# Annual Report

# 2018

NMRA
NATIONAL MEDICINES REGULATORY AUTHORITY

NATIONAL MEDICINES REGULATORY AUTHORITY (NMRA)
No. 120, Norris Canal Road, Colombo 10.

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1. Prof. Asita De Silva - Chairman
2. Dr. Kamal Jayasinghe
3. Prof. Narada Warnasooriya
4. Prof. R.L Jayakodi
5. Mrs. C. Herath
6. Ms. Priyantha Rathnayake
7. Dr. Anil Jasinghe
8. Dr. Lakkumar Fernando
9. Dr. Kapila Ranasinghe
10. Dr. Nissanka Jayawardana
11. Dr. Dilanthi Herath
12. Dr. Ananda Wijewickrama

# List of Abbreviations

| | |
|---|---|
| BPEC | Borderline Products Evaluation Committee |
| CDD Act | Cosmetic, Device and Drugs Act |
| CFDI | Chief Food and Drug Inspector |
| DO | Development Officer |
| FDI | Food and Drug Inspector |
| GDP | Good Distribution Practices |
| GLP | Good Laboratory Practice |
| GMP | Good Manufacturing Practices |
| GPP | Good Pharmacy Practices |
| ICT | Information Communication Technology |
| ID Card | Identity Card |
| IED | Inspectorate and Enforcement Division |
| ISO | International Organization for Standardization |
| IT | Information Technology |
| KKS | Karyala Karya Sahayaka |
| MA | Management Assistant |
| MDEC | Medical Devices Evaluation Committee |
| MEC | Medicine Evaluation Committee |
| NDDCB | National Dangerous Drugs Control Board |
| NDQAL | National Drug Quality Assurance Laboratory |
| NMQAL | National Medicines Quality Assurance Laboratory |
| NMRA | National Medicine Regulatory Authority |
| SCOCT | Sub Committee of Clinical Trial |
| SDG | Sustainable Development Goals |
| SSFFC | Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit |
| TRIPS | Trade-Related Aspects of Intellectual Property Rights |
| UNDP | United Nations Development Programme |
| WD | Withdrawal |
| WH | Withhold |
| WHO | World Health Organization |

# Message of the Chairman

I am pleased to present the Annual Report for the year 2018 of the National Medicines Regulatory Authority, which is an independent body of the Ministry of Health and Indigenous Medicine Services. The main function of this institute is to check the quality, safety, efficacy, and affordability of All drugs, medical devices, borderline products, and cosmetics following the National Drug Policy that has been consumed by the public.

The National Medicines Regulatory Authority has been able to regulate all aspects of medicines, medical devices, borderline products, and cosmetics used in the country in an efficient, effective, and highly transparent manner in the face of many challenges such as lack of infrastructure especially inadequate human resources. The National Medicines Regulatory Authority is proud to have the National Drug Quality Assurance Laboratory, the nationally recognized flagship laboratory that provides technical assistance to the National Medicines Regulatory Authority to ascertain whether medical products comply with the required standards.

I am also pleased with the overall staff of the National Medicines Regulatory Authority, which was established in 2015, to become financially stable by 2017 and to be independent of the General Treasury without any financial provision. Several steps have already been taken to network the systems to make the issuance of certificates and licenses to medicines outlets and other related products more efficient. I am confident that this will directly enhance the quality and efficiency of the country's healthcare system.

Under the leadership of the Chief Executive Officer, I look forward to recruiting suitably qualified officers for the National Medicines Regulatory Authority and guiding the staff to achieve the goals of the organization through employee satisfaction by developing human resources wisely.

Prof Asita de Silva

Chairman

National Medicine Regulatory Authority

# Message of the Chief Executive Officer

I being the CEO of one of the fastest growing Drug Regulatory Agencies in South - East Asia, the NMRA, feel very proud to present its Annual Report 2018. From the beginning we have recognized, understood and shared our vision, mission and goals among the members of our team which was the invaluable strength behind all these efforts. All of us together developed and agreed on a five-year corporate plan to be guided by. We are very likely to be directed and guided by our visionary leaders Hon Dr. Rajitha Senaratne the Minister of Health Nutrition and Indigenous Medicine, Prof. Asita De Silva the Chairman, NMRA and the Board of members of the Authority.

This year also, NMRA has recorded a substantial growth of its turnover through its regulatory activities. This growth has contributed very much to become independent from treasury funding which is a major qualification for a drug regulator to be recognized by WHO.

The Authority's turnover mainly depends on the processing fees, registration, sample licensing, import licensing, manufacturing licensing and provisional and full registration income from medical devices and medicines.

In this year also, substantial revenue recorded by the Authority without the contribution of the General Treasury of Sri Lanka. And also, I feel very proud that, National Medicine Regulatory Authority being able to contribute to the General Treasury as a treasury levy and as income tax by its net income.

We have identified that the strategic goal for the future of our organization is to strengthen the constitutional framework of authority. I am fully committed to achieving that goal by improving operational productivity, improving financial performance and independence, developing the human capital base, using the latest methods in IT systems and improving operational productivity.

Dr. Kamal Jayasinghe

**(**MBBS, DFM, MSc-Med, Admin, MCMA, MBA, DIPPCA**)**

Chief Executive Officer/ Director General

National Medicines Regulatory Authority

# Chapter 1

# Corporate Profile / Executive Summary

## 1.1 Introduction

National Medicines Regulatory Authority (NMRA) is the only government agency established in Sri Lanka to regulate all kind of medicines, medical devices and borderline products. And also responsible for ensuring the quality, efficacy and safety of all medicinal products, marketed in the country for affordable prices to the public.

The legal framework to regulate all kind of medicines, medical devices and cosmetics distributed within the country has been provided by the Cosmetics, Devices and Drugs Act (CDD Act) No. 27 of 1980 and the CDD Regulations of 1984 and their subsequent amendments from 1980 until July 2015. Further, National Medicines Drug Policy was developed from the CDD Act and cabinet approval was granted in 2007. In 2015, National Medicines Regulatory Authority Act 2015 No 5 (NMRA Act) was passed in parliament repealing the above acts on the same subject.

According to the NMRA Act, National Medicines Regulatory Authority (NMRA) was established in March 2015 and came in to operation with effect from 1$^{st}$ of July 2015 as a semi-autonomous organization under the Ministry of Health. Under the NMRA Act, NMRA functions as an independent authority and, it can make its own decisions and control of its activities in view of assuming safety, quality, efficacy and accessibility of all medicinal products to the patients of Sri Lanka.

Organization structure was not properly recorded yet but, following divisions were identifiable in it.

- National Medicines Quality Assurance Laboratory (NMQAL)
- Pharmaceutical Regulatory Division
- Inspectorate and Enforcement Division
- Finance Division
- Administration Division
- Legal Division

Accordingly, there are several committees to assist for the decision making process. Those committees are responsible for evaluation of Medicines (MEC), Medical Devices (MDEC),

Borderline Products (BPEC), Clinical Trials (SCOCT) and Pricing (Pricing Committee) for regulating the market price to ensure safety, quality & efficacy of all those medicinal items make them available at an affordable price for the public. In addition, there is an Appeal Committee open to the public and Advisory Committee to oversee the implementation of NMRA Act.

Further, NMRA act upon Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Good Pharmacy Practices (GPP) as legal requirements.

## 1.2 Vision, Mission, Objectives of the Organization

### 1.2.1 Vision of the Organization

**"Improve access to quality assured medicines and healthcare products"**

### 1.2.2 Mission of the Organization

**"Provide regulatory oversight and evidence based decisions for medicines and healthcare products to ensure their Safety, Quality and Efficacy for the benefit of patients"**

### 1.2.3 Objects of the Authority

a) Ensure the availability of efficacious, safe and good quality medicines, efficacious, safe and good quality medical devices and efficacious, safe and good quality borderline products to the general public at affordable prices;
b) Function as the central regulator for all matters connected with the registration, licensing, cancellation of registration or licensing, pricing, manufacture, importation, storage, transport, distribution, sale, advertising and disposal of medicines, medical devices and borderline products;
c) Ensure that all activities related to registration, licensing and importation of medicines, medical devices, borderline products and investigational medicinal products are carried out in a transparent, sustainable and equitable manner; Objects of the Authority. Establishment of the National Medicines Regulatory Authority.
d) Encourage the manufacturing of good quality medicines in Sri Lanka with a view to assuring the availability of essential medicines at affordable prices;
e) Promote the safe and rational use of medicines, medical devices and borderline products by health care professionals and consumers;
f) Recommend appropriate amendments to relevant laws pertaining to medicines, medical devices and borderline products;
g) Educate the general public, health care professionals and all stakeholders on medicines, medical devices and borderline products;
h) Regulate the promotion and marketing of medicines, medical devices and borderline products;
i) Regulate the availability of the medicines, medical devices and borderline products;
j) Conduct post marketing surveillance on quality, safety and adverse reaction of the medicines, medical devices and borderline products; and
k) Regulate all matters pertaining to the conduct of clinical trials in Sri Lanka.

