# Annual Report

# 2017


NATIONAL MEDICINES REGULATORY AUTHORITY (NMRA)

No. 120, Norris Canal Road, Colombo 10.

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# 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 2017 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. Preliminary 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 suitable 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. I hope 2018 will be a very successful year for our Authority.

Prof Asita de Silva

Chairman

National Medicine Regulatory Authority

# Message of the Chief Executive Officer

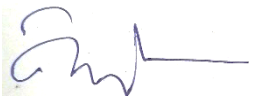
I being the CEO of one of the fastest growing Drug Regulatory Agencies in South - East Asia, the NMRA, feel very proud to present its Annual Report 2017. From the beginning we have recognized, understood and shared our vision, mission and goals among the members of our team which was the invaluable strength 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.

NMRA has recorded a turnover of Rs.554Mn 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 2017, Rs.554 Mn of 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 by Rs.28Mn to the General Treasury as a treasury levy and 115Mn as income tax by its net profit. NMRA has recorded profit before taxation Rs.404Mn during 2017 and it will lead to increase the authority performance and growth of next year.

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. Prof. Narada Warnasooriya
4. Prof. R.L Jayakodi
5. Mrs. C. Herath
6. Ms. Priyantha Rathnayake
7. Dr. Jayasundara Bandara
8. Dr. Lakkumar Fernando
9. Dr. Kapila Ranasinghe
10. Dr. Nissanka Jayawardana
11. Dr. Dilanthi Herath
12. Dr. Ananda Wijewickrama

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

Initially, organization structure was not properly recorded for NMRA, but following divisions were identifiable in it.

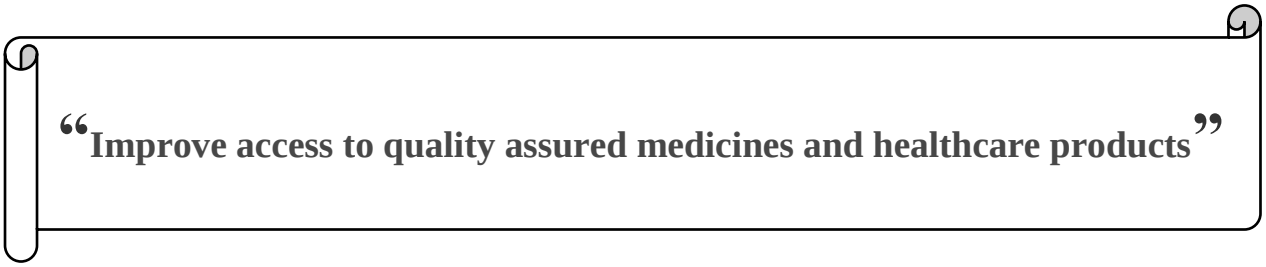
- National Medicines Quality Assurance Laboratory (NMQAL)
- Pharmaceutical Regulatory Division
- Inspectorate and Enforcement Division
- Finance Division
- Administration Division
- Legal Division

Accordingly, there are several committees to assist for the decision-making process. Those committees are responsible for evaluation of Medicines (MEC), Medical Devices (MDEC), Borderline Products (BPEC), Clinical Trials (SCOCT) and Pricing (Pricing Committee) for regulating the market price to ensure safety, quality & efficacy of all those medicinal items make them available at an affordable price for the public. In addition, there is an Appeal Committee open to the public and Advisory Committee to oversee the implementation of NMRA Act.

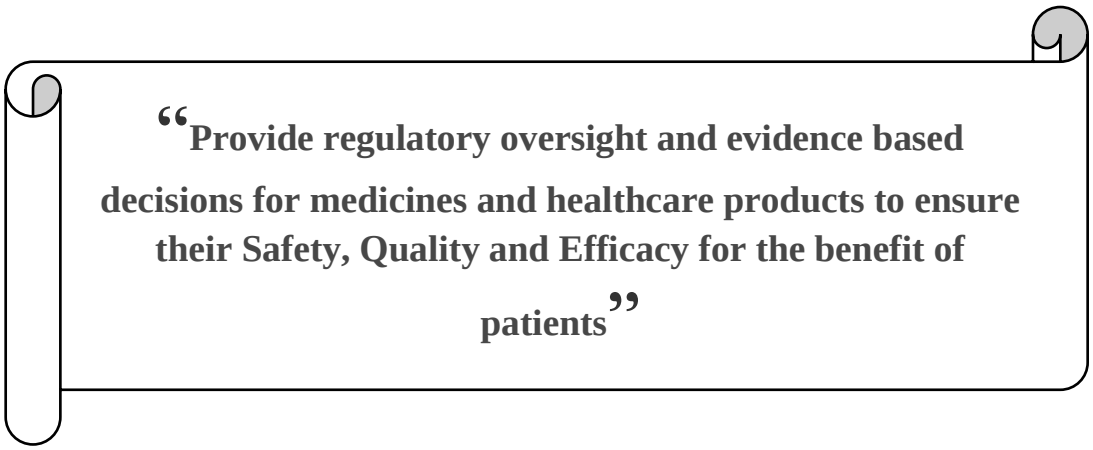
Further, NMRA act upon Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Good Pharmacy Practices (GPP) as legal requirements.

## 1.2 Vision, Mission, Objectives of the Organization

### 1.2.1 Vision of the Organization




### 1.2.2 Mission of the Organization



### 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 (Acting) | 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 | 6 | - |
| | Administrative Officer | 01 | - | 01 |

| | | | | |
|---|---|---|---|---|
| Tertiary Level | Costing Officers | 05 | - | 05 |
| Secondary Level | Pharmacists | 70 | 53 (temporary /secondment basis) | 70 |
| | Development Officers | 10 | 06 (temporary basis) | 10 |
| | Drug Inspector | 20 | 03 (secondment basis) | 20 |
| | Technical Officer (Civil) | 01 | 01 (temporary basis) | 01 |
| | ICT Assistant | 01 | 01 (Secondment) | - |
| | Management Assistant | 43 + (contract basis 10) | 10 (Secondment /temporary) | 43 |
| Primary | Driver | 10 | 01 (Permanent) 05 (temporary / Secondment basis) | 09 |
| | Plumber | 01 | - | 01 |
| | Electrician | 01 | - | 01 |
| | Lab Assistant | 08 | 04 (temporary / Secondment basis) | 08 |
| | Karyala Karya Sahayaka | 30 | 25 | 05 |
| | **Total** | **245** | **120** | **190** |

