National Medicines Regulatory - 2020.

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1. Financial Statements

1.1 Qualified Opinion

The audit of the financial statements of the National Medicines Regulatory Authority for the year ended 31 December 2020 comprising the statement of financial position as at 31 December 2020 and the statement of comprehensive income, statement of changes in equity and cash flow statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, was carried out under my direction in pursuance of provisions in Article 154 (1) of the Constitution of the Democratic Socialist Republic of Sri Lanka read in conjunction with provisions of the National Audit Act No. 19 of 2018 and Finance Act, No.38 of 1971. My comments and observations which I consider should be tabled in Parliament appear in this report.

In my opinion, except for the effects of the matters described in Paragraph 1.5 of this report, the financial statements give a true and fair view of the financial position of the Authority as at 31 December 2020, and of its financial performance and its cash flows for the year then ended in accordance with Sri Lanka Sector Accounting Standards.

1.2 Basis for Qualified Opinion

My opinion is qualified based on the matters described in paragraph 1.5 of this report.

I conducted my audit in accordance with Sri Lanka Auditing Standards (SLAS). 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

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Management is responsible for the preparation of financial statements that give a true and fair view in accordance with Sri Lanka Sector 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 Authority'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 Authority or to cease operations, or has no realistic alternative but to do so.

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

As per Sub-section 16 (1) of the National Audit Act No. 19 of 2018, the Authority 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 Centre.

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

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

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

- Appropriate audit procedures were designed and performed identify and assess the risks of material misstatement in financial statements whether due to fraud or errors in providing a basis for the expressed audit opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

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

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

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- 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 Authority'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 Institute 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 Authority, and whether such systems, procedures, books, records and other documents are in effective operation;

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

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

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

1.5 Audit Observations on the preparation of Financial Statements

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1.5.1 Internal Control over the preparation of financial statements

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The Authority is required to "devise and maintain" a system of internal accounting controls sufficient to provide reasonable assurance that , transactions are executed in accordance with management's general or specific authorization, transactions are recorded as necessary to permit preparation of financial statements in conformity with the applicable reporting standards , and to maintain accountability for assets, access to assets is permitted only in accordance with management's general or specific authorization, and the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

1.5.2 Non-compliance with reference to Sri Lanka Accounting Standards

	Non-compliance with reference to the Relevant Standard	Comment of the Management	Recommendation
(a)	Instead of being classified as current assets and non-current assets the distress loan of Rs. 8,796,260 issued to the officers in terms of Paragraphs 60 and 66 of Sri Lanka Accounting Standard 1, it had been stated as current assets. Likewise, provision for employees' gratuity of Rs. 2,150,728 to be disclosed as anon-current liability in terms of Paragraph 69 of the Standard had been shown as a current liability.	Corrections and disclosures will be made through the final accounts of the ensuing year.	Action should be taken in keeping with the accounting standard.
(b)	In order to correct the errors occurred during the preceding years, a sum of Rs.52,414,563 had been adjusted to the balance of the Statement of Changes in Equity at the beginning of the year. Nevertheless, the nature of the errors had not been disclosed in terms of Section 49 of the Sri Lanka Accounting Standard 8.	- Do-	- Do-
(c)	In terms of Sri Lanka Accounting Standard 10, if the events after the reporting date of the financial statements pose a material influence, it should be disclosed in the financial statements. Nevertheless, the deletion of data and confidential information of the Documents and Workflow Management System and an estimate of the resultant financial impact or in case such estimate could not be prepared, a statement to that effect had not been disclosed in the financial statements.	- Do-	- Do-
(d)	In terms of Paragraph 55 of Sri Lanka Accounting Standard 19, the accounting policy adopted in the calculation of employees' gratuity had been disclosed, whereas calculation of employees' gratuity had not been carried out based on that policy. Further, a distinguishable Plan Asset had not been prepared in relation to the non-defined benefit plan of Rs. 2,150,728 of the Authority.	- Do-	- Do-

