National Medicines Regulatory Authority - 2019

1.1 Disclaimer of Opinion

The audit of the financial statements of the National Medicines Regulatory Authority for the year ended 31 December 2019 comprising the statement of financial position as at 31 December 2019 and the statement of comprehensive income, statement of changes in equity and cash flow statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, was carried out under my direction in pursuance of provisions in Article 154 (1) of the Constitution of the Democratic Socialist Republic of Sri Lanka read in conjunction with provisions of the National Audit Act No. 19 of 2018 and Finance Act No. 38 of 1971. My comments and observations which I consider should be reported to Parliament appear in this report.

I do not express an opinion on the accompanying financial statements of the Authority. Because of the significance of the matters discussed in the Basis for Disclaimer of Opinion section of my report, I have not been able to obtain sufficient and appropriate audit evidence to provide a basis for an audit opinion on these financial statements.

1.2 Basis for Disclaimer of Opinion

My opinion is disclaimed based on the matters set out in paragraph 1.5 of this report.

I conducted my audit in accordance with Sri Lanka Auditing Standards (SLAuS). My responsibilities under those Standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of this report.

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 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 intend 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 Section 16 (1) of the National Audit Act No. 19 of 2018, 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 Authority.

1.4 Auditor's Responsibilities for the Audit of the 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 Authority'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 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 Authority 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 Authority*;*
- 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 Financial Statements

1.5.1 Accounting Deficiencies

	Audit Observation	Comments of the Management	Recommendation
(a)	The revenue had been understated by Rs.9,728,822 in the financial statements for the year under review and the expenditure had been overstated by Rs.16,766,765 due to accounting errors of the Authority and as a result, the financial result of the year under review had been understated by Rs. 26,495,587 in the financial statements.	These errors had taken place as it is difficult to differentiate between advance receipts and income receipts out of a very large number of receipts and due to over-accounting of expenses. Those errors will be rectified in the preparation of the accounts for the ensuing year.	The accounts for the year 2020 should be prepared and submitted after rectifying these errors.
(b)	In the rectification of non-accounting of accrued expenses amounting to Rs.2,127,713 as at 31 December 2018, the value had been debited twice to the adjustment account of the previous year.	Those errors will be rectified in the preparation of the accounts for the ensuing year.	The accounts for the year 2020 should be prepared and submitted after rectifying these errors.
(c)	Although an amount totalling to Rs.2,976,895 should be adjusted to the advance account receivable when rectifying the accounting errors related to the previous year, the advance account had been	These errors will be rectified in the preparation of the accounts for the ensuing year.	The accounts for the year 2020 should be prepared and submitted after rectifying these errors.

	stated in financial statements after balancing the advance account without making such adjustments. A difference of Rs.121,182,845 was observed between the balance of the advance account stated in the financial statements and the schedule related thereto due to such accounting errors.		
(d)	Although the Authority has been utilizing a number of fixed assets, including buildings, vehicles, laboratory, laboratory equipment, office equipment and furniture and fixtures owned by the Ministry since the inception of the Authority in 2015, action had not been taken to transfer the assets to the Authority and to adjust the fair value of the assets in the accounts.	Although the assets owned by the Ministry have been used by the Authority since 2015, the Authority was unable to assess and account those assets as the Authority had not employed a permanent staff. Moreover, those activities were further delayed due to the Covid-19 epidemic prevailed in the country during the year 2020 and therefore, action would be taken to assess and account these assets as soon as possible.	These assets should be assessed and transferred and accounted and accounts should be prepared for the year 2020 and submitted.
(e)	An amount of Rs. 5,142,750 paid for Work in Progress during the year under review had not been indicated as an investment under investment activities in cash flow statement. Moreover, the accuracy of the cash flow statement could not be verified during the audit as detailed schedules and explanations were not submitted for the adjustment value of Rs.900,468,913 mentioned in the cash flow statement.	These errors would be corrected in the preparation of the accounts for the ensuing year.	These errors should be rectified and the accounts for the year 2020 should be prepared and submitted.