## 1.5 Divisions under the NMRA

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

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

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

#### 1.5.1.1 Introduction:

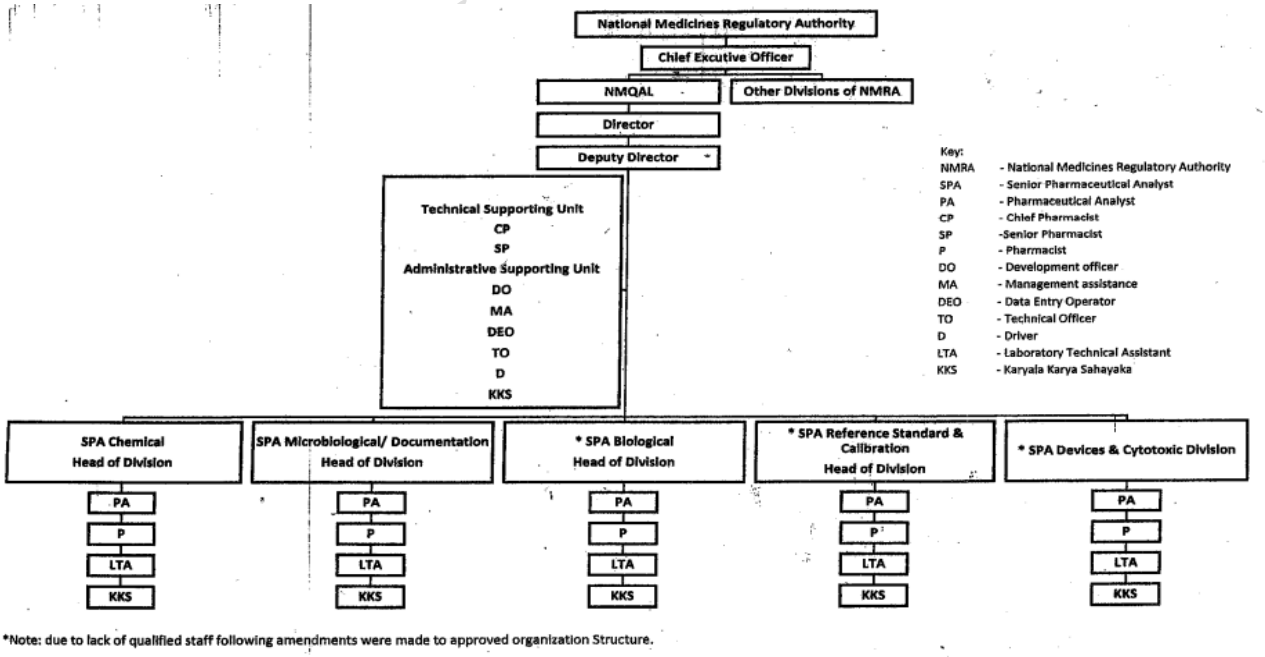
National Drug Quality Assurance Laboratory (NDQAL) was the National Laboratory established in Sri Lanka for testing Cosmetics Devices and Drugs. It was established in 1990 under Cosmetics Devices and Drug Act No.27 of 1980, with Norwegian consultancies and NORAD funds with the vision of ensuring Quality,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

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

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

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

#### 1.5.1.2 Divisional Chart of NMQAL




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

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

#### 1.5.1.3 Main functions of NMQAL

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,

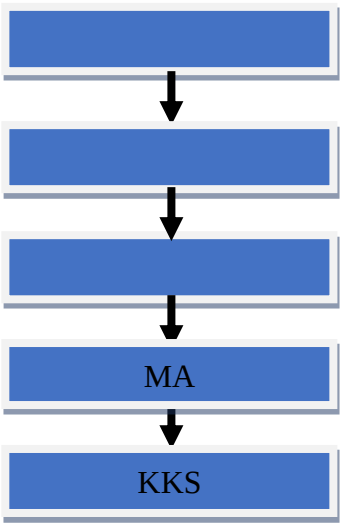
- Analysis of locally manufactured and imported Medicines, Medical Devices, Borderline products and Cosmetics at different points in the distribution chain. (Premarketing and Post marketing stages) Samples for analyses are submitted as registration samples, complaints samples, tender samples pre shipment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

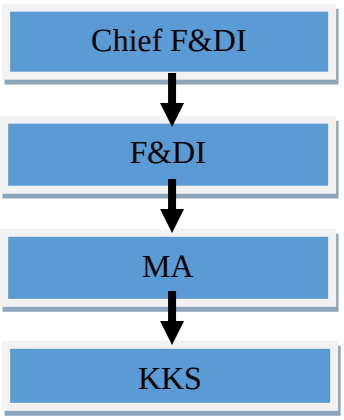
Inspectorate & Enforcement Division is a division established in the National Medicines Regulatory Authority under the NMRA Act No 05 of 2015.

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 (CFDI).

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

1.5.3.2 Divisional Chart of the Inspectorate and Enforcement Division




1.5.3.3 Functions of Inspection and Enforcement Division

1. Functioning as Authorized Officers under the NMRA Act
2. Conducting Post marketing surveillance
3. Obtaining formal and informal samples when necessary
4. Inspecting & recommending medicines handling establishments to issue licenses
5. Inspecting & recommending medicine transport vehicles to issue licenses
6. Ensuring the implementation of product recall procedure
7. Investigating & initiate legal actions on the detentions made by the SSFFC & smuggled products
8. Investigating the availability of state-owned drugs in the private market
9. Inspecting & recommending of dangerous drugs applications
10. Organizing & conducting educational programs
11. Conducting prosecutions against the violations committed under the Act
12. Coordinating & corporation with other law enforcement agencies

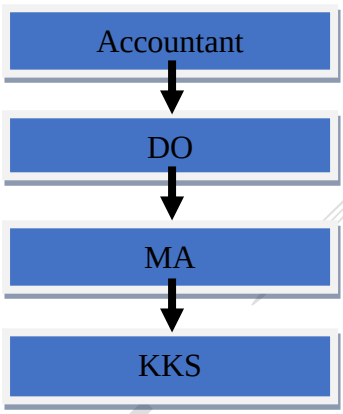
### 1.5.4 Finance Division

#### 1.5.4.1 Introduction

Finance Division of NMRA has commenced its activities from the 01.01.2016. As planed in the 2016, Accountant has recruited and functioned with the seven members including Accountant, three members from the Health Ministry, one trainee, one contract basis member and one KKS.

