## National Medicines Regulatory Authority – 2017

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The operations the National Medicines Regulatory Authority for the year ended 31 December 2017 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 Section 13(1) of the Finance Act, No.38 of 1971 and Section 20 of the National Medicines Regulatory Authority Act, No.05 of 2015. The financial statements for the year 2017 to be present in terms of Section 13 (6) of the Finance Act, had not been presented even by the date of this report. My observations on the performance of the Authority which I consider should be presented in Parliament in terms of Article 154 (6) of the Constitution of the Democratic Socialist Republic of Sri Lanka appear in this report.

### 1.2 Management's Responsibility for the Financial Statements

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Management is responsible for the preparation and fair presentation of these financial statements in accordance with Sri Lanka Accounting Standards and for such internal control as the management determines is necessary to enable the preparation of financial statements that are free from material misstatements, whether due to fraud or error.

### 2. Financial Statements

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### 2.1 Presentation of Financial Statements

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In terms of 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 of the statutory boards should be furnished to the Auditor General within 60 days from the close of the year of account. Nevertheless, the financial statements for the year 2017 had not been furnished to Audit even by the date of this report.

### 2.2 Existence of the Assets and Liabilities

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Particulars on the assets, liabilities, equity, income and expenditure stated in the financial statements prepared last by the Authority as at 31 December 2016 are given below.

| Item | Value |
|---|---|
| | Rs. |
| Non-current Assets | 5,528,972 |
| Current Assets | 100,926,209 |
| Total Assets | 106,455,181 |
| Current Liabilities | 43,102,015 |
| Non-current Liabilities | 5,795,491 |
| Total Liabilities | 48,897,506 |
| Net Assets/ Liabilities | 57,557,675 |
| | 106,455,181 |
| Total Income | 165,246,657 |
| Total Expenditure | 104,698,944 |
| Surplus Before Tax | 60,547,713 |
| Income Tax | 2,990,038 |
| Surplus After Tax | 57,557,675 |

**2.3 Lack of Evidence for Audit**

As the information such as medicines, medical equipment and the number of applications received for the registration of borderline productions during the year under review, the date of receipt, the number of applications registered and the date of registration had not been furnished to Audit with an adequate time to examine them, it could not be express an opinion on the performance of the registration of medicines, medical equipment and borderline productions.

**2.4 Non- compliance with Laws, Rules, Regulations and Management Decisions**

Instances of non- compliance with laws, rules, regulations and management decisions appear below.

| | Reference to Laws, Rules, Regulations and Management Decisions | Non-compliance |
|---|---|---|
| (a) | Section 105 of the National Medicines Regulatory Authority Act, No.05 of 2015 | Although the Authority may grant permanent or temporary registration on borderline productions and the conditions for the registration should be imposed, such conditions had not been imposed even by 23 August 2018, the date of audit. |

| | | |
|---|---|---|
| (b) | Valued Added (Amendment) Tax Act, No.06 of 2005 | A tax applicable to any taxable period should be paid to the Director General of Inland Revenue on a date not later than the 20th day of the following month from the close of the taxable period. Nevertheless, the Authority had not paid the Value Added Tax relevant to the year 2017 even by 21 September 2018. |
| (c) | Stamp Duty (Special Provision) Act, No.12 of 2006. | Although the Stamp Duty should be remitted to the Commissioner General of Inland Revenue within fifteen days from the close of each quarter every year, the Authority had not remitted the Stamp Duty relevant to the year 2017 even by 21 September 2018. |
| (d) | Financial Regulations of the Democratic Socialist Republic of Sri Lanka<br>---------- | |
| | (i) Financial Regulation 395(c) | Although a bank reconciliation statements on the position of transactions available in bank accounts by the end of each month should be prepared before 15th of the following month, bank reconciliation statements pertaining to September 2017 had not been prepared even by 23 August 2018. Accordingly, a delay for a period of 11 months could be observed for the preparation of bank reconciliation statements. |
| | (ii) Financial Regulation 454 | Goods Receiving Notes had not been issued for 8 tyres purchased for two vehicles during the year under review and it had not been entered in an inventory. |
| | (iii) Financial Regulation 757-(2) | Board of Survey reports on the stores relating to the year under review had not been furnished to the Audit even by 21 September 2018. |
| (e) | Public Administration Circular No.09/2009 dated 16 April 2009. | Although the fingerprint machines should be used without being considered the number of employees of a service station, action had not been taken to repair the inoperative fingerprint machine after the date of 31 May 2014 even by 21 September 2018. |
| (f) | Treasury Circular No.IAI/2002/02 dated 28 November 2002. | A Register of Fixed Assets had not been maintained on computers, accessories and software. |

## 3. Operating Review

### 3.1 Performance

#### 3.1.1 Operations and Review

Even though an Action Plan had been prepared for the year under review, progress reports had not been prepared and as such, progress of the Authority could not be reviewed properly.