## 1.3 Main Functions

- Registration of new medicines, medical devices and borderline products.
- Regulation of amendments of already registered products in the market
- Supervision and implementation of good manufacturing practices
- Vigilance of medicinal products in the market and advertisements
- Regulation and supervision of clinical trials
- Certification of good manufacturing products for exportation of medicinal products
- Enforcement of good pharmacy practices
- Inspection of medicinal products in the market and law enforcement

## 1.4 Cadre Availability

| Category of employees | Post | Approved Cadre | Actual Cadre | Vacancies / Excess |
|---|---|---|---|---|
| **Senior level** | Director General | 01 | 01 | - |
| | Director | 04 | 01 | 03 |
| | Director (Human Resources) | 01 | - | 01 |
| | Medical Officer | 04 | - | 04 |
| | Accountant | 01 | 01 | - |
| | Internal Auditor | 01 | - | 01 |
| | Assistant Director/Deputy Director | 06 | 01 | 05 |
| | Assistant Director/Deputy Director (ICT) | 01 | - | 01 |
| | Cost Accountant | 01 | - | 01 |
| | Legal Officer | 01 | 01 | - |
| | Pharmaceutical Analyst | 13 | 06 | - |

| | | | | |
|---|---|---|---|---|
| **Tertiary Level** | Administrative Officer | 01 | 01 (Acting) | 01 |
| | Costing Officers | 05 | - | 05 |
| **Secondary Level** | Pharmacists | 70 | 53 (temporary /secondment basis) | 70 |
| | Development Officers | 10 | - | 10 |
| | Drug Inspector | 20 | 03 (secondment basis) | 20 |
| | Technical Officer (Civil) | 01 | 01 (temporary basis) | 01 |
| | ICT Assistant | 01 | 01 (Secondment) | - |
| | Management Assistant | 43 + (contract basis 10) | 08 (Contract Basis)<br>05 (Secondment)<br>02 (Pension) | 43 |
| **Primary** | Driver | 10 | 06 (03 Secondment, 02 Permenent, 01 Temporary) | 08 |
| | Plumber | 01 | - | 01 |
| | Electrician | 01 | 01 | - |
| | Lab Assistant | 08 | 02 (Secondment basis) | 08 |
| | Karyala Karya Sahayaka | 30 | 26 | 04 |
| | **Total** | **245** | **119** | **188** |

## 1.5 Divisions under the NMRA

For the smooth functioning of the NMRA, it has following divisions.

1. National Medicines Quality Assurance Laboratory (NMQAL)
2. Pharmaceutical Regulatory Division
3. Inspectorate and Enforcement Division
4. Finance Division
5. Administration Division
6. Legal Division

### 1.5.1 National Medicines Quality Assurance Laboratory (NMQAL)

#### 1.5.1.1 Introduction

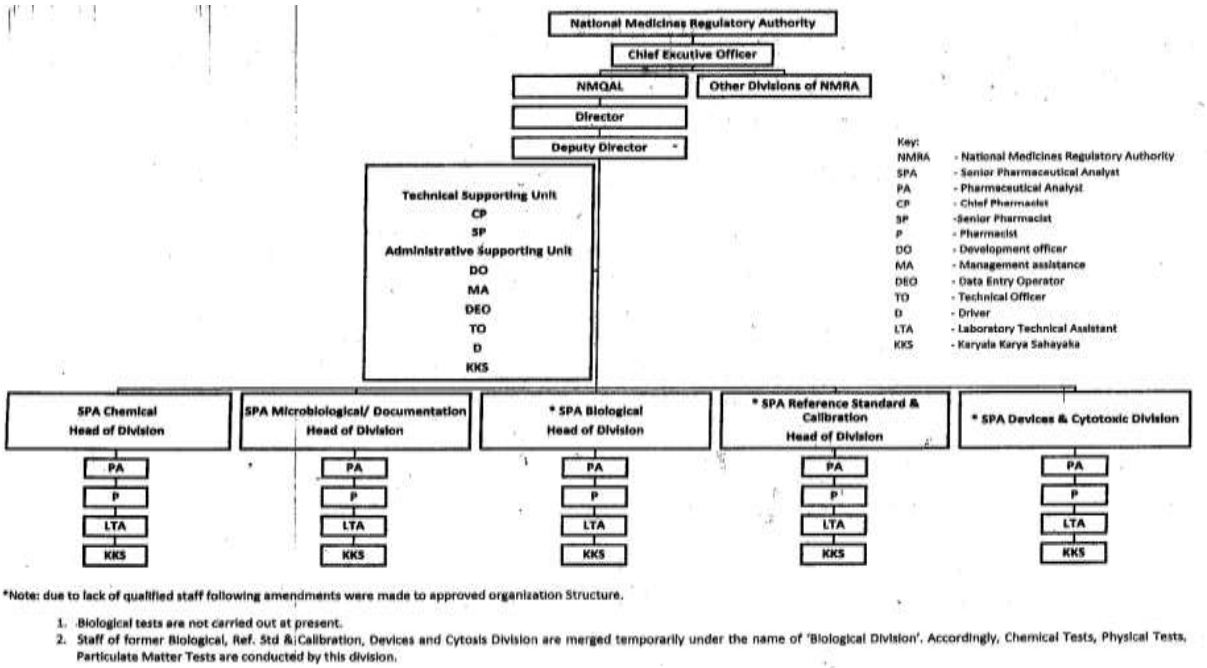
National Drug Quality Assurance Laboratory (NDQAL) was the National Laboratory established in Sri Lanka for testing Cosmetics Devices and Drugs. It was established in 1990 under Cosmetics Devices and Drug Act No.27 of 1980, with Norwegian consultancies and NORAD funds with the vision of ensuring Quality, Safety and Efficacy of the above products available in Sri Lanka.

The National Drug Regulatory Authority (NMRA) was established on July 1, 2015. Under the National Drug Regulation Act No. 5 of 2015, the National Drug Quality Assurance Laboratory (NDQAL), which was functioning under the Department of Health, was placed under the new authority. Therefore at present NDQAL is functioning under the NMRA and the laboratory is renamed as National Medicines Quality Assurance Laboratory (NMQAL).

Main divisions of NMQAL are Chemical, Microbiological, Biological, Reference Standard & Calibration and Devices. NMQAL follows the test procedures in standard pharmacopoeias and other accepted (validated) test procedures in the assessment of quality safely and efficacy.

NMQAL Functions as an additional approved analyst when the circumstances so require.

**1.5.1.2** Divisional Chart of NMQAL:




*Note: due to lack of qualified staff following amendments were made to approved organization Structure.

1. Biological tests are not carried out at present.
2. Staff of former Biological, Ref. Std &Calibration, Devices and Cytosis Division are merged temporarily under the name of 'Biological Division'. Accordingly, Chemical Tests, Physical Tests, Particulate Matter Tests are conducted by this division.

1.5.1.3 Main functions of NMQAL

National Medicines Quality Assurance Laboratory (NMQAL) provides the technical support needed to operate the quality assurance system on Medicines, Medical Devices, Borderline products and Cosmetics. The primary function of the NMQAL is to conduct laboratory tests necessary for determining compliance with product quality, safety and efficacy requirements. Functions of NMQAL are,

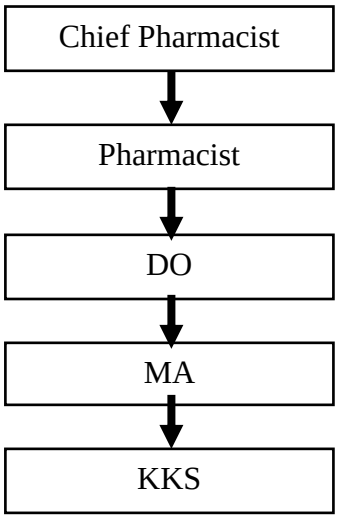
- Analysis of locally manufactured and imported Medicines, Medical Devices, Borderline products and Cosmetics at different points in the distribution chain. (Premarketing and Post marketing stages) Samples for analyses are submitted as registration samples, complaints samples, tender samples pre shipment samples, pre delivery samples and courts samples. In addition surveillance samples are collected from government and private institutions.
- Provide technical advices on evaluation of registration of Pharmaceuticals, Medical Devices and Borderline products as and when necessary.
- Participate in GMP inspections
- Participate in external quality assurance assessment scheme (proficiency testing)
- Conduct training programs on quality assurance system
- To coordinate with laboratories local or overseas when their services are deemed necessary as decided by the NMRA.

## 1.5.2. Medicines Regulatory Division

### 1.5.2.1 Introduction

In addition, to the responsibility of regulating medicines, medical devices and borderline products used within Sri Lanka to protect the interests of patients using the products in view of safely, efficacy, quality and price, NMRA further involves with the regulation of pharmaceutical manufacturing sites and island wide pharmacies as well. Pharmacovigilance is another aspect that the Division is undertaking to minimize adverse outcomes from the medicine and related products.

