National Medicine Regulatory Authority - 2018

The audit of the operations of the National Medicine Regulatory Authority for the year ended 31 December 2018 was carried out under my direction in pursuance of provisions in Article 154(1) of the Constitution of the Democratic Socialist Republic of Sri Lanka read in conjunction with provisions of the National Audit Act No. 19 of 2018 and the Finance Act No. 38 of 1971. My comments and observations which I consider should be presented to the Parliament appear in this report.

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

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As per Section 16(1) of the National Audit Act No. 19 of 2018, every auditee entity shall maintain proper books and records of all its income, expenditure, assets and liabilities, to enable annual and periodic financial statements to be prepared in respect of such entity. According to the Section 16 (2) of the said Act, the annual financial statements in respect of every other auditee entity shall be submitted by the Chief Accounting Officer to the Auditor-General along with the annual performance reports, within such period as may be provided by rules. According to the Section 38 (1) (d) of the said Act, it should be ensured the timely preparation and submission of annual reports and other financial statements and in addition the Chief Accounting Officer should be required to submit annual reports to Parliament pertaining to the auditee entity.

1.2 Non Compliance with Laws, Rules Regulations and Management Decisions

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Reference to laws, rules and regulations etc.	Non Compliance	Management comment	Recommendation
(a) National Medicine Regulatory Authority Act. No.05 of 2015.			
(i) Section 35 (b)	Although the proper implementation of the National Medicines Policy is a function of the National Advisory Committee, a national medicine policy had not been prepared and approved.	Preparation of the national medicine policy is a policy making matter and it does not come under the purview of the National Medicine Regulatory Authority.	Actions should be taken as per the Act.

	(ii)	Sections 41 (2), 66 (2) and 87 (2)	An officer among persons holding a recognized degree in Medicine, Pharmacology, Pharmacy or any other related discipline had not been appointed as the head of the Medicine Regulatory Division, Medicine Devices Regulatory Division and Border Line Production Regulatory Division.	Actions to be taken to rectify the error after having a discussion relating to new recruitments with the Salaries and Cadre Commission.	-do-
	(iii)	Sections 61, 84 (2), 85, 103 (2), 104	Actions had not been taken to inform the Public by order published in the Gazette with respect of refused registration of medicines and registered and refusal of registration relating to medical devices and border line products.	Regulations relating to medicine registered by the Authority were published by the Extraordinary Gazette No. 2144/20 dated 09 October 2019.	Actions should be taken as per the Act.
	(iv)	Section 123	An Appeals Committee had not been established in terms of the Act to hear and determine appeals.	It was aware the Minister to establish an Appeal Committee.	-do-
(b)	Value Added Tax Act (Amended) No.06 of 2005		Value Added Tax amounting to Rs.93,058,701 relating to the third and fourth quarters of the year 2018 had not been remitted on due date.	Value added tax could not be remitted on due date due to lack of staff and Value Added Tax relating to the third and fourth quarters of the year 2018 had been remitted to the Commissioner General of Inland Revenue for the time being.	Value Added Tax should be remitted on due date as per the Act.

(c)	Stamp Fees (Special Provision) Act. No. 12 of 2006.	Stamp fees amounting to Rs.20,482,266 relating to the third and fourth quarters of the year 2018 had not been remitted on due date.	Stamp fees could not be remitted on due date due to lack of staff and Value Added Tax relating to the third and fourth quarters of the year 2018 had been remitted to the Commissioner General of Inland Revenue for the time being.	Stamp fees should be remitted on due date as per the Act.
(d)	Financial Regulation 395 (c) of the Financial Regulations of the Democratic Socialist Republic of Sri Lanka	A bank reconciliation statement in connection with the transactions available at the end of the month should be prepared before 15 of the following month. However, bank reconciliation statements relating to the period of 7 months from November 2018 to May 2019 had not been prepared even up to 12 June 2019.	Bank reconciliation statements could not be prepared due to lack of staff and however bank reconciliation statements up to 21st May 2019 had been prepared for the time being. Bank reconciliations for the remaining days are being prepared immediately.	Actions should be taken as per the Financial Regulations.
(e)	Public Enterprises Circular No. PED 12 dated 02 June 2003.	Although four Audit Committee Meetings should be conducted annually, only 2 Audit Committee Meetings had been conducted in the years 2017 and 2018.No meetings had been conducted for the year 2019 even up to the date of this report.	Such deficiencies will be corrected in future.	Actions should be taken as per the Circulars.

