National Medicines Regulatory - 2022

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1. Financial Statements

1.1 Adverse Opinion

The audit of the financial statements of the National Medicines Regulatory Authority for the year ended 31 December 2022 comprising the statement of financial position as at 31 December 2022 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 the Financial Act No. 38 of 1971. My comments and observations which I consider should be reported to Parliament appear in this report.

In my opinion, because of the significance of the matters discussed in Paragraph 1.5 of this report, the accompanying financial statements of the Authority do not give a true and fair view of the financial position of the Authority as at 31 December 2022, and of their financial performance and their cash flows for the year then ended in accordance with Sri Lanka Accounting Standards

1.2 Basis for adverse opinion

An adverse opinion is issued due to the materiality of the matters discussed in paragraph 1.5 of this report.

I conducted my audit in accordance with Sri Lanka Auditing Standards (SLAuSs). My responsibilities, under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of my report. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my adverse opinion.

1.3 Responsibilities of Management and Those Charged with Governance for the Financial Statements

Management is responsible for the preparation of financial statements that give a true and fair view in accordance with Sri Lanka Accounting Standards and for such internal control as management determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the 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, 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 Authority.

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

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

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

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control.
- Evaluate the appropriateness of the accounting policies adopted by the management and the fairness of the accounting estimates used the related disclosures.
- 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 it has performed according to its powers, functions and duties; and
- Whether the resources 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

1.5.1 Internal Control over the preparation of financial statements.

Entities are 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. Issues with regard to maintenance of key accounting records such as General Ledger, Journal and Journal vouchers, payment vouchers etc. may include under this heading.

	Audit Observation	Comment of the Management	Recommendation
(a)	A sample audit revealed that payment vouchers of Rs.1,801,296 had been certified on 07 occasions during the year under review without obtaining a certificate that the goods have been received and entered in the relevant inventory or stock books in accordance with Financial Regulation 237 (b).	As of now, payment will be made after obtaining confirmation from the warehouse keeper that the goods have been received through a formal form (GRN) and entered in the stock records.	Actions should be done according to Financial Regulations.
(b)	Although payment should be made only on vouchers certified in terms of Financial Regulation 257 and it should be the duty of every officer endorsing vouchers or paying money to see that the vouchers are duly certified by an officer authorized to certify, according to the sample check, in 15 cases, payments had been made for uncertified vouchers amounting to Rs.28, 873,570.	Those deficiencies will not occur in the future.	Actions should be done according to Financial Regulations.

(c)	According to Treasury Circular No. 842 dated 19 December 1978, a fixed asset register had not been maintained in respect of property, plant and equipment with a total cost of Rs.191,539,373.	That in the future, instructions will be given to the officers in charge regarding maintaining the asset register in a formal manner.	Actions should be done according to circular provisions.

1.5.2 Non-compliance with Sri Lanka Accounting Standards

	Non-compliance with reference to relevant standard	Comments of the Management	Recommendation
(a)	As per paragraphs 38 and 38A of Sri Lanka Accounting Standard 01, prior year comparative information is required to be presented for all figures shown in the financial statements of the year under review, but the authority had not presented comparative information of the previous year for the statement of changes in equity and cash flow statement of the year under review. . Further, the comparative statement of financial position remained unbalanced and showed a difference of Rs.56, 000,000.	It is an omission in the preparation of accounts in the year 2022 and from the coming year, in the submission of financial statements, comparative information of the previous year will be presented and that the statement of comparative financial position does not balance is an omission.	Actions should be done according to Sri Lanka Accounting Standards.
(b)	According to paragraphs 54 and 57 of Sri Lanka Accounting Standard 01, the capital grant balance of Rs. 5,920,019, which should be shown under equity, had been shown under non-current liabilities, therefore the total equity and non-current liability balances of the authority in the statement of financial position had been understated and overstated respectively.	These deficiencies have occurred due to the preparation of the statement of changes in equity for the year 2022 in a new format and the relevant corrections will be made through the final accounts of the coming year.	Actions should be done according to Sri Lanka Accounting Standards.

(c)	According to paragraph 106(d)(iii) of Sri Lanka Accounting Standard 01, the treasury levy of Rs.645,817,300 in the year under review had been included in the comprehensive income statement instead of being included in the statement of changes in equity, the net income of the year under review had been understated by the same amount.	These Deficiencies have occurred due to the preparation of the statement of changes in equity for the year 2022in a new format and the relevant corrections will be made through the final accounts of the coming year.	Actions should be done according to Sri Lanka Accounting Standards.
(d)	According to paragraph 106 and 108 of Sri Lanka Accounting standard 01, the statement of changes in equity should be prepared so that only the components of equity are included, but in the statement of changes in equity of the authority as of 31 December 2022, gratuity provision and deferred tax liability balances amounting to Rs.4,697,073 and Rs. 2,638, 603 respectively had been included. Due to that, in the statement of changes in equity, the total equity at the end of the year under review had been overstated by Rs. 7,335,676.	These Deficiencies have occurred due to the preparation of the statement of changes in equity for the year 2022in a new format and the relevant corrections will be made through the final accounts of the coming year.	Actions should be done according to Sri Lanka Accounting Standards.
(e)	In accordance with paragraph 112 of Sri Lanka Accounting standard 01, the basis of preparation of the financial statements and the specific accounting policies should be presented in the notes. But the notes contained misrepresentations that were not comparable with the financial statements of the year under review, such as that impairment losses have been deducted from the cost of plant and equipment, depreciation method, effective life and scrap value of plant and equipment at the reporting date have been reassessed, call deposits are included in cash and cash equivalents Bank Overdraft is an essential part of the cash management of the Authority. That the authority's	Paying special attention to these submitted notes, necessary arrangements will be made to formally submit the notes in the final accounts of the coming year.	Actions should be done according to Sri Lanka Accounting Standards.