1.5.3 Accounting Deficiencies

	Audit Observation	Comment of the Management	Recommendation
(a)	Although non-current assets including 03 vehicles belonging to the Presidential Secretariat, 06 vehicles belonging to the Ministry of Health and the National Medicines Quality Assurance Laboratory functioned under the Ministry and its assets had been permanently given to the Authority, action had not been taken to assess and account for those assets and to recognize the depreciation expenses relating to them.	Measures are being taken on the transfer of 06 vehicles belonging to the Ministry of Health and other assets will be included in the final accounts for the year 2021.	All the assets of the Authority which have not been brought to account should be assessed and accounted for.
(b)	Without being taken action to identify and properly adjust in the accounts a sum of Rs. 2,628,262 directly received by the bank as at 31 December 2020, it had been stated as unidentified deposits in the financial statements. Hence, the current liabilities had been increased by similar value.	Being the deposits directly received by the bank, these unidentified balances occur every month and due to setting these balances in the following month, this value has to be accounted for as unidentified deposits.	Income related to the accounting period should be correctly identified and necessary adjustments thereto should be made.
(c)	As accrued expenditure of Rs. 7,113,732 as at 31 December 2020 had not been brought to account, profit of the year and current liabilities had been overstated and understated by that amount in the financial statements respectively.	Corrections will be made through the final accounts of the ensuing year.	Expenditure relating to the period of accounts should be correctly identified.
(d)	As provision for Income Tax had been excessively made by Rs.41,648,456 for the year under review, the after tax profit for the year under review and provision for Income Tax as at 31 December 2020 had been understated and overstated in the financial statements respectively.	- Do-	Provision for Income Tax relating to the period of accounts should be correctly made.

1.5.4 Unauthorized Transactions

Description on the Unauthorized Transactions	Comment of the Management	Recommendation
Although the Board of Directors had granted approval to hire 03 vehicles per day to transport the officers due to prevailing Covid 19 epidemic and to pay Rs.20,000 per day for the 03 vehicles, contrary to that 06 vehicles had been so hired and Rs.49,500 had been paid per day. Accordingly, a sum of Rs. 4,344,280 had been overpaid for the period of 10 months from March to December 2020 contrary to the approval of the Board of Directors.	Initially 02 busses were deployed on the approval of the Board of Director for the transport of staff due to Covid 19 epidemic and subsequently, the facility was increased by deploying 03 busses and 02 vans on the requirement of staff's reporting for service.	Action should be taken either to obtained approval of the Board of Directors for the overpaid amount or to recover that amount from the officers who should be held responsible.

1.5.5 Lack of Documentary Evidence for Audit

Item	Amount	Audit Evidence not Furnished	Comment of the Management	Recommendation
	Rs.			
Receipt of advances	72,972,666	Detailed schedules and details on receipts relating to a sum of Rs. 72,972,666 received as advances as at 31 December 2020 were not furnished to audit.	Relevant schedules will be furnished to audit without delay.	Relevant schedules and details on receipts should be furnished to audit.

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

Reference to Laws, Rules, Regulations etc.	Non-compliance	Comment of the Management	Recommendation
(a) National Medicines Regulatory Authority Act, No.05 of 2015.			
(i) Sections 43(2) (a) and (b)	Although the Medicines Evaluation Committee should carry out a technical evaluation of the medicines forwarded for registration and submit a report in	Applications made for registration will be forwarded to the Medicines Evaluation	Action should be taken in accordance with provisions

		respect thereof specifying the benefits and risks attached to such medicines and the quality, efficacy, safety, need and cost of such medicines with pharmacoeconomic analysis where necessary in keeping with the National Medicines Policy, no request whatsoever had been made to the Medicines Evaluation Committee consisting of specialist physicians representing the fields such as general medicine, general surgery, paediatrics, gynaecology and obstetrics and professors in Pharmacology to carry out such evaluation and submit a report on the medicines forwarded for the registration. Instead, action had been taken to issue a provisional certificate or full registered certificate after evaluating the relevant applications by a Pharmacist and thereafter examining that evaluation again by another three Pharmacists, and the details on such registrations had been submitted to the Medicines Evaluation Committee following the issue of registration certificate to the relevant company.	Committee and evaluated and submitted recommendations with effect from 05 October 2020.	of the Act.
(ii) Section 59(4)(b)		Although medicines should be submitted to the National Medicines Quality Assurance Laboratory (NMQAL) for testing of the quality thereof before registration of the medicines, without being so taken steps to test the quality of the medicine, 1,055 registration certificates had been issued during the year under review, including 1,035 temporary registration certificates and 20 fully registered certificates issued for a period of 05 years only upon the evaluation of documented information of the medicine by a Pharmacist. According to the data of the National Medicines Quality Assurance Laboratory, the total number of medicine samples tested for issuing registration certificates was 33 during the year under review.	Testing for quality of all the medicines is not practically performed, only medicines selected according to the guidance on providing samples to the Medicines Registration and Quality Test Division are tested, and registration certificates for the medicines of Meropenem For Injection, Erythromycin (All Dosage Forms),	Action should be taken in accordance with provisions of the Act.