(f)	Treasury Circular No. IAI/2002/02 dated 28 November 2002	A fixed assets register had not been maintained for computers, accessories and software in the format introduced by the Circular.	A computerized fixed asset register with respect of computer accessories and software is being maintained and actions will be taken to maintain a fixed assets register as per the relevant format.	A fixed asset register should be maintained as per the format introduced by the Circular.

2. Operational Review

2.1 Management Inefficiencies

	Audit Issue	Management Comment	Recommendation
(a)	According to the provisions mentioned in the National Medicine Regulatory Act, even though directives had been provided to empower National Advisory committee, Medicine Evaluation Committee, Medical Devices evaluation Committee, Boarder Line Product Evaluation Committee and National Medicine Quality Assurance Laboratory, the Authority had failed to legalize the said directives even up to 31 May 2019. As a result Guidelines for Good Manufacturing Practices and other Guidelines could not be prepared mentioning the procedures which should be followed by such Committees.	Relevant letters had been prepared in order to prepare Guidelines for Good Manufacturing Practices and other Guidelines by mentioning the procedures which should be followed by such Committees.	Actions should be taken to legalize the directives as per the Act and to prepare Guidelines.

(b)	The National Medicine Regulatory Authority Act No. 05 of 2015 had been empowered with effect from 01 July 2015 repealing the Cosmetics, Devices and Drugs Registration Act No. 27 of 1980. Provisions mentioned in the cancelled Act relating to manufacturing and importation of non- treatment perfumes had not been included into the new Act. Although perfumes productions of which the quantity and value could not be assessed had been imported into the country since 01 July 2015, such imports had not been monitored properly during the past 4 year's period due to absence of legal provisions as mentioned above. Proper attention had not been paid by the management regarding the arrivals of false and low quality production of perfumes and the severe health threats which can be occurred by using them.	An expert committee on cosmetics regulations was appointed at the time and the said Committee had identified relevant amendments.	Actions should be taken to revise the National Medicine Regulatory Act for regulation of imported cosmetics.
(c)	According to the Sections 58 and 82 of the National Medicine Regulatory Act, no person should import or manufacture any medicine or medical devices without registering such medicine in the Authority and without obtaining a license from the Authority. According to the Sections 59 and 83 of the said Act, license should be issued after evaluation of medicine and medical devices considering the requirement of ensuring the availability of efficacious, safe and good quality medical devices. Contrary to the provisions mentioned above, 553 letters for waivers of registration during the	Agreed with the audit observation and the relevant officers were informed to rectify the deficiencies.	Letters for waivers of registration should be issued only for the requirements mentioned in the Act.

	year 2018 and 139 letters during the period from January 2019 to 30 April had been issued for State Pharmaceutical Corporation, Medical Supplies Division and other private and government institutions. Importers of medicine and medical devices that are not registered under the Act had used the said letters for waivers of registration to clear their importation from the Sri Lanka Custom.		
(d)	According to the Section 109 of the National Medicine Regulatory Act, letters for waivers of registration should be issued in special circumstances such as save a life, control an outbreak of an infection or an epidemic or any other National Emergency. However, 99 letters for waivers of registration had been issued to the State Pharmaceuticals Corporation on the reasons such as cancellation of registration, registered suppliers not being available, registered suppliers not being submitted bids which could not be taken under the said requirement. Further there were 19 instances of issuing letters for waivers of registration for 07 medicine items from time to time.	Agreed with the audit observation and the relevant officers were informed to rectify the deficiencies.	Letters for waivers of registration should be issued only for the requirements mentioned in the Act.
(e)	Although 2 consultants had been appointed to the Committee of issuing letters for waivers of registration, in most of times only one consultant had participated to the Committee.	This committee was appointed by the Ministry of Health, two consultants were appointed to the committee and letters for waivers of registration are issued only with the approval of this committee.	Actions should be taken to get participated all members.