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

#### 1.5.4.2 Divisional Chart of the Accounts Division




#### 1.5.4.3 Functions of Finance Division

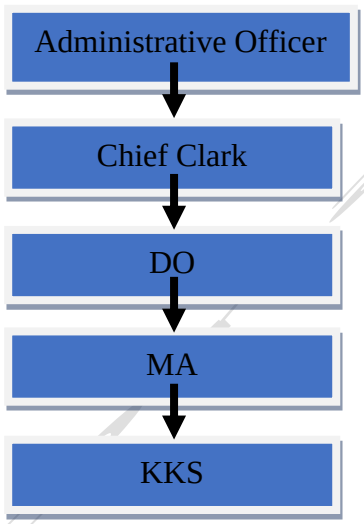
- Receiving all revenue through eighteen revenue streams.
- Preparing final accounts
- Preparing the budget for the coming year and obtaining the approval
- Maintaining all the supplies required to run the day-to-day activities of the authority
- All monetary controlling matters
- Procurement activities

### 1.5.5 Administration Division

#### 1.5.5.1 Introduction

The main function of the Administrative Division is issuing 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, attend building maintenance, repairing of electrical items, vehicle management, servicing and repairing of vehicles, 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 service 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.

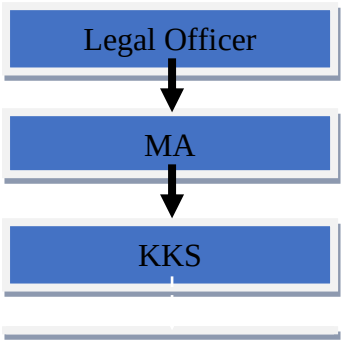
- Supervising the license and the registration certificates issuing process
- Personnel Management within the Authority
- Supervise all the activities related to maintenance of the office premises
- Maintaining utility services
- Making relevant reports in relation to the section
- Vehicle and transport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

1.5.6.1 Divisional Chart of the Legal Division




1.5.6.2 Main Functions of the Legal Division

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

# Chapter 2
# Progression and Vision

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

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

Received following laboratory equipment. 1) Karl Fischer titrator, 2) Analytical balance, 3) pH meter, 4) Thermostatic water bath, 5) Laboratory shaker, 6) Water distiller, 7) Sterilizing oven, 8) Vacuum pressure pump (02 Nos), 9) Magnetic stirrer hot plate (02 Nos), 10) Ultrasonic bath and 11) Ageing oven.
Advisory Committee was appointed by Chairman NMRA to;

a) Advice about development and improvements that can be made to the NMQAL to achieve its objectives.
b) Suggest solutions to the problems and issues that the NMQAL is presently facing.
c) Advice about improving quality of services, procurements, GLP and related matters
d) Advice the NMQAL about getting training, developing linkages about its future direction
e) Make recommendations to the NMRA about the functioning of the NMQAL.

Advisory committee submitted project concept paper for establishment of a new NMQAL for NMRA and proposed organization Chart and qualifications of key personnel of the new laboratory. These proposals submitted to the Authority Board.
NMQAL received 26 USP reference Standards (46 vials) worth us$ 15260 and USP NF 2017 printed edition free of charge from USP complementary standard program on request by Ms Deepika Bulathsinghala from USP officials while participating for WHO joint regional workshop on Surveillance & monitoring of SF medicinal Products in Indonesia in Oct 2016.

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.

2.1.1. Performance of the Division

During 2017 NMQAL analyzed about 496 samples and failures were detected in 158 samples/batches and recommendations on failures were given accordingly.

| Sample Type | Pass | Fail /WH /WD | Already WD | Not Done | Total |
|---|---|---|---|---|---|
| Complaint | 110 | 106 | - | 24 | 240 |
| Formal | 31 | 2 | - | 23 | 56 |
| Informal | 42 | 4 | - | 4 | 50 |
| Lab Request | 2 | 1 | - | - | 3 |
| Manu.Request | - | 3 | - | - | 3 |
| Registration | 114 | 32 | - | 5 | 151 |
| SPC Tender | 9 | 3 | - | - | 12 |

| | | | | | |
|---|---|---|---|---|---|
| Others | 25 | 7 | - | 2 | 34 |
| Surveillance | 5 | - | - | - | 5 |
| | **338** | **158** | **0** | **58** | **554** |

No. of certificate of Quality issued = 554-58

= 496

No. of failure report issued = 158

Percentage (%) of quality failure from the Report issued in 2017 = 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 (IED)

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 involved to achieve the objectives.
Identification of various types of violations and legal actions are initiated by this unit.
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).

## 2.4 Progress of Finance Division

After recruiting Accountant, Quick Book accounting software was introduced for smooth and efficient functioning of the day-to-day activities. Also, the fees table was introduced to calculate regulatory fees based on the values of the US Dollar.

Plans for the future

1) Accounts to be handled by the NMRA and make use of the revenue effectively to achieve organizational objectives
2) Recruiting the required staff

## 2.5 Progress of Administration Division

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

In addition, as the main function of the Administration Division the licenses and Registration Certificates are issued as follows (from July to December 2017);

| No | Certificate Type | 2017 |
|---|---|---|
| 1 | Medicine Registration | 1476 |
| 2 | Medicine Import | 3264 |
| 3 | Medicine Manufacture | 111 |
| 4 | Medicine Sample | 450 |
| 5 | Device Registration | 984 |
| 6 | Device Import | 1808 |
| 7 | Device Manufacture | 8 |
| 8 | Device Sample | 495 |
| 9 | Cosmetic Registration | - |
| 10 | Cosmetic Import | - |
| 11 | Cosmetic Manufacture | - |
| 12 | Cosmetic Sample | |
| 13 | Borderline Registration | |
| 14 | Borderline Import | - |
| 15 | Borderline Manufacture | - |
| 16 | Borderline Sample | - |
| | **TOTAL** | **8596** |

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, Legal Affairs and IT Affairs.

## 2.6 Progress of Legal Division

- Number of Total Files

| | |
|---|---|
| 233 | Opened |
| 69 | Closed |
| 164 | Pending |

- Agency Transfers

| | |
|---|---|
| Free of charges | 17 |
| Payment Basic | 22 |

- Agency Transfer Total Income

**(27.08.2017 – 31.12.2017)** **RS**: **8,394,178.00**

1. Performance of the division in 2017

The performance summary of Legal Division is undermentioned.