1.5.2 Unreconciled Control Accounts or Records

Item	Value as per Financial Statements	Value as per Corresponding Records	Difference	Comments of the Management	Recommendation
	Rs.	Rs.	Rs.		
(a) Employees' Trust Fund Account Payable	242,840	(242,840)	485,680	Trial Balances should be carried out to identify deficiencies that have been occurred.	The difference and the reasons for the difference should be identified and action should be taken to rectify any errors if there are any such errors or to prepare reconciliation statements.
(b) Employees' Provident Fund Account Payable	535,187	(535,187)	1,070,374	-Do-	-Do-
(c) Treasury Levy Provision Account	160,486,545	168,623,641	8,137,096	-Do-	-Do-
(d) Pay As You Earn (PAYE) Taxes Payable	170,312	-	170,312	-Do-	-Do-

1.5.3 Documentary Evidences not made available for Audit

Item	Amount	Evidence not available	Comments of the Management	Recommendation
	Rs. Million			
(a) Balance of the Advance Receipts Account	121.1	Schedules and time analysis	That schedules have not yet been prepared for the difference between the balance of the advance account and the balances for which schedules can be submitted.	Schedules and time analysis should be prepared and submitted at the same time of preparing and submitting the financial statements.
(b) Adjustment value of cash flow statement	900.4	Detailed schedules and explanations	Relevant changes have occurred due to an error in the preparation of the cash flow statement and errors will be rectified in the preparation of the accounts for the ensuing year.	-|Do-
(c) 12 Audit queries issued to the Authority	43.1	Answers to audit queries	Unanswered audit queries will be answered as soon as possible.	Answers must be submitted to audit queries by the due date.
(d) Applications for registration of manufacturing plants	-	6 Files containing applications	The files could not be submitted to the audit as the female officer in charge of these applications had transferred from the institution and the officers in charge of the files have already left the institution. Action would be taken to search for the files and the files would be submitted to audit as soon as possible.	Relevant files should be submitted to audit.
(e) Although the number of applications received for the registration of medicines during the year	-	Number of certificates of registration issued	Information on the number of certificates of registration issued can be properly provided in the future after the completion of the online system.	Relevant information should be submitted to audit.

	under review was 2,097, information in relation to the number of certificates of registration issued had not been submitted to audit.			
(f)	Information regarding the certificates of registration issued for 250 medical devices submitted for re-registration during the year under review had not been submitted to audit.	-	Number of certificates of registration issued	Information on the number of certificates of registration issued can be properly provided in the future after the completion of the online system.	Relevant information should be submitted to audit.
(g)	The current progress in the 37 recommendations, which had been recommended to be implemented in relation to the laboratory tests at the National Drugs Quality Assurance Laboratory mentioned in the report of the World Health Organization issued in relation to the benchmarking programme	-	Current progress in the recommendations made by the World Health Organization	For this purpose, a number of criteria contained in the Benchmark tool of the World Health Organization have been submitted to the Institution for the fulfilment of those criteria, many fundamental requirements must be satisfied to meet these criteria, and that it is difficult to fully accomplish those criteria until the requirements are fulfilled, However, these criteria are being fulfilled with the currently available facilities and the criteria thus fulfilled will be re-studied and advices will be provided further by the Evaluation Team of the World Health Organization (WHO) in the future.	The current progress in the recommendations made by the World Health Organization should be submitted to audit.

conducted by the World Health Organization regarding the Authority during the year under review had not been submitted to the audit.

1.6 Non-compliance with Laws, Rules and Regulations

Reference to Laws, Rules and Regulations etc.	Non-compliance	Comments of the Management	Recommendation
(a) The National Medicines Regulatory Authority Act No. 05 of 2015			
(i) Section 43 (2)	Provisional certificates of registration were issued for 10 new applications submitted for registration of medicines without obtaining the approval of the Medicines Evaluation Committee (MEC). Subsequent to issuing certificates of registration for 14 medicine items for 02 institutions, they were submitted to the Medicines Evaluation Committee for approval.	Any application for the registration of medicines was not submitted to the Medicines Evaluation Committee (MEC) at that stage before the application was evaluated.	Certificates of registration should be issued in compliance with the Act.