(f)	According to the National Medicine Regulatory Act, in the instances of requests not being made for renewal of the certificate before 6 months which the medicine registration certificate outdated, it should be considered the registration was cancelled automatically. However 19 instances were observed in the sample test carried out relating to 25 files that medicine registration certificate was issued in the year 2018 contrary to the said requirement.	Actions to be taken to consider the registration as automatically cancelled in the instances of requests not being made for renewal of the certificate before 6 months which the medicine registration certificate outdated.	Actions should be taken as per the Act.
(g)	It was observed in a sample test carried out relating to 28 registrations that, 16 registration certificates had been issued without examining the premises and the process of manufacturing of medicine contrary to the provisions of the National Medicine Regulatory Act.	Manufacturing process will be examined again for all registration and it was planned to complete all reports within coming 6 months.	Registration certificates should be issued following the provisions of the Act.
(h)	According to the National Medicine Regulatory Act, quality of the samples should be checked by the National Medicine Quality Assurance Laboratory before issuing registration certificates for medicine, medical devices and boarder line productions. Nevertheless 82 new temporary registration certificates and 06 new complete registration certificates which were issued for 5 years had been issued without testing samples. Further, 84 temporary renewal of registration certificates had been issued without testing samples. In addition temporary registration certificates had been issued for 07 medicines before issuing results of	Certificates were issued without testing samples because the capacity of the National Medicine Quality Assurance Laboratory was not sufficient. However, these certificates were issued based on the reports accepted by other regulatory institutions for certification of the standard and the quality of the medicine. Actions were taken to increase the capacity of the National Medicine Quality Assurance Laboratory in order to avoid such situations.	Registration certificates should be issued following the provisions of the Act.

the tested samples. Moreover registration certificates had been issued for 198 medical devices and 19 border line productions during the year under review without testing samples.

2.2 Operating Inefficiencies

	Audit Issue	Management Comment	Recommendation
(a)	Assets belonged to the National Medicine Quality Assurance Laboratory which was implemented under the Ministry and should get transferred by the Authority since 01 July 2015, had not been taken into accounts even up to 31 May 2019. Further 30 assignments remained as at 01 July 2015 had not been completed even up to 31 May 2019. Hence all samples relating to the said assignments had outdated.	Initial steps were being taken to account the assets of National Medicine Quality Assurance Laboratory, reports were issued for 03 sample tests out of 34, one sample was returned and the rest were already outdated.	Actions should be taken to transfer the assets and take in to accounts.
(b)	Although 1,767 samples had been referred to the National Medicine Quality Assurance Laboratory during the year under review, only 58 samples had been tested. The progress of testing samples was only 03 per cent.	The circular including the provisions relating to measure the quality of medicine in the Government Institutions through post marketing surveys was issued by the Secretary to the Ministry and intend to take actions according to a targeted plan after increasing the laboratory facilities.	Laboratory capacity should be increased as to be able to test all samples presented.
(c)	Applications had been forwarded for registration of 792 medicines in the year under review and registration had been rejected or applications had been withdrawn	It takes a time to the process implemented for issuing registration certificates for medicine because it should be	A file containing information on accepting applications for registration and issuing registration

	for 7 medicines. Registration certificates had been issued only for the rest of 393 medicines and the number of medicines of which the registration certificates had not been issued was 392.	done correctly and credulity, Accordingly delays may be occurred for issuing certificates.	certificates should be maintained properly and accurately and registration certificates should be issued without delay.
(d)	Applications had been forwarded for registration of 758 medical devices in the year under review and registration had been rejected or applications had been withdrawn for 16 medical devices. Registration certificates had been issued only for the rest of 279 medical devices and the number of medical devices of which the registration certificates had not been issued was 463.	It takes a time to the process implemented for issuing registration certificates for medical devices because it should be done correctly and credulity, Accordingly delays may be occurred for issuing certificates.	-do-
(e)	The progress of issuance of licenses for applications received for re registration of medicine and medical devices during the year under review had not been presented to audit.	Submission of the progress of issuance of licenses to audit was delayed due to absence of computerized network.	-do-
(f)	The following reasons were affected to the delay of issuing registration certificates and licenses. (i) There was a delay in submission of file consisted with the documents made available with the application to a pharmacist for evaluation. Further it had been taken a long time to commence the evaluation. It had been taken a period of time in a range of 09 months to 16 months to commence the evaluation of 05 files out of a sample of 08 files.	It takes a time to the process implemented for issuing registration certificates because it should be done correctly and credulity; Accordingly delays may be occurred for issuing certificates.	A standard time should be identified for issuing certificates and licenses from the date of which the applications are submitted. Actions should be taken according to a plan prepared comply with the above mentioned requirement and the delays of issuance of registration certificates and licenses should be minimized.