### 1.5.2.2 Divisional Chart of the Medicines Regulatory Division




### 1.5.2.3 Functions of Medicines Regulatory Division

Regulate all the functions under medicine, medical devices, and borderline products under NMRA act including;

- Pharmaceutical manufacturing sites locally and internationally.
- Evaluation, register and issue Import Licenses of new medicines, medical devices and borderline products
- Price Regulation
- Regulation of Island wide Pharmacies
- Pharmacovigilance

### 1.5.3 Inspectorate and Enforcement Division

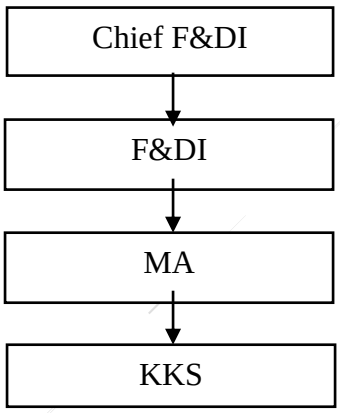
#### 1.5.3.1 Introduction

Inspectorate & Enforcement Division is a division established in the National Medicines Regulatory Authority under the NMRA Act No 05 of 2015.

The main function of the Inspectorate & Enforcement Division of the NMRA is inspecting and investigating issues pertaining to proper implementation of the provisions of the NMRA Act as may be authorized and directed by the Authority. Three senior Food & Drugs Inspector officers have been appointed to this unit to carry out these functions as Authorized Officers under the NMRA Act by Hon. Minister. Currently this unit is headed by Chief Food & Drugs Inspector (CFDI).

FDIs are considered as field officers who serve duties mostly in the field in performing duties which require constant contact with others.

#### 1.5.3.2 Divisional Chart of the Inspectorate and Enforcement Division




#### 1.5.3.3 Functions of Inspection and Enforcement Division

1. Functioning as Authorized Officers under the NMRA Act
2. Conducting Post marketing surveillance
3. Obtaining formal and informal samples when necessary
4. Inspecting & recommending medicines handling establishments to issue licenses
5. Inspecting & recommending medicine transport vehicles to issue licenses
6. Ensuring the implementation of product recall procedure
7. Investigating & initiate legal actions on the detentions made by the SSFFC & smuggled products
8. Investigating the availability of state-owned drugs in the private market

9. Inspecting & recommending of dangerous drugs applications
10. Organizing & conducting educational programs
11. Conducting prosecutions against the violations committed under the Act
12. Coordinating & corporation with other law enforcement agencies

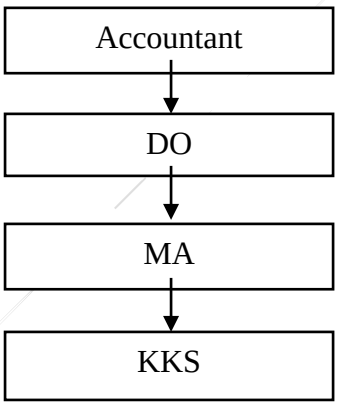
### 1.5.4 Finance Division

#### 1.5.4.1 Introduction

Finance division of NMRA has commenced its activities from the 01.01.2016. As planed in 2016 Accountant has recruited on 2017 and currently finance division functions with eleven members including Accountant, three members from the Health Ministry, five trainees, one contract basis member and one KKS.

Hoped that coming years the finance division will be smoothly maintained by recruiting the required staff.

#### 1.5.4.2 Divisional Chart of the Accounts Division




#### 1.5.4.3 Functions of Finance Division

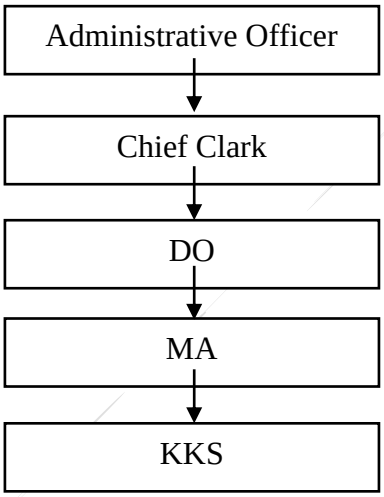
- Receiving all revenue through eighteen revenue streams.
- Bear all the expenses required to maintain the institution after independence from the Ministry of Health
- Preparing the budget for the coming year and obtaining the relevant approvals
- Maintaining all the supplies required to run the day-to-day activities of the Authority
- All monetary controlling matters
- All bulk control

### 1.5.5 Administration Division

#### 1.5.5.1 Introduction

The main function of the Administrative Division is to issue the licenses and the registration certificates to the suppliers of all kind of medicinal products based on the approval of the Pharmaceutical Regulatory Division. In addition, Building maintenance, repairing of electrical items, vehicle management, servicing and repairing, obtaining approvals for all kind bills and other payments, maintain leave and other staff arrangements, and make arrangements to enhance staff welfare. It helps the organization to deliver a high quality services to its clients, by establishing the formal communications with other institutes as well.

#### 1.5.5.2 Divisional Chart of the Administration Division




#### 1.5.5.3 Functions of Administration Division

This section is established to cover all the administrative and maintenance functions at NMRA and specifically issuing licenses and registration certificates of Drugs, Medical Devices and Borderline items.

Accordingly, main activities functioned in Administration Division is as follows.

- License Issuing after evaluations of Dossiers - Drugs (Manufacturing and Import License), Device (Manufacturing and import License), Sample License and

Registration license issuing (Drugs and Devices) Registration Certificates and Licenses typing, and email the evaluation sheets.

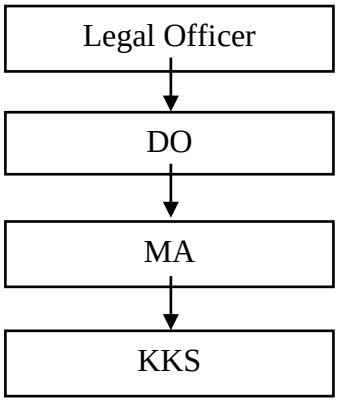
- Supervising the license and the registration certificates issuing process
- Personnel Management within the Authority
- Supervise all the activities related to maintenance of the office premises
- Maintaining utility services
- Making relevant reports in relation to the section
- Vehicle and transport management
- Coordinating the activities related to staff leave (official/local/foreign)
- Certifying the attendance of the permanents staff and training staff
- Obtain relevant services such as security, cleaning, electricity, elevator services, air conditioners, photocopiers etc. form external parities required for the Authority and arrange all bill payments
- Supervising external and internal record rooms
- Issuing staff ID cards

### 1.5.6 Legal Division

#### 1.5.6.1 Introduction

Legal Division could be introduced as one of the main areas within the scope of the National Medicines Regulatory Authority (NMRA) which is established in the year 2017. The Legal Division of the NMRA plays a key role in formulating legislation under the NMRA Act no 05 of 2015 related to the Governance of importers, manufacturers, distributors, wholesalers and retailers of medicines, medical devices, borderline products and cosmetics.

1.5.6.2 Divisional Chart of the Legal Division




1.5.6.3 Main Functions of the Legal Division

1. Recommend appropriate amendments to the NMRA Act No 5 of 2015 pertaining to medicines, medical devices, borderline products and cosmetics
2. Review emerging guidelines/ regulations and adopt to suit to the Sri Lankan context
3. Improve/amend the current regulations in order to achieve an effective and efficient regulatory system in Sri Lanka
4. Carry out Transfer of marketing authorization holders
5. Obtain legal advice from the Attorney General's Department and provide legal advice
6. Handle/ Coordinate applications regarding the Right to Information Act

# Chapter 2
# Progression and Vision

As a government policy decision to have a specific pharmaceutical regulatory authority with semi-autonomy, NMRA was formed with the NMRA Act of 2015. Its responsibility is to regulate the pharmaceutical products (medicines, medical devices and the cosmetics) to achieve the interests of general public by the means of safety, efficacy, quality and price.
Being in the early years of establishment, there were many short comings to achieve its goals. Despite all of it, NMRA has managed to deliver a remarkable service to Sri Lanka.

## 2.1 Progress of National Medicines Quality Assurance Laboratory (NMQAL)

Approval has been granted from Authority to purchase following sixteen new laboratory equipment. The total expenditure for these items was about Rs. 55.0 millions. 1) High Performance Liquid Chromatography (HPLC) , 2) Potentiometric Titrator 3) Vacuum Oven, 4) Viscometer 5) Refractometer 6) Laboratory Refrigerator 7) Ultrasonic cleaner 8) Laboratory Shaker (02 Nos), 9) Dehumidifier (02 Nos), 10) Viscometer U tube 11) Microscope 12) Rotary Evaporator 13) Horizontal LAF cabinet 14) Ventilated Laboratory Cabinet 15) Manual Dimension Tester and 16) Visual Leak Tester.
Five day training was given to five officers at Cosmetics and Pharmaceutical Laboratories, Health Sciences Authority, Singapore from 02$^{nd}$ to 6$^{th}$ April 2018.

1) Ms G L Kathriarachchi – Pharmaceutical Analyst -Head Chemical Division
2) Ms K P S S Kuruppu – Pharmaceutical Analyst –Head Reference Standard and Calibration
3) Ms K G David – Pharmacist
4) Ms K A S N Kahadawa – Pharmacist
5) Mr K T P Ranadeva - Pharmacist

NMQAL officers participated local and Foreign GMP inspections
BPharm and BSc (pharmacy) undergraduates, from University of Ruhuna, University of Peradeniya, University of Colombo, University of Sri Jayawardanapura, Kothalawala Defense Academy and Open University were trained.