			Thyroxin (All Dosage Forms) will be issued upon necessarily receipt of the quality assurance certificates.	
(iii)	Section 74(1)	The medical devices permitted for the purpose of the Act had not been listed from time to time by the Minister.	It is practically difficult to make such list and publish in the Gazette and it will be taken into account in making amendments to the Act.	Action should be taken in accordance with provisions of the Act.
(iv)	Section 109	During the year under review, 81 letters of exemption from registration had been issued due to the reasons such as cancellation of registration, lack of registered suppliers, not presenting the registered bidders which were not come under the category of special circumstances such as to save a life, to control an outbreak of an infection or an epidemic or any other national emergency or for national security. One of the above letters had been issued to a private company to release the stock of 6,000 bottles of Furosemide syrup costing Rs. 2,563,080 from the Custom that is used for the diseases such as cardiac, liver, renal diseases and hypertension. It was revealed at a laboratory test conducted after the use of 98 per cent of the above medicine in the hospitals including Lady Ridgeway Hospital for Children that the drug had failed in quality. It was observed that these types of quality failed medicines had been received to the country due to issue of letters of exemption from registration without evaluating documents on the quality of the relevant medicine or the samples, accordingly the medicines without assurance of the quality had been issued to the patients and the resultant damages to the patients could not be measured.	In terms of Section 109 of the Act and recommendations of the Ministry of Health, the applications submitted are referred to the subcommittee of experts established by the Authority and the letter of exemption from registration is issued only for the relevant stock of medicines upon the recommendation of that committee.	Letters of exemption from registration should be issued only for the special circumstances specified in the Act.

(v) Regulation issued in terms of Section 142 relating to the registration of medicines and issue of licences.			
❖ Regulation No, 4	A common register had not been maintained to document every request made for the registration of medicines. As a result, details such as date of receipt of the application for registration of medicines, application number, name of the manufacturer, country of manufacturer, authorized importer, generic name; if the medicine is a combination product, the generic name of the active ingredients, brand name, the dosage, strength of the medicine, type of the application (new application or an application for renewal), type of medicine as well as details on money received for each application, date of submission of each application to the Medicines Regulatory Division for evaluation, number of applications rejected and approved by each division, the number of applications further being processed in each division and the time taken by each division for the registration could not be obtained by the audit. Accordingly, it was observed that the registration of medicines and licensing process had not been carried out transparently.	All applications made for the registration of medicines are documented separately and the use of computerized common register for the activities relating to the new applications and the renewal of registration was commenced from 01 November 2021.	Action should be taken in accordance with the directives.
❖ Regulation No. 133 (5)	Although a data base together with the necessary information relating to the applications received, approved, rejected and suspended by the Authority or the withdrawn applications should be maintained, such data base had not been maintained by the Authority.	Action will be taken to maintain a data base in the future.	- Do-
❖ Paragraph 08 of Schedule	An information system had not been maintained to ensure that the registration certificates would be issued within the	Action will be taken to maintain an information system in	Action should be taken in accordance

	XXIII in Regulation No134	targeted processing period specified in the paragraph and to examine to that effect.	the future.	with the regulation.
(b)	Section 40 of the National Audit Act, No.19 of 2018.	An Internal Audit Division had not been established for the Authority.	Action is being taken to make relevant recruitment to the post of Internal Auditor and an Internal Audit Division will be established on completion of those activities.	Action should be taken in accordance with provisions indicated in the Act.
(c)	Paragraph 10.1 of the Establishments Code of the Democratic Socialist Republic of Sri Lanka.	Although a staff officer entitled to a 1/20 allowance is not entitled to overtime pay for his performing duties during weekends and public holidays, staff officers serving in the Authority had obtained both 1/20 allowance and an overtime allowance.	These payments were made with the approval specified in the letter No. MH / AD / 01/04/12/2016 dated 09 September 2016 issued by the Ministry of Health, Nutrition and Indigenous Medicine.	Action should be taken either to recover overpaid allowances or to recover the money from the officers who acted contrary to the provisions of the Establishments Code.
(d)	Financial Regulations of the Democratic Socialist Republic of Sri Lanka.			

	(i) Financial Regulation 237(b)	It was observed at an audit test check that 10 payment vouchers worth Rs.1,896,284 in which specific certificates relating to each expenditure had not been attached had been certified.	The relevant officials were instructed to pay attention to ensure the certification of those payments including all certificates.	Action should be taken in accordance with the Financial Regulations.