	(ii) Although evaluations had been completed and the registration fees had been paid, it had been taken a time more than 02 months to issue the certificate. (iii) There were vacancies in 17 posts of pharmacists, 17 posts of drug inspectors and 07 posts of drug analysts And 06 posts of laboratory technicians. (iv) Sufficient laboratory facilities were not available.		
(g)	According to the Section 119 (4) of the National Medicine Regulatory Act, it had not been determined a specific period of time for registration of pharmacies and issuance of licenses. During the year 2018, deferent periods of time had been taken in a range of 03 months to 07 months to issue licenses for 10 pharmacies from the date of payment for registration. Further a proper data file which can be included information relating to the process of issuing licenses for pharmacies had not been maintained by the Authority.	Delays were occurred due to lack of staff and installation of Licensing Section in 3 places within 3 years. This issue will not be arisen in future due to the commencement of issuance of licenses according to the network system since 01 September 2018.	A standard time should be identified for issuing certificates and licenses from the date of which the applications are submitted. Actions should be taken according to a plan prepared comply with the above mentioned requirement and the delays of issuance of registration certificates and licenses should be minimized. Further a file should be maintained properly including information relating to acceptance of applications and issuing registration certificates.
(h)	The following observations are made in the physical examination carried out in 20 pharmacies located in Colombo, Kohuwala, Kalubowila and Dehiwala area on 04 June 2019 by audit officers with a Drug Inspector.		

(i)	According to the section 49 and 63 of the Extraordinary Gazette of the Democratic Socialist Republic of Sri Lanka No. 378/3 dated 02 December 1985, every licensed wholesale dealer or retail dealer should exhibit the license issued to him together with the original of the certificate of registration in conspicuous place in the premises which he sells medicine. However the pharmacy license had not been exhibited in 09 pharmacies.	Licenses were not issued due to lack of staff and installation of Licensing Section in 3 places within 3 years.	Licenses should be issued efficiently and properly. Monitoring of pharmacies should be regularized.
(ii)	According to the section 43 (1) (b) of the 15 amendment of the Extraordinary Gazette of the Democratic Socialist Republic of Sri Lanka No. 722/2 dated 06 July 1992, the place prepared for sale of medicine should be an adequate place which can be supplied facilities for securing the quality of licensed medicine. Further the said place should be under the administration of registered pharmacist. However there were pharmacies which had not been consisted with such requirements. Further there were 13 pharmacies which a registered pharmacist was not available.	Issues pointed out by audit were identified correctly and actions had been taken to correct the situation.	Pharmacies should be monitored properly.
(iii)	According to the section 41 and 55 of the Extraordinary Gazette of the Democratic Socialist Republic of Sri Lanka No. 378/3 dated 02 December 1985 and the section 119 (1) of the National Medicine Regulatory	Although some pharmacies had applied for licenses, it was not issued due to lack of staff and legal actions had been taken in connection with other pharmacies.	Pharmacies should be monitored properly.

	Authority Act, no person should carry on a pharmacy without obtaining license from the Authority. Nevertheless there were 15 pharmacies which licenses had not been obtained for the relevant period of time.		
(iv)	A proper methodology had not been established to avoid the delay of issuance of license even though payments had been made and carry out business without obtaining license or renewing license. Supervision on pharmacies which should be carrying out throughout the Island had not been carried out sufficiently.	Lack of staff was affected for this situation and issues pointed out by Audit were settled in the network system.	Pharmacies should be monitored properly.

2.3 Procurement Management

Audit Issue	Management Comment	Recommendation
Authority had purchased 16 desktop, 07 laptops with Microsoft Office home and business 2016 version , 30 UPS,19 laser printers, 5 dot matrix printers and 7 Digital multifunctional photocopy machines following shopping method by incurring a sum of Rs.6,300,223. According to the Government Procurement Guideline, deficiencies were observed such as procurement time table not being prepared for this procurement, standard bidding invitation documents or any other document comply with it not being used, although it had been noted that bids had been called from 10 suppliers among 22 registered suppliers, it was observed that, written evidence not being made to confirm the selection of the said 10 suppliers, their names and the	Deficiencies pointed out by audit are accepted. Instructions were issued to relevant officers to take actions according to the Government Procurement Guideline. Using computers and accessories is essential for issuing registration certificates and other relevant licenses. There were more deficiencies because day to day work of the institute was carried out with the service of a crew of minimum officers and unskilled employees who had been recruited for practical training, for the time being staff had been recruited in certain extent and actions were taken to rectify the deficiencies.	Actions should be taken as per the Government Procurement Guideline.

methods for calling bids, even though it had been noted that the closing date of calling bids was 20 November 2017, the date called bids not being confirmed, closing date being extended up to 23 November 2017 on 21 November 2017 the day following the date which had been called quotations, only 07 bidders being informed through E-mails, specifications not being approved by the Technical Evaluation Committee , bid validation period not being specified, bid opening committee not being appointed, information relating to open bids not being reported in the due format, letter of acceptance not being issued to the bidder, not being entered in to a proper agreement, a performance bond not being obtained and a warrantee certificate not being obtained. Further good received notes had not been issued for computers and accessories supplied. It had not been entered into fixed assets register and a proper inventory as well. Instead it had been entered into a general register. Out of these computers and accessories, 04 computers had not been presented for physical verification.