	income tax was calculated in accordance with Inland Revenue Act No.10 of 2006 and that treasury levy paid was classified under cash flows generated from financing activities.		
(f)	According to paragraph 07 of Sri Lanka Accounting standard 07, only investments maturing within 03 months or less from the date of investment should be considered as cash equivalents, but the authority has stated treasury bills and treasury bonds with maturities longer than that amounting to Rs.2,414,857,497, five investments were listed under cash equivalents.	That the relevant corrections will be made in the final accounts of the coming year..	Actions should be done according to Sri Lanka Accounting Standards.
(g)	Operating profit before change in working capital is Rs.643,640,666 less due to non-preparation of cash flow statement in accordance with paragraphs 18(b) and 20 of Sri Lanka Accounting Standard 07, change in working capital items and net cash flow generated from operating activities by Rs. 245,817.300 and Rs. 397,823,366 was overstated and the net cash flow generated from investment activities was understated by Rs. 397, 823, 366.	That the relevant corrections will be made in the final accounts of the coming year..	Actions should be done according to Sri Lanka Accounting Standards.
(h)	Errors of Rs. 1,781,077 in previous years to be corrected by restating comparative values as per paragraph 42(a) Of Sri Lanka Accounting Standard 08 and corrected by restating opening balances of assets, liabilities and equity accounts as per paragraph 42(b), due Rs.1,154,844 had been adjusted directly against the accumulated fund of the year under review.	That the relevant corrections will be made in the final accounts of the coming year..	Actions should be done according to Sri Lanka Accounting Standards.

(i)	Although the nature of the corrected prior years' errors and the corrected values of the relevant line items should be disclosed in accordance with paragraphs 49(a) and 49 (b) of Sri Lanka Accounting Standard 08, the amount credited to the Accumulated Fund by the authority was Rs. 209,335,287 in the previous year. Adjustment of years was not done as above. As a result, the accuracy of the accumulated fund balance of Rs. 4,498,490,257 stated in the statement of financial position as of 31 December 2022 was not sufficiently confirmed.	That the relevant corrections will be made in the final accounts of the coming year..	Actions should be done according to Sri Lanka Accounting Standards.
(j)	According to paragraph 9(c) of Sri Lanka Accounting Standard 10, the cost of assets acquired before the end of the reporting period should be reconciled in the financial statements in determining after the reporting period, but the cost of 03 such vehicles valued at Rs.17,750,000 on 06 February 2023, due to inconsistency in the financial statements of the year under review, the balance of non-current assets as on 31 December 2022 had been understated by the same amount.	The valuation of the 3 vehicles handed over to the Authority has been assessed by the Government Valuation Department on 06.02.2023 and the necessary arrangements will be made to present it in the final accounts of the coming year.	Actions should be done according to Sri Lanka Accounting Standards.
(k)	In Accordance with paragraph 80(b) of Sri Lanka Accounting Standard 12, all adjustments recognized in the year under review for income tax of prior years should be adjusted to the income tax expense of the year under review. However, to correct the overstatement of income tax of Rs.124,779,724 indicated in the audit report of previous tear, due to an incorrect value of Rs. 201,933,336 being credited to the accumulated fund, the income tax expense of the reviewed year was overestimated by Rs. 124,779,724	The Authority has recalculated the income tax from the year 2016 and made adjustments in the financial statements of the year 2022and in those calculations the income tax expense has been overestimated and the relevant corrections will be made in the final accounts of the next year.	Actions should be done according to Sri Lanka Accounting Standards.

	and as of 31 December 2022, the accumulated fund was Rs. 77,153,612 had been overstated.		
(l)	According to paragraph 61 of Sri Lanka Accounting Standard 16, the effective life of property, plant and equipment is reviewed annually, and if the expected conditions differ from the estimates, those changes should be revised according to Sri Lanka Accounting Standard 8, but due to not doing so, as of 31 December 2022, 297 items of assets with zero book value and cost of Rs.33,242,530 were still in use and had not been disclosed in accordance with paragraph 76 of this standard..	That the relevant disclosures regarding these 297 asset items will be made through the final accounts of the coming year.	Actions should be done according to Sri Lanka Accounting Standards.

1.5.3 Accounting Deficiencies

	Audit Observation	Comments of the Management	Recommendation
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(a)	Although the correct values of income tax payable as at the beginning and end date of the year under review are Rs.27,056,509 and Rs.178,969,934 respectively, it is due as on 31 December 2022 as Rs. 151,836,233 and Rs. 10,982, 871 respectively in the financial statements, the correct income tax liability had been understated by Rs. 167,986,963. Further in calculating the taxable income of the year under review the income tax was understated by Rs.90,833,350, due to deduction of disallowable expenses amounting to Rs. 648,809,646 as treasury levy Rs. 645,817,300, other tax Rs.475,999, gratuity provision Rs. 1,862,372 and legal expenses Rs. 653,975.	However, the authority recalculated the income tax from the year 2016 and made adjustments in the financial statements of the year 2022. And in those calculations, the income tax expense has been overestimated and the related corrections will be made in the final accounts of the next year.	The income tax expense of the year and the income tax liability at the end of the year should be calculated correctly.