**Regulations/ Gazettes issued under the NMRA Act from 01.01.2017 to 31.12.2017.**

| No | Gazette No & Date | Contents | Remarks |
|---|---|---|---|
| 01 | 2006/45 - 17.02.2017 | Medical Device Pricing Regulation | 38 Intraocular Lenses |
| 02 | 2023/30 - 14.06.2017 | Fee for Registration and licensing of Medicines, medical Devices and Borderline products | |
| 03 | 2030/47 - 04.08.2017 | Medical Device Pricing Regulation | Stent |
| 04 | 2049/31 - 14.12.2017 | Amendment to the Ceiling on Pricing Regulation | 5% increase above 48 Medicinal Products |

**Pending Court Cases (up to 31.12.2017) - 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** |

**Pending Court Cases (up to 31.12.2017) – 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:එච්.සි)සිවිල්(425/2017/mn (B.J ඉන්ටනැෂනල් පුද් .සමාගම) | **Pending** | **Respondent** |

# Chapter - 3

## Overall Financial Performance


**National Medicines Regulatory Authority**

**Financial Statements for the year ended**

**31 December 2017**

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

| *As at 31 December,* | Note | 2017 Rs. | 2016 Rs. |
|---|---|---|---|
| **Assets** | | | |
| **Non current assets** | | | |
| Property, plant and equipment | 2 | 25,668,931 | 5,528,972 |
| **Total non current assets** | | **25,668,931** | **5,528,972** |
| | | | |
| **Current assets** | | | |
| Inventory | | 1,482,106 | 184,542 |
| Deposits and other receivable | 3 | 123,244 | 21,117,000 |
| Short term investments | | 100,653,965 | - |
| Cash and cash equivalents | 4 | 631,763,823 | 79,624,667 |
| **Total current assets** | | **734,023,138** | **100,926,209** |
| **Total assets** | | **759,692,069** | **106,455,181** |
| | | | |
| **Equity and liabilities** | | | |
| **Equity** | | | |
| Accumulated Fund | | 310,302,346 | 57,557,675 |
| **Total equity** | | **310,302,346** | **57,557,675** |
| | | | |
| **Non Current liabilities** | | | |
| Capital grant | 5 | 4,186,070 | 5,528,972 |
| Deferred tax | 6 | 1,845,328 | 266,519 |
| **Total non current liabilities** | | **6,031,398** | **5,795,491** |
| | | | |
| **Current liabilities** | | | |
| Advance receipts | 7 | 85,643,656 | 14,360,439 |
| Provision for Income tax | | 116,598,042 | 2,723,519 |
| VAT payable | | 105,462,594 | 16,198,667 |
| Stamp duty payable | | 36,111,233 | 7,076,700 |
| Provision for Treasury levy | | 28,882,370 | - |
| Accrued expenses and other payables | 8 | 70,660,430 | 2,742,690 |
| **Total current liabilities** | | **443,358,325** | **43,102,015** |
| **Total equity and liabilities** | | **759,692,069** | **106,455,181** |

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

R.A.Samarajeewa
Accountant

Accountant
National Medicines Regulatory Authority
120, Norris Canal Road,
Colombo 10

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

Prof.Asita De Silva
Chairman

Dr.Kamal Jayasinghe
Chief Executive Officer

22nd March 2019

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

Dr. Kamal Jayasinghe
MSc-Med.Admn, MBA,DIPM
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 | 2017 Rs. | 2016 Rs. |
|---|---|---|---|
| Revenue | 9 | 554,495,401 | 114,410,560 |
| Government grants | 10 | - | 49,796,981 |
| Intrest income | | 653,966 | - |
| Other income | | 5,010,037 | 1,039,116 |
| Administrative expenses | 11 | (60,759,242) | (25,497,060) |
| Salaries and wages | 12 | (95,610,919) | (78,394,260) |
| Other expenses | 13 | (855,116) | (1,198,671) |
| Amortization of capital grant | | 1,342,902 | 391,047 |
| **Net income before taxation** | | **404,277,030** | **60,547,713** |
| Income tax for the year | 14 | (115,453,332) | (2,990,038) |
| **Net income after taxation** | | **288,823,697** | **57,557,675** |

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 2016 | | - |
| Profit for the year | | 57,557,675 |
| **Balance as at 31 December 2016** | | **57,557,675** |
| Prior year correction | 15 | (7,196,656) |
| **Restated balance as at 31 December 2016** | | **50,361,019** |
| Profit for the year | | 288,823,697 |
| Provision for treasury levy | | (28,882,370) |
| **Balance as at 31 December 2017** | | **310,302,346** |

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

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

| *As at 31 December,* | 2017 Rs. | 2016 Rs. |
|---|---|---|
| Net income before taxation | 404,277,030 | 60,547,713 |
| Adjustment for : | | |
| Depreciation | 3,013,948 | 391,047 |
| Effect of prior year correction | 48,846 | - |
| Amortization of capital grant | (1,342,902) | (391,047) |
| Provision for treasury levy | (28,882,370) | - |
| Prior year correction | (7,196,656) | - |
| Operating profit before tax | 369,917,895 | 60,547,713 |
| | | |
| **Changes in items of working capital** | | |
| Inventory | (1,297,564) | (184,542) |
| Deposits and other receivable | 20,993,756 | (21,117,000) |
| Advance receipts | 71,283,217 | 14,360,439 |
| VAT payable | 89,263,927 | 16,198,667 |
| Stamp duty payable | 29,034,533 | 7,076,700 |
| Provision for treasury levy | 28,882,370 | - |
| Accrued expenses and other payables | 67,917,740 | 2,742,690 |
| **Cash generated from operations** | **675,995,874** | **79,624,667** |
| | | |
| **Cash flows from investing activities** | | |
| Acquisition of Property plant and equipment | (23,202,753) | (5,920,019) |
| Investment in short term deposits | (100,653,965) | - |
| **Net cash used in Investing activities** | **(123,856,718)** | **(5,920,019)** |
| | | |
| **Cash flows from financing activities** | | |
| Contribution from Treasury for capital assets | - | 5,920,019 |
| **Net cash used in financing activities** | **-** | **5,920,019** |
| | | |
| Net increase/ decrease in Cash & cash equivalents | 552,139,156 | 79,624,667 |
| Cash and cash equivalents at the beginning of the year | 79,624,667 | - |
| **Cash and cash equivalents at the beginning of the year** | **631,763,823** | **79,624,667** |

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

**NATIONAL MEDICINES REGULATORY AUTHORITY**
**NOTES TO THE FINANCIAL STATEMENTS**
*For the year ended 31 December 2017*

## 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

**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 2017***

**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 2017***

**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 2017***

**3.9 Revenue**

**3.9.1 Services**

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

**3.9.2 Interest income**

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

**3.10 Government Grants**

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

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

**3.11 Expenses**

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

**3.12 Foreign currency transaction**

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

**3.13 Tax expenses**

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

**3.13.1 Current tax**

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

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

**3.13.2 Deferred taxation**

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

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

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

**3.14 Statement of cash flows**

The statement of cash flows has been prepared using the "indirect method" in accordance with LKAS 7 "Statement of cash flows''.

Interest paid is classified as operating cash flows, interest received are classified as investing cash flows, while treasury levy paid are classified as financing cash flows for the purpose of presenting the cash flow statement.