2.4 Human Resources Management

	Audit Issue	Management comment	Recommendation
(a)	There were 104 vacancies in the cadre approved for the Authority as at 31 December 2018 including 23 vacancies of 08 executive posts, 65 vacancies in 06 non-executive posts, 16 vacancies in 04 minor posts. Although it had been over four years since the establishment of the authority, the Authority had failed to fulfill 86 vacancies out of such vacancies permanently. Recruitment scheme not being revised timely with attractive salaries and other benefits had affected to this situation. Deficiency of the staff had affected to fulfill technical activities such as medicine, medical devices, boarder line products, clinical trials and pharmaceutical regularization and day-to-day administration correctly.	For the time being discussions are being conducted with the salary and cadre commission and actions will be taken to fill vacancies after preparing recruitment scheme.	Actions should be taken to fulfill the vacancies properly within the approved cadre which is necessary for carrying out the operations of the Authority without disturbances.
(b)	A recruitment scheme had not been prepared for the posts of Assistant Director/ Deputy Director, Medical Officer, Internal Auditor, Drug Analysts, Costing Officer, Drug Inspector and Pharmacist.	For the time being discussions are being conducted with the salary and cadre commission and actions will be taken to fill vacancies after preparing recruitment scheme.	Recruitment schemes should be prepared and get it approved.

3. Accountability and Good Governess

3.1 Presentation of Financial Statements

Audit issue	Management comment	Recommendation
According to the Section 6.5.1 of the Public Enterprises Circular No.PED/12 dated 02 June 2003 and the Treasury Circular No. 01/2004 dated 24 February 2004, annual financial statements of Statutory Boards should be submitted to the Auditor General within 60 days after the close of the financial year. However financial statements for the year 2018 had not been presented to audit even up to the date of this report.	Preparing of financial statements for the year 2018 is being accelerated and actions will be taken to submit financial statements on due date in future.	Accounts should be submitted on due date as per the circular.

3.2 Annual Action Plan

	Audit Issue	Management Comment	Recommendation
(a)	Authority had failed to fulfill 14 activities included in the action plan prepared for the year 2018.	More attention was paid for preparing future action plans and follow-ups.	Actions should be taken as per the action plans and the action plan should be revised as per the requirement. Responsibility should be assigned to relevant officers to fulfill each activity and a proper supervision should be carried out in this regard.
(b)	Financial and physical progress of the activities included in the action plan prepared for the year 2018 had not been presented. Further performance indicators had not been shown in Specifically, adequately and measurable manner. Accordingly the progress of fulfilling 27 activities included in the action plan for the year 2018 could not been evaluated specifically.	More attention was paid for preparing future action plans and follow-ups.	Action plan should be prepared correctly and properly. Performance indicators should be shown in specific, adequate and measurable manner.

(c)	Even acquisition of land for the construction of a building for the Authority which the financial and physical progress had been targeted to fulfill in 100 per cent in the year under review had not been commenced as an initial step of the activity.	Relevant activities are being carried out at the moment.	Actions plan should be prepared including the activities or part of it which can be fulfilled during the year under review
(d)	Targeted activities relating to awareness programs on medicine, medical devices and boarder line production and awareness program such as post marketing surveys on quality and security of registered and licensed medicine, medical devices, boarder line production or analytical medical production had not been included in to the action plan.	Actions to be taken to prepare the action plan paying attention for the matters pointed out by Audit.	Action plan should be prepared as to be able to fulfill the objectives of the Act.

4.1 Sustainable Development Goals

Audit Issue	Management comment	Recommendation
According to the 2030 Agenda for Sustainable Development adopted by the United Nations and Circular issued by the Secretory to the Ministry of National policy and Economic Affairs No. NP/SP/SDG/17 dated 14 August 2017, even though targets which should be fulfilled for achieving sustainable goals and the gaps available to fulfil such targets and appropriate indicators to measure the progress should be identified, such indicators had not been identified by the Authority and achievements and deviations and the varies areas which should be paid special attention had not been identified as well.	Attention had been paid by the Authority mainly for the measures necessary for improvement of production of local medicine as the Sustainable Development Goals. Actions will be taken to pay further attention analytically in this regard.	Actions should be taken as per the Circular issued by the Secretory to the Ministry of National policy and Economic Affairs and 2030 Agenda for Sustainable Development Goals.