### 3.2 Management Activities

The following observations are made.

(a) The Appeal Committee which should be established in terms of Section 123 of Paragraph No.07 of the National Medicines Regulatory Authority Act, No.05 of 2015 in order to consider appeals made by any person aggrieved by an decision taken by the Authority had not been established even by 21 September 2018.

(b) In terms of Sections 38 (2) (a) and (b) of the Act, the National Medicine Quality Assurance Laboratory operated under the Ministry of Health, Nutrition and Indigenous Medicine should be taken over by the Authority with effect from 01 July 2015. Nevertheless, that laboratory had not been taken over by the Authority even by 21 September 2018, the date of audit.

(c) The following observations are made on the issue of Waiver of Registration Letters.

(i) In terms of Section 58 of Part IV of Chapter III and Section 82 of Part IV of Chapter IV of the National Medicines Regulatory Authority Act, No.05 of 2015, no person shall manufacture or import any medicine without registering such medicine with the Authority and obtaining a licence from the Authority therefor. In terms of Section 59 and 83 of the above Act, the Authority shall issue registration certificates and lincences upon the evaluation of medicines and medical devices by considering the need to ensure the availability of efficacious, safe and good quality thereof. Nevertheless, contrary to the above provisions, 655 Waiver of Registration Letters had been issued during the year 2017 while another 256 of such letters had been issued from January to 10 July 2018 to the State Pharmaceutical Corporation, Medical Supply Division and other Public and private institutions. The importers had used those Waiver of Registration Letters in order to clear the medicines and medical devices not registered and not permitted under the Act, from the Sri Lanka Customs.

(ii) Due to issue of Waiver of Registration Letters, it was unavoidable to import the medical supplies devoid of quality assurance to the country. Further, those letters had been issued free of charge from January 2017 to 14 June 2017 and it had resulted in decrease in the registration and licence charges income of the Authority during that period. Although a condition had been imposed by the Extra Ordinary Gazette dated 14 June 2017 to the effect that a charge of US$ 100 should be recovered in the issue of those letters,

information on the charges recovered had not been furnished to Audit even by 21 September 2018, the date of audit.

(iii) In terms of Section 109 of Part I of Chapter VI of the National Medicines Regulatory Authority Act No.05 of 2015, the Authority may grant permission in special circumstances such as to save a life, to control an outbreak of an infection or an epidemic or any other national emergency or for national security to import and supply a particular medicine, medical device or borderline product in specified quantities. Nevertheless, due to the reasons such as invalidation of the registration of the relevant medicine or the medical device, absence of registered suppliers and not presenting bids by the registered suppliers which were not coming under the special circumstances, 163 Waiver of Registration Letters had been issued to the Medical Supply Division and the State Pharmaceutical Corporation during the year under review. It was observed that issuing of Waiver of Registration Letters on the above grounds give rise to recede the interest of the suppliers to obtain registrations for medicines, medical devices and borderline products.

(iv) Waiver of Registration Letters had been issued again and again for 03 items of medicine in 06 instances during the year under review and there were such 06 instances during the period up to 10 July 2018.

(v) The contractor to whom the contract for the purchase of 25,200 units of the Efavirenz tablets 600 mg medicine costing Rs.483,371 and 12,600 units of such medicine costing Rs.249,831 was awarded by the State Pharmaceutical Corporation had not registered with the Authority and as such, the Authority had issued 02 Waiver of Registration Letters on 09 January 2017 and 18 September 2017. Nevertheless, notwithstanding the supplier who had obtained registration for the above medicine for a period of 05 years from 24 September 2016, the 02 Waiver of Registration Letters had been issued indicating the reason that there are no registered sources for this product.

**3.3 Operating Activities**

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The following observations are made.

(a) The matters observed at the examination conducted on the issue of registration certificates of the National Medicine Regulatory Authority for the medicines are specified below.