**3.15 Commitment and contingencies**

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

**3.16 Related party transaction**

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

**3.17 Events after the reporting date**

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

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

**2 Property, plant and equipment**

| Cost | Filng store Rs. | Lab equipment Rs. | Furniture and fittings Rs. | Office equipment Rs. | Computer equipment Rs. | Computer Software Rs. | Total Rs. |
|---|---|---|---|---|---|---|---|
| Balance as at 1 January 2016 | - | - | - | - | - | - | - |
| Additions during the year | - | - | 716,784 | 2,025,270 | 3,177,965 | - | 5,920,019 |
| Balance as at 31 December 2016 | - | - | 716,784 | 2,025,270 | 3,177,965 | - | 5,920,019 |
| Prior year coreection | - | - | 152,326 | 78,921 | 9,213 | - | 240,460 |
| Restated balance as at 31 December 2016 | - | - | 869,110 | 2,104,191 | 3,187,178 | - | 6,160,479 |
| Restated Balance as at 01 January 2017 | - | - | 869,110 | 2,104,191 | 3,187,178 | - | 6,160,479 |
| Additions during the year | 15,257,976 | 6,247,840 | 240,258 | 384,104 | 848,175 | 224,400 | 23,202,753 |
| Balance as at 31 December 2017 | 15,257,976 | 6,247,840 | 1,109,368 | 2,488,295 | 4,035,353 | 224,400 | 29,363,232 |
| **Accumulated depreciation/ ammortization** | | | | | | | |
| Balance as at 1 January 2016 | - | - | - | - | - | - | - |
| Charge for the year | - | - | 31,449 | 154,693 | 204,905 | - | 391,047 |
| Balance as at 31 December 2016 | - | - | 31,449 | 154,693 | 204,905 | - | 391,047 |
| Prior year correction | - | - | 31,022 | 67,697 | 190,587 | - | 289,306 |
| Restated balance as at 31 December 2016 | - | - | 62,471 | 222,390 | 395,492 | - | 680,353 |
| Restated Balance as at 01 January 2017 | - | - | 62,471 | 222,390 | 395,492 | - | 680,353 |
| Charge for the year | 610,319 | 833,997 | 192,889 | 451,977 | 908,166 | 16,599 | 3,013,948 |
| Balance as at 31 December 2017 | 610,319 | 833,997 | 255,360 | 674,367 | 1,303,658 | 16,599 | 3,694,301 |
| **Carrying value** | | | | | | | |
| **As at 31 December 2017** | **14,647,657** | **5,413,843** | **854,008** | **1,813,928** | **2,731,695** | **207,801** | **25,668,931** |
| **As at 31 December 2016** | **-** | **-** | **685,335** | **1,870,577** | **2,973,060** | **-** | **5,528,972** |

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,* | | 2017<br>Rs. | 2016<br>Rs. |
|---|---|---|---|
| **3** | **Deposits and other receivable** | | |
| | Deposit for fuel | 50,000 | 50,000 |
| | Other receivables | 73,244 | - |
| | Receivable Grant | - | 21,067,000 |
| | **Total deposits and prepayments** | **123,244** | **21,117,000** |
| **4** | **Cash and cash equivalents** | | |
| | Cash and cash equivalents | 631,763,823 | 79,624,667 |
| | **Total cash and cash equivalents** | **631,763,823** | **79,624,667** |
| **5** | **Capital grant** | | |
| | Capital grant | 5,528,972 | 5,920,019 |
| | Amortization of capital grant | (1,342,902) | (391,047) |
| | **Total Capital grant** | **4,186,070** | **5,528,972** |
| **6** | **Deferred tax liability** | | |
| | Accounting written down value of Property plant and equipment | 25,668,931 | 5,528,972 |
| | Tax base of Property plant and equipment | 19,078,474 | 4,577,117 |
| | Taxable Temporary deference | 6,590,457 | 951,855 |
| | Tax @ 28% | 1,845,328 | 266,519 |
| | Deferred Liability at the end of the year | **1,845,328** | **266,519** |
| | Deferred Liability as at beginning of the year | 266,519 | - |
| | Charge as deferred tax during the year | **1,578,809** | **266,519** |
| **7** | **Advance receipts** | | |
| | Fees received in advance | 85,643,656 | 14,360,439 |
| | **Total advance receipts** | **85,643,656** | **14,360,439** |
| **8** | **Accrued expenses and other payables** | | |
| | Accrued expenses | 34,864,290 | 2,742,690 |
| | Other Payables | 33,492,309 | - |
| | Retention Deposit | 877,334 | - |
| | EPF Payble | 1,240,839 | - |
| | ETF Payble | 185,659 | - |
| | **Total Accrued expenses** | **70,660,430** | **2,742,690** |

| *For the period ended 31 December,* | | 2016<br>Rs. | 2016<br>Rs. |
|---|---|---|---|
| **9** | **Revenue** | | |
| | Drug sample license income | 9,504,018 | 2,342,000 |
| | Device sample license income | 9,856,683 | 2,154,000 |
| | Drug import license income | 40,249,464 | 11,456,000 |
| | Device import license income | 34,603,084 | 12,624,000 |
| | Cosmetic import license income | 174,000 | - |
| | Drug manufacturing license income | 1,835,960 | 280,000 |
| | Device manufacturing license income | 89,541 | 13,000 |
| | **Total cont.** | **96,312,750** | **28,869,000** |

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

| | *For the period ended 31 December,* | 2017 Rs. | 2016 Rs. |
|---|---|---|---|
| 0 | **Revenue (Cont.)** | **96,312,750** | **28,869,000** |
| | Drug registration income | 81,014,008 | 35,430,100 |
| | Device registration income | 58,340,687 | 8,042,100 |
| | Cosmetic registration income | 282,000 | - |
| | Fees for labotary test | 4,879,463 | 430,000 |
| | Drug processing fees | 105,320,830 | 19,871,000 |
| | Device processing fees | 54,552,305 | 1,636,000 |
| | Cosmetic processing fees | 67,500 | - |
| | Borderline processing fees | 4,345,455 | - |
| | Clinical Trial processing fees | 970,440 | - |
| | Advertising fees | 840,750 | 50,000 |
| | Retail pharmacy license income | 24,969,858 | 12,897,360 |
| | Wholesale pharmacy license income | 12,517,515 | 3,937,900 |
| | Transport pharmacy license income | 9,871,387 | 3,247,100 |
| | Waiver of registration income | 2,775,717 | |
| | Inspection of Good Manufacturing Practices - Local | 356,906 | - |
| | Inspection of Good Manufacturing Practices - Foreign | 19,362,586 | - |
| | WHO Good Manufacturing Practices certificate | 93,174 | - |
| | COPP Certificate | 69,966 | - |
| | Submission of additional documents | 70,182,326 | - |
| | Fees from agency transfer | 7,299,840 | 0 |
| | Fees for free sale certificates | 69,938 | 0 |
| | | **554,495,401** | **114,410,560** |
| 10 | **Grants** | | |
| | Recurrent grants | - | 49,796,981 |
| | | **-** | **49,796,981** |
| 11 | **Administrative expenses** | | |
| | Depreciation | 3,013,948 | 391,047 |
| | Water | 395,075 | 358,474 |
| | Eletricity | 8,414,052 | 9,312,335 |
| | Telephone | 762,958 | 610,703 |
| | Postage | 130,001 | 23,750 |
| | Stationery | 1,390,922 | 180,782 |
| | Travelling - Local | 22,511 | 96,122 |
| | Travelling - Foreign | 5,197,342 | 198,690 |
| | Training and development expenses | 2,945,566 | 1,628,505 |
| | Labortary expenses | 1,238,256 | - |
| | Fuel expense | 604,745 | 455,818 |
| | Security charges | 2,886,487 | 3,496,015 |
| | Document handling charges | 410,109 | 385,000 |
| | Publication and advertisement charges | 906,607 | 618,225 |
| | Janitorial service | 4,222,837 | 4,539,462 |
| | Vehicle maintenance | 1,255,061 | 977,379 |
| | Maintenance of Labortary equipment | 3,579,161 | 314,650 |
| | Maintenance of fire extinguisher | 49,037 | 42,831 |
| | Maintenance of Air-conditioning | 1,521,271 | 255,258 |
| | **Total cont.** | **38,945,944** | **23,885,046** |