(b) Due to non-calculation and accounting of fixed deposit interest income of Rs. 113,764,932 for the year under review and the balance of current assets as on 31 December 2022 had been understated by the same value.	That even if the fixed deposit interest income is not indicated in the account statement given by the bank maintaining the accounts, the interest income for the same will be calculated correctly in the next year and action will be taken to include in the accounts..	Interest income for the year under review should be calculated and accounted for on accrual basis.
(c) Although the total value of treasury bills and treasury bond investments as on the beginning and ending date of the year under review was Rs. 2,144,317,223 and Rs. 2,490,867,187 respectively, it was wrongly stated as Rs. 2,141,652,055 and Rs. 2,414,857,497 as on 31 December 2022, the value of financial investments had been understated by Rs. 76,009,690. Furthermore, 22 treasury bill maturities of Rs. 3,193,611,919 and 22 treasury bill reinvestment transactions of Rs.3, 119,059,361 that occurred during the year under review had not been accounted for and although the correct treasury bill interest income for the year under review was Rs. 365,601,378, the authority over-calculated it by Rs. 1,208,036.20 and the net income for the year under review was overstated by the same amount.	By the year 2023, only 03 more treasury bills will mature, while they are not reinvested in treasury bills after they mature and all the matured and maturing treasury bills and bonds will be invested in fixed deposits, so all these problems will be solved.	Investments in treasury bills, maturity and annual interest must be accounted for correctly.
(d) As of 31 December 2022, Rs. 25,420,629 received directly to the bank had been shown as unrecognized deposits in the financial statements without proper recognition and accounting, the net income of the year under review and the current liability balance as of 31 December 2022 had been understated and overstated respectively by the same value.	The recognition of this value is done during the preparation of bank reconciliation statements and since all the deposits included in this value are deposits made directly to the bank, they are values that have not received invoices from the authority and therefore this value has to be considered as unrecognized deposits and specifically Schedules cannot be submitted for this value.	Prior to submit the financial statements for audit, the revenue account related to direct deposits should be identified and accounted for.

(e)	The Office Building where the authority is located, the National Medicines Quality Assurance Laboratory Building and those lands and 06 vehicles had not been taken over, assessed and accounted for and 03 vehicles that were taken over to the authority had not been taken over and accounted for.	Regarding the 06 vehicles, it was discussed in the Audit and Management Committee Meeting of the Ministry of Health and that further action will be taken on the advice of the Secretary of the Ministry of Health and that further work will be done early regarding the transfer of the office building to the authority.	All assets used by the authority but not owned should be taken over, valued and accounted for.

1.5.4 Absence of Written Evidence for Audit

Subject	Amount (Rs.)	Audit evidence not provided	Comments of the Management	Recommendation
Advance receipts	72,972,666	Detailed schedule and receipt details	In this regard, it was discussed in the audit and management committee meeting held in the year 2023 and that the committee gave instructions to prepare and submit a schedules for that value and accordingly the schedules are currently being prepared.	Necessary arrangements should be made to settle this balance or credit it to the State Revenue in terms of Financial Regulations 570 and 571.

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

Reference to laws, rules, regulations etc.	Non-compliance	Comments of the Management	Recommendation
(a) National Audit Act No. 19 of 2018 **Sections** 39(1) **and** 39(2).	Within 03 months of receiving the annual detailed management audit report of the Auditor General, the Auditor General, the Treasury Secretary and the concerned Minister should be	No comments had been made.	Actions should be done according to the National Audit Act.

		informed about the remedial measures proposed or the measures to be taken in to consideration after considering the said report. And If there are reasons for the implementation or impossibility of any action or matter pointed out. The reasons should be presented, but the authority had not acted in accordance with the detailed management audit report of the years 2019, 2020 and 2021.		
(b)	**Code of Financial Regulations of the Democratic Socialist Republic of Sri Lanka**			

	(i) Finance Regulations 128(1)(e), 507, 756, 757, 758, 770 and paragraph 11 of Public Finance Circular No. 01/2020 dated 28 August 2020	Although the Counting Officer should arrange for the appointment of Boards of Survey before 15 December of each financial year and forward their reports to the Auditor General with a copy to the Chief counting Officer before 31 March of the following year, since the establishment of the authority in 2015, the non-current assets with a total cost of Rs. 191,539,373 had not been surveyed and submit the reports to the Auditor General.	The goods survey activities for the year 2023 are currently being done and the related reports will be submitted to the audit as soon as the work is completed.	Actions should be done according to the Financial Regulations and Public Finance circulars.

