National Medicines Regulatory Authority – 2016

The audit of the operating activities of the National Medicines Regulatory Authority for the year ended 31 December 2016, 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 5 of the National Medicines Regulatory Authority Act No.05 of 2015. The financial statements for the year 2016 that should be furnished in terms of Section 13(6) of the Finance Act had not been furnished even by the date of this report. My observations on the operation of the Authority which I consider should be furnished to the Parliament in terms of Article 154(6) of the Constitution of the Democratic Socialist Republic of Sri Lanka appear in this report.

1.2 Establishment of the Authority and its Commencement

The operations of the National Medicines Regulatory Authority, established from 01 July 2015 in terms of Section 02 of the National Medicines Regulatory Authority Act No.05 of 2015 had been commenced from 01 January 2016. The main objectives of the Authority in terms of Section 03 of that Act had been ensuring the availability of efficacious, safe and good quality medicines, medical devices and borderline products

(a) to the general public at affordable prices, registration of medicines, medical devices and borderline products, issuing licenses to medicines, medical devices and borderline products;

(b) Functioning as the central regulator for all matters connected with the registration, licensing and cancellation of registration or licensing, pricing, manufacturing, importation, distribution, sale, advertising and disposal of medicines, medical devices and borderline products;

(c) Encouraging the manufacturing of good quality medicines in Sri Lanka with a view to assuring the availability of essential medicines at affordable prices;

(d) Promoting the safe and rational use of medicines, medical devices and borderline products by health care professionals and consumers;

(e) Recommending appropriate amendments to relevant laws pertaining to medicines, medical devices and borderline products;

(f) Educating the general public, health care professionals and all persons concerned on medicine, medical devices and borderline products;

(g) Regulating the promotion and marketing of medicines, medical devices and borderline products;

(h) Regulating the availability of medicines, medical devices and borderline products;

(i) Conducting post marketing surveillance on quality, safety and adverse reaction of the medicines, medical devices and borderline products; and

(j) Regulating all matters pertaining to the conduct of clinical trials in Sri Lanka.

1.3 Management's Responsibility for the Financial Statements

The management is responsible for the preparation and fair presentation of the financial statements of the Authority 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

2.1 Presentation of Financial Statements

Even though the Annual Financial Statements of the Boards of Constitution should be furnished to the Auditor General within 60 days after the close of the Year of Accounts in terms of Section 6.5.1 of the Public Enterprises Circular No.PED/12 of 02 June 2003 and the Treasury Circular No.01/2004 of 24 February 2004, financial statements for the year 2016 had not been furnished to audit even by the date of this report.

2.2 Lack of Evidence for Audit

The following Items could not be satisfactorily vouched or an opinion on those Items could not be furnished due to non- submission of evidence for audit indicated against each Item.

Item	Value	Evidence not made Available
	Rs.	
(a) Income of the Registration of Medicines, Medical Devices and Borderline Products.	167,951,285	(i) Information on the amount of applications received in the year under review for the registration of medicines, medical devices and borderline products and the amount of applications registered. (ii) The total income of the Authority separated into each category as stated in the Gazette Extraordinary No.1601/15 of 12 May 2009.
(b) Cheque or Cash Deposits	97,270	Receipts issued to the direct deposits amounting to Rs.97,270 including in the Bank Reconciliation Statement as at 31 December 2016, reasons if the receipts were not issued and the details on those deposits.

2.3 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 and Regulations		Non- compliances
(a) National Medicines Regulatory Authority Act No.05 of 2015		
(i)	Sections 62(1)(b), 86 and 105	A complete or a temporary registration could be awarded by the Authority relating to medicines, medical devices and borderline products and even though conditions should be imposed for each type of registration, conditions had not been imposed even by the date of this report.
(ii)	Sections 65(4), 86 and 105	The registration or the license of the medicine, medical device or the borderline product relating to that certificate should be considered as automatically cancelled in an instance where the application for the renewal of that certificate had not been made six months before the expiration of that period, by a holder of a certificate relating to medicines, medical devices and borderline products. However, it was revealed in examining a sample of 20 Files that there were 11 instances where the registration certificates had been issued in a manner contrary to those Sections.
(b) Value Added Tax (Amendment) Act No.06 of 2005		Even though the tax relating to a period which a certain tax that could be charged should be paid to the Commissioner General of Inland Revenue on a date not after the 20th of the forthcoming month after the end of the period that tax could be charged, Value Added Tax amounting to Rs.11,633,289 which had been collected in the year under review by the Authority had not been remitted to the Commissioner General of Inland Revenue even by the date of audit of 27 September 2017.