(i) In terms of Section 59 (2) of the National Medicines Regulatory Authority Act No.05 of 2015, any person who desires to manufacture or import any medicine shall submit the samples of the medicine along with the application made for the registration of such medicine, whereas samples had not been submitted relating to 62 applications of 599 applications received for the registration of new medicines during the year under review. Nevertheless, registration certificates for 35 of the above 65 applications had been issued without being conducted sample tests. Further, particulars on the issue of registration certificates for the remaining 27 applications had not been furnished to Audit.

(ii) Since the Dossier Number had not been included in the data file of the Laboratory Division in relation to the samples subjected to the test, a proper analysis could not be carried out on the progress of the sample tests. As 537 samples had been received for testing and only 85 samples had been tested by the Laboratory during the year under review, it was observed that the progress of testing samples had stood only at 16 per cent.

(iii) In terms of Section 59 (4) (b) of the National Medicines Regulatory Authority Act No.05 of 2015, the Authority shall, upon the receipt of an application, submit that application together with the sample of the medicine and all particulars, available to the National Medicine Quality Assurance Laboratory (NMQAL), for testing of the quality of the medicine. Nevertheless, there observed 14 instances where a temporary registration had been issued for the medicines prior to issuing results by that Laboratory upon carrying out sample tests.

(iv) In terms of Section 60(1) (b) of the National Medicines Regulatory Authority Act No.05 of 2015, the Authority may upon taking into consideration the reports submitted by the Medicine Evaluation Committee (MEC) and National Medicine Quality Assurance Laboratory (NMQAL) and all other relevant factors, register such medicine within the stipulated time period. Nevertheless, it was established in the examination of 47 applications that the totally different time periods had been taken for the issue of registration certificates in respect of applications forwarded for the registration of the same medicine.

(b) The following observations are made according to the examination carried out on the registration of business names and issuance of pharmacy licences within the area of authority of 05 Divisional Secretariats- Colombo, Thimbirigasyaya, Nugegoda,Rathmalana and Dehiwala-Mount Livenia during the period from 01 January 2017 to 31 July 2018.

(i) According to the Business Names Registration Record, although 21 pharmacies had been registered within the above 05 Divisions during the above period, it was observed in the examination of data file furnished by the Authority to Audit that pharmacy licence for 17 of the above pharmacies had not been obtained from the National Medicines Regulatory Authority even by 31 August 2018, the date of audit. Further, in the issue of pharmacy licences, the Authority had not maintained a formal data file for including all information from the receipt of application up to the issue of licence.

(ii) In terms of Section 119(7) of the National Medicines Regulatory Authority Act No.05 of 2015, formulation and prescription of regulations by the Minister, pertaining to the terms and conditions of a licence and the conditions to be satisfied to register a Pharmacy had not been carried out even by 21 September 2018.

(iii) In the examination of files relating to 49 pharmacies in Colombo district, there observed 40 pharmacies for which action had not been taken to renew the licences relating to the year 2017 and the Authority had not establish a methodology to look into the reasons behind the above matter and prevent further maintenance of business activities if such business are carried on without obtaining licences.

(iv) In the examination of registers pertaining to the issue of licences during the period from December 2017 up to 31 August 2018, the date of audit, it was observed that the licences were not issued according to the serial numbers and the weaknesses found in the process from the handing over of the relevant payment receipt by the applicant to the Authority up to the issue of licence had given rise to the above situation.

### 3.4 Staff Administration

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The following observations are made.

(a) The approved cadre of the Authority as at the end of the year under review stood at 232 while the actual cadre was 122. Accordingly, the number of vacancies was 111 and excess was 01. Ninety officers of the Ministry of Health, Nutrition and Indigenous Medicine had been employed in the Authority and the relevant approval had not been obtained in accordance with Section 17 of the National Medicines Regulatory Authority Act, No.05 of 2015 for the employment of 34 officers out of the above officers. Further, three retired officers had been recruited for a non-executive post included in the approved cadre and one officer had been recruited on contract basis to the post of Stenographer which had not been included in the approved cadre. Although a period of 03 years had elapsed from the establishment of the Authority by 21 September 2018, Authority had failed to fill the posts on permanent basis.