	(ii) 371(2) (b) of the Finance Regulations and para 9.1(b) of Public Finance (ii) Circular No. 01/2020 dated 28 August 2020	Although a maximum of Rs.100, 000 cash advances can be issued to a staff officer only, but cash advances of Rs. 1,862,050 had been issued to non-staff officers in 90 cases. Also, before the issued advances were settled, re-advances had been issued and more than 50 percent of the advance amount was resettled in 19 cases due to not correctly estimating the cost.	After disbursing money to the officers participating in the committees, the remaining money will be kept until settlement , and as per section 14.2 of the 14 employee classification, third-level officers are considered as staff officers, so the 90 cases indicated include third-level officers of the authority.	Actions should be done according to the Financial Regulations and Public Finance circulars.
(c)	Treasury Circulars ----------			
	Ministry of Finance and Mass Media Asset Management Circular No. 01/2017 dated 28 June 2017	Although every government institute should submit accurate information about all assets under its institute to the Comptroller General and appoint an appropriate officer to coordinate the activities, the authority had not acted accordingly.	That the Authority has appointed Accountant and Administrative Officer of the National Medicines Regulatory Authority to coordinate these activities.	As per paragraph 13 of the circular, arrangements should be made to send the information of the concerned officer to the office of the Comptroller General in the prescribed format.
(d)	**Public Enterprises Circulars** ----------			
	Public Enterprises Circular No. 95 dated 14 June 1994	Without Treasury approval, Rs.26,498,645 as special allowances and Rs.8,327,000 as Attendance allowances and the total amount of Rs.34,825,645 had been paid to the affiliated staff of the National Medicines Regulatory Authority and Ministry of Health from	In terms of 16(2)(1)(b) and (d) of the National Medicines Regulatory Authority Act No. 05 to prescribe the remuneration to be paid to employers and to establish and contribute to staff welfare and social	Actions should be done according to the Public Enterprises Circulars.

	May 2022 to April 2023,	security schemes and to ensure employee satisfaction of the officers by doing so, the Board of Directors decided to provide a special allowance to retain officers in the authority.

2. Financial Review

2.1 Financial Result

The operating result of the year under review amounted to a profit of Rs. 1,294,424,519 and the corresponding profit in the preceding year amounted to Rs. 567,192,769. Therefore an improvement amounting to Rs. 727, 231,750 of the financial result was observed. This improvement was mainly due to the increase in the total income of the authority by Rs. 1,029,745,170 and the decrease in local travel expenses, laboratory equipment and building maintenance expenses and other allowances by Rs.66,367,458 compared to the previous year.

3. Operational Review

3.1 Management Inefficiencies

Audit Observation	Comments of the Management	Recommendation
(a) According to sub-section 14(a) of the National Medicines Regulatory Authority Act No. 05 of 2015, the authority had not collected data on the quantity of drugs, medical devices, Borderline products or investigational medicinal products imported under licence.	As a temporary remedy, an advertisement on 23.02.2022 has been published on the website of the regulatory authority to inform the National Medicines regulatory Authority about the quantity of imported drugs. Medical devices and Borderline products effective from 01.03.2022 and, that the World Health Organization has recommended through the benchmark process that a section called Market Surveillance should be established in the National Medicines regulatory Authority to systematically collect and maintain this data and that through the necessary activities were started a few years ago, they are facing the difficulty of implementing a systematic and comprehensive program with other related government institutions.	Actions should be done according to the provisions of the Act.

(b)	In terms of sub sections 41(2), 66(2), and 87(2)of the Act, An officer with a degree in medicine, pharmacology and pharmacy or other related discipline, the heads of Medicine Regulatory Division, Medicine Devices Regulatory Division and Border Line Production Regulatory Division had not been appointed.	The National Medicines Regulatory Authority Act and the approved staff positions are being amended based on the service requirement of the Authority, taking into consideration the said amendments, the recruitment for the sad positions and the pharmacists who are currently employed will be recruited to the permanent staff of the Authority as soon as they are absorbed on the basis of their qualifications. It is expected that qualified officers from among the officers will be able to be appointed as heads of regulatory affairs departments in the future.	Actions should be done according to the provisions of the Act.
(c)	In terms of sub-sections 43(2) (a) and (b) and 68(2) (a) and (b) of the Act, a technical evaluation report specifying the benefits, risks, quality efficacy status, safety, need, price and where necessary, the economic analysis of the medicines and medical devices submitted for registration to the Medicines Evaluation Committee and the Medical Device Evaluation Committee was not submitted to the authority.	After evaluating all Medicines applications and making recommendations to the monthly Medicines Evaluation Committee (MEC), the report of the committee will be given to the authority and the board memo will be given to the Medicines regulatory division and the authority will be informed in detail about the evaluation procedure of a particular medicine. If it is necessary to investigate, the relevant documents are available at the Medicines Regulatory Division.	Actions should be done according to the provisions of the Act.
(d)	Accounting to sections 58, 59, 82, 83 and 109 of the Act, any medicine or medical devices should not be manufactured or imported without registering with the authority and obtaining a license from the authority and the authority was authorised to issue letters of Wavier of registration only in special cases such as to save life, to control an outbreak of an of infectious or an epidemic or any other, national emergency and national security. But on other reasons, during the year under review, 286 letters of	That in special cases, Wavier of Registration letters are issued on the recommendation of the Ministry of Health, and pharmaceutical companies are not interested in registering medicines with low commercial benefits, and even so' it is essential to set up a system for the import of those medicines when the patients need them, Also included in this free article release And when other regulatory authorities also give clearance approval for such unregistered medicines, a statement is not responsible for the quality, safety, and efficacy of the medicines.	The entry of uncertified medicines in to the country should be minimized by issuing wavier of letters only in specific cases mentioned in the Act.

