**National Medicines Regulatory Authority - 2021**

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1. Financial Statement

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1.1 Qualified Opinion

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The audit of the financial statements of the National Medicines Regulatory Authority for the year ended 31 December 2021 comprising the statement of financial position as at 31 December 2021 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, except for the effects of the matters described in Paragraph 1.5 of this report, the accompanying financial statements give a true and fair view of the financial position of the Authority as at 31 December 2021, and of its financial performance and its cash flows for the year then ended in accordance with Sri Lanka Accounting Standards.

1.2 Basis for Qualified Opinion

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My opinion is qualified based on the matters described in paragraph 1.5 of this report.
I conducted my audit in accordance with Sri Lanka Auditing Standards (SLAuSs). My responsibilities, under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of my report. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my qualified opinion.

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

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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 intends to liquidate the Authority or to cease operations, or has no realistic alternative but to do so.

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

As per Section 16(1) of the National Audit Act No. 19 of 2018, it 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 skepticism throughout the audit. I also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the 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 Preparation of Financial Statements

1.5.1 Non-compliance with Sri Lanka Accounting Standards

| | Non-compliance with Reference to Relevant Standard | Comments of the Management | Recommendation |
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| (a) | Although the statement of changes in equity should be prepared as included all components of the equity in accordance with Paragraphs 106 and 108 of Sri Lanka Accounting Standard 1, capital grants amounting to Rs.5,920,019 and capital gain amounting to Rs.64,275,375 as at 31 December 2021, had not been disclosed in the statement of changes in equity. | The necessary corrections will be made in the financial statements prepared for the next year. | Actions should be taken in terms of Sri Lanka Accounting Standards |
| (b) | As a result of the cash flow statement prepared for the year under review was not prepared in accordance with the provisions of Sri Lanka Accounting Standard 7, understatement of net cash flow from operating activities by Rs.35,614,587, overstatement of net cash flow from investment activities by Rs.34,533,678, overstatement of the value of cash and cash equivalents as at 01 January 2021 by Rs.951,159 and overstatement of the value of cash and cash equivalents as at 31 December 2021 by Rs.129,750 were shown. | -do- | -do- |

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| (c) | Although changes in accounting estimates should be adjusted in the statement of comprehensive income of the current year in accordance with Paragraph 36 of Sri Lanka Accounting Standard 8, overprovision of audit fees amounting to Rs.108,000 and under-provision of value added tax amounting to Rs.270,777 had been adjusted to the retained earnings in the statement of changes in equity. | -do- | -do- |
| (d) | Although an explanation on changes in applicable tax rates compared to previous accounting periods should be disclosed in the financial statements for the year under review in terms of Paragraph 81 (d) of Sri Lanka Accounting Standard 12, the change in the tax rate of 28 per cent applied by the Authority in previous years to 14 per cent in the year under review had not been disclosed in the financial statements. | -do- | -do- |
| (e) | As per the Paragraph 61 of Sri Lanka Accounting Standard 16, although the useful life of property, plant and equipment should be annually reviewed and if the expected conditions differ from the estimates, actions should be taken to revise those changes in accordance with Sri Lanka Accounting Standard 8, because it was not so done, a number of 187 asset items cost at Rs.7,233,052 with a zero book value as at 31 December 2021 were still being used and actions had also not been taken to disclose with regard to that in terms of Paragraph 76 of this Standard. | -do- | -do- |

1.5.2 Accounting Deficiencies

| | Audit Observation | Comments of the Management | Recommendation |
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| (a) | Actions had not been taken to transfer, assess and account for the office building where the Authority is located, the National Pharmaceutical | Although the requests have been made from the Health Department to transfer the ownership of the vehicles, | All the assets used by the Authority but not transferred the ownership |

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| | Quality Safety Research Laboratory building and those lands and 06 vehicles to the Authority and actions had not been taken to assess and account for 03 vehicles that were handed over to the Authority. | answers have not been received so far and that the vehicles will be assessed and accounted for as soon as possible. | should be taken over and all the assets owned by the Authority but not accounted for should be assessed and accounted for. |
| (b) | As a result of the matters such as revision of the number of years for which capital allowance is granted by Schedule 04 of the Act in terms of Section 16 of the Inland Revenue Act No. 24 of 2017 and in calculating income tax from the year 2018 to the year 2021 by the Authority and disregarding the fact that the reduce of tax levied on receipts and profits from the provision of health care services to 14 per cent with effect from 01 January 2020 in terms of Section 51(2) (4) (h) of the Inland Revenue (Amendment) Act No. 10 of 2021, using of opening balance incorrectly in calculating deferred tax expense for the year 2020 and calculation of capital allowance wrongly in the year under review with accounting errors, the total income tax expenditure had been overstated by Rs.138,139,464 as the current income tax amounting to Rs.124,779,725 and deferred income tax amounting to Rs.13,359,739 . Further, the income tax payable under current liabilities amounted to Rs.124,779,725 and the deferred income tax under non-current liabilities amounted to Rs.10,413,183 had been overstated in the statement of financial position as at 31 December 2021 . Accordingly, although the accurate income tax payable as at 31 December 2021 was Rs.27,056,510, as a result of the Authority had paid Rs.151,836,233 as income tax on 16 June 2022, sum of | Necessary arrangements will be made after having discussions with the Inland Revenue Department with regard to the overpayment of income tax. | In calculating the income tax, calculations should be done drawing attention on the old and new tax revisions. |

