# Annual Report

# 2019

NMRA
NATIONAL MEDICINES REGULATORY AUTHORITY

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

# Table of Contents

Page No.

# 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 2019 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 Authority in South Asia, the NMRA, feel very proud to present its Annual Report 2019. 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

# Board of Directors

1. Prof. Asita De Silva - Chairman
2. Dr. Kamal Jayasinghe
3. Dr.N. Rathnasena
4. Mrs. C. Herath
5. Ms. Ajitha Batagoda
6. Dr. Anil Jasinghe
7. Dr. Lakkumar Fernando
8. Dr. Kapila Ranasinghe
9. Dr. Nissanka Jayawardana
10. Dr. Sanath Lanerolle
11. Dr. Ananda Wijewickrama
12. Dr. Palitha Abeykoon
13. Dr. (Mrs) Nithushi Samaranayake

# 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 1st 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.

At the start of NMRA, organization structure was not properly recorded 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
- Information, Communication and Technology 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 | 52 (temporary /secondment) | 70 |
| | Development Officers | 10 | 07 | 03 |
| | Drug Inspector | 20 | 03 (secondment) | 20 |
| | Technical Officer (Civil) | 01 | - | 01 |
| | ICT Assistant | 01 | 01 (Secondment) | 01 |
| | Management Assistant | 43 + (contract basis 10) | 23 (Permanent Basis) 04 (Secondment) 02 (Contract) | 20 |
| **Primary** | Driver | 10 | 08 (03 Secondment) 05 (Permanent) | 05 |
| | Plumber | 01 | 01 | - |
| | Electrician | 01 | 01 | - |
| | Lab Assistant | 08 | 02 (Secondment basis) | 08 |
| | Karyala Karya Sahayaka | 30 | 24 | 06 |
| | **Total** | **245** | **141** | **155** |

## 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
7. Information and Communication Technology (ICT) Division

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

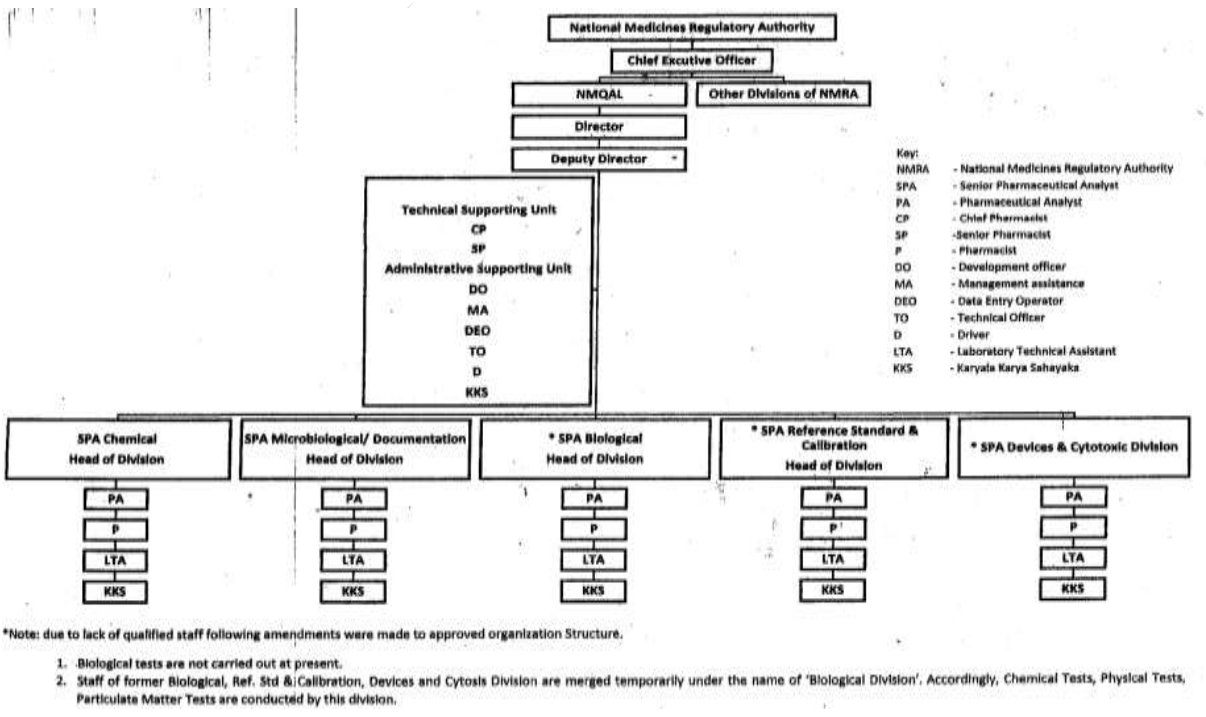
1.5.1.1 Introduction

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,

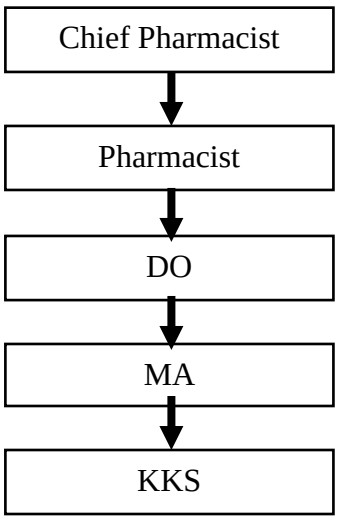
- Analysis of locally manufactured and imported Medicines, Medical Devices, Borderline products and Cosmetics at different points in the distribution chain. (Premarketing and Post marketing stages) Samples for analyses are submitted as registration samples, complaints samples, tender samples pre shipment 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. Pharmaceutical 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 Pharmaceutical Regulatory Division




1.5.2.3 Functions of Pharmaceutical 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

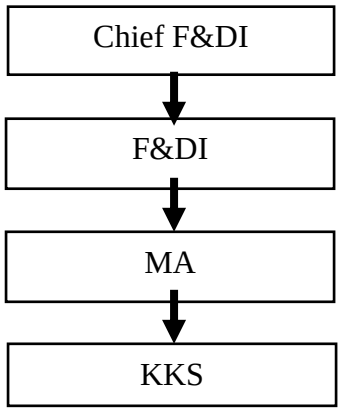
1.5.3.1 Introduction

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(C-FDI).

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

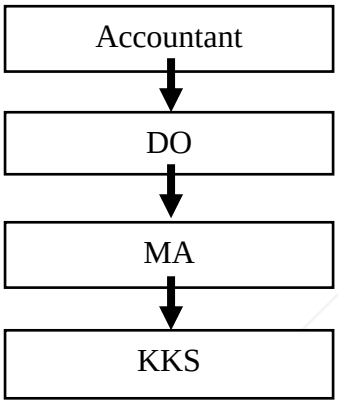
- Functioning as Authorized Officers under the NMRA Act
- Conducting Post marketing surveillance
- Obtaining formal and informal samples when necessary
- Inspecting & recommending medicines handling establishments to issue licenses
- Inspecting & recommending medicine transport vehicles to issue licenses
- Ensuring the implementation of product recall procedure
- Investigating & initiate legal actions on the detentions made by the SSFFC & smuggled products
- Investigating the availability of state-owned drugs in the private market
- Inspecting & recommending of dangerous drugs applications
- Organizing & conducting educational programs
- Conducting prosecutions against the violations committed under the Act
- 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, 2017 and 2018 new staff has recruited with two development officers and eight management assistants. Accordingly, members of finance division have increased to sixteen including Accountant, two development officers, eight management assistants, three trainees, one contract basis member and one KKS.

1.5.4.2 Divisional Chart of the Accounts Division




1.5.4.3 Functions of the finance division

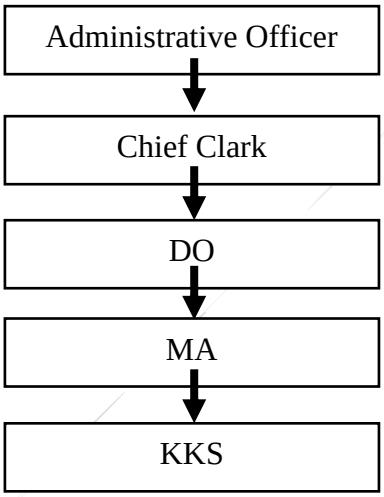
- Receiving all revenue through eighteen revenue streams.
- Preparing final accounts
- Preparing the budget for the coming year and obtaining the approval
- Maintaining all the supplies required to run the day-to-day activities of the authority
- All monetary controlling matters
- Procurement activities

### 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.

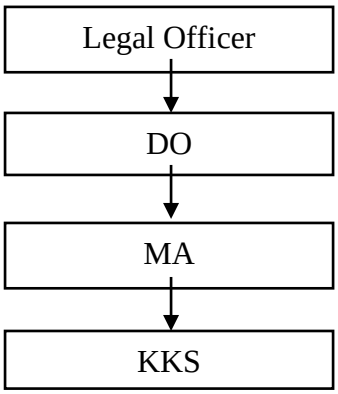
- Supervising the license and the registration certificates issuing process
- Personnel Management within the Authority
- Supervise all the activities related to maintenance of the office premises
- Maintaining utility services
- Making relevant reports in relation to the section
- Vehicle and transport 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

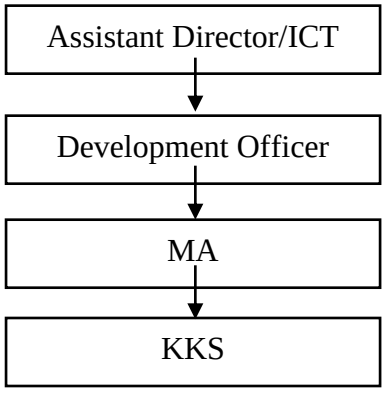
- Recommend appropriate amendments to the NMRA Act No 5 of 2015 pertaining to medicines, medical devices, borderline products and cosmetics
- Review emerging guidelines/ regulations and adopt to suit to the Sri Lankan context
- Improve/amend the current regulations in order to achieve an effective and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

### 1.5.7 Information and Communication Technology (ICT) Division

1.5.7.1 Introduction

The ICT Division was established in 2019 and one development officer works under the supervision of the Assistant Director (ICT). In parallel to the automation process (e-NMRA), an Assistant Director (ICT) was recruited in October 2019. The vision of the ICT Division is to provide an efficient, secure, reliable, and sustainable IT infrastructure to meet the business and service needs of the NMRA. The ICT Division is responsible for the management of information and communication, including the local area network, computer hardware, and software management, databases, websites, and ICT procurement administration, and is involved with ICT project management as required. The ICT Division plans to implement a datacenter to improve the ICT infrastructure of the organization by expanding the bandwidth of the existing network. The ICT Division is planning to implement ICT policies to improve the transparency, responsiveness, and accountability of the services delivered. The lack of adequate staff is the major problem facing the Division in performing its functions and planning to recruit new staff to overcome this issue.

1.5.7.2 Divisional Chart of the ICT Division



# 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 the Country.

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

Purchased following laboratory equipment worth Rs 55465060.00. 1) High Performance Liquid Chromatography (HPLC), 2) Potentiometric Titrator, 3) Vacuum Oven, 4) Refractometer 5) Ultrasonic cleaner, 6) Laboratory Shaker, 7) Dehumidifier 8) Horizontal LAF cabinet 9) Manual Dimension Tester and 10) Visual Leak Tester.
NMQAL officers participated local and Foreign GMP inspections
Dr. Sucheta Banerjee from India conduct a three-day workshop (14$^{th}$ to 16$^{th}$ Feb 2018) to upgrade its set up and build an extended (or new) facility or add up facility so that it develops into high end Quality Assurance Laboratory for NMRA.
WHO Benchmark implementation – 04$^{th}$ June 2019
Following Training Programs were planned for NMQAL staff.