	Wavier of registration had been issued on behalf of the State Pharmaceutical Corporation and the Medical Supplies Division. It is stated that the authority has not evaluated the relevant medicines during the inspection of 38 certificates of Wavier of registration that had been issued to a private company, and therefore the authority is not responsible for the quality, safety and efficacy of the relevant medicines, and the responsibility should be taken by the director of the medical supply division and the abdication of responsibility by the authority was a point of contention in the audit.		
(e)	According to sections and sub-sections 60(2), 61, 84(2(, 85, 103(2) and 104 of the Act, the registration of medicines, medical devices and Borderline products by the authority as well as the cases of refusal of registration will be published in the gazette but it should be notified to, the Authority has not acted in accordance with it since the date of its establishment.	It is practically difficult to issue daily or monthly gazettes as the necessary activities for the registration of medical devices are done daily and arrangements are made to publish them on the web page with the number of the application Arrangements are being made to publish the registration of Borderline products in the Gazette in Sinhala, Tamil and English to inform the public. The need to inform the public about the rejections has been recognized and is expected to be addressed.	Actions should be done according to the provisions of the Act.
(f)	Neither the Director General of the Sri Lanka Atomic Energy Regulatory Council nor his nominee had been appointed to the Medical Device Evaluation Committee in terms of sub-section 69(1)(b)(v) of the Act. The need to represent the Medical Device Evaluation Committee by the Sri Lanka Atomic Energy Regulatory Council, which has the powers to	Although the authority made a request regarding the appointment of an officer through the letter No. NMRA/MDEC/9/22 dated 15 September 2022, there has been no response so far and a reminder letter is expected to be sent in the future.	Actions should be done according to the provisions of the Act.

	issue licenses and regulate the import and use of radioactive equipment and materials, including medical equipment, was not fulfilled.		
(g)	According to sub-sections 72(1) and 93(1) of the Act, general guidelines had to be issued to the respective evaluation committees for evaluation of medical devices and Borderline products, but such guidelines had not been prepared. Further, the orders had not been prepared for the enforcement of guidelines on good manufacturing practices and other relevant guidelines, specifying the procedure to be followed, including specific time limits for conducting the relevant evaluations in terms of sub-sections 72(4) and 93(4)	That the guidelines for the evaluation of medical devices are in the final stages of discussion with the Medical Device Evaluation Committee, and after several more rounds of discussions, the preparation of the guidelines will be completed and so far, no general guidelines have been presented to the Borderline Product Regulatory Division , but from time to time the decisions taken by the Authority are informed to the Borderline Product Regulatory Division and the same guidelines followed by the Authority regarding good manufacturing practices for medicines are implemented in the borderline Product Regulatory Division as well	Actions should be done according to the provisions of the Act.
(h)	In terms of subsections 74(1) and 95(1) of the Act, registered medical devices and registered borderline products had not been time to time listed by the Minister.	As about three committees and sub committees are held in a month to efficiently evaluate medical devices, the recommendations given by those committees are published on the web page with the number of the application, and daily or monthly gazettes are practically issued as the necessary activities for the registration of medical devices are done daily is a difficult fact and that within a certain period of time, the necessary activities are being considered to inform the public about the recommended and non-recommended medical devices through a gazette and arrangements are being made to publish the borderline products registered in the gazette in all the three languages until 22 May 2023.	Actions should be done according to the provisions of the Act.

(i)	Medical devices and borderline products submitted for registration in terms of sub-sections 83 (4)(b) and 102(4)(b) of the Act had not been submitted to the National Medicines Quality Assurance Laboratory for testing.	That not all devices can be tested in a laboratory and recommendations are also made through clinical trials, evaluation of device research reports , evaluation of laboratory Research reports, demonstration/presentation of its performance to end users and that evaluation of samples prior to registration of each medical device is both a practical and technically unnecessary matter, so evaluations are carried out using regulatory Reliance, Research Laboratory (NMQAL) before registration and the reason for this is that most of the borderline products contains vitamins/minerals and ingredients that do not belong to the pharmaceutical category, so the NMQAL do not have the ability to test those products. That the products are not submitted for testing to the NMQAL.	Actions should be done according to the provisions of the Act.
(j)	In terms of sub-sections 83(6) and 102(6) of the Act, Orders had not been prepared by the Minister specifying the procedures to be followed, the time limits of the process, the manner in which the meetings were to be held, the procedures to be followed in the meetings and the matters to be included in the reports to be submitted during the inspection or evaluation process by the Medical Devices and Borderline Product Evaluation Committees and the National Medicines Quality Assurance Laboratory.	That guidelines for the evaluation of medical devices are in the final stages of discussion with the Medical Device evaluation Committee, and after several more rounds of discussions, are preparation of the guidelines will be completed and it was discussed from time to time that matters related to the regulation of borderline products should be amended according to the Medicines Regulation Act and the borderline production section also submitted ideas and suggestions for the same and until the implantation of the Act, borderline production was not identified as a category to be regulated in Sri Lanka, the absence of any legal documents regulatory guidelines or internationally agreed specifications for the previous queries related to it also led to the delay in the process of preparing regulations and guidelines and thus an environment for making orders correctly for	Actions should be done according to the provisions of the Act.