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| | Rs.124,779,723 had been overpaid as income tax. | | |
| (c) | Although the Authority had approved for repayments from the revenues received in 2019, 2020 and 2021, a sum of Rs.692,031 that had not been accounted for even as at 31 December 2021, had not been accounted for as expenses payable on that date. | The necessary corrections will be made in the financial statements prepared for the next year. | Expenses related to the accounting period should be accurately identified and accounted for. |
| (d) | Although the expenditure of Rs.527,065 related to the outdoor training program held by the Authority should be accounted for as training and development expenses, a sum of Rs.65,025 and Rs. 45,290 had been accounted for under other expenses and local travelling expenses respectively. Further, a sum of Rs.138,250 payable for souvenirs had also not been accounted for. | Agree with deficiencies occurred at the time of accounting of the expenses. | -do- |

1.5.3 Lack of Evidence for Audit

| Item | Evidences not Available | Comments of the Management | Recommendation |
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| Balance of Rs.72,972,666 in Advance Receivable Account as at 31 December 2021 | Relevant schedules and receipt details | A report prepared in this regard was submitted to the Audit and Management Committee and the necessary steps are being taken to write off this value. | Relevant schedules and receipt details should be submitted for audit. |

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 |
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| (a) National Medicines Regulatory Authority Act No. 05 of 2015 | | | |
| (i) Sections 58,59,82,83 and 109 | Any medicine or medical device shall not be manufactured or imported without registering with the Authority and obtaining a license from the Authority and the Authority was given powers to issue letters of exemption from registration only in special cases such as to save a life, to prevent the spread of infectious diseases or epidemics, at national interest and national security. But the letters of exemption from registration had been issued to the State Pharmaceutical Corporation and Private Institutions for the 67 medicines and 140 medical equipment during the year under review on the reasons such as cancellation of registration, lack of registered suppliers, etc., which do not fall under such circumstances. | It does not agree with the observation. Actions have been taken in terms of Section 109 of the Act with the approval of the Ministry of Health, in special cases such as to save a life or to prevent the spread of an epidemic disease, cancellation of registration, non-availability of registered suppliers, non-importation of medicines and occurring crisis situations regarding medicine in the country due to shortage of medicines in public and private sector because of factors like declining trend of registration. | Entry of uncertified medicines into the country should be minimized by issuing letters of exemption from registration only in specific cases mentioned in the Act. |
| (ii) Sections 60 (2), 61, 84(2), 85, 103(2) and 104 and sub-sections | Although the Authority should inform the public in cases of the registration of medicines, Medical Devices and Border Line Productions as well as the refusal of | It would be practically problematic to publish the registered or rejected lists in the Gazette from time to time and therefore it has been | Actions should be taken in accordance with the Provisions of the Act. |

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| | | registration through the terms published in the Gazette, 2,948 medicines registration certificates issued by the Authority and 991 rejected applications, 315 Medical Devices registration certificates and 23 rejected applications, were not published in the Gazette during the year under review and it had been posted on the website of the Authority instead. | submitted to the Committee to amend the Act in such a way as to fulfil that requirement. | |
| (iii) | Sub-section 69 (1)(a)(i) | Although the Head of the Medical Devices Regulatory Division shall act as the Chairman of the Medical Devices Evaluation Committee, the Medical Equipment Evaluation Committee had chaired by the Chairman or Chief Executive Officer of the Authority due to failure to appoint an officer to the post of Head of Medical Devices Regulatory Division. | Acting Heads (Focal Point) appointed for Regulatory Divisions will act as a member of the Medical Devices Evaluation Committee. | Arrangements should be made to formally appoint the relevant Divisional Heads. |
| (iv) | Paragraph 08 of Schedule XXIII of Order No. 4, 133 (5) and Order No. 134 of Medicines Registration and Licensing Order No. 4, 133 (5) and Order No. | A single common register to document every request for registration of medicines had not been maintained. As a result, the details such as date of application received for registration of medicines, number in the application, name of manufacturer, country of manufacture, authorized importer, medicine name, medicine names of active ingredients if the medicine is a drug compound, brand name of the medicine, | This information can be obtained from the respective divisions, a google sheet will be maintained to cover all the information from November 2021 and the progress can be made by analyzing the data. | The data base should be properly maintained as per the order. |

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| | 134 established by Special Gazette Notice No. 2145/1 dated October 14, 2019, which was issued in accordance with Section 142 | dosage form of the medicine, strength of the medicine, whether it is an application for new or renewed application, type of medicine, as well as details of money received for each application, date of submission of each application to the Medicine Regulatory Division for evaluation, number of applications rejected by the each division and number of approved applications, the number of applications still in process in the each division, time taken for registration by respective divisions could not able to obtained to audit. As a result, it was impossible to ensure whether the certificates of registration are issued within the targeted processing period. Accordingly, it was observed that it had failure to process the drug registration and licensing process transparently. Although the Chairman had submitted ideas that the Google Sheet will be maintained to cover all the information from November 2021, the passwords required to access that Google Sheet were not submitted for audit even by 31 December 2022. | | |
| (b) | Section 40 of the National Audit Act No. 19 of 2018 | An Internal Auditor had not been appointed for the Authority. | The position of Internal Auditor has been approved, recruitment procedures have been prepared, newspaper advertisements have been published, | Arrangements should be made in terms of the provisions of the Audit Act. |