- Fire awareness and demonstration of firefighting- to NMQAL staff on 20$^{th}$ June 2019 and 27$^{th}$ June 2019.
- Occupational Health Safety- to NMQAL staff on 25$^{th}$ July 2019
- ISO 17025 – To NMQAL staff –26$^{th}$ July 2019
- ISO 9001 – To NMQAL staff – 22$^{nd}$ July 2019
- Measurement Uncertainty – To Technical Staff NMQAL – 21$^{st}$ Nov 2019

WHO benchmark Assessment – Nov. 2019
ISO 17025 application submitted to Sri Lanka Accreditation Board (SLAB)
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.

| Sample Type | Pass | Fail /WH /WD | Already WD | Not Done | Total |
|---|---|---|---|---|---|
| **Complaint** | 90 | 88 | 5 | 32 | 215 |
| **Formal** | 40 | 2 | - | 16 | 58 |
| **Informal** | 18 | 3 | - | 1 | 22 |
| **Lab Request** | 1 | 0 | - | - | 1 |
| **Manu.Request** | - | - | - | - | 0 |
| **Registration** | 45 | 14 | - | 1 | 60 |
| **SPC Tender** | 14 | 2 | - | - | 16 |
| **Others** | 16 | 5 | - | - | 21 |
| **Surveillance** | 36 | 12 | - | - | 48 |
| | **260** | **126** | **5** | **50** | **441** |

| | | |
|---|---|---|
| No. of certificate of Quality issued | = | 441-50 |
| | = | 391 |
| No. of failure report issued | = | 126 |
| Percentage (%) of quality failure from the Report issued in 2019 | = | 32 |

## 2.2 Progress of Pharmaceutical 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 ensure 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 - 2019

| Serial No. | Place/District | Nature of the offence | Action taken | | |
|---|---|---|---|---|---|
| | | | Court | Result (Fine) | Paper Advertisement |
| 01 | Badulla | Selling Pregablin 150mg capsules exceeding the price. | Badulla | Rs. 10,000.00 | Yes |
| 02 | Badulla | Selling Glimepiride 1mg tablets exceeding the price. | Badulla | Rs. 35,000.00 | No |
| 03 | Bandarawela | Selling Pregablin 75mg capsules exceeding the price. | Bandarawela | Rs. 10,000.00 | No |
| 04 | Bandarawela | Selling Gabila 75mg capsules exceeding the price. | Bandarawela | Rs. 10,000.00 | No |
| 05 | Bandarawela | Selling Seromax capsules exceeding the price. | Bandarawela | Rs. 10,000.00 | No |
| 06 | Bandarawela | Selling Pregablin 150mg capsules exceeding the price. | Bandarawela | Rs. 10,000.00 | Yes |
| 07 | NMRA | Selling Losartan tablets exceeding the price. | Fort | Rs. 75,000.00 | Yes |

| No | Violation | Place & Fines imposed | | | | Total Cases | Total Fines (Rs) |
|---|---|---|---|---|---|---|---|
| | | NMRA area | Fines imposed | Other areas | Fines imposed | | |
| **01** | Violations identified with regard to abusive medicines (Tramadol & Pregablin etc) | 106 | 1,516,500.00 | 17 | 1,315,000.00 | **123** | 2,831,500.00 |
| | | | | | | | |
| **02** | Selling medicines without Direct Supervision of the Pharmacist -120(3) | 02 | 45,000.00 | 01 | 1,500,00.00 | **03** | 1,950,00.00 |
| **03** | Storing smuggled medicines (106 (1) | 04 | 500,000.00 | 04 *(Pending-02)* | 90,000.00 | **08** | 5,900,00.00 |
| **04** | Selling price controlled medicines, exceeding the Maximum Retail price (MRP) | 01 | 75,000.00 | 05 | 70,000.00 | **06** | 145,000.00 |
| **05** | Carrying on a pharmacy without a license | 03 | 130,000.00 | 10 | 5,500,00.00 | **13** | 6,800,00.00 |
| **06** | Selling medicines without a prescription | 01 | 20,000.00 | 06 | 3,85,000.00 | **07** | 1,350,00.00 |
| **07** | Importing unregistered Devices | 01 | 10,000.00 | - | - | **01** | 10,000.00 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **08** | Importing unregistered Borderline products | 01 | 25,000.00 | | - | - | **01** | 25,000.00 |
| **09** | Storing Borderline products without a license | 01 | 25,000.00 | | - | - | **01** | 25,000.00 |
| **10** | Storing medicines without a license | 02 | 2,750,00.00 | | - | - | **02** | 2,750,00.00 |
| **11** | Selling expired medicines | 02 | 65,000.00 | | 01 | 100,000.00 | **03** | 165,000.00 |
| **12** | Storing Physicians' Samples | 01 | 50,000.00 | | - | - | **01** | 50,000.00 |
| **13** | Transporting medicines without a transport license | 01 | 25,000.00 | | - | - | **01** | 25,000.00 |
| **14** | Manufacturing Medicines without a manufacturing license | 01 | 50,000.00 | | - | - | **01** | 50,000.00 |
| **15** | Manufacturing unregistered medicines | 01 | 50,000.00 | | - | - | **01** | 50,000.00 |
| **16** | Re-packing expired medicines | 01 | 50,000.00 | | - | - | **01** | 50,000.00 |
| **17** | Storing medicines under insanitary conditions | - | - | | 06 | 2,750,00.00 | **06** | 2,750,00.00 |
| **18** | Issuing wrong medicines | 01 | 5000.00 | | 02 *(Pending-01)* | 35,000.00 | **03** | 40,000.00 |
| **19** | Seizure of State-owned medicines at Pharmacies | - | - | | 03 | 85,000.00 | **03** | 85,000.00 |

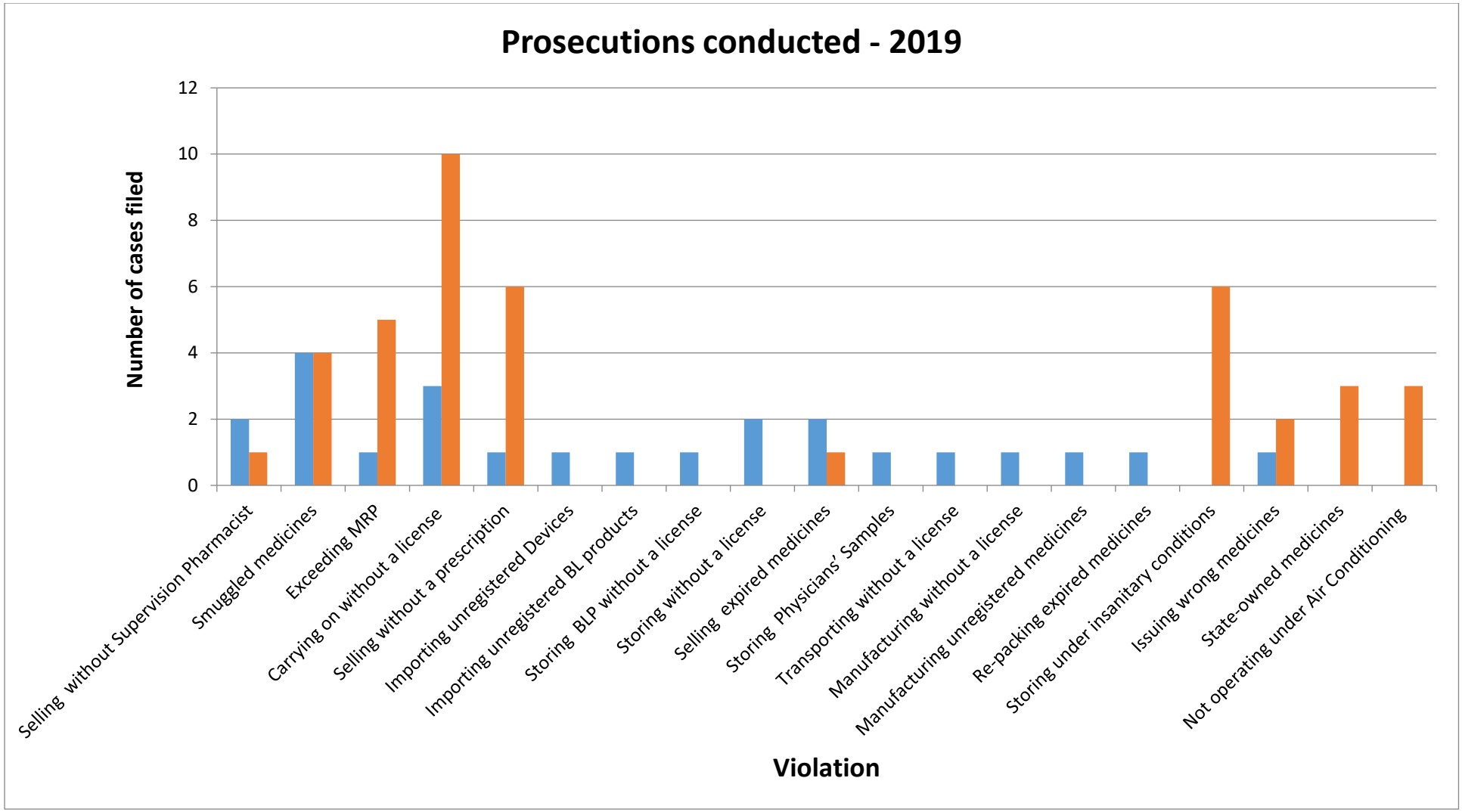
| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **20** | Not operating the Pharmacy, under Air Conditioning | - | - | | 05 | 4,650,00.00 | **05** | 4,650,00.00 |
| | | | | | | | | |
| | **Total fines imposed** | | 2,921,500.00 | | | 3,520,000.00 | | **Rs 6,441,500.00** |
| | Total number of **cases** filed | **131** | **-** | | **54** | **-** | **185 Cases** | |

- **Note -** NMRA Area-CMC, MC- Kotte, MC-Dehiwala /Mt.Lavinia, MC-Moratuwa,

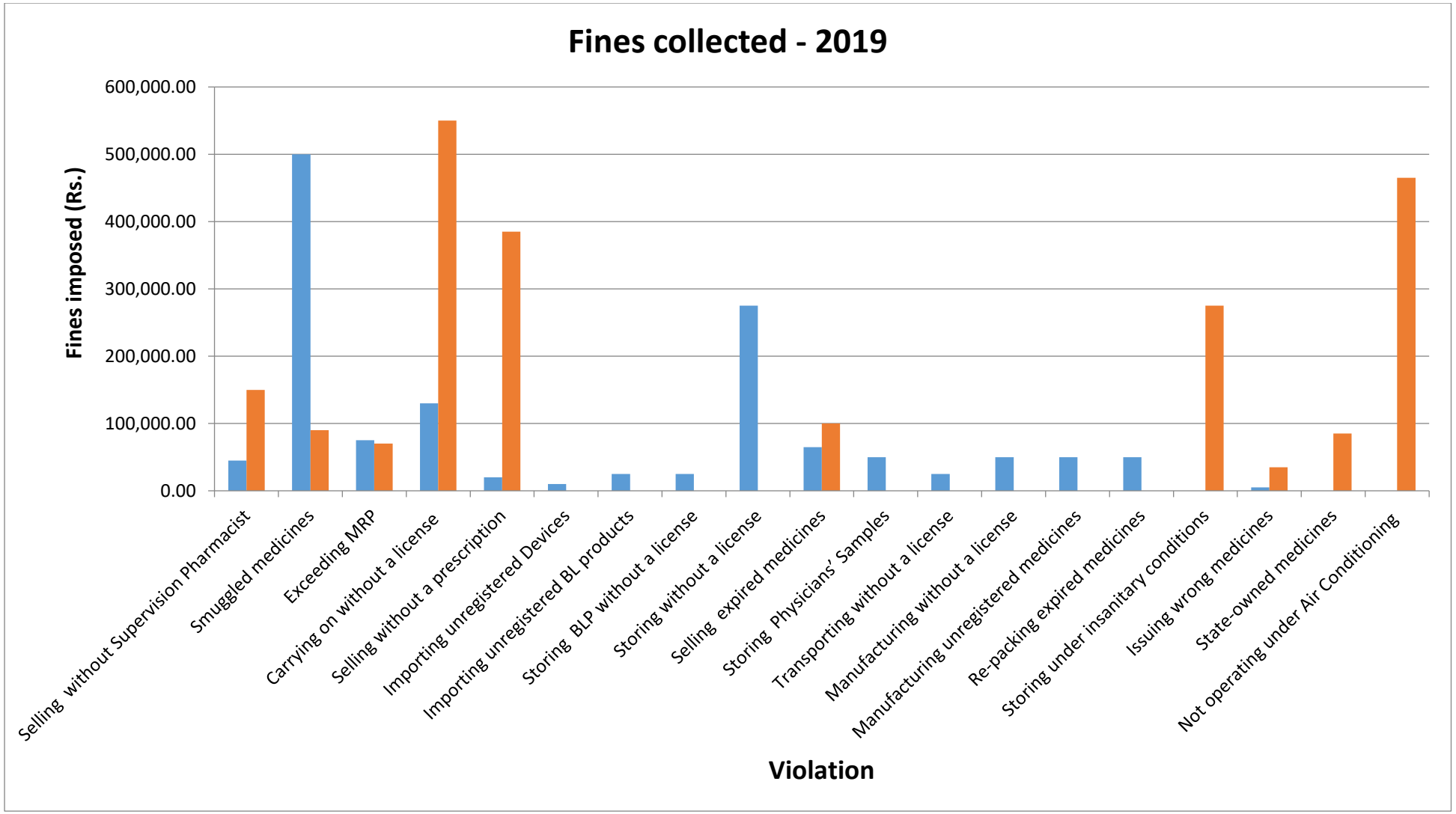
Other areas- Details sent by FDII in Ampara, Puttalam, Matara, Batticola & Matale Districts only, included in this table.