		restricted products has not been created so far.	
(k)	According to Section 123 of the National Medicines Regulatory Authority Act No. 05 of 2015, an appeals committee had not been established to hear and determine appeals submitted to the authority.	It was decided in the board meeting dated 17 March 2023 to appoint an appeal committee and as per the relevant section of the Authority Act, the appeal committee should be appointed by the minister, so the necessary activities are currently being done to request the minister of health to appoint the appeal committee.	Actions should be done according to the provisions of the Act.
(l)	According to paragraph 5.1 of part II of Public Finance Circular No. 01/2020 dated 28 August 2020, all government institutions shall review the fees charged for the services provided by their institutions to the public and revise them once every three years subject to a maximum of 15 percent. Although the authority in accordance with due to non-action , the revenue of authority had lost fee income of Rs. 306,176,273 during the year under review. 01/2020(i) dated 20 December 2022 directs all government agencies that have not increased their service fees in the years 2020,2021 and 2022to increase their fees by 20 percent before 31 March 2023, although it was emphasized that it should be reported to the Public Finance Department , the authority has not complied with it until now. And formal approval was also not obtained to avoid revision of rates overriding the circular.	In the Discussion in this regard at the audit and management committee meeting of the Ministry of Health held on 07 March 2022, ″A decision by the administration of the National medicines Regulatory Authority on how to revise the service fees considering the current dollar value against the rupee and the service fee income currently received by the authority, the representative of the Treasury informed that it is appropriate to take further action and Accordingly, informed in this regard, a board paper will be submitted to the board of directors and further work will be done according to the decisions taken there.	A formal approval must be obtained to proceed as per the circular or to avoid revising the rates in excess of the circular..

(m)	As per Fee Orders No. 02, 03 and 04 of special Gazette No. 2052/33 dated 05 January 2018. Fees should be charged when applying for Wavier of registration for private supplies of medicines, medical equipment and borderline products, but the authority had lost fees of Rs. 10,686,209 that could have been charged for 123 applications for wavier of registration of medical devices in the private sector that had been rejected during the tear under review due to the charging of fees in granting approval for wavier of registration. Although an internal circular was issued on 25 January 2023 to correct this, no action was taken in terms of Finance Regulation128 (j) against the officers responsible for the huge loss of revenue caused to the Government by contravening the fee order from 2018 to the year under review.	Even before the release of the Gazette dated 05 January 2018. Arrangements have been made to continue to implement the same method followed by the previous institution for the applications for exemption from registration received by the authority and that is not a deliberate attempt to outdo the Gazette, that as soon as the audit pointed out the seriousness of the issue, after the internal circular dated 05 January 2023 and Gazette Np. 2052/33 dated 05 January 2018, after giving approval for public sector supplies, fees are charged when applying for private sector supplies.	Officials responsible for huge loss of revenue to the government should be dealt with under Finance Regulation 128(j)
(n)	Fees No.02, 03 and 04of special Gazette No. 2052/33 for sample analysis should be charged in accordance with schedule viii of the Fee Order. Which did not include provisions on samples exempt for analysis fees. But the authority did not charge for the samples submitted by government institutions like government hospitals, medical supply department and courts. Accordingly analysis fees were not charged for 328 out of 378 samples taken for analysis in the year under review and 421 out of 427 samples taken in the previous year.	Before the establishment of the Drug Regulatory Authority, under the surveillance program implemented under the Ministry of Health, the laboratory officers went to the government health institutions and took samples and they did not charge money for taking the samples and with the aim of encouraging the receipt of complaint samples to the laboratory' It was implemented after the establishment of the National Medicines Regulatory Authority and As no decision has been taken on how to pay for it, this will continue to be implemented as a public health care service for the welfare of the public as before.	Fee Order should be revised after obtaining formal approval for samples exempted from analysis fees.

(o)	The National Medicines Quality Assurance Laboratory had submitted an application to the Sri Lanka Accreditation Board on 06 February 2020to obtain the certificate of conformity assessment regarding the laboratory's standard, but had failed to obtain the standard certificate.	A virtual assessment was conducted on 26 November 2021 after the deficiencies mentioned in the review report were prepared and sent, and further deficiencies were notified on 20 March 2023 and for on-site assessment on 05 July 2023. The Sri Lanka Accreditation Board notified the National Medicines Quality Assurance Laboratory on 03 May 2023 that the date was used.	Every effort should be made to obtain the basic requirements for obtaining this certificate.
(p)	According to Section 39 of the National Medicines Regulatory Authority Act No. 5 of 2015, the progress was only 64 percent as only 241 samples were tested out of 378 drug samples that were submitted to the National Medicines Quality Assurance Laboratory during the year under review. Furthermore, although the test report should be issued within 90 days according to Section 39(4) of the Act and the Standard Operating Procedures of the laboratory, the reports of 47 samples submitted from 2019 to 2021 were not issued by the end of the year under review and were not audited date of May 8, 2023, the reports of 37 samples had not been issued.	That before the establishment of the National Medicines Regulatory Authority in the year 2015, less than 1/3 of the approved technical staff are working and according to the standard operating procedure of the laboratory, it has become difficult to analyze the relevant samples and issue quality reports within 90 days, and that after the establishment of the National Medicines Regulatory Authority, new technical officers have not been recruited for the work of the laboratory, but despite the best efforts under the existing technical staff, it has become problematic in some cases to issue quality reports as scheduled.	The quality reports related to the medicines samples submitted to the NMQAL should be issued in due time.
(q)	The contract for automating the authority's data system has been awarded to a private company for a period of 05 years for Rs.29 million and Rs. 12,253,328 had been paid by May 2021. But due to the negligence or deliberateness of the concerned private company, some information that had been included in this data system had been deleted and this service had been disabled until the investigations of the Criminal	According to the complaint made by the Authority that the information belonging to the relevant data system has been destroyed. The Criminal Investigation Department has reported the facts before the Colombo Magistrate Court. And the Attorney General Appears on behalf of the complaint and the Information and Communication Technology Agency in the said case and since the investigation related to this case is still going on and other activities are being done, after the completion of those	An appropriate information system that can be easily managed should be established promptly to correct the deficiencies in the authority's data system.