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| | | | applications have been invited and dates have been fixed for conducting interviews. | |
| (c) | Paragraphs 4.1 and 10.1 of Chapter VIII of the Establishments Code of the Democratic Socialist Republic of Sri Lanka | Although a staff officer entitled to 1/20 allowance is not entitled to overtime allowance for duty on weekends and public holidays, both 1/20 allowance and overtime allowance had been paid as Rs. 2,060,455 for 998 days of holiday and Rs.1,977,619 for 8,520 hours of overtime to 26 staff officers including an executive officer working in the Authority. | These allowances have been paid based on the approval obtained from the Ministry of Health. | Actions should be taken to recover the overpaid gratuities or to obtain the approval of the Director General Establishments in cases contrary to the provisions of the Establishments Code. |
| (d) | Financial Regulations of the Democratic Socialist Republic of Sri Lanka<br>---------- | | | |
| | (i) Financial Regulation 237 (b) | It was revealed in an audit test check that the payment vouchers amounting to Rs.578,958 were certified on 08 occasions during the year under review without obtaining a certificate that the goods were received and entered in the relevant inventory or stock books. | It is assured that not to happen such defects in future. | Actions should be taken in terms of Financial Regulations. |
| | (ii) Financial Regulation 371(2) (b) and Public Finance Department Circular No. 01/2020 dated | Although the maximum ad hoc advances of Rs.100,000 can be issued only to a staff office, ad hoc advances of Rs. 1,794,000 had been issued to 08 non-staff officers on 17 occasions. Further, there were | Issuing of advances has been regularized from the year 2022. | Actions should be taken in terms of Financial Regulations and Public Finance Circular. |

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| | 28 August 2020 | also cases where advances were re-issued before the settling of advances issued. | | |
| | (iii) 128 (1) (e), 507, 756, 757, 758, 770 and Paragraph 11.1 of Part I of Public Finance Circular No. 01/2020 dated 28 August 2020 | Although the Accounting Officer shall arrange for the appointment of Boards of Survey before the 15th December of each financial year and forward their reports to the Auditor-General with a copy to the Chief Accounting Officer before 31 March of the following year, counting of the non-current assets with a total cost of Rs.114,561,686 and submission of the reports to the Auditor General had not been made since the establishment of the Authority in 2015 . | The related activities in this regard will be completed promptly and the relevant reports will be submitted. | -do- |
| | (iv) Financial Regulations 1645(a) and 1647(e) | The officer in charge of vehicles had not duly completed and updated the vehicle log books as per General Format 267 for each vehicle in his custody. Similarly, the officer in charge of vehicles had not maintained a Register of vehicles on the motor vehicles in his custody. | Arrangements have been made to maintain an Inventory Register and Log Books in respect of the vehicles. | Actions should be taken in terms of Financial Regulations. |
| (e) | Treasury Circulars | | | |
| | (i) Treasury Circular No. 842 dated 19 December 1978 | A Register of Fixed Assets had not been maintained in respect of property plant and equipment with the total cost of Rs.114,561,686 . | Necessary corrections will be made in future. | Actions should be taken to maintain a Register of Fixed Assets in terms of Treasury Circulars. |

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| | (ii) Assets Management Circular No. 01/2017 dated 28 June 2017 of Ministry of Finance and Mass Media | Every Government institution should submit accurate information about all assets under it to the Comptroller General and although each institution should nominate a suitable officer to coordinate the activities, the Authority had not acted accordingly. | Necessary corrections will be made in future. | Actions should be taken in terms of Circulars. |
| (f) | Public Enterprises Circulars<br>---------- | | | |
| | (i) Circular No. 95 dated 14 June 1994 and No. PED/12 dated 02 June 2003 | Implementing a Covid 19 incentive scheme for staff without Treasury approval, a sum of Rs.17,843,781 in the preceding year, Rs.44,273,092 in the year under review and Rs.62,116,873 had been paid as allowances by calculating allowances at the rate of 1 ½ days per day reported for duty, without considering as normal duty days and holidays. | These payments have been suspended by now. | Actions should be taken to recover the allowances paid or to obtain the approval of the Treasury. |
| | (ii) Paragraphs 5.1.1, 5.1.2 and 5.1.3 of Circular No. PED/12 dated 02 June 2003 | Although a Corporate Plan should be prepared as per Paragraphs 5.1.1 and 5.1.2 of the Circular and copies of the same should be submitted to the Line Ministry, Department of Public Enterprises, Treasury and Auditor General 15 days before the commencement of the accounting year as per Paragraph 5.1.3, the Authority had not prepared a Corporate Plan for the year under review. | Actions will be taken to prepare the Corporate Plan in future. | Actions should be taken in terms of Circular Provisions. |

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| | (iii) Paragraph 5.2 of Circular No. PED/03 /2015 dated 17 June 2015 | A sum of Rs.454,827 had been paid as Covid 19 allowances during the year under review to the Chairman of the Authority without obtaining any approval in contrary to the Circular provisions. | These payments have been suspended by now. | Arrangements should be made to recover the allowances paid or to obtain the approval of the Department of Public Enterprises. |
| (g) | Public Administration Circulars | | | |
| | (i) Paragraphs 02 (b) and (c) of Public Administration Circular No. 21/2013 dated 07 October 2013 | Arrangements should be made to deploy on holidays on prior approval and to make payments for a maximum of 02 days per calendar month and although the prior approval of the Secretary of the relevant Ministry should be obtained in person if employment for more than 02 days is required, a sum of Rs.909,042 had been paid for 415 holidays during the year under review to the 22 staff officers including an Executive Officers of the Authority without having such an approval. | These payments have been made based on the approval of the letters of Ministry of Health. | Actions should be taken in terms of the provisions in the Public Administration Circular . |
| | (ii) Paragraph 3.1 of Public Administration Circular No. 30/2016 dated 29 December 2016 | Although a fuel re-check should be carried out after a period of 12 months after each fuel check or after 25,000 km or after a major engine overhaul, whichever occurs first, actions had not been taken in the same manner in respect of 09 vehicles which are being used by the Authority. | The necessary instructions have been given to the relevant parties to carry out tests on the fuel combustion of the vehicles. | Actions should be taken in terms of the Public Administration circular instructions . |