Implementation of Price Regulations – 2019

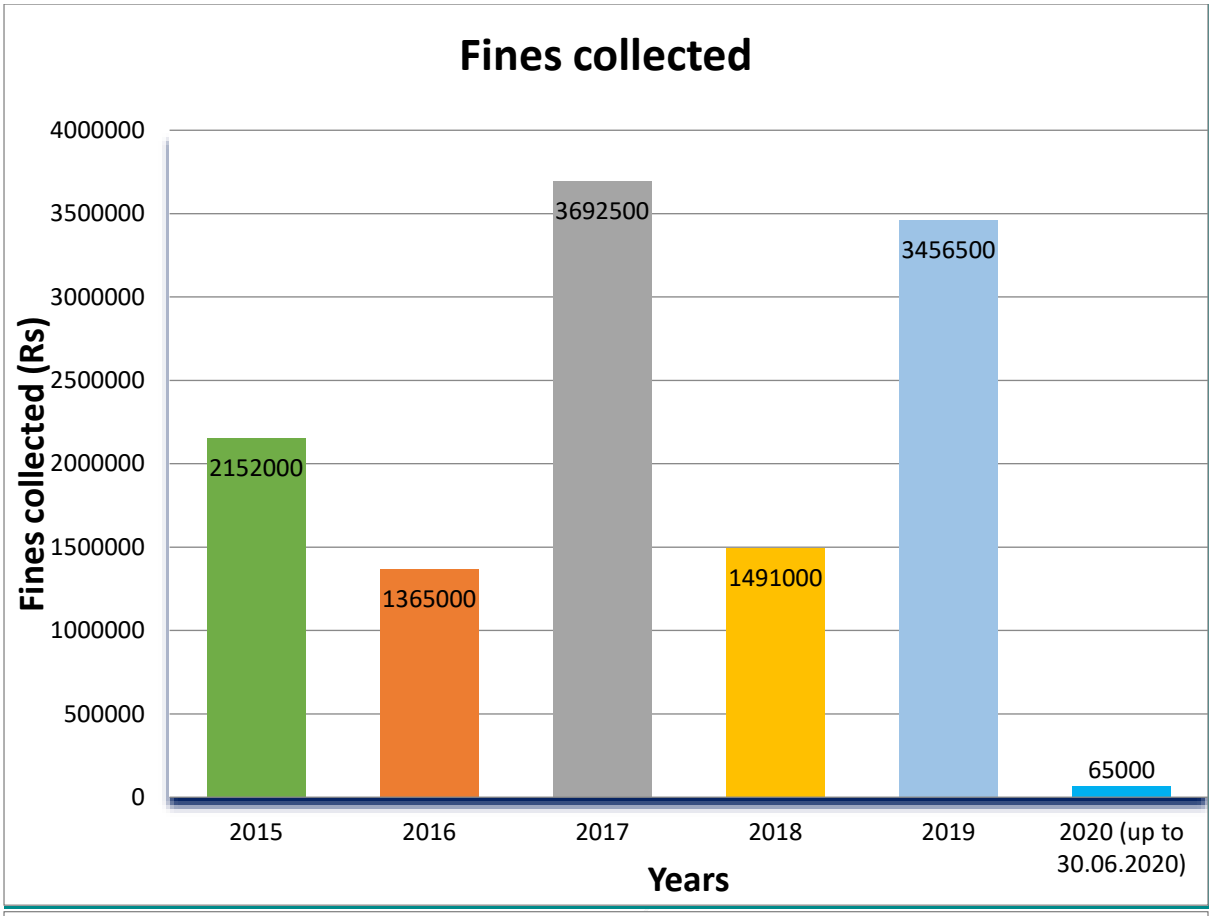
| Serial No. | Place/District | Nature of the offence | Action taken | | |
|---|---|---|---|---|---|
| | | | Court | Result (Fine) | Paper Advertisement |
| 01 | Badulla | Selling Pregablin 150mg capsules exceeding the price. | Badulla | Rs. 10,000.00 | Yes |
| 02 | Badulla | Selling Glimepiride 1mg tablets exceeding the price. | Badulla | Rs. 35,000.00 | No |
| 03 | Bandarawela | Selling Pregablin 75mg capsules exceeding the price. | Bandarawela | Rs. 10,000.00 | No |
| 04 | Bandarawela | Selling Gabila 75mg capsules exceeding the price. | Bandarawela | Rs. 10,000.00 | No |
| 05 | Bandarawela | Selling Seromax capsules exceeding the price. | Bandarawela | Rs. 10,000.00 | No |
| 06 | Bandarawela | Selling Pregablin 150mg capsules exceeding the price. | Bandarawela | Rs. 10,000.00 | Yes |
| 07 | NMRA | Selling Losartan tablets exceeding the price. | Fort | Rs. 75,000.00 | Yes |

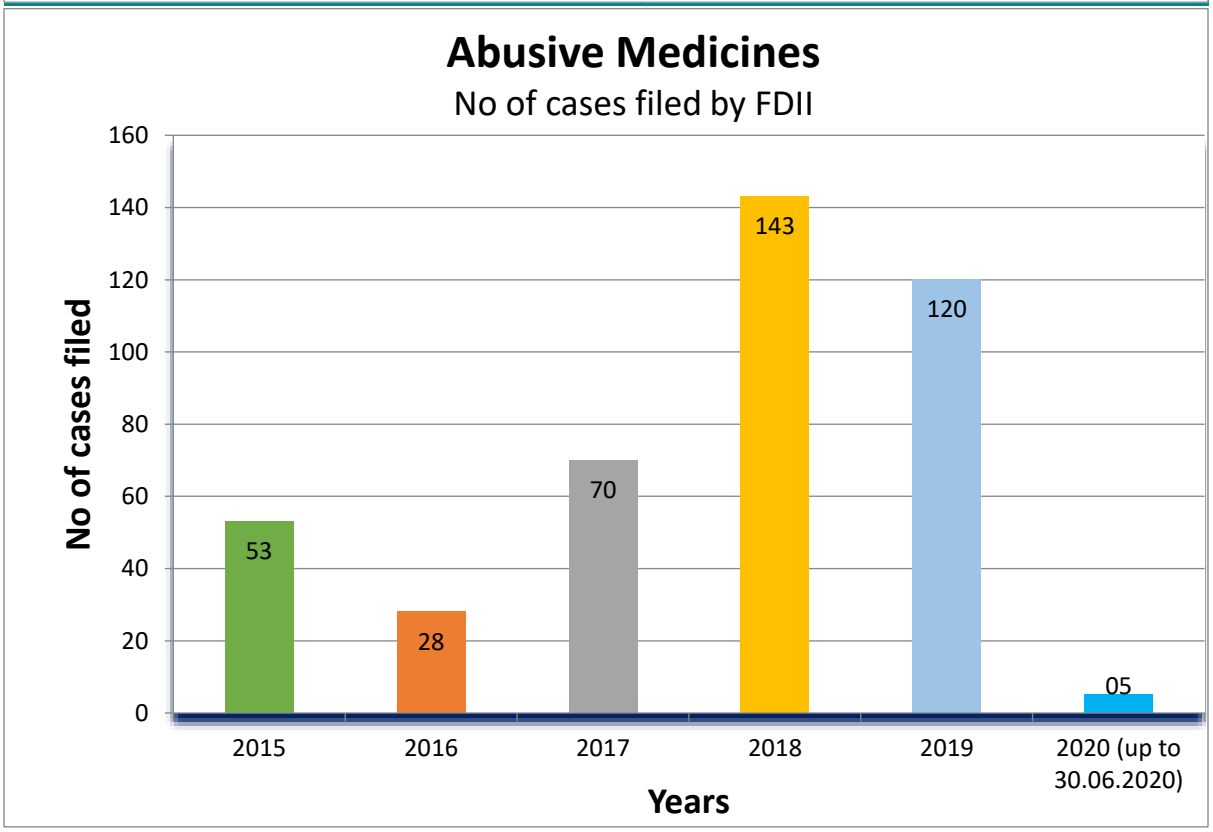



NMRA Area - CMC, Kotte MC, Moratuwa MC, Dehiwala-Mount Lavinia MC.
Other Areas – Batticaloa, Matale, Matara, Puttalam.




NMRA Area - CMC, Kotte MC, Moratuwa MC, Dehiwala-Mount Lavinia MC.
Other Areas – Batticaloa, Matale, Matara, Puttalam


Fines collected
Fines collected (Rs)
4000000
3500000
3000000
2500000
2000000
1500000
1000000
500000
0
2152000
1365000
3692500
1491000
3456500
65000
2015
2016
2017
2018
2019
2020 (up to 30.06.2020)
Years


Abusive Medicines
No of cases filed by FDII
No of cases filed
160
140
120
100
80
60
40
20
0
53
28
70
143
120
05
2015
2016
2017
2018
2019
2020 (up to 30.06.2020)
Years

## 2.4 Progress of Finance Division

Acting Accountant has headed the division for three months until a new accountant was recruited in October 2019. Also Quick Book software was upgraded with 15 accesses. And actions have taken to correct the mistakes as guided by the general audit.

Finance division started its activities including receiving and confirming payments via e-NMRA system.

**Plans for the future**

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

## 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 as follows;

| No | Certificate Type | 2019 |
|---|---|---|
| **1** | Medicine Registration | 2531 |
| **2** | Medicine Import | 511 |
| **3** | Medicine Manufacture | 276 |
| **4** | Medicine Sample | 1099 |
| **5** | Medical Device Registration | 1463 |
| **6** | Medical Device Import | 325 |
| **7** | Medical Device Manufacture | 54 |
| **8** | Medical Device Sample | 1460 |
| **9** | Cosmetic Registration | 2175 |
| **10** | Cosmetic Import | 279 |
| **11** | Cosmetic Manufacture | 217 |
| **12** | Cosmetic Sample | 1759 |

| | | |
|---|---|---|
| **13** | Borderline Registration | 35 |
| **14** | Borderline Import | 4 |
| **15** | Borderline Manufacture | - |
| **16** | Borderline Sample | 103 |
| | **TOTAL** | **12291** |

Plans for future

1) Human resource is planned to be improved further to improve efficiency of the organization.
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 (up to 31.12.2019)

| | |
|---|---|
| Closed files 2017 (21.04.2017-31.12.2017) | 69 |
| Closed files 2018 (01.01.2018 Up to 31.12.2018) | 166 |
| Closed files 2019 (01.01.2019 Up to 31.12.2019) | 225 |
| Total | 460 |

- Agency Transfer Closed Files 130

| | |
|---|---|
| Number of Free of charges files from (01.01.2019 – 31.12.2019) | 15 |
| Number of Payment Basic files from (01.01.2019 – 31.12.2019) | 115 |
| Total | 130 |

- Agency Transfer Total Income

(From 01.01.2019 – 31.12.2019) Rs. 46,968,696.00

The performance summary of Legal Division is undermentioned.