	(ii) Financial Regulations 371 (2) (b) and Public Finance Department Circular No. 03/2015 dated 14 July 2015	Even though the maximum amount of ad hoc sub-imprests that can be given to a staff officer is Rs. 100,000, ad hoc sub-imprests of Rs.1,329,200 had been issued on 12 occasions exceeding that limit and in most cases the ad hoc sub-imprests had been re-issued before settling the sub iprests obtained. Further, ad hoc sub-imprests of Rs. 1,961,700 had been settled after a delay of 03 days to 185 days from the completion of the relevant work.	Having been attached an officer to the subject necessary internal awareness was made to rectify those deficiencies.	Action should be taken in accordance with Financial Regulations and circular provisions.
	(iii) Financial Regulations 128 (1)(e), 507,756, 757,758, 770 and Paragraph 3.1.6 of Public Finance Circular No. 05/2016 dated 31 March 2016.	Although the Accounting Officer should make arrangements to appoint the Board of Surveys before 15 December of each financial year and submit its reports to the Auditor General with a copy to the Chief Accounting Officer before 17 March of the following year, non-current assets totalling Rs. 55,492,978 had not been surveyed and reports thereof had not been submitted to the Auditor General since the establishment of the Authority in 2015.	Arrangements are being made to conduct the Board of Survey for the year 2021 and the survey reports for the year 2022 will be submitted to the Auditor General as soon as possible	Action should be taken in accordance with Financial Regulations and circular provisions.
	(iv) Financial Regulation 1645 (a) and 1647(e)	Log entry books had not been maintained for 09 vehicles used by the Authority and a vehicle inventory had also not been maintained.	At present, measures are being taken to maintain vehicle log entry books and a vehicle inventory.	Action should be taken in accordance with Financial Regulations.
(e)	Guideline 4.2 of the Government Procurement Guidelines	Authority had not prepare a Procurement Plan for the year under review.	The procurement plan will be formally prepared focusing on the Government Procurement Guidelines in the future.	Action should be taken in accordance with the Government Procurement Guidelines.
(f)	Treasury Circular			
	(i) Circular No.842 dated 19 December 1978.	No Register of Fixed Assets had been maintained in respect of Property, Plant and Equipment costing Rs. 91,211,454 as at 31 December 2020.	A Register of Fixed Assets is being prepared at present.	Action should be taken in accordance with Circular Provisions.

	(ii) Assets Management Circular No.01/2017 dated 28 June 2017.	Every public institution is required to submit accurate information on all assets under its control to the Comptroller General, and each institution should appoint an appropriate official to coordinate such activities, whereas the Authority had not taken steps accordingly.	Action will be taken to submit accurate information on all assets existed during the years 2020/2021 to the Comptroller General and to appoint a Coordinating Officer.	-Do-
(g)	Public Enterprises Circular, No. 95 dated 14 June 1994.	An incentive scheme relating to Covid-19 had been implemented for the staff without being approved by the Treasury. Irrespective of the normal working days or holidays, allowances had been calculated in a manner equivalent to one and half days per working day, thus paying a sum totalling Rs. 17,843,781 to the staff of the Authority as allowance for the year under review.	Considering all the matters relating to those payments, such payments were suspended with effect from November 2021.	Action should be taken either to obtain Treasury approval on the allowances already paid or recover the sum from the officers responsible.
(h)	Paragraph 5.2.5 of the Public Enterprises Circular, No. PED/12, dated 02 June 2003.	A copy of the budget report approved by the Board of Directors, should have been sent to the Line Ministry, Department of Public Enterprises, the Treasury, and the Auditor General prior to 15 days from the beginning of the year. However, it had not been so done.	Action has been taken to prepare the annual budget for the year 2022 and thereby forwarding a copy thereof after being approved by the Board of Directors.	Action should be taken in accordance with Circular Provisions.
(i)	Public Finance Circular, No. PED/03/2015 dated 17 June 2015.	Contrary to provisions of circulars and without any approval , a sum totalling Rs.250,886 had been paid to the Chairman of the Authority as Covid-19 allowances.	Considering all the matters relating to those payments, such payments were suspended with effect from November 2021.	Action should be taken either to obtain Treasury approval on the allowances already paid or recover the sum from the officers responsible.
(j)	Paragraph 3.1 of the Public Administration Circular, No. 30/2016 dated 29	A fuel consumption test should be carried out after a period of 12 months following each fuel consumption test, running 25,000 kilo meters or a major overhaul on the engine, whichever occurs	Instructions have already been given to conduct fuel consumption tests on all the vehicles.	Provisions of Circulars should be followed.