(ii) Section 51	Certificates of registration were issued for 04 types of medicines related to 04 foreign manufacturing plants, of which evaluation had not been initiated and for 34 types of medicines of 22 foreign manufacturing plants before granting approval for the manufacturing plants. Although a test for good manufacturing practice, which should have been conducted for a foreign manufactory within a year had not been conducted for more than 05 years, registration certificates had been issued for medicines manufactured in that manufactory on 06 occasions.	Answers had not been submitted.	-Do-
(iii) Sections 58, 59, 82 and 83	In the year 2019, the Authority had issued 516 letters of exemption from registration for the State Pharmaceutical Corporation, the Medical Supplies Division and other government and private institutions without complying to the provisions of the Act.	When inquired from the relevant Division in this regard, the Division had admitted that such waiver of registration letters had been issued and such waiver of registration letters had been issued on various essential reasons.	Letters of exemption from registration should be issued only for the requirements specified in the Act. Otherwise, action should be taken to amend the Act.
(iv) Section 59 (4) (b)	Ninety-nine (99) provisional certificates of registration and 49 full registration certificates for 05 years were issued for applications received for new registration of medicines without taking samples during the year under review and 29 certificates of registration were issued for applications received for re-registration of medicines.	The National Drugs Quality Assurance Laboratory does not have facilities to evaluate all the applications received for registration of medicines at the Laboratory. Hence, the registration is done based on the test reports provided by the manufacturer and based on test reports obtained from other institutions.	Necessary facilities should be provided to issue certificates of registration in accordance with the Act.

(v) Section 64	Requests for the evaluation of 25 items of medicines of 03 institutions that had been evaluated in the year 2020 had not been submitted to the Medicines Evaluation Committee and full registration certificates had been issued.	In this stage, any application submitted for the registration of medicines was not forwarded to the Medicines Evaluation Committee (MEC) before the application was evaluated.	Certificates of registration should be issued in accordance with the Act.
(vi) Section 83 (4) (b)	During the year under review, 246 provisional certificates of registration were issued for 579 applications received for new registration of medical devices without obtaining samples and only 01 sample was tested by the Laboratory during the year under review.	The National Drugs Quality Assurance Laboratory does not have the facilities to test samples of medical devices and the registration is done on the basis of the chemical report and the clinical evaluation report issued by the manufacturer and the certificate of registration issued by the National Institute of Equipment Registration in the country of manufacture.	Necessary facilities should be provided to issue certificates of registration in accordance with the Act.
(vii) Section 109	Eighty-nine (89) letters of exemption from registration were issued to the State Pharmaceutical Corporation during the year under review for reasons that were not specified in the Act. Letters of exemption from registration had been issued again and again to the same supplier or the same manufacturer in 06 instances for 03 items of medicines during the year under review.	When inquired from the relevant Division in this regard, the Division had admitted that such waiver of registration letters had been issued and such waiver of registration letters had been issued on various essential reasons.	Letters of exemption from registration should be issued only for the requirements specified in the Act. Otherwise, action should be taken to amend the Act.
(viii) Section 119 (1)	It was revealed at a physical inspection conducted on 27 August 2020 in relation to 26 pharmacies in the	Licenses had not been updated in the proper occasion due to delays and technical errors occurred in changing the system of issuing licenses to the online	Licenses should be issued properly and efficiently. Regulation of Pharmacies should be