Investigation Department were completed. The report submitted by the expert committee appointed in this regard on 15 July 2022 stated that the data that had been deleted from the system could not be restored and so far no action has been taken to recover the loss or take any action against the concerned company.	activities, action will be taken to recover the loss or take action against the concerned company	

3.2 Operational Inefficiencies

Audit Observation	Comments of the Management	Recommendation
During the reviewed year, out of the income of Rs.5,604,061 which was refunded on 80 occasions, Rs.3,021,246 was income related to previous years and based on that income, the authority had already paid an additional income tax of Rs.460,573. Furthermore, 48 percent of the total revenue refunds or Rs. 2,701,407 were overcharges due to the negligence and mistakes of the authority officials.	The officials of the authority have been informed and advised regarding the refunds of collected income and that the activity will be done by a committee.	Actions should be done to minimize the chances of income repayment.

3.3 Procurement Management

Audit Observation	Comments of the Management	Recommendation
Although the contract of Revamping the Medicine Database was awarded to a private entity on 11 November 2020, a formal contract agreement was not entered into according to 8.9.1(b) of the 2006 Procurement Guidelines. Furthermore, as per 8.12.2 of the guidelines, Rs.4, 774,752 had been paid by 31 December 2021 without obtaining a certificate of completion, but this system was still inactive.	That these payments for the data system have been made after obtaining a certificate of completion (by making a note in the relevant file) in accordance with Code 8.12.2 of the Code of Guidelines and that any errors occurred in the use of this data system. The entry has been temporarily stopped and the data will be re-entered after fixing the errors.	Procurement guidelines should be followed and system defects should be fixed and operationalized promptly.

3.4 Human Resource Management

	Audit Observation	Comments of the Management	Recommendation
(a)	As on 31 December 2022, the Authority had 235 approved permanent staff and 22 on contract basis, totaling 257 approved staff. Although the total actual staff was 158, out of which 37 were surplus numbers not included in the approved staff, so the actual number of vacancies out of the total approved staff as on 31 December 2022 was 135.	That so far 235 posts for the authority and 12 posts of Drug Analyst on contract basis and 10 posts of Management Assistant has been approved and actual staff strength is 158 as on 31st December 2022.	Necessary and non-necessary posts should be identified and approved staff should be revised.
(b)	On 03 November 2020, 70 new posts were approved as 30 Pharmacist positions and 40 assistant Pharmacist positions by abolishing 70 pharmacist positions in the approved staff of the authority. But as only 28 Assistant Pharmacist had been recruited by 31 December 2022, the method of absorption or recruitment as recommended by the Department of Management Services to fill the vacancies of 30 Pharmacist and 12 Assistant Pharmacist as of the date of this report. had not been implemented. The roles related to these vacant positions are performed by 37 officers who hold the position of pharmacist, which is a post abolished by the Ministry of Health, and based on the absorption method for Pharmacist positions, those pharmacists have the opportunity to absorb the Pharmacist positions, but the process is delayed. It was observed that they are treated unfairly and that situation can affect their performance.	By cancelling the 70 pharmacist posts approved by the National Medicines Regulatory Authority, the Department of Management Services approved 30 Pharmacist posts and 40 Assistant Pharmacist posts on 21 December 2020, and the recruitment procedures for the same were approved on 31 March 2021, and the Management That the Department of Services approved the process of absorption of pharmacists employed by the Authority for the posts of Pharmacist and Assistant Pharmacist on 14 June 2021, Accordingly, although 29 assistant Pharmacist have been recruited since 15 December 2021 by publishing newspaper advertisements on 13 June 2021. Three of them have resigned and 26 are working and Since the pharmacists employed by the authority must be absorbed into the authority, the secretary of health Ministry has also been informed to take necessary steps to absorb them for the positions of Pharmacist on 30 December 2021 and that the Authority is awaiting the reply of their consent/disagreement to which the absorption process is likely to proceed after receiving their reply.	Arrangements should be made to implement the method of absorption or recruitment as per the recommendations of the Department of Management Services.