December 2016.	first. However, it had not been so done with respect to 09 vehicles being used by the Authority.	

1.7 General Administration of Information Technology Infrastructure

Audit Observation	Comment of the Management	Recommendation
The contract for automating the information system of the Authority had been awarded to a private company on 03 May 2018 for a period of 05 years at a contract value of Rs. 29 million. An agreement had been entered into in order to implement the Documents and Workflow Management System under the model of Operational Expenditure Financing; and, a sum of Rs. 12,253,328 had been paid to the contractor during the period from June 2019 up to May 2021. Nevertheless, some of the information maintained in the information system had been deleted either deliberately or due to negligence of the said company. As of 30 November 2021, the service of the system remained non-functional until the end of the investigations conducted by the Criminal Investigation Department in that connection. Furthermore, a Memorandum of Understanding had been entered into with the Information and Communication Technology Agency on 25 June 2018 for a period of one year in order to obtain consultancy, management and technical assistance for the said system, but no action had been taken to extend that agreement in parallel with the 05 year contract period. Moreover, contrary to the contract agreement, action had not been taken to draw attention on the confidentiality of the information, change the passwords, and avoid the misuse of information. Once the completion of automation process, an audit trial had not been carried out with the manual and automated systems being executed parallelly. Furthermore, the management had not been concerned with the matters such as, the possibility of management and conservation of files with copies of the documents being safely stored along with the relevant data up to a period of 05 years, obtaining copies automatically daily, weekly and monthly, and obtaining insurance policy on professional liability;	Following the instructions given by the Board of Directors, this project will be implemented under an accurate methodology in due course.	All the activities such as, implementation of the project, supervision, and consultancy should be done with transparency, effectively and productively in an accurate methodology. The agreement entered into should be extended by the end of each year, and action should be taken in accordance therewith.

and, payments had been made to the company without obtaining secured copies of the data and annexures. The assets in the system costing Rs.7,558,128 should have been capitalized though, that amount had been written off against the profit instead.

2. Financial Review

2.1 Financial Results

The operating result of the year under review was a profit of Rs. 673,604,866 as compared to the corresponding profit of Rs. 795,694,791 for the preceding year, thus observing a deterioration of Rs. 122,089,925 in the financial result. This deterioration had mainly been attributed by the decrease in total revenue by Rs. 132,319,772 and the grant of Rs. 50,000,000 made to the Covid Fund.

3. Operating Review

3.1 Management Inefficiencies

	Audit Observation	Comment of the Management	Recommendation
a)	A private company had been entrusted with the contract on 01 December 2015 to transport, safely store and maintain the completed files. A sum of Rs. 4,503,080 had been paid to the contractor during the 05 year period from the date of awarding the contract up to 31 December 2020. However, it was not verified as per the file that the payments were made after verifying in terms of Paragraphs 3.3 and 3.4 of the agreement that necessary storage facilities were available and the standard procedure to avert fire hazards was followed. Information such as, locations of storing the files, security provided for the documents, and the manner in which such documents were stored, was not known to the Authority even by 23 October 2021. Having stated that some of the files under custody of the then contractor had been damaged by floods in the year 2016, making payments to the contractor for the period of one year from May 2016 to April 2017 had been	After the damage caused by floods in 2016, those files had been transferred to two other stores. Action had been taken to take copies of the damaged files. Audit trial will be carried out as soon as possible in this year thus taking action to ensure safety of the files. Attention has been drawn by the Authority to maintain a record room.	Attention should be drawn on the possibility of constructing a record room for the Authority. It is necessary to ensure the facilities of the stores, safety from the fire hazards, and the standard practice is followed.