		Colombo District, that there was one pharmacy that had been operating without a valid license and 23 pharmacies that had been operating without updating the license for the period of validity. Moreover, there were 12 pharmacies, where a registered pharmacist was not in service at the time of conducting the physical inspection and 15 pharmacies which had not displayed the license for carrying on a pharmacy and pharmacist registration certificate and 05 pharmacies which had not displayed photographs of pharmacists and 04 pharmacies were operating without using air conditioners. There were also 02 pharmacies where medicines were kept at the place where the photocopy machine was located.	system and due to the COVID 19 epidemic prevailing in the country. Necessary action will be taken to rectify these shortcomings immediately after the conducive circumstances are established for unrestricted operation.	formalized.
(b)	Regulation No. 8 of Part I of the Regulations contained in the Gazette No. 2145/1 dated 14 October 2019	The full registration had been granted for 07 items of medicines during the year under review and for 25 items of medicine in 2020 before the expiry of the tenure of the provisional registration of a medicine. Moreover, the full registration was granted for 24 items of medicine of 03 institutions when there was nearly 02 years for the expiry of the validity of the provisional license.	The Authority had conducted a special investigation into the findings of the audit and all the recommendations in this regard had been implemented. Moreover, the relevant officers were made aware to prevent the occurrence of such incidents further. Formal procedures in this regard have already been designed and they are being implemented by now.	Registration should be granted in accordance with the Regulations of the Act and the relevant Gazette.

(c)	Extraordinary Gazette No. 2123/35 dated 15 May 2019	Although maximum retail price had been set for 61 medicines, the Authority had set prices higher than the maximum retail price in the certificates of registration issued for 03 medicines in 03 occasions.	An error had occurred in stating the maximum retail price in the certificates of registration of each medicine, above the maximum retail price specified in the Gazette and this error had taken place due to non-identification of the relevant 03 medicines as price regulated medicines by the gazette notification owing to a certain mistake.	Action should be taken in terms of the Regulations specified in the Gazette.
(d)	Sections 10 and 16 of the Employees' Provident Fund Act No. 15 of 1958.	The Authority had to pay a surcharge of Rs.388,261 during the year under review due to non-remittance of the contribution of the Employees' Provident Fund by the Authority for the period from January 2016 to September 2018.	The routine duties of the Authority were carried out using the trainees of the National Apprentice and Industrial Training Institute as the Authority did not have a permanent staff during the year 2019. Permanent staff for the Authority has already been recruited and dues will be remitted on the due dates avoiding the imposition of such surcharges in the future.	Action should be taken in accordance with the Act.
(e)	Value Added Tax (Amendment) Act No. 06 of 2005	The Inland Revenue Department had imposed a surcharge of Rs.36,864,100 during the year under review due to the delay in the payment of value added tax payable by the Authority for the years 2016 and 2017. Moreover, value added tax payable for the first, second and third quarters of the year 2020 had not been correctly identified and remitted to the Inland Revenue Department even by 11 January 2021.	Discussions are being currently held with the Inland Revenue Department in relation to the imposition of the surcharge and action will be taken immediately after reaching a compromise. The remittance of Value Added Tax to the Inland Revenue Department was delayed due to the inability of the Authority to carry out its daily activities for a period of several months from the end of March 2020 due to the Covid-19 epidemic prevailed in the country during the previous year.	Action should be taken in accordance with the Act.

