatory Authority (NMRA) had not issued the said certificate to them up to now. The validity period of Certificate of Good Manufacturing Practice issued to the other actual manufacturer is remained continued.	Having updated Certificate of Good Manufacturing Practice (GMP) by the institutes which were contracted to joint ventures should be supervised.
(viii)	Quality control testing had not been carried out for 2 pharmaceutical items which had been purchased from joint ventures and supplied to the Medical Supplies Division during the year under review and facilities for testing the quality of 5 surgical consumable items had not been owned by the Corporation. Therefore samples of each production categories had been referred to the Industrial	It is expected to submit samples received by the Corporation after getting tested by the Industrial Technology Institute (ITI) in future. As per the agreements entered into with joint ventures, samples are tested randomly and the Certificate of Analysis presented with each supply by joint ventures is studied very carefully.	An independent confirmation should be carried out regarding the quality of pharmaceuticals supplied to the Medical Supplies Division under the joint ventures.

	Technology Institute (ITI) by the suppliers themselves and the quality of pharmaceuticals had been considered based only the testing reports issued by the said institute. Accordingly an adequate independent confirmation had not been carried out for the pharmaceuticals supplied to the Medical Supplies Division under the joint ventures.		
(ix)	According to the section 7.1 of the joint venture agreement in connection with quality control and regulation of medical supplies, any physical verification had not been carried out by the Corporation even up to 13 November 2019 in connection with the production process and the quality of productions relating to two actual manufacturing organizations of which the surgical consumables had been manufactured and supplied under the joint venture agreements in the years 2018 and 2019. Accordingly, such productions had been supplied to the Medical Supplies Division under the trade name of the Corporation without having adequate independent confirmation about the quality or the standard of production of such productions.	Certificates of Registration of Drugs and Surgical Consumables issued by the National Drug Regulatory Authority and the Quality Test Report issued by the Industrial Technology Institute to the joint venture which the drugs and surgical consumables are purchased from are examined and actions will be taken to carry out adequate physical verifications relating to the production process of joint ventures and to confirm the quality in future.	An independent confirmation should be carried out regarding the quality of pharmaceuticals supplied to the Medical Supplies Division under the joint ventures.
(x)	According to the section 10 of the joint venture agreement, performance bonds had not been obtained in connection with 10 items of pharmaceuticals valued at Rs.824.95 million for which the Corporation had awarded orders during the year under review.	There was an outstanding amount to be paid to an institute relating to the year 2019 and the said supplier had not submitted the performance bond due to this reason. However pharmaceuticals were submitted to the Medical Supplies Division because of the requirement of supply of pharmaceuticals. Actions are being taken to obtain performance bonds for every supply for now on.	Procurement management should be done according to the terms of Government Procurement Guidelines and as per the conditions of joint venture agreements.

4. Deficiencies in Contract Administration

Audit issue	Management comment	Recommendation
It was observed in physical audit verification carried out on 12 February and 01 June 2020 that there were huge deficiencies such as cracks in a four storied building which had been constructed incurring total sum of Rs.118.58 million and opened on 12 October 2018, leakage of rain water into the building from various places, less constructions than the amount mentioned in Bill Of Quantities. Payments being made for the full amount relating to such items without considering such deficiencies etc. It was further confirmed that according to the report of the Central Engineering Consultancy Bureau received by the Corporation on 12 June 2020, Standard Construction Practices had not been followed in construction of the said building and such deficiencies had occurred due to the said reason.	There were a lot of deficiencies in this building, a report was obtained from the Central Engineering Consultancy Bureau (CECB) in this regard, the Deputy Director General (Engineering) of the Ministry of Health had come for an investigation after informing to the Secretary to the Ministry of Health to have an investigation in connection with the matters mentioned in the said report and the audit report. Meanwhile the contractor had corrected such deficiencies. Actions will be taken to adjust prices after measuring again by the consultants in connection with the construction made less than the Bill of Quantities and to set off the over payments from the retention money and actions will be taken depending on the decision made by the Secretary to the Ministry of Health.	Contract administration should be done properly according to the Government Procurement Guidelines and further actions should be taken after having a proper investigation regarding this construction.

5. Accountability and Good Governess

Annual action Plan

Audit issue	Management comment	Recommendation
The following observations are made in connection with the five year corporate plan prepared for the period of 5 years from 2018 to 2022 and the progress of the achievements of activities included in the action plan prepared for the year 2019.		
(i) According to the Public Enterprises Circular No. PED 12 dated 02 June 2003 and the paragraph 5.1.2 of the	Action will be taken to submit the current progress of relevant activities as soon as possible in future	Actions should be taken as per the relevant circular and the Guideline

	Public Enterprises Guideline for Good Governess, the cooperate plan should be prepared including the Key Performance Indicators as to be able to evaluate the performance of activities which should be achieved during the time periods. However key performance indicators relating to certain activities included in the corporate plan prepared by the Corporation had not been shown specifically, materially and measurably. As a result the progress of 17 activities included in the action plan prepared for the year under review could not be evaluated specifically.	and the corporate plan will be prepared including key performance indicators (KPI) in future.	
(ii)	It had failed to fulfill 19 activities included in the action plan during the year under review. In addition progress of 11 other activities had not been reported and only the physical progress had been shown for 6 other activities without showing the financial progress. Therefore the progress of the said 17 activities could not be measured specifically.	Action will be taken to submit the current progress of relevant activities as soon as possible.	Actions should be taken as per the relevant circular and the Guideline
(iii)	According to the corporate plan prepared for a period of 5 years from the year 2015 to the year 2019 and the action plan , even though distributers and charted dealers should be identified where necessary to expand the sales network, it was failed to identify new distributers and charted dealers during the said period.	Actions were not taken to identify new distributers or charted dealers due to lack of adequate stocks as a result of the JICA project for increasing the production capacity of the Corporation. Approval of the Board of Directors was obtained to recruit new distributers for the year 2020 and actions will be	Operation activities should be organized, as per the corporate and action plans.

		taken to expand the sales network in future.	
(iv)	According to the activity 3.1.3 of the action plans prepared during the period of 5 years from the year 2015 to the year 2019, actions had not been taken to carry out market surveys and investigations properly.	It was difficult to obtain correct market information regarding sales due to the fact that adequate stocks not being available continuously to meet the private market demand and hence actions are being taken to obtain such information verbally in the instances where necessary.	-do-