	suspended, but no formal inquiry had been conducted on the damaged files. Furthermore, an agreement had not been entered in to with the contractor for the year 2021 even by 23 October 2021 but his services were being obtained even by the date of this report. The Authority had not brought their attention on establishing an own record room by analyzing the cost incurred in that connection over a period of 06 years.		
b)	When a sample of 19 dossiers, under which registration certifications on medical devices had been issued, was examined in the year 2020, it was observed that some of those dossiers had been handed over by the relevant companies in the years 2016 and 2017, and a period ranging from 150 to 1,395 days had been spent to issue certificates after evaluating those dossiers. Matters further observed included : the Chief Executive Officer had taken 15 – 181 days to provide 451 dossiers for evaluation; external evaluators had been entrusted with evaluation after a period of one year; and, action had not been taken to obtain the evaluation reports or take follow up action.	Not commented	A formal inquiry should be conducted in that connection.
c)	Requests had been made for registration of 583 new medical devices in the year under review, but registration certificates had been issued only for 149 devices even by 01 April 2021 whereas 04 of them had been turned down with decisions pending on 02 other devices. Registration could not be given for the rest of the 428 medical devices.	- Do.	- Do.
d)	Contrary to Sections 41 (2), 66(2), and 87(2) of the National Medicines Regulatory Act, No. 05 of 2015, officers holding a recognized degree in Medicine, Pharmacology, Pharmacy or any other related discipline, had not been appointed to the Medicine Regulatory Division, Medical Devices Regulatory Division and the	Highly experienced Pharmacists in the health sector are officiating in those Divisions. Officers qualified enough among the ones absorbed into the	It is necessary to make sure that provisions of the Circular are adhered to.

	Borderline Production Regulatory Division.	permanent staff of the authority, would be appointed as Heads of the Divisions relating to regulating activities.	
e)	Contrary to Sections 60 (2), 61, 84 (2), 85, 103(2), and 104 of the National Medicines Regulatory Act, No. 05 of 2015, the Authority should have informed the public trough the Gazette on the refusal to register medicines, medical devices, and borderline products. Nevertheless, it had not been so done.	It is acknowledged that the said process had not taken place regularly, and this will be done on regular basis in due course.	Provisions of the Circular should be followed.

3.2 Operating Inefficiencies

	Audit Observation	Comment of the Management	Recommendation
a)	The National Medicines Quality Assurance Laboratory had submitted an application to the Sri Lanka Accreditation Board on 06 February 2020 in order to obtain a certificate of conformity. However, that certificate could not be obtained even by the date of audit on 31 December 2021. Furthermore, it was not verified that the Authority had obtained other certificates on standard.	Conversions required by the Sri Lanka Accreditation Board is being done at present. Once the process is completed, the laboratory will again be evaluated by the Sri Lanka Accreditation Board.	Certificate of conformity on the standard of the laboratory should be obtained.
b)	In terms of Sections 72(1), and 93(1) of the National Medicines Regulatory Authority Act, No. 05 of 2015, the Authority should prepare guidelines on the medical devices and borderline products presented for evaluation, and such guidelines should be provided for the Medical Devices and	All of the general guidelines have been prepared (by each Division) for the evaluation of medicines, medical devices, borderline products and other relevant items; and, such guidelines have been published on the webpage of the Authority. Instructions issued by the World Health Organization	General guidelines on the evaluation of medical devices and borderline products, and regulations for the registration of products and issue of certificates, should be made.

	Borderline Evaluation Committee. As per Section 142, regulations should be made relating to the issue of licenses and registration of medical devices and borderline products. Nevertheless, such guidelines had not been prepared and published in the Gazette, nor had the regulations on the registration and issue of licenses been made.	from time to time, and the evaluation activities of the evaluation committee also belong to the said regulation process. Having considered the possibility of issuing guidelines separately, corrective measures will be taken in due course.	
c)	Contrary to Section 123 of the National Medicines Regulatory Authority Act, No. 05 of 2015, an Appeals Committee had not been appointed to hear and determine appeals presented to the Authority.	As the Appeals Committee should be appointed by the Minister, the Minister has been informed in that connection.	Provisions of the Act should be followed.
d)	The number of samples tested by the National Medicines Quality Assurance Laboratory in the preceding year in terms of Section 39 of the National Medicines Regulatory Authority Act, No. 05 of 2015, represented 60 per cent of the total number of samples presented in that year. Furthermore, only 334 of the 468 samples presented during the year under review had been tested showing the progress of 71 per cent.	Testing all the samples received by the laboratory within the same year is difficult. This is a process taking part in every year. Quality reports on the samples remaining in the year would be issued later, and reports on 443 of the 468 samples received in the year 2020 have been issued representing 95 per cent.	Action necessary to increase the number of samples being tested, should be taken.
e)	Revenue totalling Rs.6,464,208 had been refunded in 107 instances during the years 2019 and 2020 due to reasons such as, overcharge of Value Added Tax by the Authority from external institutions, double	The collected revenue is refunded to the parties responsible due to miscellaneous reasons. There were 107 instances of refund only in the years 2019 and 2020. External parties as well as internal	Action should be taken to identify the unjustifiable reasons that prompted to refund the revenue, thereby identifying and recovering the overpaid income tax and Treasury levy.