**Regulations/ Gazettes issued under the NMRA Act from 01.01.2019 to 31.12.2019.**

| No. | Gazette No | Gazette Name |
|---|---|---|
| 1 | 2110/08 - 11.02.2019 | Amendment to the item 4 of 2086/37 |
| 2 | 2114/54 - 15.03.2019 | Amendment to the Medical Device Pricing Regulation 14.4% increase Medical Device |
| 3 | 2123/35 -15.05.2019 | Amendment to the Ceiling on Pricing Regulation 14.4% increase Medicinal Products |
| 4 | 2145/1 – 14.10.2019 | National Medicines (Registration and Licensing of Medicine) Regulations, 2019 |
| 5 | 2145/2 – 14.10.2019 | National Medicines (Clinical Trials) Regulations, 2019 |
| 6 | 2146/3 - 21.10.2019 | Pricing Regulations, 2019 |
| 7 | 2149/25 -14.11.2019 | The Regulations for the Issue of Lot Release Certificate for Vaccines and Sera, No. 1 of 2019 |

**Pending Court Cases (up to 31.12.2019) – Filled by the NMRA**

| **NO** | **LO Number** | **CASE** | **Status** | **Position of the NMRA** |
|---|---|---|---|---|
| 1 | NMRA/LO/10/2017 | මීගමුව මහේස්ත්‍රාත් අධිකරණයේ J93933 නඩුවේ මූලික විරෝධතා සම්බන්ධව නීති උපදෙස් පැතීම).MTS / FDI /LA/ 2011) | **Pending** | **Plaintiff** |
| 2 | NMRA/LO/11/2017 | මිනුවන්ගොඩ මහේස්ත්‍රාත් අධිකරණ නඩු අංක 70066 (LO/415/11) | **Pending** | **Plaintiff** |
| 3 | NMRA/LO/12/2017 | මීගමුව මහේස්ත්‍රාත් අධිකරණය K 13644 (LO/321/13) | **Pending** | **Plaintiff** |
| 4 | NMRA/LO13/2017 | මතුගම මහේස්ත්‍රාත් අධිකරණය අංක 71118/11 (MTS /FDI / Legal /2014) | **Pending** | **Plaintiff** |
| 6 | NMRA/LO/15/2017 | වත්තල මහේස්ත්‍රාත් අධිකරණයේ විභාග වන අංක: 45379/09 දරණ නඩුව (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 | නීති උපදෙස් ලබා ගැනීම ප්‍රතිශෝධන පෙත්සම අංක HDRA/118/09 | **Pending** | **Plaintiff** |
| 9 | NMRA/LO/434/2018 | පානදුර අධිකරණයේ M/C 53946 | **Pending** | **Plaintiff** |
| 10 | NMRA/LO/439/2018 | බටහිර ඖෂධ නඩුව<br>නඩු අංක : 62475 නුවරඑළිය<br>මහේස්ත්‍රාත් අධිකරණය | **Pending** | **Plaintiff** |
| 11 | NMRA/LO/494/2019 | අම්පාර අධිකරණයේ<br>M/C<br>90068 | **Pending** | **Plaintiff** |
| 12 | NMRA/LO/590/2019 | අම්පාර අධිකරණයේ<br>M/C 92792 | **Pending** | **Plaintiff** |
| 13 | NMRA/LO/726/2019 | Case No.82460 Gampaha MC | **Pending** | **Plaintiff** |

**Pending Court Cases (up to 31.12.2019) – Filled against the NMRA**

| **NO** | **LO Number** | **CASE** | **Status** | **Position of the NMRA** |
|---|---|---|---|---|
| 1 | NMRA/LO/121/2017 | බස්නාහිර පළාත් කොළඹ වාණිජ මහාධිකරණ නඩු අංක-:<br>එච්.සි)සිවිල්(425/2017/mn (B.J<br>ඉන්ටනැෂනල් පුද් .සමාගම | **Pending** | **Respondent** |
| 2 | NMRA/LO/411/2018 | Nawaloka Hospitals PLC & Others Vs Hon.Dr.Rajitha Senarathne & Others<br>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<br>C.A. (Writ) Application No.284/2012 | **Pending** | **Respondent** |

| | | | | |
|---|---|---|---|---|
| 4 | NMRA/LO/465/2019 | C.A Writ/400/2018 -Markss HLC (Pvt) Ltd | **Pending** | **Respondent** |
| 5 | NMRA/LO/518/2019 | CA Writ Case No. 80/2019 - CCL Pharmaceuticals Lanka (Ltd againts National Medicines Regulatory Authority & Others | **Pending** | **Respondent** |
| 6 | NMRA/LO/553/2019 | CA Writ 124/2019 - Markss HLC (Pvt) Ltd | **Pending** | **Respondent** |
| 7 | NMRA/LO/562/2019 | CA Writ 196/2019 - CCL Pharmaceuticals Lanka VS NMRA | **Pending** | **Respondent** |
| 8 | NMRA/LO/707/2019 | C.A. Writ/499/2019 Markss HLC (Pvt) Ltd against SPC & 4 | **Pending** | **Respondent** |
| 9 | NMRA/LO/720/2019 | C.A/ Writ/517/2019 | **Pending** | **Respondent** |
| 10 | NMRA/LO/731/2019 | CA/Writ/501/2019 | **Pending** | **Respondent** |
| 11 | NMRA/LO/734/2019 | Case filed by Weerakoon Mudiyanselage Bisomanike Jayathunga & another against Hon.Minister & 34 others | **Pending** | **Respondent** |

# Chapter - 3

## Overall Financial Performance


# National Medicines Regulatory Authority

**Financial Statements for the year ended**

**31 December 2019**

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

| *As at 31 December,* | Note | 2019 Rs. | 2018 Rs. |
|---|---|---|---|
| **Assets** | | | |
| **Non current assets** | | | |
| Property, plant and equipment | 2 | 50,226,858 | 29,016,461 |
| Working on Progress | 2.1 | 5,472,075 | |
| **Total non current assets** | | **55,698,933** | **29,016,461** |
| | | | |
| **Current assets** | | | |
| Inventory | 3 | 1,992,864 | 2,389,127 |
| Deposits and other receivable | 4 | 980,863 | 177,499 |
| Short term investments | 5 | 2,479,226,476 | 1,361,721,541 |
| Cash and cash equivalents | 6 | 412,220,462 | 549,535,303 |
| **Total current assets** | | **2,894,420,664** | **1,913,823,469** |
| **Total assets** | | **2,950,119,597** | **1,942,839,930** |
| | | | |
| **Equity and liabilities** | | | |
| **Equity** | | | |
| Accumulated Fund | | 1,745,743,546 | 1,047,449,960 |
| **Total equity** | | **1,745,743,546** | **1,047,449,960** |
| | | | |
| **Non Current liabilities** | | | |
| Capital grant | 7 | 1,500,266 | 2,843,168 |
| Deferred tax | 8 | 2,971,330 | 2,946,556 |
| **Total non current liabilities** | | **4,471,596** | **5,789,724** |
| | | | |
| **Current liabilities** | | | |
| Advance receipts | 9 | 271,932,395 | 96,988,980 |
| Provision for Income tax | 19 | 619,465,553 | 423,956,875 |
| VAT payable | 10 | 63,915,809 | 179,731,189 |
| Stamp duty payable | 11 | 6,181,736 | 40,140,404 |
| Provision for Treasury levy | 12 | 160,486,545 | 109,799,436 |
| Accrued expenses and other payables | 13 | 77,922,417 | 38,983,361 |
| **Total current liabilities** | | **1,199,904,455** | **889,600,246** |
| **Total equity and liabilities** | | **2,950,119,597** | **1,942,839,930** |

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 financial statements were approved by Board of Directors and signed on their behalf.

Prof.Asita De Silva
Chairman

Dr.Kamal Jayasinghe
Chief Executive Officer

23rd October 2020

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

Dr. Kamal Jayasinghe
MBBS, DFM, MSc-Med Admn, MBA, DIPPCA
Chief Executive Officer
National Medicines Regulatory Authority
120, Norris Canal Road, Colombo 10.

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

| *For the year ended 31 December,* | Note | 2019 Rs. | 2018 Rs. |
|---|---|---|---|
| Revenue | 14 | 1,191,761,598 | 1,247,566,713 |
| Intrest income | | 167,504,937 | 61,067,576 |
| Other income | 15 | 374,570 | 1,079,748 |
| Administrative expenses | 16 | (132,884,803) | (89,458,597) |
| Salaries and wages | 17 | (106,205,576) | (96,902,836) |
| Other expenses | 18 | (17,061,320) | (1,351,225) |
| Amortization of capital grant | | 1,342,902 | 1,342,902 |
| **Net income before taxation** | | **1,104,832,308** | **1,123,344,281** |
| Income tax for the year | 19 | (309,137,517) | (314,173,618) |
| **Net income after taxation** | | **795,694,791** | **809,170,663** |

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 | | 310,302,346 |
| Prior year correction | | 8,894,017 |
| **Restated balance as at 31 December 2017** | | 319,196,363 |
| Profit for the year | | 809,170,663 |
| Provision for treasury levy | | (80,917,066) |
| **Balance as at 31 December 2018** | | **1,047,449,960** |
| Prior year correction | | (17,831,726) |
| **Restated balance as at 31 December 2018** | | **1,029,618,234** |
| Profit for the year | | 795,694,791 |
| Provision for treasury levy | | (79,569,479) |
| **Balance as at 31 December 2019** | | **1,745,743,546** |

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

4

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

| *As at 31 December,* | 2019<br>Rs. | 2018<br>Rs. |
|---|---|---|
| Net income before taxation | 1,104,832,308 | 1,123,344,281 |
| Adjustment for : | | |
| Depreciation | 11,628,106 | 7,873,174 |
| Interest income | (167,504,937) | (61,067,576) |
| Amortization of capital grant | (1,342,902) | (1,342,902) |
| Gratuity Expense | 893,668 | |
| Provision for treasury levy | | - |
| Prior year correction | | - |
| Operating profit before tax | 948,506,243 | 1,068,806,977 |
| **Changes in items of working capital** | **948,506,243** | **1,068,806,977** |
| Inventory | 396,263 | (907,021) |
| Deposits and other receivable | (803,364) | (54,255) |
| Advance receipts | 174,943,415 | 11,345,324 |
| VAT payable | (115,815,380) | 74,268,595 |
| Stamp duty payable | (33,958,668) | 4,029,171 |
| Provision for treasury levy | 50,687,109 | 80,917,066 |
| Accrued expenses and other payables | 38,939,056 | (31,677,069) |
| Provision for treasury levy | | (80,917,066) |
| Short Term Investment Increase | (1,117,504,935) | |
| Efect of Prior year correction | | 3,108,322 |
| Adjustment | 900,468,913 | 72,139 |
| **Cash generated from operations** | **845,858,652** | **1,128,992,183** |
| | | |
| **Cash flows from investing activities** | | |
| Acquisition of Property plant and equipment | (33,173,495) | (11,220,703) |
| Investment in short term deposits | (1,117,504,935) | (1,261,067,576) |
| Interest income | 167,504,937 | 61,067,576 |
| **Net cash used in Investing activities** | **(983,173,493)** | **(1,211,220,703)** |
| | | |
| **Cash flows from financing activities** | | |
| Contribution from Treasury for capital assets | | - |
| **Net cash used in financing activities** | | - |
| | | |
| Net increase/ decrease in Cash & cash equivalents | (137,314,840) | (82,228,520) |
| Cash and cash equivalents at the beginning of the year | 549,535,302 | 631,763,823 |
| **Cash and cash equivalents at the ending of the year** | **412,220,462** | **549,535,302** |

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

5

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**
***For the year ended 31 December 2019***

## 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 2019***

**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.

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**
***For the year ended 31 December 2019***

**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 2019***

**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 2019***

**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.

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**
***For the year ended 31 December 2019***