(b) As 8 officers comprising 06 Development Officers and two Laboratory Assistants of the Ministry of Health, Nutrition and Indigenous Medicine employed in the Authority as at 31 December 2017 had been released to the Ministry of Health, Nutrition and Indigenous Medicine upon termination of the period of employment in the Authority, those posts further remained vacant by 10 August 2018, the date of audit. Moreover, for the purpose of recruiting 10 officers to the post of Development Officer and one officer to the post of Information and Communication Technical Assistant, a newspaper advertisement had been published on 06 August 2017. Nevertheless, it had been failed to recruit relevant officers by conducting a written competitive examination and/ or through an interview board in terms of Paragraph 5.4 of the Scheme of Recruitment even by 21 September 2018, the date of audit.

(c) The officer who had been selected for the post of Director (Human Resources) by calling for applications through a newspaper advertisement published on 12 June 2016 had refused the acceptance of the said post on 24 November 2016, whereas action had not been taken to recruit a new officer on permanent basis even by 21 September 2018 and an officer had been recruited on acting basis instead.

(d) For the purpose of recruiting one officer to the post of Administrative Officer and 41 officers to the post of Management Assistant, newspaper advertisements had been published on 12 June 2016 and 22 November 2016 respectively. Nevertheless, relevant recruitments had not been made even by 21 September 2018 and 19 officers had been recruited to the post of Management Assistant on contract basis.

(e) It had been failed either to prepare a scheme of recruitment or revise the approved cadre relating to 06 posts –Assistant Director/Deputy Director, Internal Auditor, Drugs Analyst, Expenditure Officer, Pharmacologist and the Pharmacist included in the approved cadre of the Authority even by 21 September 2018.

(f) Duty lists had not been properly given to 97 officers employed in the Authority as at 31 December 2017.

### 3.5 Procurement and Contract Process

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The following observations are made.

(a) A Procurement Timetable in accordance with the Guideline 4.2.2 (b) of the Government Procurement Guidelines had not been prepared relating to the Procurement Plan prepared for the year under review.

(b) The Authority had purchased 6 items totaled Rs.1,351,167 under the shopping method during the year under review. Nevertheless, a suitable specimen in the standard bids calling documents had not been used as required by Guideline 5.3.1 of the Government Procurement Guidelines.

(c) Although an air-conditioner costing Rs.182,850 had been procured and installed in the above procurement, conditions on maintenance and services had not been included in the bid documents in calling for bids and as such, the Authority had to get the maintenance and services done under whatever the rate prescribed by the relevant company. Further, the air-conditioner purchased had not been entered in the inventory even by 14 July 2018.

(d) In the above procurement, a formal agreement had not been entered into according to Guideline 8.9.1(b) of the Government Procurement Guidelines in connection with the purchase of 05 Laptops costing Rs.670,000.

(f) A total cost estimate had not been prepared for the procurement of planning, procuring and establishing a record room with movable shelves costing Rs.13,972,626 by following national competitive bids calling method and due to the deficiencies occurred in the preparation of specifications, instead of curved staircase constructed at a cost of Rs.325,000 another staircase had to be constructed again at a cost of Rs.275,000, thus resulting in an uneconomic expenditure of Rs.325,000.

## 4. Sustainable Development Goals

### 4.1 Achievement of Sustainable Development Goals.

Every institution shall take steps in compliance with the Agenda 2030 of the United Nations Sustainable Development Goals. Nevertheless, it was not established as to whether the Authority had been aware of the manner in which it should take steps in connection with the functions coming under purview of the Authority.

## 5. Systems and Controls

Deficiencies observed in systems and controls during the course of the audit were brought to the notice of the Chairman of the Authority from time to time. Special attention is needed in respect of the following areas of systems and controls.

| | Area of control | Observation |
|---|---|---|
| (a) | Revenue Accounting | Failure in classifying and accounting the revenue |
| (b) | Issuance of Waiver of Registration Letters | Not taking action to maintain the issue of Waiver of Registration Letters at minimum level. |
| (c) | Recruitment of the Staff | Failure to attach the staff in terms of the Act. |
| (d) | Fixed Assets Control | Failure to take over the assets from the Ministry. |
| (e) | Issuance of Pharmacy Licences | Not taking action to maintain a formal data system. |
| (f) | Financial Control | Not properly preparing the bank reconciliation statements and existence of delays in their preparation. |
| (g) | Procurement | Failure in appointing the bid opening committees and not recording the details on opening bids in a prescribed form. |