1.7 Fund Management

| Audit Observation | Comments of the Management | Recommendation |
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| A total of Rs.629,030 as participation allowances, Covid allowances and bonuses for various committees held in 2020 and 2021 had been held by the Accountant in his hand for between 159 and 865 days to pay to respective officials or without taking actions to bank again within 14 days in terms of Financial Regulation 271 (2)(a) and (b) . Due to the payment vouchers prepared for the payment of these allowance were not submitted for audit, on the following day that was 08 June 2022 a sum of Rs.629,030 had directly been banked. In addition to that, it was ascertained in the cash verification carried out on 23 August 2022 a total of Rs.537,600 as committee participation allowances, bonuses, attendance allowances and overtime allowances of the year 2022 had been held in hand in between 15 days and 228 days. It was observed that this is an illegal use of government funds and although the money remaining unpaid and the documents related to that should be kept locked in a safe or other safe place designated for that purpose, in terms of Financial Regulation 271 (1), the money was kept in the accountant's office desk drawer in an unsecured manner and the safe, secured by two locks and a code, had been kept in idle in the main office building. | The Accounting Officer had not submitted comments. | A formal inquiry should be conducted and further actions should be taken and the concerned officer should be ordered to act as per the Financial Regulations. |

1.8 Common Controls in Information Technology (IT)

| Audit Observation | Comments of the Management | Recommendation |
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| The contract for automating the data system of the Authority had been awarded to a private company on 03 May 2018 for a period of 05 years for a total contract value of Rs.29 Million. It had been entered into the implementation of this document and workflow management system as a service by obtaining the Operational Expenditure Financing Model and an amount of Rs.12,253,328 had been paid to the contracted company during the period from June 2019 to May 2021. But some of the information entered into this data system had been deleted due to negligence or intentionality of the concerned private company and the service had become inactive even by 31 August 2022 until the end of the investigations carried out by the Criminal Investigation Department. Likewise, although a Memorandum of Understanding had been entered into with the Sri Lanka Information and Communication Technology Agency for a period of one year on 25 June 2018 to obtain the necessary consultancy, management and technical advice in the implementation of this system, actions had not been taken to extend the agreement parallel to the contract period of 05 years. Further, steps had not been taken to protect the confidentiality of the information, to change passwords or to prevent the misuse of the information in accordance with the contractual agreement and after automating the system, an Audit Trial had not been conducted on the internal workflow of the Authority implementing the both the manual and automation systems in parallel . Similarly, the management was not concerned with the issues of file management, preservation and ability to securely store copies of documents with relevant data for up to 5 years, obtaining automatic copies on a daily, weekly and monthly basis and obtaining a confirmation of professional liability insurance and payments had been made to the company without obtaining securing copies of | Since the e-NMRA system is not being used even by now after the crash, the Google Sheets are used to enter data related to the registration of medicines, devices, etc., it is difficult to perform the tasks expected of a system by this application, it is a temporary data entry method made to facilitate internal organization activities until a formal system is established. | An adequate information system that can be easily managed should be established promptly to correct the deficiencies in the authority's data system. |

relevant data and attachment information. As per the terms of the agreement, although the assets in this system cost at Rs.7,558,128 should be capitalized, instead, the amount had been written off against the profit. According to the report issued on 15 July 2022 by the expert committee appointed to check and restore the deleted data regarding this incident, it had confirmed that the data that had been deleted from the system could not be restored. Although the registration of drugs, equipment etc. is done using a Google application (Google Form) as a temporary solution after the activities of the system is disabled, it was observed that the system was maintained with deficiencies.

## 2. Financial Review

### 2.1 Financial Results

The operating result of the year under review was a net income of Rs.567,192,769 and the corresponding net income for the preceding year was Rs.673,604,866. Accordingly, a deterioration of Rs.106,412,097 in the financial result was observed. Incurring of Rs.400,000,000 as Treasury Levy had mainly attributed to this deterioration.

## 3. Operating Review

### 3.1 Management Inefficiencies

| | Audit Observation | Comments of the Management | Recommendation |
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| (a) | The Authority had not collected data on the quantity of medicines imported under license by the Authority, Medical Devices, Border Line Productions or Investigational Medicinal Products in terms of Section 14(J) of National Medicines Regulatory Authority Act No. 05 of 2015. | A separate unit has been established to collect data on quantity and unit prices of imported medical equipment, an advertisement has been published on the website on 23 February 2022 to inform the Authority about the amount of imported medicines from 01 March 2022, the importers who submit applications for renewal of registration have started entering the amounts imported in previous years of the respective | Actions should be taken in accordance with the Provisions of the Act. |