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**

| | Filng store | Lab equipment | Furniture and fittings | Office equipment | Computer equipment | Computer Software | Public Addressing System | Total |
|---|---|---|---|---|---|---|---|---|
| **Cost** | Rs. | Rs. | Rs. | Rs. | Rs. | Rs. | Rs. | Rs. |
| Balance as at 1 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 |
| Restated Balance as at 01 January 2019 | 15,257,976 | 9,451,740 | 2,084,965 | 5,319,876 | 7,915,653 | 224,400 | 329,325 | 40,583,935 |
| Correction - Working Progress | | | | | | | (329,325) | (329,325) |
| Additions during the year | - | 31,436,266 | 714,659 | 852,070 | 170,500 | - | | 33,173,495 |
| Balance as at 31 December 2019 | 15,257,976 | 40,888,006 | 2,799,624 | 6,171,946 | 8,086,153 | 224,400 | - | 73,428,105 |
| **Accumulated depreciation/ ammortization** | | | | | | | | |
| Balance as at 1 January 2018 | 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 |
| Restated 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 |
| Restated Balance as at 01 January 2019 | 3,661,914 | 2,396,055 | 576,651 | 1,666,742 | 3,175,818 | 72,699 | 17,594 | 11,567,474 |
| Prior Year Correction | | | | | | | (17,594) | (17,594) |
| Charge for the year | 3,051,595 | 4,899,729 | 450,471 | 1,179,955 | 2,013,517 | 56,100 | | 11,651,366 |
| Balance as at 31 December 2019 | 6,713,509 | 7,295,784 | 1,027,123 | 2,846,697 | 5,189,334 | 128,799 | - | 23,201,247 |
| **Carrying value** | | | | | | | | |
| **As at 31 December 2019** | **8,544,467** | **33,592,222** | **1,772,502** | **3,325,249** | **2,896,819** | **95,601** | - | **50,226,858** |

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,* | | 2019 Rs. | 2018 Rs. |
|---|---|---|---|
| 2.1 | **Capital Working Progress** | | |
| | On going Public Finger Print Scanners | 269,359 | - |
| | On going cost Public Addresing System | 499,589 | - |
| | On going cost CCTV Systems | 4,658,794 | - |
| | On going cost Narahenpita building | 44,333 | - |
| | | **5,472,075** | - |
| 3 | **Inventory** | | |
| | Openning Inventory | 2,389,127 | 1,482,106 |
| | Purchased for year | 1,995,957 | 2,716,697 |
| | | 4,385,084 | 4,198,803 |
| | Consumption | 2,392,220 | 1,809,677 |
| | Closing Inventory | **1,992,864** | **2,389,127** |
| 4 | **Deposits and other receivable** | | |
| | Deposit for fuel | 50,000 | 50,000 |
| | Other receivables | 194,083 | 127,499 |
| | Prepayments | 736,780 | - |
| | **Total deposits and prepayments** | **980,863** | **177,499** |
| 5 | **Short term investments** | | |
| | Openning Balance | 1,361,721,541 | 100,653,965 |
| | Invest for the Year | 949,999,998 | 1,200,000,000 |
| | Interest for the year | 167,504,937 | 61,067,576 |
| | | **2,479,226,476** | **1,361,721,541** |
| 6 | **Cash and cash equivalents** | | |
| | BOC Current Account | 412,220,462 | 549,535,303 |
| | **Total cash and cash equivalents** | **412,220,462** | **549,535,303** |
| 7 | **Capital grant** | | |
| | Capital grant | 2,843,168 | 4,186,070 |
| | Amortization of capital grant | (1,342,902) | (1,342,902) |
| | **Total Capital grant** | **1,500,266** | **2,843,168** |
| 8 | **Deferred tax liability** | | |
| | Accounting written down value of Property plant and equipment | 50,226,858 | 29,016,461 |
| | Tax base of Property plant and equipment | 29,091,550 | 18,493,047 |
| | Taxable Temporary deference | 21,135,309 | 10,523,414 |
| | Tax @ 28% | 5,917,886 | 2,946,556 |
| | Deferred Liability at the end of the year | **5,917,886** | **2,946,556** |
| | Deferred Liability as at beginning of the year | 2,946,556 | 1,845,328 |
| | Charge as deferred tax during the year | **2,971,330** | **1,101,228** |

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

| | | | |
|---|---|---|---|
| 9 | **Advance receipts** | | |
| | Fees received in advance | 150,749,550 | 96,988,980 |
| | **Total advance receipts** | **150,749,550** | **96,988,980** |

| | | 2019 | 2018 |
|---|---|---|---|
| 10 | **VAT payable** | **Rs.** | **Rs.** |
| | Openning Balance | 179,731,189 | 109,758,402 |
| | Input VAT for 2017 | (4,295,808) | |
| | VAT for the year | 166,720,204 | 182,242,708 |
| | Input VAT | (4,520,965) | (2,476,049) |
| | Credit Note Balance | - | (35,469) |
| | Paid for the year | (98,283,430) | (111,245,195) |
| | Prior Year Correction | (175,435,381) | 1,486,792 |
| | VAT Payable | **63,915,809** | **179,731,189** |
| 11 | **Stamp duty payable** | | |
| | Openning Balance | 40,140,404 | 36,111,233 |
| | Stamp Duty for the year | 34,722,460 | 40,140,404 |
| | Paid for the year | (28,540,724) | (31,201,280) |
| | Prior Year Curection | (40,140,404) | (4,909,953) |
| | Stamp duty payable | **6,181,736** | **40,140,404** |
| 12 | **Provision for Treasury levy** | | |
| | Net income after taxation | 795,694,791 | 809,170,663 |
| | Provision 10% | 79,569,479 | 80,917,066 |
| | Provision for 2018 | 80,917,066 | 28,882,370 |
| | | **160,486,545** | **109,799,436** |
| 13 | **Accrued expenses and other payables** | | |
| | Accrued expenses | 45,712,570 | 6,955,689 |
| | Other Payables | 4,872,390 | 31,643,275 |
| | Retention Deposit | - | 6,832 |
| | EPF Payble | 535,187 | 707,207 |
| | ETF Payble | 242,840 | (208,829) |
| | Payee Payable | 170,312 | (120,812) |
| | Pension Payable | 14,213,371 | - |
| | Secondment Allowances Payable | 11,282,079 | |
| | Provision for Gratuity | 893,668 | |
| | **Total Accrued expenses** | **77,922,417** | **38,983,361** |

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

| | | 2019 Rs. | 2018 Rs. |
|---|---|---|---|
| **14** | **Revenue** | | |
| | Drug sample license income | 18,760,318 | 23,058,332 |
| | Device sample license income | 18,345,905 | 22,226,363 |
| | Drug import license income | 96,156,458 | 119,691,308 |
| | Device import license income | 63,870,299 | 80,662,691 |
| | Cosmetic import license income | 6,726,500 | 6,738,559 |
| | Drug manufacturing license income | 5,859,540 | 5,008,623 |
| | Device manufacturing license income | 960,327 | 481,967 |
| | Drug registration income | 115,165,232 | 140,476,132 |
| | Device registration income | 62,057,397 | 87,600,471 |
| | Cosmetic registration income | 7,863,500 | 9,264,775 |
| | Fees for labotary test | 7,921,631 | 5,526,579 |
| | Drug processing fees | 239,968,215 | 305,549,954 |
| | Device processing fees | 147,981,580.00 | 162,412,652.00 |
| | Cosmetic processing fees | 983,000 | 1,791,336 |
| | Borderline processing fees | 11,193,119 | 21,233,147 |
| | Clinical Trial processing fees | - | 2,400,342 |
| | Advertising fees | 2,164,703 | 1,575,341 |
| | Retail pharmacy license income | 26,665,061 | 30,850,341 |
| | Wholesale pharmacy license income | 6,108,897 | 9,844,185 |
| | Transport pharmacy license income | 19,135,314 | 21,287,366 |
| | Waiver of registration income | 9,643,738 | 3,030,052 |
| | Inspection of Good Manufacturing Practices - Local | 826,412 | 369,612 |
| | Inspection of Good Manufacturing Practices - Foreign | 89,014,754 | 11,862,707 |
| | WHO Good Manufacturing Practices certificate | - | 730,930 |
| | COPP Certificate | 162,533 | 8,813 |
| | Submission of additional documents | 51,670,640 | 130,061,365 |
| | Fees from agency transfer | 41,196,078 | 32,616,855 |
| | Fees for free sale certificates | 54,454 | 55,697 |
| | Clarrification | 13,830,962 | 9,732 |
| | Category A/B processing fees | 4,202,362 | 3,498,837 |
| | Cosmetic Manufacturing | 217,000 | 171,540 |
| | Additional Drug | 83,961,047 | 349,825 |
| | Cosmatic Samples | 463,400 | 1,081,321 |
| | Borderline for Test Samples | 1,103,156 | 960,605 |
| | Fees for Variation Review | 3,679,155 | 1,348,486 |
| | Device Providence Registration | - | 1,833,066 |
| | Company Profile | 27,740,076 | 1,594,000 |
| | Approval for Repacking | 820,443 | 41,954 |
| | Import Registered Borderline | 654,214 | 86,951 |
| | Certificate of Registration Borderline | 1,272,716 | 173,901 |
| | NCE | 3,361,462 | |
| | | **1,191,761,598** | **1,247,566,713** |

| | | | |
|---|---|---|---|
| **15** | **Other Income** | | |
| | Non Refundable Tender PMT | 199,250 | |
| | Other Income | 8,320 | |
| | Supplier Registration 2019 | 167,000 | |
| | | 374,570 | |

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

| | | | |
|---|---|---|---|
| **16** | **Administrative expenses** | | |
| | Depreciation | 11,628,106 | 7,873,174 |
| | Water | 611,710 | 447,826 |
| | Eletricity | 8,633,989 | 8,168,972 |
| | Telephone | 913,710 | 974,894 |
| | Postage | 368,925 | 371,723 |
| | Stationery | 1,995,957 | 1,809,676 |
| | Travelling - Local | 45,641 | 181,975 |
| | Travelling - Foreign | 33,549,596 | 12,517,630 |
| | Training and development expenses | 17,935,115 | 10,563,614 |
| | Labortary expenses | 24,830,467 | 6,608,047 |
| | Fuel expense | 948,494 | 796,301 |
| | Security charges | 3,524,619 | 3,589,887 |
| | Document handling charges | 1,142,262 | 1,035,978 |
| | Publication, Translation and advertisement charges | 2,373,271 | 1,665,271 |
| | Janitorial service | 2,924,475 | 4,442,664 |
| | Vehicle maintenance | 1,863,140 | 1,677,910 |
| | Maintenance of Labortary equipment | | - |
| | Maintenance of fire extinguisher | 33,201 | 92,237 |
| | Maintenance of Air-conditioning | 6,371,486 | 2,011,251 |
| | Maintenance of building | 6,371,486 | 5,097,276 |
| | Maintenance of computer items and other | 875,563 | 2,038,916 |
| | Expenses for Good Manufacturing Practice visits | | 12,500,764 |
| | Recervation of conference hall | - | 775,557 |
| | Drating corporate plan | | 6,567 |
| | Maintenance of website | 559,085 | 411,263 |
| | Expenses for drafting regulations | | - |
| | Courier service | | 3,402 |
| | Rates and taxes | | - |
| | Audit fee | 1,023,000 | 1,281,178 |
| | WHO meeting expenses | 1,862,297 | 882,440 |
| | 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 |
| | Books & Jornels | 1,350,237 | - |
| | Consultation Fee | 167,073 | 431,175 |
| | Gratuity Expense | 893,668 | - |
| | Maintence of photocopy machine | 88,230 | - |
| | **Total** | **132,884,803** | **89,458,597** |
| **17** | **Salaries and wages** | | |
| | Salaries and wages | 78,657,424 | 60,564,596 |
| | Other allowances | 5,616,991 | 10,198,127 |
| | Overtime payment | 9,537,275 | 8,913,217 |
| | Secondment allowance | 2,013,516 | 7,438,689 |
| | Contribution for pension | 3,938,179 | 7,438,689 |
| | Contribution for Employee Provident Fund | 5,573,051 | 1,879,614 |
| | Contribution for Employee Trust Fund | 835,958 | 469,904 |
| | Contribution for W & OP | 30,308 | |
| | National Insurance Trust Fund E | 2,875 | |
| | **Total** | **106,205,576** | **96,902,836** |