	payments being made owing to negligence and errors of the officers, collection of revenue in excess of the specified fee, non-issue of import licenses following the expiration of registration, and failure in issuing transport licenses owing to changes in names and expiration of the validity period of stocks licenses. However, of the matters based on which the revenue had been refunded, the effect of the negligence and errors of the officers had not been recognized thereby failing to take action to recover the overpaid income tax and taxes of the Treasury, surcharge the responsible officers, and bring remedial measures to minimize the refund of revenue by maintaining a register containing all the information in that connection.	officers were apprised from time to time in the year 2021 to avoid this situation. As a result, the instances of refund could be reduced to 18 in the year 2021.	
f)	The number of pharmacies registered as at 31 December 2020 had not been made available to the Audit. During the year under review, only 48 pharmacies had been inspected by the Authority whereas offices of the provincial health officers had inspected only 23 pharmacies.	Cases had been filed against 48 pharmacies after being inspected. The number of pharmacies inspected was higher than that. The reasons that caused the reduction in the number of cases filed included : curfew imposed in the year 2020, pharmacies had to be closed, and lack of attention drawn to take legal action in the context that the pharmacies had to be open under any circumstance following instructions of the Government to avert a shortage of medicines. Measures have been taken to inspect the pharmacies under	A methodology suitable to inspect the pharmacies and take legal action whenever necessary, should be introduced.

	a proper plan and targets during this year.	

3.3 Transactions of Contentious Nature

Audit Observation	Comment of the Management	Recommendation
It had been targeted as per the regulations relating to the registration of medicines and issue of licenses that 300 working days would be spent on the evaluation of a registered dossier, 180 working days would be spent to evaluate a registered dossier on priority basis, and 15 working days would be spent on the initial examination on the completeness of a registered dossier. However, the same Pharmacist, under the knowledge of the Chief Executive Officer, had evaluated within 01-02 days 17 of 93 dossiers presented to obtain certificates to import samples and registration certificates in the year under review by 03 companies located at the same address comprising 02 directors with same names along with another company liaised to that company whereas another 24 dossiers had been evaluated with or without knowledge of the Chief Executive Officer. Moreover, it was confirmed through an independent report of experts that the said dossiers had not been evaluated properly. It was further revealed that the said pharmacist had spent 281-427 days in the year 2019 to evaluate a dossier pertaining to other companies. The applicants who obtained provisional registration, should request for re-registration prior to 06 months before the lapse of the validity period of the provisional registration being 02 years. In 35 instances however, full registration certificate had been issued to the said network of companies within a period of 03 months from the date of issuing the provisional certificates, and evaluation, examining process and approvals of the Chief Executive Officer relating to the said registration had been done within 01-02 days in a manner favourable to that company. Although a period of over one year had elapsed since the Secretary to the Ministry of Health had been informed on the said irregular act, no information was revealed that an investigation had been conducted or a methodology had been put in place to avert such a practice. Instead, 04 responsible pharmacists had been	Not commented.	A formal inquiry should be conducted in this connection.

released to the Ministry of Health on administrative grounds on 12 August 2020 with no disciplinary inquiry at all.

3.4 Procurement Management

Audit Observation	Comment of the Management	Recommendation
As for the contracts the value of which exceeds Rs. 500,000, a formal contract agreement should be entered into in terms of Guideline 8.9.1 (b)of the Government Procurement Guidelines. However, no written agreement had been entered into with the suppliers in respect of the contracts for supply and installation of 10 air conditioners costing Rs. 1,122,095 and purchase of 47 Tabs costing Rs. 2,529,540. As such, services for those items such as maintenance activities, could not be provided.	Those deficiencies will be averted in due course, and procurements will be done in accordance with the Procurement Guidelines.	Provisions of the Government Procurement Guidelines should be followed.