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

*For the year ended 31 December,*

| | | | 2017 | 2016 |
|---|---|---|---|---|
| | | | Rs. | Rs. |
| **11** | **Administrative expenses** | | **38,945,944** | **23,885,046** |
| | Maintenance of building | | 724,468 | 488,573 |
| | Maintenance of computer items and other | | 778,402 | - |
| | Expenses for Good Manufacturing Practice visits | | 18,127,163 | 1,045,040 |
| | Recervation of conference hall | | 129,500 | - |
| | Drating corporate plan | | 582,735 | - |
| | Maintenance of website | | 79,000 | - |
| | Expenses for drafting regulations | | 23,840 | - |
| | Courier service | | 8,610 | - |
| | Rates and taxes | | 78,401 | 78,401 |
| | Audit fee | | 1,281,178 | - |
| | **Total** | | **60,759,242** | **25,497,060** |
| **12** | **Salaries and wages** | | | |
| | Salaries and wages | | 65,291,547 | 73,143,068 |
| | Other allowances | | 6,131,029 | 1,504,701 |
| | Overtime payment | | 6,378,649 | 3,589,378 |
| | Secondment allowance | | 8,387,083 | |
| | Contribution for pension | | 8,387,083 | 157,113 |
| | Contribution for Employee Provident Fund | | 856,729 | - |
| | Contribution for Employee Trust Fund | | 178,798 | - |
| | **Total** | | **95,610,919** | **78,394,260** |
| **13** | **Other expenses** | | | |
| | Other repair and maintenance | | 659,905 | 879,648 |
| | Refreshment and other expenses | | 195,213 | 255,402 |
| | Unreconciled expense | | - | 63,621 |
| | **Total** | | **855,117** | **1,198,671** |
| **14** | **Income tax for the year** | | | |
| **14.1** | Income tax expense for the year | | 113,874,523 | 2,723,519 |
| | Deferred tax expense for the year | | 1,578,809 | 266,519 |
| | **Tax expense for the year** | | **115,453,332** | **2,990,038** |
| **14.1** | Net income before taxation | | 404,277,029 | 60,547,713 |
| | Add : Disallowable expense | | 3,209,160 | 710,070 |
| | Less : Allowable expense | | (8,941,856) | (1,342,902) |
| | Less : Income not subject to income tax | | (1,342,902) | (50,188,028) |
| | Adjusted profit for the year | | 397,201,431 | 9,726,853 |
| | Other profit and income liable to tax | | - | - |
| | Total statutory income/ Taxable income | | 397,201,431 | 9,726,853 |
| | Income tax for the year | at 28% | 111,216,401 | 2,723,519 |
| | Tax Credits: | | | |
| | Notional Tax | | (65,397) | - |
| | Income tax expense for the year | | 111,151,004 | 2,723,519 |
| | **Total tax payable as at the year end** | | **113,874,523** | **2,723,519** |

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

**15 Prior year adjustment**

Prior year adjustment was made to ractify the following matters;

| | |
|---|---|
| Accruel of income | |
| Unrecognized donated assets | 289,306 |
| Depriciation of Unrecognized donated assets | 240,460 |
| Accrued of income and expenditure | 5,862,512 |
| Provision for Audit fees 2016 | 1,285,298 |
| Total Adjusted Amount | **7,196,656** |

**16 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 .

| | 2017 Rs. | 2016 Rs. |
|---|---|---|
| Short term employee benefits | 2,031,382 | 2,028,633 |
| | **2,031,382** | **2,028,633** |

**17 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.

**18 Contingent Liabilities**

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

**19 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. Futher, eighteen cases were filed by the Authority against violation of provisions in the Act. Furthermore Sixty cases are pending before the court which were field by the Food & Drug inspectors in island wide due to violation of provisions the National Medicines Regulatory Authority Act as of 22nd March 2018.

**20 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 22nd March 2019.

C-136

# ජාතික විගණන කාර්යාලය
## தேசிய கணக்காய்வு அலுவலகம்
## NATIONAL AUDIT OFFICE

මගේ අංකය / எனது இல. / My No. } එච්එස්එම්/ඒ/එන්එම්ආර්ඒ/1/17/74 මබේ අංකය / உமது இல. / Your No. }

දිනය / திகதி / Date } 2018 නොවැම්බර් 29 දින

Acct

CGO Accounts / NMRA

Fyi, Observations & NA.

30-12-18

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ජාතික ඖෂධ නියාමන අධිකාරිය.

**ජාතික ඖෂධ නියාමන අධිකාරියේ 2017 දෙසැම්බර් 31 දිනෙන් අවසන් වර්ෂය සඳහා වූ ගණුදෙනු පිළිබඳ විගණකාධිපති වාර්තාව**

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මාගේ සමාංක හා 2018 ඔක්තෝබර් 15 දිනැති ලිපියට යොමුවේ.

02. ඉහත සඳහන් ලිපිය සමඟ එවන ලද මාගේ වාර්තාවේ ඉංග්‍රීසි අනුවාදය මේ සමඟ එවා ඇත.

ඊ.ඒ.ජී. ආනන්ද

නියෝජ්‍ය විගණකාධිපති

විගණකාධිපති වෙනුවට.