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| | | pharmaceutical in the GOOGLE SHEET from 04 March 2022 and the Medicines Regulatory Authority does not have the data on the quantities of imported Border Line Productions. | |
| (b) | An officer with a degree in Medicine, Pharmacology, Pharmacy or any other related disciplines had not been appointed as Heads of the Medicine Regulatory Division, Medicine Devices Regulatory Division and Border Line Production Regulatory in terms of Sub-sections 41 (2), 66 (2) and 87 (2) of the National Medicines Regulatory Authority Act No. 05 of 2015. | The officers of the Ministry of Health with high experience have been appointed as Heads of those Divisions, based on the service requirement of the Authority and the qualifications of the pharmacists, qualified officers are expected to be appointed as Heads of the regulatory affairs divisions just after the absorption is completed. | -do- |
| (c) | Although the Director General of the Sri Lanka Atomic Energy Regulatory Council or his Nominee shall be appointed to the Medical Device Evaluation Committee in terms of Sub-section 69(1)(b)(v) of the National Medicines Regulatory Authority Act No. 05 of 2015, the appointment had not been made. The necessity to represent the Medical Device Evaluation Committee to the Sri Lanka Atomic Energy Regulatory Council, which has the powers to issue licenses and regulate the import and use of radioactive equipment and materials, including medical equipment, was not fulfilled. | The certificates from the Sri Lanka Atomic Energy Regulatory Council are obtained while importing radioactive devices and materials and issuing licenses for importation of samples for registration. | -do- |
| (d) | Although the General Guidelines should be issued to the each evaluation committees for evaluation of Medical Devices and Border Line Productions in terms of Sub-sections 72(1) and 93(1) of the National Medicines Regulatory Authority Act No. 05 of 2015, such Guidelines had not been prepared. Further, the directives relating to Medical Devices and Border Line Productions had also not been prepared to enforce the Guidelines on good manufacturing practices and other relevant | General guidelines and directives for their enforcement have currently been prepared and discussed and there are no directives for the regulatory of Border Line Productions. | -do- |

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| | guidelines recommended by the Authority, specifying the procedures to be followed including the specific timeframes for conducting the relevant evaluations in terms of Sub-sections 72 (4) and 93 (4). | | |
| (e) | Authorized Therapeutic Devices and registered Border Line Productions had not been listed by the Minister from time to time in terms of Sub-sections 74 (1) and 95 (1) of the National Medicines Regulatory Authority Act No. 05 of 2015. | As 50 to 100 applications have been recommended for registration or rejection every two weeks, it is practically difficult to issue gazettes regularly and the comments on that have been submitted to the Act Amendment Committee. | -do- |
| (f) | The orders had not been formulated by the Minister, stating specifically the procedure to be followed in the inspection or evaluation process by the Medical Devices and Border Line Productions Committee and the National Medicines Quality Assurance Laboratory, the time limits of the inspection or evaluation process, the manner in which meetings should be held by the Medical Device Evaluation Committee and specifying the procedures to be followed in the meetings and the matters to be included in the reports to be submitted in terms of Section 83(6) and 102(6) of the National Medicines Regulatory Authority Act No. 05 of 2015. | The related orders will be prepared in future. | -do- |
| (g) | An Appeals Committee had not been constituted to hear and decide the appeals submitted to the Authority as per the Section 123 of the National Medicines Regulatory Authority Act No. 05 of 2015. | The Appeal Committee should be appointed by the Honourable Minister. | -do- |
| (h) | All the Government institutions shall review and revise the fees charged by their bodies for services rendered to the public every three years subject to a maximum of 15 per cent and submit by the relevant Accounting Officer for the approval of the Secretary to the Treasury or the Deputy Secretary to the Treasury with the recommendation of the Secretary of their Ministry in terms of | The special attention will be paid in this regard and necessary arrangements will be made. | -do- |

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| | Paragraph 5.1 of Part II of Public Finance Circular No. 01/2020 dated 28 August 2020 . The Authority had revised the charges levied at last on 05 January 2018 for the issuance of registration certificates in respect of medicinal Devices and Border Line Products, granting licenses, granting of approvals such as approval for exemption from registration, approval for packaging, approval for transfer of agency, conduct of inspections and other services provided. Accordingly, although the actions should be taken to review the charges during the year under review and do the relevant revisions and submit for the Treasury approval, as it had not acted accordingly, the fee income had lost by Rs.187,913,601 in the year under review. | | |
| (i) | A total income of Rs.1,620,119 had been refunded on 18 occasions during the year under review due to misstates of officials and various other reasons. Although this situation has existed for several years, adequate steps had not been taken to mitigate it. | Due to the mistakes of the officers of the Authority, the revenue will have to be refunded, a Collected Income Refund Committee has been appointed in the year 2022 to regularize these refunds and a system has been introduced to refund the rest of the income excluding VAT and stamp duty with the approval of that Committee. | Actions should be taken to minimize the instances of refund of income. |
| (j) | Although an application was submitted to the Sri Lanka Accreditation Board on 06 February 2020 to obtain the Certificate of Conformity Assessment regarding the quality of the laboratory by the National Medicines Quality Assurance Laboratory, it had failed to obtain the standard certificate by 31 July 2022 and information about other quality certificates obtained was also not submitted for audit. | Obtaining of this certificate has been delayed as the laboratory does not have the basic requirements yet for obtaining this certificate. | Every effort should be made to obtain the basic requirements to receive this certificate. |
| (k) | A total amount of Rs.756,173 had been overpaid to the Inland Revenue Department during the year under review as surcharges | Agree with the observation. | The money paid in excess as surcharge and VAT should be |