Plans for future:

1) Recruit of highly qualified competent technical staff with various scientific backgrounds and other supportive staff.
2) Develop an organizational chart for NMQAL aligned with the NMRA organizational structure.
3) Re-start the analyses of more samples at the post marketing stage.
4) Develop a maintenance procedure for sophisticated and highly sensitive analytical equipment as the support provided by the local agents are inadequate.
5) Establish a separate purchasing unit at NMRA to procure all laboratory needs (Equipment, chemicals, solvents, reagents, primary and other standards, glassware and other accessories etc.)
6) Strengthen the internal communications/procedures/support for a better service.
7) Develop the laboratory activities to achieve ISO 17025 accreditation and/or to obtain WHO prequalification states.

Performance of the Division:

During 2018 NMQAL analyzed about 427 samples and failures were detected in 128 samples/batches and recommendations on failures were given accordingly.

| Sample Type | Pass | Fail /WH /WD | Already WD | Not Done | Total |
|---|---|---|---|---|---|
| **Complaint** | 102 | 81 | - | 34 | 217 |
| **Formal** | 51 | 4 | - | 28 | 83 |
| **Informal** | 58 | 10 | 2 | 5 | 75 |
| **Lab Request** | 3 | 3 | - | - | 6 |
| **Manu.Request** | - | 7 | - | - | 7 |
| **Registration** | 46 | 19 | - | 1 | 66 |
| **SPC Tender** | 1 | 1 | - | - | 2 |
| **Others** | 10 | - | - | - | 10 |
| **Surveillance** | 26 | 3 | - | - | 29 |
| | **297** | **128** | **2** | **68** | **495** |

No. of certificate of Quality issued = 495-68

= 427

No. of failure report issued = 128

Percentage (%) of quality failure from the Report issued in 2018 = 30

## 2.2 Progress of Medicines Regulatory Division

Routine duties of Pharmaceutical Regulatory Division are completed with maximum efficiency despite of low human resource availability. All the regulatory works are done by all regulatory pharmacists with multiple job roles to carry out the responsibilities of NMRA. Discussions was made to develop teams on different job roles for the year.

Plans for future

1) Recruiting the required human resources (Pharmacists, Management Assistants, KKS)
2) Subdivision of the division to create teams of similar job roles to improve efficiency
3) Electronic system requirement to be fulfilled to reduce over processing and improve the efficiency of the division

## 2.3 Progress of Inspection and Enforcement Division

Since the prime objective of the NMRA is to insure safety, quality and efficacy of medicinal products in the island I.E.D is actively motivated in according to the above objectives.
Identification of various violations and initiate the legal actions are mainly preformed.
The law is implemented by this division to protect consumers. Officers of this unit are closely working with the other law enforcement agencies (Police/Custom/Army/NDDCB) to protect consumers.

Implementation of Price Regulations - 2018

| Serial No. | Place/District | Nature of the offence | Action taken | | |
|---|---|---|---|---|---|
| | | | Court | Result (Fine) | Paper Advertisement |
| **01** | Ratnapura | Selling Clarithromycin capsules exceeding the price. | Embilipitiya | Rs. 25,000.00 | Yes |
| **02** | Ratnapura | Selling Augmentin capsules exceeding the price. | Embilipitiya | Rs. 25,000.00 | Yes |

Abusive Medicines

Prosecutions conducted by FDII, with the support of Police (STF, PNB) Navy, Excise, Coastal guard, Customs & other Law Enforcement Agencies.

2018. All Island

| District | Anuradhapura | Gampaha | Kegalle | NMRA Area | Total |
|---|---|---|---|---|---|
| **No of cases** | 07 | 71 | 12 | 44 | ***134*** |
| **Fines imposed** | Rs. 260000 | Rs. 375000 | Rs. 375000 | Rs. 1016000 | ***Rs. 202,6000*** |

## 2.4 Progress of Finance Division

The main target recruiting the Accountant was successfully accomplished at 2017.also four trainees was recruited. Also Quick Book accounting software was introduced to the division for the smooth and efficient functioning of the day to day activities. Also fees table was introduced for all revenues came as the regulatory fees calculated based on the value of the USD.

Plans for the future

1. Accounts to be handled by the NMRA and make use of the revenue effectively to achieve organizational objectives

2. Recruiting the required staff

## 2.5 Progress of Administration Division

Routine administrative and management duties were carried out. Staff welfare was looked into. Administrative assistance was extended to all the divisions to continue with the primary duties of them to achieve organizational goals.

In addition, as the main function of the Administration Division the licenses and Registration Certificates are issued based on the recommendations given by Pharmaceutical Regulatory Division as follows;

| No | Certificate Type | 2018 |
|---|---|---|
| **1** | Medicine Registration | 3246 |
| **2** | Medicine Import | 796 |
| **3** | Medicine Manufacture | 288 |
| **4** | Medicine Sample | 1499 |
| **5** | Medical Device Registration | 2081 |
| **6** | Medical Device Import | 328 |
| **7** | Medical Device Manufacture | 31 |
| **8** | Medical Device Sample | 1432 |
| **9** | Cosmetic Registration | 2663 |
| **10** | Cosmetic Import | 73 |
| **11** | Cosmetic Manufacture | 158 |
| **12** | Cosmetic Sample | 1411 |
| **13** | Borderline Registration | 7 |
| **14** | Borderline Import | - |
| **15** | Borderline Manufacture | 2 |
| **16** | Borderline Sample | 61 |
| | **TOTAL** | **14076** |

Plans for future

1) Human resource is planned to be improved further to improve efficiency of the organization.

| No | Gazette | Contents | Remarks |
|---|---|---|---|

2) Organizational structure to be finalized and necessary alterations to be made according to the government guidelines.
3) Separate divisions to be established for Human Resources.

## 2.6 Progress of Legal Division

- Total Closed Files 235
  - Closed files 2017 (21.04.2017-31.21.2017) 69
  - Closed files 2018 (01.01.2018 Up to 31.12.2018) 166
  - Total 235

- Total Pending Files 225
  - Carried forward pending files from 2017 161
  - Pending Files from 01.01.2018 – 31.12.2018 64
  - Total 225

- Agency Transfer Closed Files 124
  - Free of charges from (01.01.2018 – 31.12.2018) 24
  - Payment Basic from (01.01.2018 – 31.12.2018) 100
  - Total 124

- Agency Transfer Total Income

  **(From 01.01.2018 – 31.12.2018) Rs. 37,540,110.00**

Performance of the division in 2018

The performance summary of Legal Division is undermentioned.

**Regulations/ Gazettes issued under the NMRA Act from 01.01.2018 to 31.12.2018**

| | No/Date | | |
|---|---|---|---|
| 01 | 2052/33 - 05.01.2018 | Amendment to the Fee for Registration and licensing of Medicines, medical Devices and Borderline products | |
| 02 | 2086/37 - 31.08.2018 | • Maximum retail prices of 13 Medicinal Products<br>• Maximum Tender Prices of 10 Medicinal Products<br>• Maximum retail prices of 02 Medical Device | |

**Pending Court Cases (up to 31.12.2018) - Filled by the NMRA**

| NO | LO Number | CASE | Status | Position of the NMRA |
|---|---|---|---|---|
| 1 | NMRA/LO/10/2017 | Seeking legal advice regarding preliminary objections in Negombo Magistrate's Court case J93933)MTS / FDI /LA/ 2011) | **Pending** | **Plaintiff** |
| 2 | NMRA/LO/11/2017 | Minuwangoda Magistrate Court Case No 70066 (LO/415/11) | **Pending** | **Plaintiff** |
| 3 | NMRA/LO/12/2017 | Negambo Magistrate Court K 13644 (LO/321/13) | **Pending** | **Plaintiff** |
| 4 | NMRA/LO13/2017 | Matugama Magistrate Court No 71118/11 (MTS /FDI / Legal /2014) | **Pending** | **Plaintiff** |
| 6 | NMRA/LO/15/2017 | Case No. :45379/09 pending in the Wattala Magistrate's Court (LO/213/14) | **Pending** | **Plaintiff** |
| 7 | NMRA/LO/24/2017 | SC(FR)Application No:102/2016 vs NMRA, Consumer Affairs Authority Rishad Bathiudeen,Mano Ganeshan, Pro.Daya Edirisinghe, AG Appropriate use of Languages for Labelling Drugs in Sri Lanka | **Pending** | **Plaintiff** |
| 8 | NMRA/LO/162/2017 | Getting legal advice revision petition no - HDRA/118/09 | **Pending** | **Plaintiff** |
| 9 | NMRA/LO/434/2018 | Panadura court M/C 53946 | **Pending** | **Plaintiff** |

| | | | | |
|---|---|---|---|---|
| 10 | NMRA/LO/439/2018 | The Case of Western Medicine Case No. : 62475 Nuwara Eliya Magistrate's Court | **Pending** | **Plaintiff** |

**Pending Court Cases (up to 31.12.2018) – Filled against the NMRA**

| NO | LO Number | CASE | Status | Position of the NMRA |
|---|---|---|---|---|
| 1 | NMRA/LO/121/2017 | Western Provinces Colombo Commercial High Court Case No :H.C)Civil(425/2017/mn (B.J International (pvt) LTD) | **Pending** | **Respondent** |
| 2 | NMRA/LO/411/2018 | Nawaloka Hospitals PLC & Others Vs Hon.Dr.Rajitha Senarathne & Others C.A. (Writ) Application No.285/18 | **Pending** | **Respondent** |
| 3 | NMRA/LO/412/2018 | Asiri Hospital Holdings PLC & Others Vs Hon.Dr.Rajitha Senarathne & Others C.A. (Writ) Application No.284/2012 | **Pending** | **Respondent** |