(f)	Section 113 of the Income Tax Act No. 10 of 2006	As the remittance of the Income Tax of the Authority to the Inland Revenue Department was delayed, a surcharge amounting to Rs. 1,361,759 had to be paid during the year under review for the year 2016/2017.	Since the preparation of the final accounts was delayed due to the non-existence of a permanent staff in the Authority, the remittance of income tax to the Inland Revenue Department was delayed and as a result, the Authority had to pay a surcharge of Rs. 1,361,759. Year-end accounts will be prepared and relevant payments will be made avoiding reoccurrence of such delays.	Action should be taken in accordance with the Act.
(g)	Section 7.4.1 of the Public Enterprises Circular No. PED 12 dated 02 June 2003	Although the Audit Committee was supposed to hold 04 meeting sessions annually, even a single meeting had not been held for the year 2019.	The Authority was unable to hold audit committee meetings for the year 2019 due to non-existence of a permanent staff for the Authority in the year 2019. Although permanent staff was appointed by the end of the year 2019, there was no enough time to hold Audit Committee meetings. Action is being taken at the moment to avoid these shortcomings and 2 Audit Committee meetings have been held for the year 2020.	Action should be taken in accordance with the provisions of the Circulars.
(h)	Public Enterprises Circular No. 02/2018 dated 14 November 2018	Excess money amounting to Rs. 200 million to Rs.900 million in the current account of the Authority had not been effectively invested during the 12 months of the year under review.	Although the balance in the bank account had been maintained without investing the money in the bank account of the Authority during the first quarter of the year 2019, the Authority had taken steps to invest the remaining amount in the Treasury Bills from 2 May 2019 by retaining the required cash balance for the monthly expenses. Moreover, necessary action is being further taken to invest the balance amounts under the Sweeping Facility and ZBA Facility of the Bank of Ceylon after investing money in the Treasury Bills.	Action should be taken in accordance with the provisions of the Circulars.

2. Financial Review

According to the financial statements presented, the operating result of the year under review amounted to a profit of Rs.795,694,791 and the corresponding profit in the preceding year was Rs.809,170,663. Accordingly, a deterioration amounting to Rs.13,475,872 was observed in the financial result. The major reasons for the deterioration are the reduction in income earned from registration and the increase in administrative and other expenses. However, a formal system had not been established to identify and account all the income, including registration fees and license fees, received by the bank in cash and directly for the due accounting period. The income for the year under review had not been accurately identified as all the cash received was credited to the advance receipts account and subsequently an income identification system was adopted.

3 Operational Review

3.1 Management Inefficiencies

	Audit Observation	Comments of the Management	Recommendation
(a)	In terms of Section 38 (2) (a) of the National Medicines Regulatory Authority Act, No.05 of 2015, action had not been taken to transfer the National Drug Quality Assurance Laboratory, which was in operation under the Ministry, to the Authority and to assess its assets and to include the assets under the accounts of the Authority.	Assets owned by the National Quality Assurance Laboratory could not be assessed and accounted as the Authority did not have a permanent staff and these assets will be assessed and accounted as soon as possible.	These assets should be assessed and transferred to the Authority and then the assets should be accounted.
(b)	In terms of Sections 41 (2), 66(2) and 87 (2) of the National Medicines Regulatory Authority Act No. 05 of 2015, an officer with a degree in Medicine, Pharmacology, Pharmacy or any other related discipline had not been appointed as Heads of the Medicines Regulatory Division, Medical Devices Regulatory Division and the Borderline Products Regulatory Division.	At present, officers with the highest qualifications and experience from among the officers employed in those Divisions have been appointed as Heads of the Divisions under the direct supervision of the Chief Executive Officer of the National Medicines Regulatory Authority and necessary action is being taken to recruit the officers with relevant qualifications in accordance with the Act.	Action should be taken in accordance with the Act.