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| | and VAT due to the matters such as late remittance to Employees' Provident Fund in the year 2018, failure to claiming of VAT exemption in due time and although the requests were made to recover the VAT paid to the State Pharmaceutical Manufacturing Corporation the request was rejected. | | recovered from the responsible officers. |
| (l) | Although fees are payable on application for exemption from registration for private supply of drugs, medical devices and limited products, in terms of Free Regulation No. 02, 03 and 04 of 2017 published in Extraordinary Gazette No. 2023/30 dated 14 June 2017 as amended by Extraordinary Gazette No. 2052/33 dated 05 January 2018, due to the fact that the Authority has proceeded to levy fees when granting approval for exemption from registration, the Authority had lost the fee income of Rs. 11,473,421 which could have been charged for 207 applications for exemption from registration of Medical Devices in the private sector which had been rejected. The Authority had lost an incalculable amount of revenue as a result of taking actions so, in respect of the Medicines, Medical Devices and Border Line Productions during the period from 2018 to 22 August 2022 . | As there was uncertainty about the collection of money after considering the requests of the applicants and at the time of submitting an application as mentioned in the Gazette, the money was recovered only after the application was approved as per the instructions given verbally by the then CEO. | Fees should be charged as mentioned in the Gazette. |
| (m) | The Authority had awarded the contract to transport and safely store and maintain the completed files to a private company from 01 December 2015. A sum of Rs.6,062,550 had been paid to the contractor during the period of 06 years from the commencement of the contract to 31 December 2021. Although payment to the contractor was stopped for the year from May 2016 to April 2017 stating that part of the files in the contractor's custody in 2016 were damaged by the flood, a formal investigation had not been conducted regarding the files that were damaged by the | The files that had destructed by the flood were safely moved to another warehouse and the related checks were carried out, after that the duplicates of the files were taken from the relevant institutions, however, the officers have been instructed to check the records of the files currently available in these warehouses and make the necessary corrections, necessary arrangements have been made to carry out the on-site inspection in 2022, a contract has | Arrangements should be made to carry out a formal investigation on the flood destruction and focus on the construction of an archive for the Authority. |

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| | flood. Further, the services of the contractor were still being obtained even by 30 June 2022, the Authority itself had not paid attention to the establishment of an archive after analysing the costs for this purpose for 06 years. | already been made with the relevant institution to confirm the security of the files and discussions are being carried out to make necessary arrangements to be able to maintain an archive owned by the Authority. | |

3.2 Operational Inefficiencies

| | Audit Observation | Comments of the Management | Recommendation |
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| (a) | Out of the drug samples that were submitted to the National Medicines Quality Assurance Laboratory to check the quality, the information on the number of drug samples whereas the test reports were not submitted by 01 January 2021 had not been submitted to audit in accordance with Section 39 of the National Medicines Regulatory Authority Act No. 05 of 2015. However, test certificates had been issued only for 157 out of 216 drug samples received in 2019 and 2020 and 299 out of 477 drug samples received in the year under review. Accordingly, out of the drug samples received in the 03 years from 2019 to 2021 the number of samples for which test reports had not been issued by 31 July 2022 was 91 and 42 of them were the samples submitted by the court. The opinion that it will cause the related court proceedings to be delayed for a considerable period of time could not be ruled out in audit. | That quality reports on all samples received for analysis will be issued in the same year or in the following years. | The quality reports related to the samples of medicines submitted to the laboratory should be issued promptly and the data and information on it should be properly maintained. |
| (b) | Instead of issuing re-registration certificates for the applications submitted for medicines re-registration, a method of extending the existing registration was followed, a formal approval for that had not been obtained. Out of 3,892 applications submitted for re-registration of medicines during the year under review, the existing registration of the 2,904 applications had been extended and | Agree with the observation. | Actions should be taken in accordance with the provisions of the Act. |

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| | 988 applications had been rejected. As a result of following the method of extension of registration, it was observed that the provisions related to medicine evaluation were violated in terms of sub-sections 47(3) and 59(4) of the National Medicines Regulatory Authority Act No. 5 of 2015. | | |
| (c) | Although a technical evaluation report specifying the benefits, risks, feasibility, quality , safety, necessity , price and where necessary, the pharmaco-economic analysis of those medicine and medical devices submitted for registration to the Medicines Evaluation Committee and the Medical Devices Evaluation Committee shall be submitted in terms of Sub-sections 43(2) (a) and (b) and 68 (2) (a) and (b) of the National Medicines Regulatory Authority Act No. 05 of 2015, the Medicine Evaluation Committee and the Medical Devices Evaluation Committee had not submitted such a technical evaluation report to the Authority. | Although such technical evaluation shall be carried out by the Medical Device Evaluation Committee, it is practically impossible to provide those reports as the Medical Device Evaluation Committee meets once a month and evaluates between 50 and 100 applications, therefore, this assessment is therefore carried out by the Medical Devices Regulatory Division, the Therapeutic Devices Regulatory Division has made recommendations to the Authority Act Amendment Committee on these issues and the technical evaluation of medicines pharmaceutical done by the Medicine Evaluation Sub-committee. | -do- |
| (d) | It had not submitted to the National Medicines Quality Assurance Laboratory to check the quality of Medical Devices and Borderline Products submitted for registration in terms of sub-sections 83 (4) (b) and 102(4)(b) of the National Medicines Regulatory Authority Act No. 05 of 2015. The Chairman of the Authority had submitted comments that the necessary facilities for that were not available in the laboratory. | Although a Third Party Test Report obtained from a third party should be submitted in case of need for clinical evaluation of medical devices, the National Medicines Quality Assurance Laboratory does not have the complete facilities to obtain such reports even up to now, products made of various ingredients are registered under Border Line Productions, as many of those products contain ingredients that belong to the pharmaceutical category and the ingredients that do not belong to the pharmaceutical category, there is | -do- |