පිටපත් : 1. ලේකම් - සෞඛ්‍ය, පෝෂණ හා දේශීය වෛද්‍ය අමාත්‍යාංශය

2. ලේකම් - මුදල් හා ආර්ථික කටයුතු අමාත්‍යාංශය

අංක 306/72, පොල්දූව පාර, බත්තරමුල්ල, ශ්‍රී ලංකාව. இல. 306/72, பொல்துவ வீதி, பத்தரமுல்லை, இலங்கை. No. 306/72, Polduwa Road, Battaramulla, Sri Lanka.
+94 11 2 88 70 28 - 34 +94 11 2 88 72 23 ag@auditorgeneral.gov.lk www.auditorgeneral.gov.lk

ජාතික විගණන කාර්යාලය
தேசிய கணக்காய்வு அலுவலகம்
NATIONAL AUDIT OFFICE

මගේ අංකය / எனது இல. / My No. HSM/A/NMRA/1/17/74 ඔබේ අංකය / உமது இல. / Your No. දිනය / திகதி / Date 15 October 2018

The Chairman
National Medicines Regulatory Authority

**Report of the Auditor General on the Transactions of the National Medicines Regulatory Authority for the year ended 31 December 2017**

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The operations the National Medicines Regulatory Authority for the year ended 31 December 2017 was carried out under my direction in pursuance of provisions in Article 154(1) of the Constitution of the Democratic Socialist Republic of Sri Lanka read in conjunction with Section 13(1) of the Finance Act, No.38 of 1971 and Section 20 of the National Medicines Regulatory Authority Act, No.05 of 2015. The financial statements for the year 2017 to be present in terms of Section 13 (6) of the Finance Act, had not been presented even by the date of this report. My observations on the performance of the Authority which I consider should be presented in Parliament in terms of Article 154 (6) of the Constitution of the Democratic Socialist Republic of Sri Lanka appear in this report.

**1.2 Management's Responsibility for the Financial Statements**

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Management is responsible for the preparation and fair presentation of these financial statements in accordance with Sri Lanka Accounting Standards and for such internal control as the management determines is necessary to enable the preparation of financial statements that are free from material misstatements, whether due to fraud or error.

අංක 306/72, පොල්දූව පාර, බත්තරමුල්ල, ශ්‍රී ලංකාව. இல. 306/72, பொல்துவ வீதி, பத்தரமுல்லை, இலங்கை. No. 306/72, Polduwa Road, Battaramulla, Sri Lanka.
+94 11 2 88 70 28 - 34 +94 11 2 88 72 23 ag@auditorgeneral.gov.lk www.auditorgeneral.gov.lk

## 2. Financial Statements

### 2.1 Presentation of Financial Statements

In terms of Section 6.5.1 of the Public Enterprises Circular No.PED/12 dated 02 June 2003 and Treasury Circular No.01/2004 dated 24 February 2004, the financial statements of the statutory boards should be furnished to the Auditor General within 60 days from the close of the year of account. Nevertheless, the financial statements for the year 2017 had not been furnished to Audit even by the date of this report.

### 2.2 Existence of the Assets and Liabilities

Particulars on the assets, liabilities, equity, income and expenditure stated in the financial statements prepared last by the Authority as at 31 December 2016 are given below.

| Item | Value |
|---|---|
| | Rs. |
| Non-current Assets | 5,528,972 |
| Current Assets | 100,926,209 |
| Total Assets | 106,455,181 |
| Current Liabilities | 43,102,015 |
| Non-current Liabilities | 5,795,491 |
| Total Liabilities | 48,897,506 |
| Net Assets/ Liabilities | 57,557,675 |
| | 106,455,181 |
| Total Income | 165,246,657 |
| Total Expenditure | 104,698,944 |

| | |
|---|---|
| Surplus Before Tax | 60,547,713 |
| Income Tax | 2,990,038 |
| Surplus After Tax | 57,557,675 |

**2.3 Lack of Evidence for Audit**

As the information such as medicines, medical equipment and the number of applications received for the registration of borderline productions during the year under review, the date of receipt, the number of applications registered and the date of registration had not been furnished to Audit with an adequate time to examine them, it could not be express an opinion on the performance of the registration of medicines, medical equipment and borderline productions.

**2.4 Non- compliance with Laws, Rules, Regulations and Management Decisions**

Instances of non- compliance with laws, rules, regulations and management decisions appear below.

| | Reference to Laws, Rules, Regulations and Management Decisions | Non-compliance |
|---|---|---|
| (a) | Section 105 of the National Medicines Regulatory Authority Act, No.05 of 2015 | Although the Authority may grant permanent or temporary registration on borderline productions and the conditions for the registration should be imposed, such conditions had not been imposed even by 23 August 2018, the date of audit. |

| | | |
|---|---|---|
| (b) | Valued Added (Amendment) Tax Act, No.06 of 2005 | A tax applicable to any taxable period should be paid to the Director General of Inland Revenue on a date not later than the 20th day of the following month from the close of the taxable period. Nevertheless, the Authority had not paid the Value Added Tax relevant to the year 2017 even by 21 September 2018. |
| (c) | Stamp Duty (Special Provision) Act, No.12 of 2006. | Although the Stamp Duty should be remitted to the Commissioner General of Inland Revenue within fifteen days from the close of each quarter every year, the Authority had not remitted the Stamp Duty relevant to the year 2017 even by 21 September 2018. |
| (d) | Financial Regulations of the Democratic Socialist Republic of Sri Lanka | |
| | --- | |
| | (i) Financial Regulation 395(c) | Although a bank reconciliation statements on the position of transactions available in bank accounts by the end of each month should be prepared before 15th of the following month, bank reconciliation statements pertaining to September 2017 had not been prepared even by 23 August 2018. Accordingly, a delay for a period of 11 months could be observed for the preparation of bank reconciliation statements. |

| | | |
|---|---|---|
| | (ii) Financial Regulation 454 | Goods Receiving Notes had not been issued for 8 tyres purchased for two vehicles during the year under review and it had not been entered in an inventory. |
| | (iii) Financial Regulation 757-(2) | Board of Survey reports on the stores relating to the year under review had not been furnished to the Audit even by 21 September 2018. |
| (e) | Public Administration Circular No.09/2009 dated 16 April 2009. | Although the fingerprint machines should be used without being considered the number of employees of a service station, action had not been taken to repair the inoperative fingerprint machine even by 21 September 2018. |
| (f) | Treasury Circular No.IAI/2002/02 dated 28 November 2002. | A Register of Fixed Assets had not been maintained on computers, accessories and software. |

## 3. Operating Review

### 3.1 Performance

#### 3.1.1 Operations and Review

Even though an Action Plan had been prepared for the year under review, progress reports had not been prepared and as such, progress of the Authority could not be reviewed properly.

### 3.2 Management Activities

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The following observations are made.

(a) The Appeal Committee which should be established in terms of Section 123 of Paragraph No.07 of the National Medicines Regulatory Authority Act, No.05 of 2015 in order to consider appeals made by any person aggrieved by an decision taken by the Authority had not been established even by 21 September 2018.