(c)	In terms of Sections 61, 84 (2), 85, 103 (2) and 104 of the National Medicines Regulatory Authority Act No. 05 of 2015, action had not been taken to notify the public by Order published in the Gazette the medicines, registration of which is refused and medical devices and borderline products, which are registered and the registration of which is refused.	In terms of Section 60 (2) of the National Medicines Regulatory Authority Act No. 05 of 2015, the Regulations including medicines registered by the Authority have been published by the notification in the Gazette Extraordinary No. 2144/20 dated 09.10.2019.	The Authority should have acted in accordance with the Act as the Authority had published the Regulations including the registered medicines and it had not taken action to notify the public by Order published in the Gazette the medicines, registration of which is refused and medical devices and borderline products, which are registered and the registration of which is refused.
(d)	In terms of Section 123 of the National Medicines Regulatory Authority Act No. 05 of 2015, an Appeals Committee had not been constituted to hear and determine appeals made to the Authority.	The Minister has been informed of appointing an Appeals Committee as the Minister shall appoint an Appeals Committee.	Action should be taken in accordance with the Act.
(e)	Eight hundred and sixty one (861) medical devices had been submitted for new registration during the year under review and certificates of registration had been issued only for 247 medical devices by 27 August 2020. The Authority could not grant registration for the remaining 614 medical devices.	Medical devices are sent to the expert institutions for registration and information on clinical evaluation of the medical devices are obtained and the rest of the evaluations are carried out in relation to the registration and then the registration is granted and a certain period of time should be spent for that purpose. Applications are evaluated by convening the experts to this Authority for conducting clinical evaluations and it was not possible to convene the Officers to the Authority by March 2020 due to the prevalence of the Covid-19 epidemic.	Action should be taken to evaluate and grant the registration within a specified period.
(f)	The register, in which every application received for the new registration of a medicine was	Although the register, in which every application received for the new registration of a medicine was	The capacity of the Laboratory should be improved for enabling

	recorded was misplaced during the period from 01 January 2019 to 26 April 2019 and 1,168 samples were received for new registration of medicines and 440 samples for re-registration of medicines during the subsequent period. However, only 60 samples had been tested by the Laboratory during the year under review and it was not possible for the laboratory to test the remaining 1,548 samples.	recorded, was misplaced during the said period, the information was submitted to the audit using an Excel worksheet copy. During the above period, 13 samples were sent to the Laboratory for registration and quality reports for all those samples have been issued.	the laboratory to test all the samples submitted for testing.
(g)	A specific time period for registration and licensing of pharmacies is not stipulated within Section 119 (4) of the National Medicines Regulatory Authority Act. Various periods ranged from 04 months to 01 year during the year under review had been spent from the date of charging money up to the date of issuing licenses for 119 pharmacies and there were 117 occasions where a period ranged from 01 month to 10 months had been spent even after printing the pharmacy licenses for the issuance of those licenses with the signature of the relevant Authority. Acceptable reasons were not submitted for spending such a long period from the date of printing of the licenses up to the issuance of licenses.	The delays had occurred due to the covering of the functions such as basic inspection of files and drafting of the licenses with the assistance of the Office Assistants for more than 6 months without obtaining the assistance of the Management Assistants required to discharge those duties and spending a long period of time to update the relevant database due to changes in the format of the license after the introduction of new regulations. These activities have now been updated.	The standard time taken to issue certificates and licenses from the date of submission of applications should be identified. Accordingly, the delay in issuing certificates of registration and licenses should be minimized by following a pre-prepared plan.
(h)	The Authority has taken steps to issue pharmacy licenses (retail and wholesale) in three steps through the Online Computer Automation System with effect from 01 September 2019. However, the pharmacy owners commented that the system was not user friendly as the pharmacy owners have no understanding of this method, no knowledge on information technology, they do not have	The owners of the pharmacies have not yet complained directly to the Authority that the system was not user friendly, action has been taken by investigating in to this issue further, this system is very complex and steps have been taken to make as many corrections as possible despite some delays, certain time has been spent for making these corrections, the Authority has lost some revenue	According to the agreement to design the automation system, the relevant corrections should be made by that Institution.

	efficient computer items and problems on internet facilities. As a result, obtaining of pharmacy licenses had further decreased. The income earned from pharmacy licenses by the Authority had decreased by Rs.30,842,902 as at 31 August in the year under review when compared with the income earned in the previous year. Not updating the functioning of the online computer automation system had been one of the reasons for this situation.	due to practical problems in the use of this system and action is now being taken to correct this situation.	
(i)	Although money had been paid for obtaining pharmacy licenses, the Authority had not established a formal system for avoiding the delay in the issuance of licenses and preventing the conduct of business activities without obtaining licenses or renewing licenses. The supervisory activities on Drug outlets throughout the country had not been adequately carried out.	Although 20 posts of Drug Inspectors have been approved, the Division has not been able to recruit officers for the post due to delays in making recommendations on the scheme of recruitment and salary scale by the National Salaries Commission. Requests have been made to obtain the required Management Assistants for the Division and requests have already been made to rectify the shortcomings in the online system to prevent delays in issuing licenses.	The facilities required for the systematic and efficient issuance of licenses should be provided and the regulation of pharmacies should be formalized.