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| | | no ability in National Medicines Quality Assurance to check those productions. | |
| (e) | Although the maximum time for completing the evaluation of a file submitted for registration (Dossier) is 300 days, registration certificates had not been issued even by 25 June 2022 for the 146 Dossiers submitted in the year 2020. Although the 02 days were spent for the main evaluation activities of 06 Dossiers and less than a month for the main evaluation activities of 04 other Dossiers in the examination of a sample of 25 Dossiers of Medical Devices registered during the year under review from a period of 01 to 03 years had been spent to complete the registration. The Chief Executive Officer had spent between 01 ½ months and 01 year to transfer them to the pharmacists from the date of receipt of 18 Dossiers to the Authority and the Pharmacists had spent between 05 months and 01 year and 09 months to submit 11 Dossiers to the relevant College or External Evaluator for performance evaluation. After the performance evaluation, the Pharmacists had spent 05 months to 01 year and 04 months to commence the technical evaluation of 09 Dossiers and from that day, the Chief Executive Officer had spent 14 days to 02 months to give approval for 09 Dossiers approved for registration by Medical Devices Evaluation Committee. However, the Authority had not taken adequate measures to minimize these delays and make the registration process efficient and speedy. | It is not agreed with the observation, due to the fact that the nature, size, risk, clinical examination, sending to the professional college, surgical work as well as use on a patient and using for biological samples of the Medical Devices should be tested by one or more methods, despite the establishment of the Regulatory Authority, the structural changes that should have taken place were not occurred, the lack of storage facilities, the lack of adequate officers, the lack of applications, the lack of response, the time taken to correct them is added to the total time and the spread of the COVID epidemic in the country have also affected this, and however, this situation has been identified and a number of solutions have been provided. | Sufficient measures should be taken to make the evaluation and registration process efficient. |
| (f) | As a result of a Dossier submitted for registration of Medical Devices that should have been submitted to the College of Dentistry and Stomatology for performance evaluation had been submitted to the | It is not agreed with the observation, choosing a vocational school for clinical evaluation is a highly technical matter. | Sufficient measures should be taken to make clinical evaluation efficient based on technical |

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| | Maharagama Apeksha Hospital first, then to a Chemical Pathologist (Consultant-Chemical Pathology) and finally submitted to the College of Dentists, the registration certificate had been issued after a period of 03 years and 03 months from the date of receipt of the Dossier. Likewise, as a result of a Dossier which should have been submitted to the College of Anaesthesiologist for the registration of Medical Devices was submitted to the College of ENT Surgeons, the registration certificate had been issued after a period of 02 years 01 months from the date of receipt of the Dossier. Accordingly, it was observed that the Authority had not introduced a formal guidance to the Evaluation Committee regarding the decision of the college where the performance evaluation of the Medical Devices should be carried out and that there are cases where the registration process is delayed due to not selecting the right college based on professional judgement. | | considerations. |
| (g) | In the course of maintaining the Dossiers submitted for registration and preparing the relevant documents, incorrect information had been included carelessly or deliberately and the dates on which certain tasks were performed, the information about the officers who had performed and some essential documents had not been included in the Dossiers. Dates of submission and return of Dossier and samples to concerned college for performance evaluation, dates of commencement and completion of technical evaluation by pharmacists as well as recommendation, code and signature of pharmacists were not mentioned in certain Dossiers and incorrect information had been entered in the Technical Evaluation Checklist. Within some dossiers, the summary report on the application and | Comments have not been furnished. | A performance and technical evaluation checklist should be included in the Dossier. |

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| | Technical Evaluation Checklist where pharmacists perform the technical evaluation and make recommendations had not been included. | | |
| (h) | Although 20 members were appointed to the Medical Devices Evaluation Committee, the participation of members was as low as 35 per cent in the 10 meetings held during the year under review and due to the fact that 07 members had not participated even in a single meeting, the knowledge in specialist areas such as laboratory services, biomedical engineering, dental services, biochemistry, surgical pathology and radiology had contributed to the decisions of the Committee. | Twenty members have been appointed for the Medical Devices Evaluation Committee, all those members are notified by e-mail to participate in the Committee, similarly, the same awareness is done over the phone. | Arrangements should be made to obtain maximum participation of the Medical Devices Evaluation Committee members. |
| (i) | Although the money had been paid on the online system to obtain the pharmacy license, due to crash of online computer automation system in August 2021, instead of issuing a new license, the licenses issued in 2019 and 2020 had been rubber-stamped and the signatures were made on it by extending dates. There were the cases where the date extensions were not documented and also the signatures were not made for the date extensions. | Since it was difficult to set up a new system immediately, to issue licenses due to crash in online system, the system was adopted as a temporary measure, that the scan copies of all the licenses extended in this way have been stored in the computer according to the District order. | A safety programme should be put in place to extend the validity period of licences. |