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

| | | | | |
|---|---|---|---|---|
| **18** | **Other expenses** | | | |
| | Other repair and maintenance | | | 731,843 |
| | Refreshment and other expenses | | 884,887 | 47,257 |
| | Bank Charges | | 450 | 2,000 |
| | Staff Tea | | 2,088,689 | - |
| | Lawyer Fee | | 1,601,475 | - |
| | Payment for Commitees | | 1,842,578 | - |
| | Other Expenses | | 1,423,254 | 570,125 |
| | Expert for Reviwing of Dossiers | | 2,888,774 | |
| | E NMRA Workshop Expenses | | 4,378,726 | |
| | Surcharges | | 1,786,817 | |
| | Payment for ISO | | 165,670 | |
| | **Total** | | **17,061,320** | **1,351,225** |
| **19** | **Income tax for the year** | | | |
| **19.2** | Income tax expense for the year | | 306,166,187 | 313,072,390 |
| | Deferred tax expense for the year | | 2,971,330 | 1,101,228 |
| | **Tax expense for the year** | | **309,137,517** | **314,173,618** |
| **19.2** | Net income before taxation | | 1,104,832,308 | 1,123,344,281 |
| | Add : Disallowable expense | | 12,536,253 | 7,920,431 |
| | Less : Allowable expense | | (22,574,992) | (11,806,130) |
| | Less : Income not subject to income tax | | (1,342,902) | (1,342,902) |
| | Adjusted profit for the year | | 1,093,450,668 | 1,118,115,679 |
| | Other profit and income liable to tax | | - | - |
| | Total statutory income/ Taxable income | | 1,093,450,668 | 1,118,115,679 |
| | Income tax for the year | at 28% | 306,166,187 | 313,072,390 |
| | Tax Credits: | | | |
| | Notional Tax | | - | - |
| | Prior Year Correction | | 226,976 | |
| | Income tax expense for the year | | 306,166,187 | 313,072,390 |
| | **Total tax payable as at the year end** | | **619,465,553** | **426,946,913** |
| **20** | **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 | | 2,976,895 | 360,985 |
| | Other | | 14,854,831 | 3,108,322 |
| | Total Adjusted Amount | | **17,831,726** | **8,894,017** |

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

**21 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 .

| | 2019 Rs. | 2018 Rs. |
|---|---|---|
| Short term employee benefits | 0 | 0 |
| | - | - |

**22 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.

**23 Contingent Liabilities**

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

**24 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,118 cases were filed by the NMRA against vialation of provisions in the Act. Futhermore, one cases is pending before the court which were filed by the Food and Drug inspectors in NMRA due to vialation of provision the NMRA Act as of 31st December 2019.

**25 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 23rd September 2020.

**Report of the Auditor General on the Financial Statements of the National Medicines Regulatory Authority and Its Affairs for the year ended 31 December 2019 in pursuance of Article 154 (6) of the Constitution of the Democratic Socialist Republic of Sri Lanka**

## 1.1 Disclaimer of Opinion

The audit of the financial statements of the National Medicines Regulatory Authority for the year ended 31 December 2019 comprising the statement of financial position as at 31 December 2019 and the statement of comprehensive income, statement of changes in equity and cash flow statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, was carried out under my direction in pursuance of provisions in Article 154 (1) of the Constitution of the Democratic Socialist Republic of Sri Lanka read in conjunction with provisions of the National Audit Act No. 19 of 2018 and Finance Act No. 38 of 1971. My comments and observations which I consider should be reported to Parliament appear in this report.

I do not express an opinion on the accompanying financial statements of the Authority. Because of the significance of the matters discussed in the Basis for Disclaimer of Opinion section of my report, I have not been able to obtain sufficient and appropriate audit evidence to provide a basis for an audit opinion on these financial statements.

## 1.2 Basis for Disclaimer of Opinion

My opinion is disclaimed based on the matters set out in paragraph 1.5 of this report.
I conducted my audit in accordance with Sri Lanka Auditing Standards (SLAuS) My responsibilities under those Standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of this report.

### 1.3 Responsibilities of Management and Those Charged with Governance for the Financial Statements

Management is responsible for the preparation of financial statements that give a true and fair view in accordance with Sri Lanka Accounting Standards, and for such internal control as management determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Authority's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intend to liquidate the Authority or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the Authority's financial reporting process.

As per Section 16 (1) of the National Audit Act No. 19 of 2018, Authority is required to maintain proper books and records of all its income, expenditure, assets and liabilities, to enable annual and periodic financial statements to be prepared of the Authority.

### 1.4 Auditor's Responsibilities for the Audit of the Financial Statements

My objective is to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes my opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Sri Lanka Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with Sri Lanka Auditing Standards, I exercise professional judgment and maintain professional scepticism throughout the audit. I also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Authority's internal control.

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

- Conclude on the appropriateness of the management's use of the going concern basis of accounting and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Authority's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my auditor's report. However, future events or conditions may cause the Authority to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

The scope of the audit also extended to examine as far as possible, and as far as necessary the following;

- Whether the organization, systems, procedures, books, records and other documents have been properly and adequately designed from the point of view of the presentation of information to enable a continuous evaluation of the activities of the Authority, and whether such systems, procedures, books, records and other documents are in effective operation;

- Whether the Authority has complied with applicable written law, or other general or special directions issued by the governing body of the Authority;

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

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

## 1.5 Financial Statements

### 1.5.1 Accounting Deficiencies

| | Audit Observation | Comments of the Management | Recommendation |
|---|---|---|---|
| (a) | The revenue had been understated by Rs.9,728,822 in the financial statements for the year under review and the expenditure had been overstated | These errors had taken place as it is difficult to differentiate between advance receipts and income receipts out of a | The accounts for the year 2020 should be prepared and submitted after rectifying these errors. |

| | | | |
|---|---|---|---|
| | by Rs.16,766,765 due to accounting errors of the Authority and as a result, the financial result of the year under review had been understated by Rs. 26,495,587 in the financial statements. | very large number of receipts and due to over-accounting of expenses. Those errors will be rectified in the preparation of the accounts for the ensuing year. | |
| (b) | In the rectification of non-accounting of accrued expenses amounting to Rs.2,127,713 as at 31 December 2018, the value had been debited twice to the adjustment account of the previous year. | Those errors will be rectified in the preparation of the accounts for the ensuing year. | The accounts for the year 2020 should be prepared and submitted after rectifying these errors. |
| (c) | Although an amount totalling to Rs.2,976,895 should be adjusted to the advance account receivable when rectifying the accounting errors related to the previous year, the advance account had been stated in financial statements after balancing the advance account without making such adjustments. A difference of Rs.121,182,845 was observed between the balance of the advance account stated in the financial statements and the schedule related thereto due to such accounting errors. | These errors will be rectified in the preparation of the accounts for the ensuing year. | The accounts for the year 2020 should be prepared and submitted after rectifying these errors. |

5

| | | | |
|---|---|---|---|
| (d) | Although the Authority has been utilizing a number of fixed assets, including buildings, vehicles, laboratory, laboratory equipment, office equipment and furniture and fixtures owned by the Ministry since the inception of the Authority in 2015, action had not been taken to transfer the assets to the Authority and to adjust the fair value of the assets in the accounts. | Although the assets owned by the Ministry have been used by the Authority since 2015, the Authority was unable to assess and account those assets as the Authority had not employed a permanent staff. Moreover, those activities were further delayed due to the Covid-19 epidemic prevailed in the country during the year 2020 and therefore, action would be taken to assess and account these assets as soon as possible. | These assets should be assessed and transferred and accounted and accounts should be prepared for the year 2020 and submitted. |
| (e) | An amount of Rs. 5,142,750 paid for Work in Progress during the year under review had not been indicated as an investment under investment activities in cash flow statement Moreover, the accuracy of the cash flow statement could not be verified during the audit as detailed schedules and explanations were not submitted for the | These errors would be corrected in the preparation of the accounts for the ensuing year. | These errors should be rectified and the accounts for the year 2020 should be prepared and submitted. |

6

adjustment value of Rs.900,468,913 mentioned in the cash flow statement.

### 1.5.2 Unreconciled Control Accounts or Records

| Item | Value as per Financial Statements | Value as per Corresponding Records | Difference | Comments of the Management | Recommendation |
|---|---|---|---|---|---|
| | Rs. | Rs. | Rs. | | |
| (a) Employees' Trust Fund Account Payable | 242,840 | (242,840) | 485,680 | Trial Balances should be carried out to identify deficiencies that have been occurred. | The difference and the reasons for the difference should be identified and action should be taken to rectify any errors if there are any such errors or to prepare reconciliation statements. |
| (b) Employees' Provident Fund Account Payable | 535,187 | (535,187) | 1,070,374 | -Do- | -Do- |
| (c) Treasury Levy | 160,486,545 | 168,623,641 | 8,137,096 | -Do- | -Do- |

7

| | | | | | | |
|---|---|---|---|---|---|---|
| | Provision Account | | | | | |
| (d) | Pay As You Earn (PAYE) Taxes Payable | 170,312 | - | 170,312 | -Do- | -Do- |

### 1.5.3 Documentary Evidences not made available for Audit

| Item | Amount | Evidence not available | Comments of the Management | Recommendation |
|---|---|---|---|---|
| | Rs. Million | | | |
| (a) Balance of the Advance Receipts Account | 121.1 | Schedules and time analysis | That schedules have not yet been prepared for the difference between the balance of the advance account and the balances for which schedules can be submitted. | Schedules and time analysis should be prepared and submitted at the same time of preparing and submitting the financial statements. |
| (b) Adjustment value of cash flow statement | 900.4 | Detailed schedules and explanations | Relevant changes have occurred due to an error in the preparation of the cash flow statement and errors will be rectified in the preparation of the | -[Do- |

8

| | | | | |
|---|---|---|---|---|
| | | | accounts for the ensuing year. | |
| (c) 12 Audit queries issued to the Authority | 43.1 | Answers to audit queries | Unanswered audit queries will be answered as soon as possible. | Answers must be submitted to audit queries by the due date. |
| (d) Applications for registration of manufacturing plants | - | 6 Files containing applications | The files could not be submitted to the audit as the female officer in charge of these applications had transferred from the institution and the officers in charge of the files have already left the institution. Action would be taken to search for the files and the files would be submitted to audit as soon as possible. | Relevant files should be submitted to audit. |
| (e) Although the number of applications received for the registration of medicines during the year under review was 2,097, information in relation to the | - | Number of certificates of registration issued | Information on the number of certificates of registration issued can be properly provided in the future after the completion of the online system. | Relevant information should be submitted to audit. |

9

| | | | | |
|---|---|---|---|---|
| | number of certificates of registration issued had not been submitted to audit. | | | |
| (f) | Information regarding the certificates of registration issued for 250 medical devices submitted for re-registration during the year under review had not been submitted to audit. | - | Number of certificates of registration issued | Information on the number of certificates of registration issued can be properly provided in the future after the completion of the online system. | Relevant information should be submitted to audit. |
| (g) | The current progress in the 37 recommendations, which had been recommended to be implemented in relation to the laboratory tests at the | - | Current progress in the recommendations made by the World Health Organization | For this purpose, a number of criteria contained in the Benchmark tool of the World Health Organization have been submitted to the Institution for the fulfilment of those criteria, many fundamental requirements must be satisfied to meet | The current progress in the recommendations made by the World Health Organization should be submitted to audit. |

10

National Drugs Quality Assurance Laboratory mentioned in the report of the World Health Organization issued in relation to the benchmarking programme conducted by the World Health Organization regarding the Authority during the year under review had not been submitted to the audit.

these criteria, and that it is difficult to fully accomplish those criteria until the requirements are fulfilled, However, these criteria are being fulfilled with the currently available facilities and the criteria thus fulfilled will be re-studied and advices will be provided further by the Evaluation Team of the World Health Organization (WHO) in the future.