(c) Stamp Fees (Special Provisions) Act No.12 of 2006	Even though the stamp fees should be remitted to the Commissioner General of Inland Revenue within 15 days after the close of each quarter of every year, stamp fees amounting to Rs.4,608,980 which had been collected relating to the second and third quarter of the year 2016 by the Authority had not been remitted to the Commissioner General of Inland Revenue even by the date of audit of 27 September 2017.
(d) Financial Regulations of the Democratic Socialist Republic of Sri Lanka	
(i) Financial Regulation 395(c)	A Bank Reconciliation Statement should be prepared before the 15th of the next month relating to the position of transactions as at the end of each month, of the Bank Accounts. However, even though the Bank Reconciliation Statement relating to the month of August 2017 should be prepared by the date of audit of 27 September 2017, only the Bank Reconciliation Statement relating to April 2017 had been prepared by that date. As such, a delay of 04 months remained relating to preparing the Bank Reconciliation Statements.
(ii) Financial Regulations 394,396	Action had not been taken in terms of the Financial Regulations relating to 03 cancelled cheques of which the total value being a sum of Rs.16,265,812 and 02 cheques which were issued but unrealized which had lapsed over 6 months, including in the Bank Reconciliation Statement as at 31 December 2016.
(e) Public Finance Circular No.364(3) of 30 September 2002 and Guidelines 5.4.11 and 5.4.12 of the Government Procurement Guidelines	Details on the Value Added Tax amounting to Rs.11,633,289 relating to the year under review had not been informed to the Commissioner General of Inland Revenue with a copy to the Auditor General.
(f) Public Administration Circular No.09/2009 of 16 April 2009	Even though Time Notifying Machines should be used without considering the number of employees in a place of work, steps had not been taken by the Authority to repair the Fingerprint Machines which remained inoperative after the date of 31 May 2014.

(g) Treasury Circular No.842 of 19 December 1978	A Register of Fixed Assets relating to property, plant and equipment had not been maintained by the Authority even by the end of the year under review.

3. Operating Review

3.1 Performance

An opinion on the performance of the Authority could not be furnished due to details on the number of applications received in the year under review for the registration of medicines, medical devices and borderline products and the number of applications registered, details on the Divisions and Committees that should be established in the Authority in terms of the provisions stated in the National Medicines Regulatory Authority Act No.05 of 2015, not being furnished to audit.

3.2 Management Activities

The following observations are made.

(a) The Divisions of Information, Education, Communication and Research Division, Manufacturing Regulatory Division and Organization Development Division out of the 11 Divisions that should be established in the Authority in terms of Section 30(2) of Chapter 2 of the National Medicines Regulatory Authority Act No.05 of 2015 had not been established even by 31 December 2016.

(b) The 02 Committees of the National Advisory Committee and the Appeals Committee out of the 6 Committees that should be established in terms of Sections 30,43,68,89,118 and 123 of the Chapters 2,3,4,5,6 and 7 of the National Medicines Regulatory Authority Act No.05 of 2015 had not been established by 31 December 2016.

(c) Even though the National Medicines Quality Assurance Laboratory that remained being implemented under the Ministry of Health, Nutrition and Indigenous Medicine should be entrusted to the Authority with effect from 01 July 2015, the Laboratory had not been entrusted to the Authority even by the date of audit of 17 October 2017.

(d) It had been failed to determine and to obtain the approval for the staff for the National Medicines Quality Assurance Laboratory and to attach the 64 officers deployed in service in the current period, to the Authority even by the date of audit of 17 October 2017.

(e) Even though the equipment and samples of medicines obtained for inquiring, examination, analysis, and for clinical trials should be destroyed after their expiration, 180 such expired samples relating to the period from the year 2013 to the date of audit of 10 October 2017 had been retained in the National Medicines Quality Assurance Laboratory without being destroyed.

(f) Matters observed relating to issuing of the Letters of Non- objection are given below.