3.5 Human Resource Management

Audit Observation	Comment of the Management	Recommendation
The cadre approved for the Authority as at 31 December 2020 was 257 including 235 permanent employees and 22 employees on contract basis. However, the actual cadre as at that date was 120 of whom 59 had been attached to the posts on secondment basis. Especially, 45 pharmacists evaluating the applications for registration of medicines, had been appointed on secondment basis. Furthermore, 182 vacancies existed including 12 posts in the staff grade such as Director, Deputy Director, and Medical Officer. Furthermore, there existed 70 newly approved posts of Pharmaceutical Assessor and Assistant Pharmaceutical Assessor together with 08 approved posts of laboratory assistant. However, action had not been taken even by 07 October 2021 to recruit officers to	A number of 235 posts had been approved on 07 January 2022 for the permanent staff of the Authority, and 161 employees are in service. The Permanent staff is 111 with a pharmacist employed on secondment basis. Twenty nine Assistant Pharmaceutical Assessors for medicines have been recruited.	The process of absorption and recruitment should be expedited.

those posts. It was observed that vacancies in the posts of drug inspector, and pharma analyst would directly affect the functions of the performance of the Authority such as, inspection of pharmacies, issue of licenses, registration of medicines and medical devices, examining the quality of medicines being presented for registration, and inspection and approval of good manufacturing practices(GMP).

4. Accountability and Good Governance

4.1 Presentation of Financial Statements

Audit Observation	Comment of the Management	Recommendation
The annual financial statements should be presented to the Auditor General within a period of 60 days after the end of the year of accounts in terms of Section 6.5.1 of the Public Enterprises Circular, No. PED/12, dated 02 June 2003. However, financial statements of the year 2020 had been presented to the Auditor General on 16 September 2021 after a delay of 07 months.	Agreed with the observation.	Action should be taken in accordance with the Public Finance Circular.

4.2 Tabling the Annual Report in Parliament

Audit Observation	Comment of the Management	Recommendation
An annual report on the activities carried out in the relevant year of finance should be presented by the Authority to the Minister within a period of six months from the end of the year of finance in terms of Section 23 of the National Medicines Regulatory Authority Act, No. 05 of 2015. That report should be annexed to the report of the Auditor General, the report on accounts of the	The annual reports prepared for the years 2016 and 2017 have been handed over to the Ministry of Health and the State Ministry of Production Supply and Regulation of Pharmaceuticals, Supply and Regulation. The format of presentation has been changed and annual reports	Action should be taken in accordance with provisions of the Act.

Authority audited for the relevant year, and a report on the affairs for the ensuing year. The said report should be presented to Parliament by the Minister within a period of 06 months since the date of receipt. However, annual reports had not been prepared and presented to the Minister and Parliament since the year 2017.	are being prepared according to a new format.	

4.3 Corporate Plan

Audit Observation	Comment of the Management	Recommendation
The Corporate Plan, Action Plan, Procurement Plan and the annual budget of the Authority should have been prepared in parallel, but it had not been so done.	Action is taken to properly prepare those plans.	The Corporate Plan, Action Plan, Procurement Plan and the annual budget should be prepared in parallel.

4.4 Annual Action Plan

	Audit Observation	Comment of the Management	Recommendation
a)	According to Paragraph 04 of the Public Finance Circular, No. 01/2014 dated 17 February 2014 issued by the Secretary of the Treasury, Statutory institutions should prepare an annual action plan with a long term vision for the achievement of objectives mentioned in the Act by including organizational structure of the institution, approved and actual cadre, budget for the relevant year, and the internal audit plan. However, the Authority had prepared only a draft of the action plan for the year under review, and the said information had not been included therein.	Action is taken to properly prepare the action plan.	Provisions of the Public Finance Circular should be followed.
b)	Progress of the activities included in the draft action plan prepared for the year under review, had not been made	Those programs could not be implemented due to	Action should be taken to materialize the

	available to the Audit. Five activities for which provision totalling Rs. 576 million had been allocated, were not initiated. The said amount represented 82 per cent of the annual budget estimate totalling Rs. 700 million.	reasons such as, change in the Cabinet approval later, donation of 03 vehicles by the Presidential Secretariat by suspending the purchase of new vehicles, failure of the National Medicines Quality Assurance Laboratory to provide the specifications, and the spread of Corona Pandemic in the year 2020.	objectives mentioned in the action plan.

4.5 Sustainable Development Goals

Audit Observation	Comment of the Management	Recommendation
According to "2030 Agenda" of the United Nations on sustainable development and the provisions of Circular, No. NP/SP/SDG/17 issued by the Secretary to the Ministry of National Policies and Economic Affairs on 14 August 2017, the Authority should have recognized targets for achieving the sustainable development goals together with the constraints thereon and performance indicators to measures the progress. However, the Authority had not identified such indicators thus failing to measure the progress of achievements, deviations and the areas requiring attention.	Action is taken to bring attention on the targets to be achieved by the Authority in respect of sustainable development goals.	Action should be taken to identify suitable indicators to measure the progress of achieving the targets relating to the sustainable development goals.