3.2 Operational Inefficiencies

	Audit Observation	Comments of the Management	Recommendation
(a)	Although the National Drugs Quality Assurance Laboratory submitted an application to the Sri Lanka Accreditation Board on 06 February 2020 to obtain the Conformity Assessment Certificate for the standard of the laboratory, it was unable to obtain the certificate for compliance with standar	Although an application was submitted to the Sri Lanka Accreditation Board on 06 February 2020, further delays in obtaining the certificate is unavoidable as certain requirements, to be fulfilled for obtaining this certificate for compliance with sta	Requirements to be fulfilled further for obtaining the certificate for compl iance with standard s hould be accomplished as soon as possible for obtaining the

	d even by 31 December 2020, the date of the audit. Information on the other certificates for compliance with stand ard obtained had not been submitted to audit.	ndard, have not yet been accomplished and owing to the covid-19 epidemic prevailed during the previous year and still prevailing in the Country.	certificate.
(b)	According to the Benchmarking Programme conducted by the World Health Organization in relation to the Authority during the year under review, the Organization observed that 07 criteria tested regarding the National Drug Quality Assurance Laboratory had been partially implemented and 02 criteria had not been fully implemented.	In this regard, a number of criteria contained in the Benchmark tool of the World Health Organization have been submitted to the institution for fulfilling those criteria and a number of basic requirements must be essentially fulfilled to accomplish these criteria, it is difficult to fully accomplish those criteria until the requirements are fulfilled. However, these criteria are being accomplished according to the facilities that are currently available and the accomplished criteria will be restudied by the Evaluation Team of the World Health Organization (WHO) in the future and further advices will be issued in that regard.	Action should be taken to implement the relevant criteria as soon as possible as per the recommendations of the World Health Organization.
(c)	Although the progress in testing samples for medicines and medical devices in the year 2013 was 97 percent and 100 percent respectively, it had dropped by the year 2019 to 73 percent and 58 percent respectively. Although 217 samples were tested for new registration of medicines in 2013, only 60 samples were tested in the year 2019.	The samples provided for registration have been analysed and reports have been issued.	The capacity of the Laboratory should be improved in order to test of all the samples submitted to the Laboratory.

3.3 Procurement Management

	Audit Observation	Comments of the Management	Recommendation
(a)	During the year under review, 06 air conditioners, 41 units of 13 office equipment items and 02 fingerprint machines were purchased by incurring an amount of Rs. 1,724,196. According to the Government Procurement Guidelines, shortcomings such as non-preparation of procurement schedule in these procurements, non-approval of the relevant specifications by the Technical Evaluation Committee, not fixing a bid validity period for the procurement, not obtaining bid security and performance security, non-issuance of acceptance letters to the bidder and non-issuance of purchase orders to the supplier and not entering in to agreement with the supplier were observed.	Although these procurements were carried out due to the essentiality in maintaining the proper functioning of the institution, these omissions were occurred due to lack of proper training and discharging of works such as rectifying previous omissions by only one officer. Relevant officers have already been made aware to avoid all such shortcomings and to carry out the procurement activities accurately.	Action should be taken in accordance with the Government Procurement Guidelines.
(b)	An amount of Rs. 4,378,726 had been spent during the year under review for the installation of a computerized system (Implementation of Document and Workflow Management System - Automation) for the Authority. An agreement was entered into with the relevant institution on 03 May 2018 to install the computerized system. The project was to be completed and handed over to the Authority by 03 September 2018, within 120 days from that date. However, the completed computerized system had not been submitted to the Authority for implementing the system even by 31 December 2020. Dates had not been extended as scheduled and action had not been taken to recover the late fee amounting to Rs. 3,196,518 as per the special terms of the project agreement.	Special attention will be paid to the matters pointed out in the audit and action would be taken to plan and achieve the said objectives.	Relevant improvements should be made to accomplish all the intended requirements in accordance with the agreements applicable to the installation of the computerized system.