(i) Any medicines or medical devices should not either be manufactured or imported by any person without either being registered in the Authority or without obtaining a license from the Authority in terms of Section 58 of Part IV of Chapter III and in terms of Section 82 of Part IV of the National Medicines Regulatory Authority Act No.05 of 2015. The issuance of the Registration Certificates and License should be carried out by the Authority after the evaluation either of medicines or medical devices considering the necessity for ensuring that efficacious, safe and good quality medicines or medical devices are being provided in terms of Sections 59 and 83 of that Act.. Six- hundred and forty- nine Letters of Non- objection had been issued in the year 2016 for the State Pharmaceuticals Corporation, Medical Supplies Division and for other Government and Private Institutions and 557 such Letters had been issued from January to 20 October 2017 contrary to the above provisions. The Letters of Non- objection had been used for the exemption from the Sri Lanka Customs to the importers not registered under the Act and to authorized importers of medicines and medical devices.

(ii) The inflow of medical supplies without a confirmation on quality in to the country could not be prevented due to the issuance of the Letters of Non- objection and, it had been a reason to the decrease of the registration and the license fees income of the Authority on those Letters being issued without charging a fee.

(iii) Issuing of the Letters of Non-objection had been increased from about 7 per cent in the year 2017 as compared with the year 2016 in comparing the number of Letters of Non-objection issued from the period from January to 20 October 2016 and from January to October 2017.

(iv) The permission could be granted by the Authority to import and to supply medicines, medical devices or borderline products in specific amounts either in matters of occasion such as either to save a life or for the prevention of spreading of an infectious disease or an epidemic disease or for any other national need or for the national security in terms of Section 109 of Part I of Chapter VI of the National Medicines Regulatory Authority Act No.05 of 2015. However, 183 Letters of Non- objection had been issued to the Medical Supplies Division and to the State Pharmaceuticals Corporation in the year under review on reasons such as the cancellation of registration of the relevant medicine or the medical device, the non- existence of registered suppliers, not relevant to the category of the above needs. As such, it is observed that the issuance of the Letters of Non- objection on the aforesaid reasons had caused in reducing the interest of the suppliers to obtain the registration of the medicines, medical devices and borderline products.

(v) Eight Letters of Non- objection had been issued by the Authority to the same manufacturer or supplier for the supply of medicines valued at Rs.56,068,038 in 08 instances in the year 2017, despite there were two suppliers who had obtained the full registration for the "Dextran 40 Injection sodium chloride injection IP 10% 0.9 500m*l"* medicine for a period of 05 years before the establishment of the Authority on 07 March 2013 or, and 16 March 2016.

(vi) Seven instances where Letters of Non- objection had been issued to the same supplier over again in the year under review and 10 such instances in the period up to 20 October 2017 remained.

3.3 Procurement and Contract Process

The following observations are made.

(a) It was observed in terms of the matters given below that the transparency and the economical nature had not been achieved in the procurements relating to the purchase of 13 Air- Conditioners and office equipments by spending a sum of Rs.1,643,000 and Rs.579,026 respectively by the Authority.

(i) Standard Bidding Documents had not been used in terms of the Guideline 5.3.1 (c) of the Government Procurement Guidelines and even though the Bidding Documents should be approved by the Technical Evaluation Committee and the Procurement Committee respectively after the examination, the approval of those Committees could not be obtained for the Bidding Documents due to calling for bids 15 days and 1 month respectively before the appointment of the Technical Evaluation Committee relating to these purchases.

(ii) The responsibility of opening bids had been entrusted to the Procurement Committee in terms of the Guideline 6.3.3(a) of the Government Procurement Guidelines and it could be entrusted to the Bid Opening Committee of that Authority by the Procurement Committee. Even though this committee should consist at least of two members approved by the Procurement Committee, a Bid Opening Committee had not been appointed relating to 2 of these purchases. Moreover, even though the activities on opening bids should be reported in a prescribed Form in terms of the Guideline 6.3.6 of the Government Procurement Guidelines, , even such report had not been prepared.

(iii) Even though the power of authority for purchasing goods from Rs.1 million to Rs.5 million should be obtained from the Procurement Committee of the Department in terms of the Guideline 2.14.1 of Supplement 28 of the Government Procurement Guidelines in following the Shopping Method in the Procurement of Goods, the power of authority for the procurement of purchasing 13 Air- Conditioners costing Rs.1,643,000 had been obtained from the Divisional Procurement Committee.

(iv) The maintenance cost of those machines had not been included into the Bidding Documents prepared for the purchase of 13 Air Conditioners. Quotations had been called for the maintenance cost from that supplier after the selection of the supplier. As such, it could not be specified whether the selected supplier was the supplier who furnished the minimum quotation on not being able to carry out a comparative evaluation with the maintenance cost of the other suppliers.