# Chapter - 3

# Overall Financial Performance

National Medicines
Regulatory Authority

**Financial Statements for the year ended**
**31 December 2018**

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**STATEMENT OF FINANCIAL POSITION**

| As at 31 December, | Note | 2018 Rs. | 2017 Rs. |
|---|---|---|---|
| **Assets** | | | |
| **Non current assets** | | | |
| Property, plant and equipment | 2 | 29,016,461 | 25,668,931 |
| **Total non current assets** | | **29,016,461** | **25,668,931** |
| | | | |
| **Current assets** | | | |
| Inventory | 3 | 2,389,127 | 1,482,106 |
| Deposits and other receivable | 4 | 177,499 | 123,244 |
| Short term investments | 5 | 1,361,721,541 | 100,653,965 |
| Cash and cash equivalents | 6 | 549,535,303 | 631,763,823 |
| **Total current assets** | | **1,913,823,469** | **734,023,138** |
| **Total assets** | | **1,942,839,930** | **759,692,069** |
| | | | |
| **Equity and liabilities** | | | |
| **Equity** | | | |
| Accumulated Fund | | 1,047,449,960 | 310,302,346 |
| **Total equity** | | **1,047,449,960** | **310,302,346** |
| | | | |
| **Non Current liabilities** | | | |
| Capital grant | 7 | 2,843,168 | 4,186,070 |
| Deferred tax | 8 | 2,946,556 | 1,845,328 |
| **Total non current liabilities** | | **5,789,724** | **6,031,398** |
| | | | |
| **Current liabilities** | | | |
| Advance receipts | 9 | 96,988,980 | 85,643,656 |
| Provision for Income tax | 18 | 423,956,875 | 116,598,042 |
| VAT payable | 10 | 179,731,189 | 105,462,594 |
| Stamp duty payable | 11 | 40,140,404 | 36,111,233 |
| Provision for Treasury levy | 12 | 109,799,436 | 28,882,370 |
| Accrued expenses and other payables | 13 | 38,983,361 | 70,660,430 |
| **Total current liabilities** | | **889,600,246** | **443,358,325** |
| **Total equity and liabilities** | | **1,942,839,930** | **759,692,069** |

The accounting policies and annexed notes to the financial statements are an integral part of these financial statements.

K.M.Y.K Karunarathna
Accountant

K. M. Y. K. Karunarathne
Bsc. Bus.Admin., HNDA
ACCOUNTANT
National Medicines Regulatory Authority
120, Norris Canal Road,
Colombo 10.

The Members of the Authority are responsible for the preparation and presentation of these financial statements.
Signed and approved for and on behalf of the Members of the Authority:

Prof.Asita De Silva
Chairman

Dr.Kamal Jayasinghe
Chief Executive Officer

15th November 2019

Prof. Asita de Silva
MBBS, DPM (Ceylon), FRCP (Lond)
Chairman
National Medicines Regulatory Authority
Sri Lanka

Dr. Kamal Jayasinghe
MBBS, DFM, MSc-Med Admn, MBA, DIPP
Chief Executive Officer
National Medicines Regulatiry Author
120, Norris Canal Road, Colombo 1

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**NATIONAL MEDICINES REGULATORY AUTHORITY**
**STATEMENT OF COMPREHENSIVE INCOME**

| For the year ended 31 December, | Note | 2018 Rs. | 2017 Rs. |
|---|---|---|---|
| Revenue | 14 | 1,247,566,713 | 554,495,401 |
| Intrest income | | 61,067,576 | 653,966 |
| Other income | | 1,079,748 | 5,010,037 |
| Administrative expenses | 15 | (89,458,597) | (60,759,242) |
| Salaries and wages | 16 | (96,902,836) | (95,610,919) |
| Other expenses | 17 | (1,351,225) | (855,116) |
| Amortization of capital grant | | 1,342,902 | 1,342,902 |
| **Net income before taxation** | | **1,123,344,281** | **404,277,030** |
| Income tax for the year | 18 | (314,173,618) | (115,453,332) |
| **Net income after taxation** | | **809,170,663** | **288,823,697** |

The accounting policies and annexed notes to the financial statements are an integral part of these financial statements.

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**STATEMENT OF CHANGES IN EQUITY**

| For the year ended | Note | Accumulated Fund Rs. |
|---|---|---|
| Balance as at 1 January 2017 | | 57,557,675 |
| Prior year correction | | (7,196,656) |
| **Restated balance as at 31 December 2017** | | 50,361,019 |
| Profit for the year | | 288,823,697 |
| Provision for treasury levy | | (28,882,370) |
| **Balance as at 31 December 2017** | | **310,302,346** |
| Prior year correction | 15 | 8,894,017 |
| **Restated balance as at 31 December 2018** | | - |
| Profit for the year | | 809,170,663 |
| Provision for treasury levy | | (80,917,066) |
| **Balance as at 31 December 2018** | | **1,047,449,960** |

The accounting policies and annexed notes to the financial statements are an integral part of these financial statements.

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**NATIONAL MEDICINES REGULATORY AUTHORITY**
**STATEMENT OF CASH FLOW**

| *As at 31 December,* | 2018<br>Rs. | 2017<br>Rs. |
|---|---|---|
| Net income before taxation | 1,123,344,281 | 404,277,030 |
| Adjustment for : | | |
| Depreciation | 7,873,174 | 3,013,948 |
| Interest income | (61,067,576) | 48,846 |
| Amortization of capital grant | (1,342,902) | (1,342,902) |
| Provision for treasury levy | - | (28,882,370) |
| Prior year correction | - | (7,196,656) |
| Operating profit before tax | 1,068,806,977 | 369,917,895 |
| **Changes in items of working capital** | **1,068,806,977** | |
| Inventory | (907,021) | (1,297,564) |
| Deposits and other receivable | (54,255) | 20,993,756 |
| Advance receipts | 11,345,324 | 71,283,217 |
| VAT payable | 74,268,595 | 89,263,927 |
| Stamp duty payable | 4,029,171 | 29,034,533 |
| Provision for treasury levy | 80,917,066 | 28,882,370 |
| Accrued expenses and other payables | (31,677,069) | 67,917,740 |
| Provision for treasury levy | (80,917,066) | |
| Efect of Prior year correction | 3,108,322 | |
| Adjestment | 72,139 | |
| **Cash generated from operations** | **1,128,992,183** | **675,995,874** |
| | | |
| **Cash flows from investing activities** | | |
| Acquisition of Property plant and equipment | (11,220,703) | (23,202,753) |
| Investment in short term deposits | (1,261,067,576) | (100,653,965) |
| Interest income | 61,067,576 | |
| **Net cash used in Investing activities** | **(1,211,220,703)** | **(123,856,718)** |
| | | |
| **Cash flows from financing activities** | | |
| Contribution from Treasury for capital assets | - | - |
| **Net cash used in financing activities** | - | - |
| | | |
| Net increase/ decrease in Cash & cash equivalents | (82,228,520) | 552,139,156 |
| Cash and cash equivalents at the beginning of the year | 631,763,823 | 79,624,667 |
| **Cash and cash equivalents at the beginning of the year** | **549,535,302** | **631,763,823** |

The accounting policies and annexed notes to the financial statements are an integral part of these financial statements.

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**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**
***For the year ended 31 December 2018***

## 1. Accounting policies

### 1.1 Reporting entity

National Medicines Regulatory Authority (the "Authority") is incorporated under the National Medicines Regulatory Authority Act, No 5 of 2015 with effect from 01st July 2015. It is a Government Authority under the preview of Ministry of Health and Nutrition and Indigenous of Medicine and located at No: 120, Norris Canal Road, Colombo 10, Sri Lanka. Powers and all functions of National Medicines Quality Assurance Lab (NMQAL) is vested with the Authority.

### 1.2 Principal activity and nature of the operation

The objective of the Authority is ensuring the availability of efficacious, safe and good quality medicines, medical devices and borderline products to the general public at affordable prices. The Authority is registering and issuing licenses and involve in other regulatory activities in relation to the medicines, medical devices, borderline products, clinical trial and pharmacies.

## 2. Basis of preparation

### 2.1 Statement of compliance

The financial statements have been prepared in accordance with Sri Lanka Accounting Standards (SLFRS/LKAS) issued by the institute of Chartered Accountants of Sri Lanka.

### 2.2 Responsibility for financial statements

The members of the authority are responsible for the preparation and fair presentation of the financial statements.

### 2.3 Basis of measurement

The financial statements have been prepared on the historical cost basis except for the assets and liabilities recognized at fair value as explained in the respective notes to the financial statements.

These financial statements have been prepared on the basis that the authority would continue as a going concern for the foreseeable future.

### 2.4 Functional and presentation currency

The financial statements are prepared in Sri Lankan Rupees, which is the Authority's functional currency.

