**National Medicine Regulatory Authority – 2018**

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## 1. Financial Statements

### 1.1 Qualified Opinion

The audit of the financial statements of the National Medicine Regulatory Authority for the year ended 31 December 2018 comprising the statement of financial position as at 31 December 2018 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 Finance Act No.38 of 1971. My comments and observations which I consider should be reported to the Parliament appeared in the transaction report of the National Medicine Regulatory Authority included in the part XVIII, Volume II of the Series of Parliamentary Publications tabled in the parliament on 09 January 2020. In addition to that, further observations which should be read in conjunction with the said report on the financial statements of the National Medicine Regulatory Authority for the year ended 31 December 2018 appear in this report.

In my opinion, except for the effects of the matters described in the paragraph 1.5 of this report, the financial statements give a true and fair view of the financial position of the Authority as at 31 December 2018 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

My opinion is qualified based on the matters described in the 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

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 the management determines is necessary to enable the preparation of financial statements that are free from material misstatements, 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 intend 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, the Authority 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 misstatements, 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 guarantee that an audit conducted in accordance with Sri Lanka Auditing Standards will always detected 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 a part of an audit in accordance with Sri Lanka Auditing Standards, I exercise professional judgment and maintain professional scepticism 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 Authority's internal control.

- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the management.

- 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 Council 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 was expanded as possible as to examine the following matters in any time as required.

- 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 the Authority has performed according to its powers, functions and duties; and

- Whether the resources of the Authority had been procured and utilized economically, efficiently and effectively within the time frames and in compliance with the applicable laws.

**1.5 Financial Statements**

**1.5.1 Non compliances with Sri Lanka Accounting Standards**

| Non-compliance with reference to the relevant Standard | Management Comment | Recommendation |
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| (a) Contrary to the terms of paragraph 32 of the Sri Lanka Accounting Standard 1, two debit balances totalling Rs.329,641 and two credit balances totalling Rs.1,369,307 had been set off against to other opposite accounts and shown in the financial statements. Further, according to the paragraph 113 of the Sri Lanka Accounting Standard 1, notes had not been presented to analyse the interest income of Rs.61,067,576 and the other income of Rs.1,079,748 which had been included in the Statement of Comprehensive Income. | Actions to be taken correctly to enter in the financial statements for the coming year. | Actions should be taken as per the Sri Lanka Accounting Standard. |

### 1.5.2 Accounting Deficiencies

| | Audit observation | Management Comment | Recommendation |
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| (a) | A total sum of Rs.8,015,487 received during the year under review as revenue for coming years had been taken into accounts as revenue for the year under review whilst a total sum of Rs.14,033,676 received as revenue for the year under review had been taken into accounts as revenue received in advance. In addition to that, revenue received during the year under review amounting to Rs.577,230 had been posted twice into the relevant revenue accounts. | To be corrected in preparing accounts for the coming year. | Financial statements should be presented to audit after correcting such error in the preceding year. |
| (b) | A sum of Rs.1,390,470 received during the year under review as revenue for 85 clinical medical equipment licenses issued during the year under review had been credited to two revenue accounts. | -do- | -do- |
| (c) | A sum of Rs.1,073,594 received during the year 2017 as fees for 20 Medicine Registration Certificate issued in the year 2017 had been shown as revenue for the year under review. | -do- | -do- |
| (d) | Although the contribution for the pension scheme which had been paid during the year under review for the previous year amounting to Rs.366,724 should be debited to the accrued pension contribution fund account, instead of, it had been debited to the secondary allowances expenditure account. | To be corrected in preparing accounts for the coming year. | Financial statements should be presented to audit after correcting such error in the preceding year. |
| (e) | Although the value of cheques issued for payment of contribution for pension scheme should be debited to the cash book and credited to the pension contribution fund account because those cheques were cancelled, out of the value of cheques, a sum of Rs.2,873,417 had been credited to | -do- | -do- |

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| | the prior year adjustment account and the rest of Rs.1,089,610 had been credited to accrued other expenditure account. | | |
| (f) | Accrued expenditure as at 31 December 2018 amounting to Rs.2,638,792 had not been taken into accounts. | -do- | -do- |
| (g) | The value of Value Added Tax (VAT) amounting to Rs.1,196,353 which had been paid to external parties by the Authority had not been set off to the Value Added Tax (VAT) payable to the Department of Inland Revenue and the value of Value Added Tax (VAT) which had been collected from the revenue of examination of good production practice fees during the year under review amounting to Rs.6,178,406 had been credited to the received advances account. | To be corrected in preparing accounts for the coming year. | Financial statements should be presented to audit after correcting such error in the preceding year. |
| (h) | The interest income on Treasury Bills relating to the year under review had been overstated by Rs.241,679 in the accounts and the income tax liability relating to the year under review had been understated by Rs.226,976 in the accounts. | -do- | -do- |
| (i) | The grant of Rs.1,263,521 which had been received from the World Health Organization for the expenses of the programme "WHO Benchmarking Tool" had not been taken into accounts as a special grant and the actual expenditure of Rs.1,059,800 had not been amortized. | -do- | -do- |
| (j) | A difference of Rs.34,680,636 relating to 5 subjects had been observed between the balance shown in the financial statements and the relevant schedules and reasons for the said difference had not been disclosed to audit. | To be corrected in preparing accounts for the coming year. | Financial statements should be presented to audit after correcting such error in the preceding year. |
| (k) | Schedules and age analysis for the balance of the received advances account amounting to Rs.33,423,063 had not been presented to audit. | The mistake of advances registers, schedules and age analysis not being | -do- |

maintained in the correct format is accepted. Unavailability of permanent staff caused to the said mistake and all the relevant officers were informed about the requirement of minimizing the accounting errors.

## 2. Financial Review

According to the financial statements, the operating results for the year under review were a surplus of Rs.809,170,663 and the corresponding surplus for the previous year was Rs.288,823,697. Thus an increase of Rs.520,346,966 was observed in the financial result. Increase of registration revenue by 125 per cent had mainly affected to the said improvement. However, a proper mechanism had not been established to recognize all revenue including registration fees and license fees which had been received by cash and directly to the bank according to the relevant accounting period. A practice of crediting all receives to a received advance account and identifying revenue subsequently had been followed. Therefore the revenue for the year under review had not been recognized correctly.