	Certain systems from among the systems that were under development are still in the Implementation Stage and the system had to be further upgraded and modified during the developing stage of the system according to the requirements of the officers who use the system. Additions and enhancements had to be made from time to time as desired objectives and requirements of the system that had been clearly identified had not been initially incorporated in to project proposals and requirements.		

3.4 Human Resource Management

	Audit Observation	Comments of the Management	Recommendation
(a)	The approved cadre of the Authority was 235 as at 31 December 2019, out of which the number of vacancies was 84. The number of vacancies had increased up to 101 by 31 December 2020. Moreover, it was not possible to prepare schemes of recruitment for 07 posts included in the approved cadre and to revise the approved cadre. Although 51 new officers were recruited to the Authority during the year under review, 17 officers out of them had resigned by 31 December 2020. The Authority had failed to retain the officers within the Authority by making the officers satisfied through revising the approved cadre and the schemes of recruitment. This shortage in the staff had profoundly affected the carrying out of the overall operational and administrative functions of the Authority.	At present, discussions are being held with the relevant responsible parties and action will be taken to fill the vacancies immediately after the schemes of recruitment are prepared and approved.	Staff vacancies required to maintain the functioning of the Authority without interruption should be duly filled within the approved cadre.
(b)	Testing of samples at the National Drugs Quality Assurance Laboratory was carried out only by 06 Drug Analysts and any laboratory Assistant	As the Ministry of Health has not yet provided 03 Laboratory Assistants to the Authority, the work of the laboratory is being	Staff vacancies required to conduct the functioning of the Authority

had not been assigned for that purpose even by 31 December 2020.	carried out with obstructions. Since the approval for the Schemes of Recruitment in relation to the post of Laboratory Assistant has already been granted by the Department of Management Services, it is scheduled to make recruitments expeditiously in the future.	without obstructions should be duly filled within the approved cadre.

4. Accountability and Good Governance

4.1 Presentation of Financial Statements

Audit Observation	Comments of the Management	Recommendation
Although the annual financial statements of the Statutory Boards should be submitted to the Auditor General within 60 days after the closure of the accounting year in terms of Section 6.5.1 of Public Enterprises Circular No. PED/12 of 02 June 2003 and in terms of the Treasury Circular No. 01/2004 of 24 February 2004, financial statements for the year 2019 had been submitted for audit on 11 November 2020, after a delay of 08 months.	The Authority was unable to carry out its daily activities for a several months from the end of March 2020 and only a very small number of employees were requested to attend the Authority to carry out the essential daily activities due to the Covid-19 epidemic prevailed in the country during the year 2020. Under these circumstances, the preparation of the final accounts for the year 2019 was delayed.	Accounts should be submitted on the due date as per the Circular.

4.2 Annual Action Plan

Audit Observation	Comments of the Management	Recommendation
The performance criteria for the activities included in the Action Plan for the year under review were not stated specifically, quantitatively and measurably and therefore, the progress of those activities could not be accurately assessed and the Authority had failed even to initiate any function related to the 11 activities included in the Action Plan during the year under review.	Action has already been taken to prepare the Action Plan of the Authority by eliminating the shortcomings in the Action Plan prepared for the year 2019.	The action plan must be prepared accurately and systematically. The Performance Criteria should be indicated specifically, quantitatively and measurably. Action should be taken in compliance with the

Action Plans and the Action Plan should be revised according to the requirement. The responsibility of performing each activity should be specifically assigned to the relevant officers and formal supervision should be carried out in this regard.