### 2.5 Use of estimates and judgments

The preparation of financial statements in conformity with SLFRS for SMEs requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from those estimates.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Information about critical judgments in applying accounting policies that have the most significant effect on the amounts recognised in the financial statements are included in the followings.

Retirement benefit obligation
Useful life time of the depreciable assets

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**
*For the year ended 31 December 2018*

**2.6 Materiality and aggregation**

Each material class of similar items is presented separately in the financial statements. Items of dissimilar nature or function are presented separately unless they are immaterial.

**2.7 Comparative information**

The comparative information has been reclassifying where necessary to confirm to the current year's presentation.

**3. Summary of significant accounting policies**

The accounting policies set out below are consistently followed during the year.

**3.1 Plant and equipment**

**3.1.1 Recognition and measurement**

Items of plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses.

All items of property plant and equipment are recognized initially at cost. The cost of plant and equipment includes expenditure that is directly attributable to the acquisition of the asset. The cost of self-constructed assets includes the cost of materials and direct labor, any other costs directly attributable to bringing the asset to a working condition for its intended use. Purchased software that is integral to the functionality of the related equipment is capitalized as a part of that equipment.

When parts of an item of plant and equipment have different useful lives, they are accounted for as separate items (major components) of plant and equipment.

**3.1.2 Subsequent costs**

The cost of replacing a part of an item of plant & equipment is recognized in carrying amount of the item if it is probable that the future economic benefits embodied within the part will flow to the Authority and its cost can be measured reliably. The carrying amounts of the parts that are replaced are derecognized from the cost of the assets.

The cost of the day-to-day servicing of plant & equipment are recognized in the statement of comprehensive income as incurred.

**3.1.3 Depreciation**

Depreciation is recognized in the statement of comprehensive income on a straight-line basis over the estimated useful lives of items of each part of an item of plant and equipment.

The estimated useful lives for the current and comparative periods are as follows.

| | |
|---|---|
| Furniture & Fittings | 05 years |
| Office Equipment | 05 years |
| Computer Equipment | 04 years |
| Filing Store | 05 years |
| Lab Equipment | 05 years |
| Computer Software | 04 years |

Depreciation of an asset begins when it is available for use and ceases at the earlier of the date that the asset is classified as held for sale and the date that the asset is derecognized.

Depreciation methods, useful lives and residual values are reassessed at the reporting date.

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**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**
*For the year ended 31 December 2018*

**3.1.4 De-recognition**

The carrying amount of an item of property, plant and equipment is de-recognized upon disposal or when no future economic benefits are expected from its use or disposal. The gain or loss arising from the derecognition of an item of property, plant and equipment is included in profit or loss when item is derecognition.

**3.2 Financial Instruments**

**3.2.1 Initial recognition and subsequent measurement**

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

Financial assets are classified, at initial recognition, as subsequently measured at amortized cost, fair value through other comprehensive income (OCI) and fair value through profit or loss.

**3.2.2 Subsequent measurement**

For purposes of subsequent measurement, financial assets are classified in four categories

i. Financial assets at amortized cost (debt instruments)
ii. Financial assets at fair value through OCI with recycling of cumulative gains and losses (debt instrument)
iii. Financial assets designated at fair value through OCI with recycling of cumulative gains and losses upon derecognition (equity instruments)
iv. Financial assets at fair value through profit or loss

**3.2.3 Financial assets at amortized cost (debt instrument)**

This category is the most relevant to the authority. The group measures financial assets at amortized cost if both of the following condition are met,

The financial assets are held within a business model with the objective to hold financial assets in order to collect contractual cash flows and

The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payment of principle and interest on the principal amount outstanding.

Financial assets at amortized cost are subsequently measured using the effective interest (EIR) method and are subject to impairment. Gains and losses are recognized in profit or loss when the assets are derecognized, modified or impaired.

**3.2.4 Derecognition of financial assets**

A financial asset is primarily derecognized when the rights to receive cash flows from the assets have expired.

**3.3 Trade & other receivables**

Trade and other receivables are stated at their estimated realizable amounts.

**3.4 Cash & cash equivalents**

Cash and cash equivalents comprise cash balances and call deposits. Bank overdrafts that are repayable on demand and form an integral part of the Authority's cash management are included as a component of cash and cash equivalents for the purpose of the statement of cash flows.

Cash flow statement is prepared under the indirect method as per Section 07, Statement of Cash Flows if any.

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**
***For the year ended 31 December 2018***

**3.5 Inventories**

Inventories are recognized at cost and net realizable value, whichever is lower after making due allowance for obsolete and slow-moving items which are valued at 'First in first out' basis.

**3.6 Liabilities and provisions**

Liabilities classified as current liabilities on the statement of financial position are those which fall due for payment on demand or within one year from the reporting date. Non-current liabilities are those balances that fall due for payment later than one year from the reporting date.

All known liabilities have been accounted and considered for preparation of financial statements.

**3.6.1 Provisions**

A provision is recognized if, as a result of a past event, the Authority has a present legal or constructive obligation that can be estimated reliably, and it is probable that an outflow of economic benefits will be required to settle the obligation

**3.7 Employee benefits**

**3.7.1 Defined contribution plan**

A defined contribution plan is a post-employment benefit plan under which an entity pays fixed contributions into a separate entity and will have no legal or constructive obligation to pay further amounts. Obligations for contributions to defined contribution pension plans are recognized as an employee benefit expense in statement of comprehensive income when they are due. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in future payments is available.

The Authority contributes 12% and 3% of gross emoluments of employees as provident fund (EPF), and trust fund (ETF) contribution respectively.

**3.7.2 Defined benefit plan**

A defined benefit plan is a post-employment benefit plan other than a defined contribution plan. The liability recognized in the statement of financial position in respect of defined benefits plan is the present value of the defined benefit obligation at the reporting date. The defined benefit obligation is calculated annually using the projected unit credit method by qualifies actuary as recommended by LKAS 19. The present value of the defined benefit obligation is determined by discounting the estimated future cashflows using interest rate that are denominated in the currency in which the benefits will be paid and that have terms of maturity approximating to the terms of the liability.

Provision will be made in the financial statements for retiring gratuities after the completion of five years continued service of employees with conformity of Gratuity Act No.12 of 1983.

**3.8 Trade and other payables**

Trade and other payables are stated at their cost.

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**
***For the year ended 31 December 2018***

**3.9 Revenue**

**3.9.1 Services**

Revenue from services rendered is recognized in the income statement on completion of the transaction cycle and the passing of risks and rewards, at the reporting date.

**3.9.2 Interest income**

Interest income is recognized as it accrues in the income statement. Interest income of long-term financial instrument are recorded using the effective interest rate (EIR).

**3.10 Government Grants**

Government Grants are assistance by government in the form of transfers of resources to an entity.

Government grant related to assets, non-monetary grants at fair value, shall be presented in the statement of financial position either by setting up the grant as deferred income or by deducting the grant in arriving at the carrying amount of the asset.

**3.11 Expenses**

All expenditure incurred in the running of the business has been charged to statement of comprehensive income in arriving at the profit for the year.

**3.12 Foreign currency transaction**

Transaction in foreign currencies are initially recorded by the authority the spot rate of at their respective functional currency at the date the transaction first qualifies for recognition.
Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date.

**3.13 Tax expenses**

Income tax expense comprises current and deferred tax. Income tax expense is recognized in the statement of comprehensive income except to the extent that it relates to items recognized directly in equity, in which case it is recognized in equity.

**3.13.1 Current tax**

Current tax is the expected tax payable on the taxable income for the period, using tax rates enacted or substantively enacted at the reporting date, and any adjustment to tax payable in respect of previous periods.

The Authority liability to taxation has been computed according to the provision of the Inland Revenue Act No. 10 of 2006 and amendments thereon.

**3.13.2 Deferred taxation**

Deferred tax is recognized using the liability method, providing for temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes.

Deferred tax is not recognized for the following temporary differences: the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit nor loss.

A deferred tax asset is recognized to the extent that it is probable that future taxable profits will be available against which the temporary difference can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized.

**3.14 Statement of cash flows**

The statement of cash flows has been prepared using the "indirect method" in accordance with LKAS 7 "Statement of cash flows".
Interest paid is classified as operating cash flows, interest received are classified as investing cash flows, while treasury levy paid are classified as financing cash flows for the purpose of presenting the cash flow statement.

**3.15 Commitment and contingencies**

Contingencies are possible assets or obligations that arise from a past event and would be confirmed only on the occurrence or non-occurrence of uncertain future events, which are beyond the Authority's control.

**3.16 Related party transaction**

Contingencies are possible assets or obligation that arise from past event and would be confirmed only on the occurrence or non-occurrence of uncertain future events, which not wholly within control of the Group.

**3.17 Events after the reporting date**

All material events after the reporting date have been considered and where appropriate adjustments or disclosures have been made in notes to the financial statements.