11

## 1.6 Non-compliance with Laws, Rules and Regulations

| Reference to Laws, Rules and Regulations etc. | Non-compliance | Comments of the Management | Recommendation |
|---|---|---|---|
| (a) The National Medicines Regulatory Authority Act No. 05 of 2015 | | | |
| (i) Section 43 (2) | Provisional certificates of registration were issued for 10 new applications submitted for registration of medicines without obtaining the approval of the Medicines Evaluation Committee (MEC). Subsequent to issuing certificates of registration for 14 medicine items for 02 institutions, they were submitted to the Medicines Evaluation Committee for | Any application for the registration of medicines was not submitted to the Medicines Evaluation Committee (MEC) at that stage before the application was evaluated. | Certificates of registration should be issued in compliance with the Act. |

12

| | | | |
|---|---|---|---|
| | approval. | | |
| (ii) Section 51 | Certificates of registration were issued for 04 types of medicines related to 04 foreign manufacturing plants, of which evaluation had not been initiated and for 34 types of medicines of 22 foreign manufacturing plants before granting approval for the manufacturing plants. Although a test for good manufacturing practice, which should have been conducted for a foreign manufactory within a year had not been conducted for more than 05 years, registration certificates had been issued for medicines manufactured in that manufactory on 06 occasions. | Answers had not been submitted. | -Do- |
| (iii) Sections 58, 59, 82 | In the year 2019, the Authority had issued | When inquired from the relevant Division in this | Letters of exemption from |

| | | | | |
|---|---|---|---|---|
| | and 83 | 516 letters of exemption from registration for the State Pharmaceutical Corporation, the Medical Supplies Division and other government and private institutions without complying to the provisions of the Act. | regard, the Division had admitted that such waiver of registration letters had been issued and such waiver of registration letters had been issued on various essential reasons. | registration should be issued only for the requirements specified in the Act. Otherwise, action should be taken to amend the Act. |
| (iv) | Section 59 (4) (b) | Ninety-nine (99) provisional certificates of registration and 49 full registration certificates for 05 years were issued for applications received for new registration of medicines without taking samples during the year under review and 29 certificates of registration were issued for applications received for re-registration of medicines. | The National Drugs Quality Assurance Laboratory does not have facilities to evaluate all the applications received for registration of medicines at the Laboratory. Hence, the registration is done based on the test reports provided by the manufacturer and based on test reports obtained from other institutions. | Necessary facilities should be provided to issue certificates of registration in accordance with the Act. |
| (v) | Section 64 | Requests for the evaluation of 25 items of medicines of 03 institutions that had | In this stage, any application submitted for the registration of medicines was not forwarded to the Medicines | Certificates of registration should be issue in accordance with the |

| | | | |
|---|---|---|---|
| | been evaluated in the year 2020 had not been submitted to the Medicines Evaluation Committee and full registration certificates had been issued. | Evaluation Committee (MEC) before the application was evaluated. | Act. |
| (vi) Section 83 (4) (b) | During the year under review, 246 provisional certificates of registration were issued for 579 applications received for new registration of medical devices without obtaining samples and only 01 sample was tested by the Laboratory during the year under review. | The National Drugs Quality Assurance Laboratory does not have the facilities to test samples of medical devices and the registration is done on the basis of the chemical report and the clinical evaluation report issued by the manufacturer and the certificate of registration issued by the National Institute of Equipment Registration in the country of manufacture. | Necessary facilities should be provided to issue certificates of registration in accordance with the Act. |
| (vii) Section 109 | Eighty-nine (89) letters of exemption from registration were issued to the State Pharmaceutical Corporation during the year under review for reasons that were not specified in the Act. Letters of exemption from registration had | When inquired from the relevant Division in this regard, the Division had admitted that such waiver of registration letters had been issued and such waiver of registration letters had been issued on various essential reasons. | Letters of exemption from registration should be issued only for the requirements specified in the Act. Otherwise, action should be taken to amend the Act. |

| | | | | |
|---|---|---|---|---|
| | | been issued again and again to the same supplier or the same manufacturer in 06 instances for 03 items of medicines during the year under review. | | |
| (viii) | Section 119 (1) | It was revealed at a physical inspection conducted on 27 August 2020 in relation to 26 pharmacies in the Colombo District, that there was one pharmacy that had been operating without a valid license and 23 pharmacies that had been operating without updating the license for the period of validity. Moreover, there were 12 pharmacies, where a registered pharmacist was not in service at the time of conducting the physical inspection and 15 pharmacies which had not displayed the license for carrying on a pharmacy and pharmacist registration | Licenses had not been updated in the proper occasion due to delays and technical errors occurred in changing the system of issuing licenses to the online system and due to the COVID 19 epidemic prevailing in the country. Necessary action will be taken to rectify these shortcomings immediately after the conducive circumstances are established for unrestricted operation. | Licenses should be issued properly and efficiently. Regulation of Pharmacies should be formalized. |

| | | | | |
|---|---|---|---|---|
| | | certificate and 05 pharmacies which had not displayed photographs of pharmacists and 04 pharmacies were operating without using air conditioners. There were also 02 pharmacies where medicines were kept at the place where the photocopy machine was located. | | |
| (b) | Regulation No. 8 of Part I of the Regulations contained in the Gazette No. 2145/1 dated 14 October 2019 | The full registration had been granted for 07 items of medicines during the year under review and for 25 items of medicine in 2020 before the expiry of the tenure of the provisional registration of a medicine. Moreover, the full registration was granted for 24 items of medicine of 03 institutions when there was nearly 02 years for the expiry of the validity of the | The Authority had conducted a special investigation into the findings of the audit and all the recommendations in this regard had been implemented. Moreover, the relevant officers were made aware to prevent the occurrence of such incidents further. Formal procedures in this regard have already been designed and they are being implemented by now. | Registration should be granted in accordance with the Regulations of the Act and the relevant Gazette. |

provisional license.

| | | | | |
|---|---|---|---|---|
| (c) | Extraordinary Gazette No. 2123/35 dated 15 May 2019 | Although maximum retail price had been set for 61 medicines, the Authority had set prices higher than the maximum retail price in the certificates of registration issued for 03 medicines in 03 occasions. | An error had occurred in stating the maximum retail price in the certificates of registration of each medicine, above the maximum retail price specified in the Gazette and this error had taken place due to non-identification of the relevant 03 medicines as price regulated medicines by the gazette notification owing to a certain mistake. | Action should be taken in terms of the Regulations specified in the Gazette. |
| (d) | Sections 10 and 16 of the Employees' Provident Fund Act No. 15 of 1958. | The Authority had to pay a surcharge of Rs.388,261 during the year under review due to non-remittance of the contribution of the Employees' Provident Fund by the Authority for the period from January 2016 to September 2018. | The routine duties of the Authority were carried out using the trainees of the National Apprentice and Industrial Training Institute as the Authority did not have a permanent staff during the year 2019. Permanent staff for the Authority has already been recruited and dues will be remitted on the due dates avoiding the imposition of such surcharges in the future. | Action should be taken in accordance with the Act. |

| | | | | |
|---|---|---|---|---|
| (e) | Value Added Tax (Amendment) Act No. 06 of 2005 | The Inland Revenue Department had imposed a surcharge of Rs.36,864,100 during the year under review due to the delay in the payment of value added tax payable by the Authority for the years 2016 and 2017. Moreover, value added tax payable for the first, second and third quarters of the year 2020 had not been correctly identified and remitted to the Inland Revenue Department even by 11 January 2021. | Discussions are being currently held with the Inland Revenue Department in relation to the imposition of the surcharge and action will be taken immediately after reaching a compromise. The remittance of Value Added Tax to the Inland Revenue Department was delayed due to the inability of the Authority to carry out its daily activities for a period of several months from the end of March 2020 due to the Covid-19 epidemic prevailed in the country during the previous year. | Action should be taken in accordance with the Act. |
| (f) | Section 113 of the Income Tax Act No. 10 of 2006 | As the remittance of the Income Tax of the Authority to the Inland Revenue Department was delayed, a surcharge amounting to Rs. 1,361,759 had to be paid during the year under review for the year 2016/2017. | Since the preparation of the final accounts was delayed due to the non-existence of a permanent staff in the Authority, the remittance of income tax to the Inland Revenue Department was delayed and as a result, the Authority had to pay a surcharge of Rs. 1,361,759. Year-end accounts will be prepared and relevant payments will be made | Action should be taken in accordance with the Act. |

| | | | | |
|---|---|---|---|---|
| | | | avoiding reoccurrence of such delays. | |
| (g) | Section 7.4.1 of the Public Enterprises Circular No. PED 12 dated 02 June 2003 | Although the Audit Committee was supposed to hold 04 meeting sessions annually, even a single meeting had not been held for the year 2019. | The Authority was unable to hold audit committee meetings for the year 2019 due to non-existence of a permanent staff for the Authority in the year 2019. Although permanent staff was appointed by the end of the year 2019, there was no enough time to hold Audit Committee meetings. Action is being taken at the moment to avoid these shortcomings and 2 Audit Committee meetings have been held for the year 2020. | Action should be taken in accordance with the provisions of the Circulars. |
| (h) | Public Enterprises Circular No. 02/2018 dated 14 November 2018 | Excess money amounting to Rs. 200 million to Rs.900 million in the current account of the Authority had not been effectively invested during the 12 months of the year under review. | Although the balance in the bank account had been maintained without investing the money in the bank account of the Authority during the first quarter of the year 2019, the Authority had taken steps to invest the remaining amount in the Treasury Bills from 2 May 2019 by retaining the required cash balance for the monthly expenses. Moreover, necessary action is being | Action should be taken in accordance with the provisions of the Circulars. |

further taken to invest the balance amounts under the Sweeping Facility and ZBA Facility of the Bank of Ceylon after investing money in the Treasury Bills.

## 2. Financial Review

According to the financial statements presented, the operating result of the year under review amounted to a profit of Rs.795,694,791 and the corresponding profit in the preceding year was Rs.809,170,663. Accordingly, a deterioration amounting to Rs.13,475,872 was observed in the financial result. The major reasons for the deterioration are the reduction in income earned from registration and the increase in administrative and other expenses. However, a formal system had not been established to identify and account all the income, including registration fees and license fees, received by the bank in cash and directly for the due accounting period. The income for the year under review had not been accurately identified as all the cash received was credited to the advance receipts account and subsequently an income identification system was adopted.

## 3 Operational Review

### 3.1 Management Inefficiencies

| | Audit Observation | Comments of the Management | Recommendation |
|---|---|---|---|
| (a) | In terms of Section 38 (2) (a) of the National Medicines Regulatory Authority Act, No.05 of 2015, action had not | Assets owned by the National Quality Assurance Laboratory could not be assessed and accounted as the Authority did | These assets should be assessed and transferred to the Authority and then the |

| | | | |
|---|---|---|---|
| | been taken to transfer the National Drug Quality Assurance Laboratory, which was in operation under the Ministry, to the Authority and to assess its assets and to include the assets under the accounts of the Authority. | not have a permanent staff and these assets will be assessed and accounted as soon as possible. | assets should be accounted. |
| (b) | In terms of Sections 41 (2), 66(2) and 87 (2) of the National Medicines Regulatory Authority Act No. 05 of 2015, an officer with a degree in Medicine, Pharmacology, Pharmacy or any other related discipline had not been appointed as Heads of the Medicines Regulatory Division, Medical Devices Regulatory Division and the Borderline Products Regulatory Division. | At present, officers with the highest qualifications and experience from among the officers employed in those Divisions have been appointed as Heads of the Divisions under the direct supervision of the Chief Executive Officer of the National Medicines Regulatory Authority and necessary action is being taken to recruit the officers with relevant qualifications in accordance with the Act. | Action should be taken in accordance with the Act. |
| (c) | In terms of Sections 61, 84 (2), 85, 103 (2) and 104 of the National Medicines Regulatory Authority Act No. 05 of 2015, action had not been taken to notify the public by Order published in the Gazette the medicines, registration of which is refused and medical devices and borderline | In terms of Section 60 (2) of the National Medicines Regulatory Authority Act No. 05 of 2015, the Regulations including medicines registered by the Authority have been published by the notification in the Gazette Extraordinary No. 2144/20 dated 09.10.2019. | The Authority should have acted in accordance with the Act as the Authority had published the Regulations including the registered medicines and it had not taken action to notify the public by |