(v) Bids should be accepted only at a single place either by the registered post or by obtaining a receipt by handing over bids personally to the officer who had conferred power by the Procurement Entity in the specifically scheduled place or by putting inside the sealed Tender Box if it had mentioned in the Bidding Documents that there is a sealed Tender Box in terms of Sections i, ii, iii of the Guideline 6.3.1 (a) of the Government Procurement Guidelines. However, action had been taken by the Technical Evaluation Committee for the evaluation of the bid of a private institution sent by Fax on 26 May 2016 relating to the purchase of office equipment. As such, it was problematic to audit on the transparency of the Procurement Process due to action being taken by the Authority for purchasing the Items of high back chair and half cupboard with filing rack from the supplier who furnished bids by Fax by spending a sum of Rs.84,813.

3.4 Personnel Administration

The following observations are made.

(a) A total of 103 vacancies as 22 vacancies relating to 08 posts of the Staff Grade Level,69 vacancies relating to 05 posts of the Non- Staff Grade Level and 12 vacancies relating to 04 posts of the Minor Staff remained in the approved cadre of the National Medicines Regulatory Authority as at 31 December 2016. Even though action had been taken by the Authority to recruit two officers only for the post of the Legal Officer and for the post of Driver permanently out of those vacancies, action had not been taken to fill the remaining 101 vacancies even by 31 August 2017.

(b) Fourteen officers had been occupied to service for 12 posts of the Office Assistant and 02 posts of Typist exceeding the approved cadre as at 31 December 2016.

(c) The authority had failed to recruit staff in terms of Section 17 of the National Medicines Regulatory Authority Act No.5 of 2015 and 30 officers of the Combined Service and 107 officers of the Ministry of Health and Indigenous Medicine had been occupied in service as at 31 December 2016 without properly releasing from service. As such, even though an approximate period of 02 years had lapsed since the establishment of the Authority by 31 August 2017, the Authority had failed to permanently fill those posts.

(d) A Scheme of Recruitment had not been prepared for the 06 posts of the Assistant Director/ Deputy Director, Drug Analyst, Cost Officer, Drug Inspector, Pharmacist and Laboratory Assistant including in the approved cadre of the National Medicines Regulatory Authority even by 31 August 2017.

(e) Newspaper advertisements had been published on 12 June 2016 and on 22 November 2016 respectively for the recruitment of one officer for the post of the Administrative Officer and 41 officers for the post of Management Assistant and action had not been taken to make those recruitments even by the date of audit of 31 August 2017 in terms of Section 5.4 of the Scheme of Recruitment relating to those posts.

(f) Necessary action had not been taken by the Authority from 24 November 2016 to the date of audit of 31 August 2017 to recruit a new officer on the officer selected by a newspaper advertisement dated 12 June 2016 for the post of the Director (Human Resources) refusing to assume duties of that post on 24 November 2016.

(g) Employment Particulars had not been properly provided for 124 officers occupied to service in the National Medicines Regulatory Authority as at 31 December 2016.

(h) Twenty- one posts in the Staff- Grade level, 9 posts in the Non- Staff Grade level and 6 posts of Minor Employees including in the cadre approved for the National Medicines Quality Assurance Laboratory as at 31 December 2016 remained vacant and the Laboratory had been maintained up to the date of audit of 25 October 2017 with those vacancies and, 9 minor employees had been occupied in service exceeding the approved cadre for 2 posts of other minor employees.

4. Accountability and Good Governance

4.1 Corporate Plan

The Corporate Plan of the Authority had not been furnished to audit.

4.2 Action Plan

The Action Plan for the year 2016 had not been furnished to audit.

4.3 Procurement Plan

A Main Procurement Plan including the procurement activities intended for a period of at least three (03) years had not been prepared in terms of the Guideline 4.2.1(b) of the Government Procurement Guidelines 2006 and a Procurement Plan and Procurement Time Table for the year under review had not been prepared.

5. Systems and Controls

Deficiencies in systems and controls observed during the course of 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.

Areas of Systems and Controls	Observations
(a) Accounting of Income	Non- classification and accounting of the income.
(b) Issuing Letters of Non- objection	Not taking action to maintain at a minimum level.
(c) Recruitment of Staff	Not occupying the staff in terms of the Act.
(d) Control of Fixed Assets	Non transfer of fixed assets from the Ministry.

(e) Maintenance of the Registers relating to the registration certificates of medicines and medical devices	Non- inclusion of the members in some registration certificates in the registers maintained according to the numerical order of the registration certificates.
(f) Financial Control	Not properly preparing the Bank Reconciliation Statements and delays in preparing it.