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS
*As at,*

**2 Property, plant and equipment**

| Cost | Filng store Rs. | Lab equipment Rs. | Furniture and fittings Rs. | Office equipment Rs. | Computer equipment Rs. | Computer Software Rs. | Public Addressing System Rs. | Total Rs. |
|---|---|---|---|---|---|---|---|---|
| Balance as at 1 January 2017 | - | - | 869,110 | 2,104,191 | 3,187,178 | - | - | 6,160,479 |
| Additions during the year | 15,257,976 | 6,247,840 | 240,258 | 384,104 | 848,175 | 224,400 | - | 23,202,753 |
| Balance as at 31 December 2017 | 15,257,976 | 6,247,840 | 1,109,368 | 2,488,295 | 4,035,353 | 224,400 | - | 29,363,232 |
| Restated Balance as at 01 January 2018 | 15,257,976 | 6,247,840 | 1,109,368 | 2,488,295 | 4,035,353 | 224,400 | - | 29,363,232 |
| Additions during the year | - | 3,203,900 | 975,598 | 2,831,581 | 3,880,300 | - | 329,325 | 11,220,703 |
| Balance as at 31 December 2018 | 15,257,976 | 9,451,740 | 2,084,965 | 5,319,876 | 7,915,653 | 224,400 | 329,325 | 40,583,935 |
| **Accumulated depreciation/ ammortization** | | | | | | | | |
| Balance as at 1 January 2017 | - | - | 62,471 | 222,390 | 395,492 | - | | 680,353 |
| Charge for the year | 610,319 | 833,997 | 192,889 | 451,977 | 908,166 | 16,599 | | 3,013,948 |
| Restated balance as at 31 December 2017 | 610,319 | 833,997 | 255,360 | 674,367 | 1,303,658 | 16,599 | - | 3,694,301 |
| Restated Balance as at 01 January 2017 | 610,319 | 833,997 | 255,360 | 674,367 | 1,303,658 | 16,599 | | 3,694,301 |
| Charge for the year | 3,051,595 | 1,562,058 | 321,291 | 992,375 | 1,872,160 | 56,100 | 17,594 | 7,873,174 |
| Balance as at 31 December 2018 | 3,661,914 | 2,396,055 | 576,651 | 1,666,742 | 3,175,818 | 72,699 | 17,594 | 11,567,474 |
| **Carrying value** | | | | | | | | |
| **As at 31 December 2018** | **11,596,062** | **7,055,685** | **1,508,314** | **3,653,134** | **4,739,835** | **151,701** | **311,731** | **29,016,461** |
| **As at 31 December 2017** | **14,647,657** | **5,413,843** | **854,008** | **1,813,928** | **2,731,695** | **207,801** | **207,801** | **25,668,931** |

Currently the Authority is using infrastructure facilities such as building, lab equipments, vehicles and other assets, which are belong to Ministry of Health Nutrition and Indigenous Medicines and the Authority is in the process of acquiring those assets for it self.

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**

| *For the year ended 31 December,* | | 2018 Rs. | 2017 Rs. |
|---|---|---|---|
| 3 | **Inventory** | | |
| | Openning Inventory | 1,482,106 | - |
| | Purchesed for year | 2,716,697 | - |
| | | 4,198,803 | - |
| | Issu for the year | 1,809,677 | - |
| | Closing Inventory | **2,389,127** | **1,482,106** |
| 4 | **Deposits and other receivable** | | |
| | Deposit for fuel | 50,000 | 50,000 |
| | Other receivables | 127,499 | 73,244 |
| | **Total deposits and prepayments** | **177,499** | **123,244** |
| 5 | **Short term investments** | | |
| | Openning Balance | 100,653,965 | - |
| | Invest for the Year | 1,200,000,000 | - |
| | Interest for the year | 61,067,576 | - |
| | | **1,361,721,541** | **100,653,965** |
| 6 | **Cash and cash equivalents** | | |
| | Cash and cash equivalents | 549,535,303 | 631,763,823 |
| | **Total cash and cash equivalents** | **549,535,303** | **631,763,823** |
| 7 | **Capital grant** | | |
| | Capital grant | 4,186,070 | 5,528,972 |
| | Amortization of capital grant | (1,342,902) | (1,342,902) |
| | **Total Capital grant** | **2,843,168** | **4,186,070** |
| 6 | **Deferred tax liability** | | |
| | Accounting written down value of Property plant and equipment | 29,016,461 | 25,668,931 |
| | Tax base of Property plant and equipment | 18,493,047 | 19,078,474 |
| | Taxable Temporary deference | 10,523,414 | 6,590,457 |
| | Tax @ 28% | 2,946,556 | 1,845,328 |
| | Deferred Liability at the end of the year | **2,946,556** | **1,845,328** |
| | Deferred Liability as at beginning of the year | 1,845,328 | 266,519 |
| | Charge as deferred tax during the year | **1,101,228** | **1,578,809** |
| 9 | **Advance receipts** | | |
| | Fees received in advance | 96,988,980 | 85,643,656 |
| | **Total advance receipts** | **96,988,980** | **85,643,656** |

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**

| | | 2018 | 2017 |
|---|---|---|---|
| | | Rs. | Rs. |
| **10** | **VAT payable** | | |
| | Openning Balance | 109,758,402 | - |
| | VAT for the year | 182,242,708 | - |
| | Input VAT | (2,476,049) | - |
| | Credit Note Balance | (35,469) | - |
| | Paid for the year | (111,245,195) | - |
| | Prior Year Curection | 1,486,792 | - |
| | VAT Payable | **179,731,189** | **105,462,594** |
| **11** | **Stamp duty payable** | | |
| | Openning Balance | 36,111,233 | - |
| | Stamp Duty for the year | 40,140,404 | - |
| | Paid for the year | (31,201,280) | - |
| | Prior Year Curection | (4,909,953) | - |
| | Stamp duty payable | **40,140,404** | **36,111,233** |
| **12** | **Provision for Treasury levy** | | |
| | Net income after taxation | 809,170,663 | 288,823,697 |
| | Provision 10% | 80,917,066 | 28,882,370 |
| | Provision for 2017 | 28,882,370 | - |
| | | 109,799,436 | 28,882,370 |
| **13** | **Accrued expenses and other payables** | | |
| | Accrued expenses | 6,955,689 | 34,864,290 |
| | Other Payables | 31,643,275 | 33,492,309 |
| | Retention Deposit | 6,832 | 877,334 |
| | EPF Payble | 707,207 | 1,240,839 |
| | ETF Payble | (208,829) | 185,659 |
| | Payee Payable | (120,812) | - |
| | **Total Accrued expenses** | **38,983,361** | **70,660,430** |

| | | 2018 | 2017 |
|---|---|---|---|
| | | Rs. | Rs. |
| **14** | **Revenue** | | |
| | Drug sample license income | 23,058,332 | 9,504,018 |
| | Device sample license income | 22,226,363 | 9,856,683 |
| | Drug import license income | 119,691,308 | 40,249,464 |
| | Device import license income | 80,662,691 | 34,603,084 |
| | Cosmetic import license income | 6,738,559 | 74,000 |
| | Drug manufacturing license income | 5,008,623 | 1,835,960 |
| | Device manufacturing license income | 481,967 | 89,541 |
| | **Total cont.** | **257,867,843** | **96,312,750** |

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**

| *For the period ended 31 December,* | | 2018 | 2017 |
|---|---|---|---|
| | | Rs. | Rs. |
| 14 | **Revenue (Cont.)** | **257,867,843** | **96,312,750** |
| | Drug registration income | 140,476,132 | 81,014,008 |
| | Device registration income | 87,600,471 | 58,340,687 |
| | Cosmetic registration income | 9,264,775 | 282,000 |
| | Fees for labotary test | 5,526,579 | 4,879,463 |
| | Drug processing fees | 305,549,954 | 105,320,830 |
| | Device processing fees | 162412652 | 54,552,305 |
| | Cosmetic processing fees | 1,791,336 | 67,500 |
| | Borderline processing fees | 21,233,147 | 4,345,455 |
| | Clinical Trial processing fees | 2,400,342 | 970,440 |
| | Advertising fees | 1,575,341 | 840,750 |
| | Retail pharmacy license income | 30,850,341 | 24,969,858 |
| | Wholesale pharmacy license income | 9,844,185 | 12,517,515 |
| | Transport pharmacy license income | 21,287,366 | 9,871,387 |
| | Waiver of registration income | 3,030,052 | 2775717 |
| | Inspection of Good Manufacturing Practices - Local | 369,612 | 356,906 |
| | Inspection of Good Manufacturing Practices - Foreign | 11,862,707 | 19,362,586 |
| | WHO Good Manufacturing Practices certificate | 730,930 | 93,174 |
| | COPP Certificate | 8,813 | 69,966 |
| | Submission of additional documents | 130,061,365 | 70,182,326 |
| | Fees from agency transfer | 32,616,855 | 7,299,840.00 |
| | Fees for free sale certificates | 55,697 | 69,938.00 |
| | Clarrification | 9,732 | - |
| | Category A/B processing fees | 3,498,837 | - |
| | Cosmetic Manufacturing | 171,540 | - |
| | Additional Drug | 349,825 | - |
| | Clinical Trial Samples | 1,081,321 | - |
| | Borderline for Test Samples | 960,605 | - |
| | Fees for Variation Review | 1,348,486 | - |
| | Device Providence Registration | 1,833,066 | - |
| | Company Profile | 1,594,000 | - |
| | Approval for Repacking | 41,954 | - |
| | Import Registered Borderline | 86,951 | - |
| | Certificate of Registration Borderline | 173,901 | - |
| | | **1,247,566,713** | **554,495,401** |
| 15 | **Administrative expenses** | | |
| | Depreciation | 7,873,174 | 3,013,948 |
| | Water | 447,826 | 395,075 |
| | Eletricity | 8,168,972 | 8,414,052 |
| | Telephone | 974,894 | 762,958 |
| | Postage | 371,723 | 130,001 |
| | Stationery | 1,809,676 | 1,390,922 |
| | Travelling - Local | 181,975 | 22,511 |
| | Travelling - Foreign | 12,517,630 | 5,197,342 |
| | Training and development expenses | 10,563,614 | 2,945,566 |
| | Labortary expenses | 6,608,047 | 1,238,256 |
| | **Total cont.** | **49,517,531** | **23,510,630** |

