

National Medicines Regulatory Authority – 2016

The audit of financial statements of the National Medicines Regulatory Authority for the year ended 31 December 2016 comprising the statement of financial position as at 31 December 2016 and the statement of comprehensive income, statement of changes in equity and cash flow statement for the year ended and a summary of significant accounting policies and other explanatory information, 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.15 of 2015. The Report of the Auditor General on the transactions of the Authority was issued to the Chairman of the Authority on 14 February 2018 on the delay in furnishing the financial statements for the year ended 31 December 2016. My comments and observations which I consider should be published with the Annual Report of the Authority in terms of Section 14(2)(c) of the Finance Act appear in this report.

1.2 Management’s Responsibility for the Financial Statements

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.

1.3 Auditor’s Responsibility

My responsibility is to express an opinion on these financial statements based on my audit. I conducted my audit in accordance with Sri Lanka Auditing Standards consistent with International Auditing Standards of Supreme Audit Institutions (ISSAI 1000- 1810). Those Standards require that I comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatements.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor’s judgement, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Authority’s preparation and fair presentation of financial statements 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 Authority’s internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of financial statements. Sub- sections (3) and (4) of the Finance Act, No.38 of 1971 give discretionary powers to the Auditor General to determine the scope and extent of the audit.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my audit opinion.

1.4 Basis for Qualified Opinion

My opinion is qualified based on the matters described in paragraph 2.2 of this report.

2. Financial Statements

2.1 Qualified Opinion

In my opinion, except for the effects of the matters described in paragraph 2.2 of this report, the financial statements give a true and fair view of the financial position of the National Medicines Regulatory Authority as at 31 December 2016 and its financial performance and cash flows for the year then ended in accordance with Sri Lanka Accounting Standards.

2.2 Comments on Financial Statements

2.2.1 Sri Lanka Accounting Standards

Even though the Accounting Policies used, relevant to understand the financial statements should be disclosed in terms of the Paragraph 117 of the Sri Lanka Accounting Standard 1, Accounting Policies on the remaining stocks and Government Grants had not been disclosed by the Authority.

2.2.2 Accounting Policies

Even though the Historical Cost Method being the measuring method commonly used in preparing the financial statements by the Institutions in terms of the Paragraph 456 of the Conceptual Framework for Financial Reporting, it remains being consolidated with other measuring methods. It had been stated that only the Historical Cost Method will be based under the Accounting Policy 2.2 in the financial statements without identifying measuring methods separately for the Assets and Liabilities of the Authority.

2.2.3 Accounting Deficiencies

The following observations are made.

- (a) The Medicines Trade and Medicines Import License Fees Income amounting to Rs.300,000 received in the year under review for the year 2017 had been brought to account as an income in the year under review.
- (b) The income relating to the year under review had not been identified and had not been brought to account in the sum of Rs.14,360,439 stated as the income received forward under Non- current Liabilities as at 31 December of the year under review.
- (c) A sum of Rs.12,000 relating to 04 Medicines Manufacturing Licenses issued in the year under review had been credited to the Payable Advance Account instead of crediting to the Income Account.

- (d) Fixed assets totaling Rs.240,460 including 09 items of fixed assets amounting to Rs.231,246 included in the inventory register, donated by the chairman of the authority and including the value of UPS amounting to Rs. 9,214 donated by the medical supplies division had not been brought to account.
- (e) The Property, Plant and Equipment Depreciation relating to the year under review had been brought to account less than a sum of Rs.11,477.

2.2.4 Lack of Evidence for Audit

The Schedules, Detailed Information and Age Analysis relating to the Advance Receipts relating to the Device Import License Income amounting to Rs.12,624,000, Un- reconciled Expenses amounting to Rs.63,621 included in Other Expenses in the Statement of Income and Advance Receipts amounting to Rs.14,360,439 included in the Non- current Liabilities as at 31 December 2016 had not been furnished to audit.

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, Regulations and Management Decisions

Observations

- | Reference to Laws, Rules, Regulations and Management Decisions | Observations |
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| Gazette Extraordinary Paper No.1601/15 of 12 May 2009. | <ul style="list-style-type: none"> (i) Even though fees amounting to Rs.10,000 each should be charged for the renewal of a Registration Certificate for the issuance of a Temporary Certification of Registration of Medicine and in a manner that the Certificate could be valid for five years in terms of the Gazette Notification, a sum of Rs.3,000 each had been charged for those certificates issued as per the Gazette Notification Paper, contrary to the provisions in the Gazette Notification Paper. (ii) Even though the fee for the initial registration of a medical device that would be valid for five years had been a sum of Rs.7,500 and a total sum of Rs.21,000 as a sum of Rs.5,000 for 04 of those certificates and a sum of Rs.1,000 for a certificate and the fee for the issuance of a temporary certificate for the registration of a medical device had been a sum of Rs.2,000 as per the Gazette Notification Paper, a total sum of Rs.2,000 had been charged as a sum of Rs.1,000 each for 02 of those certificates. |