3.3 Procurement Management

| | Audit Observation | Comments of the Management | Recommendation |
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| (a) | The contract was awarded on 17 December 2020 to the bidder who had submitted the lowest bid of Rs.4,898,750 for the work of partitioning the office rooms in the new office building which had been acquired on rental basis. In this procurement, Guidelines 2.8.1 (b), 2.12, 5.4.8, 6.3.3, 6.3.6 and 8.12.2 of the | The quotations have been called by e-mail due to transport restrictions occurred as a result of the Corona situation, due to the fact that the lease agreement of the new building has been signed with effect | Guidelines of the Government Procurement Guidelines should be followed. |

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| | Government Procurement Guidelines were not followed and advances of Rs.979,750 had been issued without obtaining advance payment security in terms of 5.4.4 of the Guideline. | from 20 November 2020 and also the rooms have to be reserved and the facilities to the staff have to be provided with, the quotations were obtained in that manner. | |
| (b) | Although the furniture had been purchased by following the shopping method at a cost of Rs.6,854,519 and also not less than 05 sealed bids were to be called in terms of 2.14.1 of the Government Procurement Manual, only 03 bids were called and purchase had been made. Further, this purchase was carried out, taking actions in contrary to the Guidelines such as 2.8.1 (b), 6.3.5 (a), (b), (c), 6.3.6, 8.12.3 (a), (b), (c) of the Government Procurement Guidelines. | Although the quotations were called from three suppliers, due to the Corona situation in the country, the huge shortage of stationery, newspapers not being printed properly and the lease agreement of the building has been signed with effect from 20 November 2020, approval of the Procurement Committee has not been taken approval for that and these deficiencies will be rectified in future due to calling quotations was not practical. | -do- |
| (c) | Although the approval of the Secretary to the Line Ministry should be obtained for the vehicle repairs exceeding Rs.200,000 in terms of Guideline 9.3.1 (b) of the Government Procurement Guidelines, a total of Rs.3,676,401 had been spent for the repair of 03 vehicles owned by the Authority beyond that limit and actions had not been taken to obtain the approval for that. Likewise, there were no log records whether the spare parts removed during repair were undertaken. The officer in charge of vehicles had not accepted those spare parts. | Actions will be taken to obtain the necessary approvals for such repairs in future. | -do- |

3.4 Human Resources Management

| Audit Observation | Comments of the Management | Recommendation |
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| The total approved number of staff of the Authority as at 31 December 2021 was 257 with 235 approved permanent staff and 22 on contract basis. Although the total actual staff was 160, because, out of which 38 were the excess number that was not included in the approved staff, the actual number of vacancies out of total approved staff as at 31 December 2021 was 135. Since 16 posts or 84 per cent of the 19 senior management posts in the approved staff were in vacant, it had failed to identify necessary and unnecessary positions and revise the approved staff and it was observed that the vacancy of required posts may have an impact on the overall performance of the Authority. The method of absorption or recruitment as recommended by the Department of Management Services to fill up the vacancies of 30 Medicines Evaluation Officers and 12 Assistant Medicine Evaluation Officers had not been implemented even by the date of this report. | Among the approved permanent posts, there are currently only 109 vacancies, although the 12 drug analyst posts have been approved to be recruited on contract basis, the related recruitment procedure has not been approved by the Department of Management Services and applications have been called to the interviews to fill the vacancies of 09 more posts that the date has been fixed. | Actions should be taken to identify required and non-required positions and revise the approved staff and implement the absorption or recruitment method as recommended by the Department of Management Services. |

4. Accountability and Good Governance

4.1 Submission of Financial Statements

| Audit Observation | Comments of the Management | Recommendation |
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| Although the annual financial statements should be submitted to the Auditor General within 60 days of the closure of the accounting year in | There was delay in preparation of the final accounts duly and receiving the approval by the Board of | Actions should be taken in accordance with the provisions in the Circulars. |

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| accordance with Section 6.5.1 of the Public Enterprises Circular No. PED/12 dated 02 June 2003 and Treasury Circular No. 01/2004 dated 24 February 2004, the financial statements for the year 2021 were submitted for audit on 22 April 2022 after a delay of 02 months. | Directors. | |

4.2 Tabling of Annual Report in Parliament

| Audit Observation | Comments of the Management | Recommendation |
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| Within a period of six months after the end of the financial year, the Authority should submit an Annual Report to the Minister on the activities carried out during that financial year in terms of Section 23 of the National Medicines Regulatory Authority Act No. 05 of 2015 and the report of audited accounts of the Authority for the relevant year and a report on the proposed activities for the coming year should be attached to that report along with the Auditor General's Report. Although the Minister should submit the report to Parliament within a period of six months from the date of receipt, the Annual Reports have not been prepared and submitted to the Minister and Parliament since 2017. | The translation and printing works of the Annual Reports for the years 2017, 2018, 2019 and 2020 has remained and the final accounts for the year 2021 have been sent for audit and that the gathering of other information to be included in the annual report is being done. | Actions should be taken in accordance with the provisions of the Act. |

4.3 Corporate Plan

| Audit Observation | Comments of the Management | Recommendation |
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| Although the 2022 – 2026 Five Year Corporate Plan should be prepared 15 days before the commencement of the year 2022, although the Authority had spent Rs.1,641,600 to prepare it by 04 July 2022, the Corporate Plan had not been prepared even by that date. | It took some time to formalize the 2022-2026 five-year Corporate Plan with the help of an external institution and formalize it in a correct format and that the work is currently in the final stage. | Actions should be taken in terms of Public Enterprises Circulars. |