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**

| *For the year ended 31 December,* | | 2018 | 2017 |
|---|---|---|---|
| | | Rs. | Rs. |
| 15 | **Administrative expenses** | **49,517,531** | **23,510,630** |
| | Fuel expense | 796,301 | 604,745 |
| | Security charges | 3,589,887 | 2,886,487 |
| | Document handling charges | 1,035,978 | 410,109 |
| | Publication and advertisement charges | 1,665,271 | 906,607 |
| | Janitorial service | 4,442,664 | 4,222,837 |
| | Vehicle maintenance | 1,677,910 | 1,255,061 |
| | Maintenance of Labortary equipment | - | 3,579,161 |
| | Maintenance of fire extinguisher | 92,237 | 49,037 |
| | Maintenance of Air-conditioning | 2,011,251 | 1,521,271 |
| | Maintenance of building | 5,097,276 | 724,468 |
| | Maintenance of computer items and other | 2,038,916 | 778,402 |
| | Expenses for Good Manufacturing Practice visits | 12,500,764 | 18,127,163 |
| | Recervation of conference hall | 775,557 | 129,500 |
| | Drating corporate plan | 6,567 | 582,735 |
| | Maintenance of website | 411,263 | 79,000 |
| | Expenses for drafting regulations | - | 23,840 |
| | Courier service | 3,402 | 8,610 |
| | Rates and taxes | - | 78,401 |
| | Audit fee | 1,281,178 | 1,281,178 |
| | WHO meeting expenses | (1,359,502) | - |
| | Tender Board expenses | 98,500 | - |
| | Entertainment | 115,800 | - |
| | Exam fee | 1,910,022 | - |
| | Audit Committee Expenses | 99,000 | - |
| | Expert for Reviwing of Dossiers | 1,219,650 | - |
| | Consultation Fee | 431,175 | - |
| | **Total** | **89,458,597** | **60,759,242** |
| 16 | **Salaries and wages** | | |
| | Salaries and wages | 60,564,596 | 65,291,547 |
| | Other allowances | 10,198,127 | 6,131,029 |
| | Overtime payment | 8,913,217 | 6,378,649 |
| | Secondment allowance | 7,438,689 | 8,387,083 |
| | Contribution for pension | 7,438,689 | 8,387,083 |
| | Contribution for Employee Provident Fund | 1,879,614 | 856,729 |
| | Contribution for Employee Trust Fund | 469,904 | 178,798 |
| | **Total** | **96,902,836** | **95,610,919** |
| 17 | **Other expenses** | | |
| | Other repair and maintenance | 731,843 | 659,904 |
| | Refreshment and other expenses | 47,257 | 195,213 |
| | Bank Charges | 2,000 | - |
| | Other Expenses | 570,125 | - |
| | **Total** | **1,351,225** | **855,116** |

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**

| | | | | |
|---|---|---|---|---|
| **18** | **Income tax for the year** | | | |
| **18.1** | Income tax expense for the year | | 313,072,390 | 113,874,523 |
| | Deferred tax expense for the year | | 1,101,228 | 1,578,809 |
| | **Tax expense for the year** | | **314,173,618** | **115,453,332** |
| **18.1** | Net income before taxation | | 1,123,344,281 | 404,277,030 |
| | Add : Disallowable expense | | 7,920,431 | 3,209,160 |
| | Less : Allowable expense | | (11,806,130) | (8,941,856) |
| | Less : Income not subject to income tax | | (1,342,902) | (1,342,902) |
| | Adjusted profit for the year | | 1,118,115,679 | 397,201,432 |
| | Other profit and income liable to tax | | - | - |
| | Total statutory income/ Taxable income | | 1,118,115,679 | 397,201,432 |
| | Income tax for the year | at 28% | 313,072,390 | 111,216,401 |
| | Tax Credits: | | | |
| | Notional Tax | | - | (65,397.00) |
| | Income tax expense for the year | | 313,072,390 | 111,151,004 |
| | **Total tax payable as at the year end** | | **426,946,913** | **113,874,523** |

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**

**19 Prior year adjustment**

Prior year adjustment was made to ractify the following matters;

| | |
|---|---|
| VAT Payable | 1,486,792 |
| Stamp Duty Payable | 4,909,953 |
| Income Tax Provinces | 2,723,519 |
| Advance | 360,985 |
| Other | 3,108,322 |
| Total Adjusted Amount | **8,894,017** |

**20 Related Party Transaction**

**Key Management Compensation**

The Authority's key management personnels include the Chairman, Chief Executive Officer and other Members of the Authority.

Compensation paid to key management personel during the periods were as follows .

| | 2018 Rs. | 2017 Rs. |
|---|---|---|
| Short term employee benefits | 0 | 0 |
| | - | - |

**21 Events after the reporting date**

There were no material events occuring after the reporting date which require adjustments to or disclosures in the financial statements.

**22 Contingent Liabilities**

There is no any comiittement and contingencies as at the reporting date.

**23 Litigation and claims**

Five cases were filed against the Authority in the Court of Appeal. Among those cases compensation of Rs.497,700,000 is claimed for only one case bearinng No HC(civil) 425/2017MR and the decision is still pending. Further,eighteen cases were filed by the NMRA against vialation of provisions in the Act. Futhermore, twenty cases are pending before the court which were filed by the Food and Drug inspectors in island wide due to vialation of provision the NMRA Act as of 22nd March 2018.

**24 Board of Members responsisbility**

Board of members are responsible for the preparation and presentation of these financial statements in accordance with Sri Lanka Accounting Standards.

**21 Approval of financial statements**

These Financial statements were approved by the Board of members and authorized for issue on 15th November 2019.

**Report of the Auditor General on the Transactions of the National Medicine Regulatory Authority for the year ended 31 December 2018 in terms of Article 154 (6) of the Constitution of the Democratic Socialist Republic of Sri Lanka**

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**

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.

| | | | | |
|---|---|---|---|---|
| (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. |

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| | (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. |

| | | | | |
|---|---|---|---|---|
| (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. |

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## 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. |

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| (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 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. | 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. |

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| (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. |

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| (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. |

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| (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 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. | 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. |

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## 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. |

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|---|---|---|---|
| (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 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. | It takes a time to the process implemented for issuing registration certificates for medicine because it should be done correctly and credulity, Accordingly delays may be occurred for issuing certificates. | A file containing information on accepting applications for registration and issuing registration 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- |

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|---|---|---|---|
| (f) | The following reasons were affected to the delay of issuing registration certificates and licenses.<br>(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.<br>(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.<br>(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.<br>(iv) Sufficient laboratory facilities were not available. | 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. |

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| (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. |

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| (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 | Issues pointed out by audit were identified correctly and actions had been taken to correct the situation. | Pharmacies should be monitored properly. |

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| 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. | | |
| (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 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. | 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. |
| (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. |

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## 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 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 | 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. |

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.

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## 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. |

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## 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. |

# Chapter - 4

# Performance Achieving Sustainable Development Goals (SDG)

International development looks at improving the lives of individuals worldwide through the areas of needs and interests. With areas such as health, education, democracy, sustainability, and economics, people are better equipped to live more equitable lives with greater opportunities. The United Nation, through the UNDP, works on Sustainable Development Goals (SDG), in order to "end poverty, protect the planet, and ensure that all people enjoy peace and prosperity by 2030". Countries are working to ensure that poverty, AIDS, and discrimination against women and girls are addressed in over 170 countries and territories.

Out of the 17 Goals, Goal No. 3 is "Good Health and Well-Being" to Ensuring people live healthy lives can cut child mortality and raise life expectancy, is closely related to the scope of NMRA.

Accordingly, all the functions of NMRA are arranged to achieve the targets of this SDG No. 3 as guided;

**3.8** Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

**3. A** Strengthen the implementation of the World Health Organization Framework Convention on Tobacco Control in all countries, as appropriate.

**3.B** Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

**3. C** Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and Small Island developing States.

All these targets are addressed by the scope of NMRA by regulating of medicines and medical devices in the aspects of safety, quality, efficacy and price.

# Chapter - 5

# Human Resource Profile

## 5.1 Cadre Management

| | Approved Cadre | Existing Cadre | Vacancy |
|---|---|---|---|
| **Senior Level** | 34 | 11 | 23 |
| **Tertiary Level** | 6 | 1 | 5 |
| **Secondary Level** | 155 | 72 | 83 |
| **Primary Level** | 50 | 35 | 15 |
| TOTAL | **245** | **119** | **126** |