(c)	Since 18 positions or 71 percent of the 21 senior management positions in the approved staff of the authority were vacant, it was observed that the authority had failed to identify necessary and unnecessary positions and amended the approved staff and it was observed the presence of necessary positions vacant may have an impact on the overall performance of the authority.	There are 21 senior management posts approved to the authority and among those senior management posts, recruitment was made for the post of Director (Human Resources), but according to the decision of the Board of Directors, that officer was removed from service and although recruitment was also done for the post of legal officer, the said officer was also resigned from the service of the Authority.	Actions should be done to fill these vacancies promptly.
(d)	In the last year, Rs. 308,487 had been spent and applications were invited for the posts of Director (Human Resources) and Internal Auditor by publishing newspaper advertisements, but the posts were still vacant by 31 December 2022.	Interviews had been conducted for the posts of Director (Human Resources) and internal Auditor and due to non-availability of suitable candidates, the Board of Directors decided to cancel the marks of those interviews and that a letter has been sent seeking permission from the prime Minister's Office to recruit for the post of Internal Auditor and that after receiving the permission it is expected to carry out the recruitment for this post And that after the completion of the process of making revisions in the recruitment procedures to recruit a more qualified officer for the post of Director (Human Resources), it will be possible to recruit for the post.	Actions should be done to fill these vacancies promptly.
(e)	20 posts of drug inspectors were approved for drug and pharmacy regulatory activities, but only two food and drug inspectors assigned to the authority from the Ministry of Health were employed. It was observed that this lack of staff can directly affect the performance related to the main functions of the Authority, which are the regulation of drugs and pharmacies.	Although 20 posts of drug inspectors have been approved for the National Medicines Regulatory Authority, the recruitment procedures were not prepared as it was recognized that there should be some revision and accordingly only two officers temporarily posted under the Ministry of Health are working, and this is not enough. Even though letters were issued to the Ministry of Health requesting to provide officers on secondary basis, there was no response.	Actions should be done to fill these vacancies promptly.

(f) More than 07 years have passed since the National Medicine Quality Assurance Laboratory was handed over to the National Medicine Regulatory Authority, but the required staff has not been approved yet.	It has been identified that the posts related to the National Medicine Quality Assurance Laboratory and how they should be revised have now been identified and approval has been given for the recruitment of 12 drug analyst officers on a contract basis until the posts are established permanently, and the Prime Minister's Office to carry out those recruitments. That the recruitment can be done after approval.	Arrangements should be made to approve the necessary staff for the National Medicine Quality Assurance Laboratory.

4. Accountability and Good Governance

4.1 Presentation of financial statements

Audit Observation	Comments of the Management	Recommendation
Although the annual financial statements and draft annual report must be submitted to the Auditor General within 60 days of the end of the accounting year as per paragraph 6.6 of the Public Enterprises Circular No. 01/2021 dated 16 November 2021, the financial statements of the year under review had been submitted on 24 March 2023 with a delay of 24 days. and the draft annual report had not been submitted for audit.	That the final accounts will be submitted to the audit within the correct period without such delay in the coming year.	Actions should be done according to the circular provisions.

4.2 Annual Report

Audit Observation	Comments of the Management	Recommendation
According to section 23 of the National Medicines Regulatory Authority Act No. 05 of 2015, within six months after the end of the financial year, the authority must submit an annual report to the Minister on the activities carried out during that financial year, and the report should include the Auditor General's report for the relevant year. The audited account of the authority and a report on the proposed activities for the coming year should also be attached. Although	That the authority has submitted the annual reports for the years 2017, 2018, 2019 and 2020 to the Parliament and the annual report for the year 2021 is to be submitted to the Ministry of Health this week and the annual report for the year 2022 is currently being prepared.	The annual report of the yea 2021 should be prepared an submitted to the Ministe and Parliament as soon a possible.

the Minister should submit the report to the Parliament within six months from the date of receipt, the annual report for the year 2021 has not been prepared and submitted to the Minister and the Parliament so far.		

4.3 Strategic Plan

Audit Observation	Comments of the Management	Recommendation
Although in accordance with paragraph 2.3 of the Public Enterprises Circular No. 01/2021 dated 16 November 2021, the strategic plan must be prepared and submitted to the Secretary of the Treasury through the Secretary of the Line Ministry and the Director General of the Department of Public Enterprises or the Director General of the National Budget Department 15 days before the beginning of the accounting year; The authority had not done so and instead of the strategic plan, a corporate plan for the years 2022-2026 had been prepared. That corporate plan did not identify the efficiency gap and the development gap between the objectives of the authority and the current situation, which should be included in the strategic plan, and the strategies needed to close the gap had not been planned.	That the necessary arrangements are currently being made to formalize these activities.	Actions should be done according to the circular provisions.

4.4 Annual Action Plan

Audit Observation	Comments of the Management	Recommendation
According to paragraph 2.3 of Public Enterprises Circular No. 01/2021 dated 16 November 2021, there were no specific time targets for each activity in the action plan prepared by the authority.	That the necessary arrangements are currently being made to formalize these activities.	Actions should be done according to the circular provisions.

4.5 Internal Audit.

Audit Observation	Comments of the Management	Recommendation
In accordance with Section 40 of the National Audit Act No. 19 of 2018 and Paragraph 4.4 of the Public Enterprises Circular No. 01/2021 dated 16 November 2021, an internal audit section had not been established for the authority and an internal auditor had not been appointed to report directly to the governing body regarding the affairs of the authority.	Although interviews had been conducted for the post of Internal Auditor, due to the absence of a suitable candidate, the Board of Directors canceled the marks of those interviews and after receiving permission from the letter sent to the Prime Minister's Office seeking permission for recruitment; it is expected to recruit for this post.	Actions should be done in according to the Audit Act and relevant circular provisions.

4.6 Budget Control

Audit Observation	Comments of the Management	Recommendation
The budgeted cash flow statement was not presented in the annual budget and forecast financial statements prepared in accordance with paragraph 2.3 of Public Enterprises Circular No. 01/2021 dated 16 November 2021.	That the necessary arrangements are currently being made to formalize these activities.	Action should be done according to the circular provisions.