| | | | |
|---|---|---|---|
| | products, which are registered and the registration of which is refused. | | Order published in the Gazette the medicines, registration of which is refused and medical devices and borderline products, which are registered and the registration of which is refused. |
| (d) | In terms of Section 123 of the National Medicines Regulatory Authority Act No. 05 of 2015, an Appeals Committee had not been constituted to hear and determine appeals made to the Authority. | The Minister has been informed of appointing an Appeals Committee as the Minister shall appoint an Appeals Committee. | Action should be taken in accordance with the Act. |
| (e) | Eight hundred and sixty one (861) medical devices had been submitted for new registration during the year under review and certificates of registration had been issued only for 247 medical devices by 27 August 2020. The Authority could not grant registration for the remaining 614 medical devices. | Medical devices are sent to the expert institutions for registration and information on clinical evaluation of the medical devices are obtained and the rest of the evaluations are carried out in relation to the registration and then the registration is granted and a certain period of time should be spent for that purpose. Applications are evaluated by convening the experts to this Authority for conducting clinical evaluations and it was not possible to convene the | Action should be taken to evaluate and grant the registration within a specified period. |

| | | | |
|---|---|---|---|
| | | Officers to the Authority by March 2020 due to the prevalence of the Covid-19 epidemic. | |
| (f) | The register, in which every application received for the new registration of a medicine was recorded was misplaced during the period from 01 January 2019 to 26 April 2019 and 1,168 samples were received for new registration of medicines and 440 samples for re-registration of medicines during the subsequent period. However, only 60 samples had been tested by the Laboratory during the year under review and it was not possible for the laboratory to test the remaining 1,548 samples. | Although the register, in which every application received for the new registration of a medicine was recorded, was misplaced during the said period, the information was submitted to the audit using an Excel worksheet copy. During the above period, 13 samples were sent to the Laboratory for registration and quality reports for all those samples have been issued. | The capacity of the Laboratory should be improved for enabling the laboratory to test all the samples submitted for testing. |
| (g) | A specific time period for registration and licensing of pharmacies is not stipulated within Section 119 (4) of the National Medicines Regulatory Authority Act. Various periods ranged from 04 months to 01 year during the year under review had been spent from the date of charging money up to the date of issuing licenses for | The delays had occurred due to the covering of the functions such as basic inspection of files and drafting of the licenses with the assistance of the Office Assistants for more than 6 months without obtaining the assistance of the Management Assistants required to discharge those duties and spending a long period of time to update | The standard time taken to issue certificates and licenses from the date of submission of applications should be identified. Accordingly, the delay in issuing certificates of registration and licenses should be |

| | | | |
|---|---|---|---|
| | 119 pharmacies and there were 117 occasions where a period ranged from 01 month to 10 months had been spent even after printing the pharmacy licenses for the issuance of those licenses with the signature of the relevant Authority. Acceptable reasons were not submitted for spending such a long period from the date of printing of the licenses up to the issuance of licenses. | the relevant database due to changes in the format of the license after the introduction of new regulations. These activities have now been updated. | minimized by following a pre-prepared plan. |
| (h) | The Authority has taken steps to issue pharmacy licenses (retail and wholesale) in three steps through the Online Computer Automation System with effect from 01 September 2019. However, the pharmacy owners commented that the system was not user friendly as the pharmacy owners have no understanding of this method, no knowledge on information technology, they do not have efficient computer items and problems on internet facilities. As a result, obtaining of pharmacy licenses had further decreased. The income earned | The owners of the pharmacies have not yet complained directly to the Authority that the system was not user friendly, action has been taken by investigating in to this issue further, this system is very complex and steps have been taken to make as many corrections as possible despite some delays, certain time has been spent for making these corrections, the Authority has lost some revenue due to practical problems in the use of this system and action is now being taken to correct this situation. | According to the agreement to design the automation system, the relevant corrections should be made by that Institution. |

| | | | |
|---|---|---|---|
| | from pharmacy licenses by the Authority had decreased by Rs.30,842,902 as at 31 August in the year under review when compared with the income earned in the previous year. Not updating the functioning of the online computer automation system had been one of the reasons for this situation. | | |
| (i) | Although money had been paid for obtaining pharmacy licenses, the Authority had not established a formal system for avoiding the delay in the issuance of licenses and preventing the conduct of business activities without obtaining licenses or renewing licenses. The supervisory activities on Drug outlets throughout the country had not been adequately carried out. | Although 20 posts of Drug Inspectors have been approved, the Division has not been able to recruit officers for the post due to delays in making recommendations on the scheme of recruitment and salary scale by the National Salaries Commission. Requests have been made to obtain the required Management Assistants for the Division and requests have already been made to rectify the shortcomings in the online system to prevent delays in issuing licenses. | The facilities required for the systematic and efficient issuance of licenses should be provided and the regulation of pharmacies should be formalized. |

### 3.2 Operational Inefficiencies

| | Audit Observation | Comments of the Management | Recommendation |
|---|---|---|---|
| (a) | Although the National Drugs Quality Assurance Laboratory submitted an application to the Sri Lanka Accreditation Board on 06 February 2020 to obtain the Conformity Assessment Certificate for the standard of the laboratory, it was unable to obtain the certificate for compliance with stan dard even by 31 December 2020, the date of the audit. Information on the other certificates for compliance with sta ndard obtained had not been submitted to audit. | Although an application was submitted to the Sri Lanka Accreditation Board on 06 February 2020, further delays in obtaining the certificate is unavoidable as certain requirements, to be fulfilled for obtaining this certificate for compliance with standard, have not yet been accomplished and owing to the covid-19 epidemic prevailed during the previous year and still prevailing in the Country. | Requirements to be fulfilled further for obtaining the certificate for com pliance with standa rd should be accomplished as soon as possible for obtaining the certificate. |
| (b) | According to the Benchmarking Programme conducted by the World Health Organization in relation to the Authority during the year under review, the Organization observed that 07 criteria tested regarding the National Drug Quality Assurance Laboratory had been partially implemented and 02 criteria had not been fully implemented. | In this regard, a number of criteria contained in the Benchmark tool of the World Health Organization have been submitted to the institution for fulfilling those criteria and a number of basic requirements must be essentially fulfilled to accomplish these criteria, it is difficult to fully accomplish those criteria until the | Action should be taken to implement the relevant criteria as soon as possible as per the recommendations of the World Health Organization. |

| | | | |
|---|---|---|---|
| | | requirements are fulfilled. However, these criteria are being accomplished according to the facilities that are currently available and the accomplished criteria will be restudied by the Evaluation Team of the World Health Organization (WHO) in the future and further advices will be issued in that regard. | |
| (c) | Although the progress in testing samples for medicines and medical devices in the year 2013 was 97 percent and 100 percent respectively, it had dropped by the year 2019 to 73 percent and 58 percent respectively. Although 217 samples were tested for new registration of medicines in 2013, only 60 samples were tested in the year 2019. | The samples provided for registration have been analysed and reports have been issued. | The capacity of the Laboratory should be improved in order to test of all the samples submitted to the Laboratory. |

### 3.3 Procurement Management

| | Audit Observation | Comments of the Management | Recommendation |
|---|---|---|---|
| (a) | During the year under review, 06 air conditioners, 41 units of 13 office equipment items and 02 fingerprint | Although these procurements were carried out due to the | Action should be taken in accordance with |

| | | | |
|---|---|---|---|
| | machines were purchased by incurring an amount of Rs. 1,724,196. According to the Government Procurement Guidelines, shortcomings such as non-preparation of procurement schedule in these procurements, non-approval of the relevant specifications by the Technical Evaluation Committee, not fixing a bid validity period for the procurement, not obtaining bid security and performance security, non-issuance of acceptance letters to the bidder and non-issuance of purchase orders to the supplier and not entering in to agreement with the supplier were observed. | essentiality in maintaining the proper functioning of the institution, these omissions were occurred due to lack of proper training and discharging of works such as rectifying previous omissions by only one officer. Relevant officers have already been made aware to avoid all such shortcomings and to carry out the procurement activities accurately. | the Government Procurement Guidelines. |
| (b) | An amount of Rs. 4,378,726 had been spent during the year under review for the installation of a computerized system (Implementation of Document and Workflow Management System - Automation) for the Authority. An agreement was entered into with the relevant institution on 03 May 2018 to install the computerized system. The project was to be completed and handed over to the Authority by 03 September 2018, within 120 days from that date. However, the completed computerized system had not been submitted to the Authority | Special attention will be paid to the matters pointed out in the audit and action would be taken to plan and achieve the said objectives. | Relevant improvements should be made to accomplish all the intended requirements in accordance with the agreements applicable to the installation of the computerized system. |

| | | | |
|---|---|---|---|
| | for implementing the system even by 31 December 2020. Dates had not been extended as scheduled and action had not been taken to recover the late fee amounting to Rs. 3,196,518 as per the special terms of the project agreement. Certain systems from among the systems that were under development are still in the Implementation Stage and the system had to be further upgraded and modified during the developing stage of the system according to the requirements of the officers who use the system. Additions and enhancements had to be made from time to time as desired objectives and requirements of the system that had been clearly identified had not been initially incorporated in to project proposals and requirements. | | |

### 3.4 Human Resource Management

| | Audit Observation | Comments of the Management | Recommendation |
|---|---|---|---|
| (a) | The approved cadre of the Authority was 235 as at 31 December 2019, out of which the number of vacancies was 84. The number of vacancies had increased | At present, discussions are being held with the relevant responsible parties and action will be taken to fill the vacancies immediately after | Staff vacancies required to maintain the functioning of the Authority without |

| | | | |
|---|---|---|---|
| | up to 101 by 31 December 2020. Moreover, it was not possible to prepare schemes of recruitment for 07 posts included in the approved cadre and to revise the approved cadre. Although 51 new officers were recruited to the Authority during the year under review, 17 officers out of them had resigned by 31 December 2020. The Authority had failed to retain the officers within the Authority by making the officers satisfied through revising the approved cadre and the schemes of recruitment. This shortage in the staff had profoundly affected the carrying out of the overall operational and administrative functions of the Authority. | the schemes of recruitment are prepared and approved. | interruption should be duly filled within the approved cadre. |
| (b) | Testing of samples at the National Drugs Quality Assurance Laboratory was carried out only by 06 Drug Analysts and any laboratory Assistant had not been assigned for that purpose even by 31 December 2020. | As the Ministry of Health has not yet provided 03 Laboratory Assistants to the Authority, the work of the laboratory is being carried out with obstructions. Since the approval for the Schemes of Recruitment in relation to the post of Laboratory Assistant has already been granted by the Department of Management Services, it is scheduled to make | Staff vacancies required to conduct the functioning of the Authority without obstructions should be duly filled within the approved cadre. |

recruitments expeditiously in the future.

## 4. Accountability and Good Governance

### 4.1 Presentation of Financial Statements

| Audit Observation | Comments of the Management | Recommendation |
|---|---|---|
| Although the annual financial statements of the Statutory Boards should be submitted to the Auditor General within 60 days after the closure of the accounting year in terms of Section 6.5.1 of Public Enterprises Circular No. PED/12 of 02 June 2003 and in terms of the Treasury Circular No. 01/2004 of 24 February 2004, financial statements for the year 2019 had been submitted for audit on 11 November 2020, after a delay of 08 months. | The Authority was unable to carry out its daily activities for a several months from the end of March 2020 and only a very small number of employees were requested to attend the Authority to carry out the essential daily activities due to the Covid-19 epidemic prevailed in the country during the year 2020. Under these circumstances, the preparation of the final accounts for the year 2019 was delayed. | Accounts should be submitted on the due date as per the Circular. |

## 4.2 Annual Action Plan

| Audit Observation | Comments of the Management | Recommendation |
|---|---|---|
| The performance criteria for the activities included in the Action Plan for the year under review were not stated specifically, quantitatively and measurably and therefore, the progress of those activities could not be accurately assessed and the Authority had failed even to initiate any function related to the 11 activities included in the Action Plan during the year under review. | Action has already been taken to prepare the Action Plan of the Authority by eliminating the shortcomings in the Action Plan prepared for the year 2019. | The action plan must be prepared accurately and systematically. The Performance Criteria should be indicated specifically, quantitatively and measurably. Action should be taken in compliance with the Action Plans and the Action Plan should be revised according to the requirement. The responsibility of performing each activity should be specifically assigned to the relevant officers and formal supervision should be carried out in this regard. |

# 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 | 12 | 22 |
| **Tertiary Level** | 6 | 1 | 5 |
| **Secondary Level** | 155 | 92 | 63 |
| **Primary Level** | 50 | 36 | 14 |
| TOTAL | **245** | **141** | **104** |