(b) In terms of Sections 38 (2) (a) and (b) of the Act, the National Medicine Quality Assurance Laboratory operated under the Ministry of Health, Nutrition and Indigenous Medicine should be taken over by the Authority with effect from 01 July 2015. Nevertheless, that laboratory had not been taken over by the Authority even by 21 September 2018, the date of audit.

(c) The following observations are made on the issue of Waiver of Registration Letters.

(i) In terms of Section 58 of Part IV of Chapter III and Section 82 of Part IV of Chapter IV of the National Medicines Regulatory Authority Act, No.05 of 2015, no person shall manufacture or import any medicine without registering such medicine with the Authority and obtaining a licence from the Authority therefor. In terms of Section 59 and 83 of the above Act, the Authority shall issue registration certificates and lincences upon the evaluation of medicines and medical devices by considering the need to ensure the availability of efficacious, safe and good quality thereof. Nevertheless, contrary to the above provisions, 655 Waiver of Registration Letters had been issued during the year 2017 while another 256 of such letters had been issued from January to 10 July 2018 to the State Pharmaceutical Corporation, Medical Supply Division and other Public and private institutions. The importers had used those Waiver of Registration Letters in order to clear the medicines and medical devices not registered and not permitted under the Act, from the Sri Lanka Customs.

(ii) Due to issue of Waiver of Registration Letters, it was unavoidable to import the medical supplies devoid of quality assurance to the country. Further, those letters had been issued free of charge from January 2017 to 14 June 2017 and it had resulted in decrease in the registration and licence charges income of the Authority during that period. Although a condition had been imposed by the Extra Ordinary Gazette dated 14 June 2017 to the effect that a charge of US$ 100 should be recovered in the issue of those letters, information on the charges recovered had not been furnished to Audit even by 21 September 2018, the date of audit.

(iii) In terms of Section 109 of Part I of Chapter VI of the National Medicines Regulatory Authority Act No.05 of 2015, the Authority may grant permission in special circumstances such as to save a life, to control an outbreak of an infection or an epidemic or any other national emergency or for national security to import and supply a particular medicine, medical device or borderline product in specified quantities. Nevertheless, due to the reasons such as invalidation of the registration of the relevant medicine or the medical device, absence of registered suppliers and not presenting bids by the registered suppliers which were not coming under the special circumstances, 163 Waiver of Registration Letters had been issued to the Medical Supply Division and the State Pharmaceutical Corporation during the year under review. It was observed that issuing of Waiver of Registration Letters on the above grounds give rise to recede the interest of the suppliers to obtain registrations for medicines, medical devices and borderline products.

(iv) Waiver of Registration Letters had been issued again and again for 03 items of medicine in 06 instances during the year under review and there were such 06 instances during the period up to 10 July 2018.

(v) The contractor to whom the contract for the purchase of 25,200 units of the Efavirenz tablets 600 mg medicine costing Rs.483,371 and 12,600 units of such medicine costing Rs.249,831 was awarded by the State Pharmaceutical Corporation had not registered with the Authority and as such, the Authority had issued 02 Waiver of Registration Letters on 09 January 2017 and 18 September 2017. Nevertheless, notwithstanding the supplier who had obtained registration for the above medicine for a period of 05 years from 24 September 2016, the 02 Waiver of Registration Letters had been issued indicating the reason that there are no registered sources for this product.

**3.3 Operating Activities**

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The following observations are made.

(a) The matters observed at the examination conducted on the issue of registration certificates of the National Medicine Regulatory Authority for the medicines are specified below.

(i) In terms of Section 59 (2) of the National Medicines Regulatory Authority Act No.05 of 2015, any person who desires to manufacture or import any medicine shall submit the samples of the medicine along with the application made for the registration of such medicine, whereas samples had not been submitted relating to 62 applications of 599 applications received for the registration of new medicines during the year under review. Nevertheless, registration certificates for 35 of the above 62 applications had been issued without being conducted sample tests. Further, particulars on the issue of registration certificates for the remaining 27 applications had not been furnished to Audit.

(ii) Since the Dossier Number had not been included in the data file of the Laboratory Division in relation to the samples subjected to the test, a proper analysis could not be carried out on the progress of the sample tests. As 537 samples had been received for testing and only 85

samples had been tested by the Laboratory during the year under review, it was observed that the progress of testing samples had stood only at 16 per cent.

(iii) In terms of Section 59 (4) (b) of the National Medicines Regulatory Authority Act No.05 of 2015, the Authority shall, upon the receipt of an application, submit that application together with the sample of the medicine and all particulars, available to the National Medicine Quality Assurance Laboratory (NMQAL), for testing of the quality of the medicine. Nevertheless, there observed 14 instances where a temporary registration had been issued for the medicines prior to issuing results by that Laboratory upon carrying out sample tests.

(iv) In terms of Section 60(1) (b) of the National Medicines Regulatory Authority Act No.05 of 2015, the Authority may upon taking into consideration the reports submitted by the Medicine Evaluation Committee (MEC) and National Medicine Quality Assurance Laboratory (NMQAL) and all other relevant factors, register such medicine within the stipulated time period. Nevertheless, it was established in the examination of 47 applications that the totally different time periods had been taken for the issue of registration certificates in respect of applications forwarded for the registration of the same medicine.

(b) The following observations are made according to the examination carried out on the registration of business names and issuance of pharmacy licences within the area of authority of 05 Divisional Secretariats- Colombo, Thimbirigasyaya, Nugegoda,Rathmalana and Dehiwala-Mount Livenia during the period from 01 January 2017 to 31 July 2018.

(i) According to the Business Names Registration Record, although 21 pharmacies had been registered within the above 05 Divisions during the above period, it was observed in the examination of data file furnished by the Authority to Audit that pharmacy licence for 17 of the

above pharmacies had not been obtained from the National Medicines Regulatory Authority even by 31 August 2018, the date of audit. Further, in the issue of pharmacy licences, the Authority had not maintained a formal data file for including all information from the receipt of application up to the issue of licence.

(ii) In terms of Section 119(7) of the National Medicines Regulatory Authority Act No.05 of 2015, formulation and prescription of regulations by the Minister, pertaining to the terms and conditions of a licence and the conditions to be satisfied to register a Pharmacy had not been carried out even by 21 September 2018.

(iii) In the examination of files relating to 49 pharmacies in Colombo district, there observed 40 pharmacies for which action had not been taken to renew the licences relating to the year 2017 and the Authority had not establish a methodology to look into the reasons behind the above matter and prevent further maintenance of business activities if such business are carried on without obtaining licences.

(iv) In the examination of registers pertaining to the issue of licences during the period from December 2017 up to 31 August 2018, the date of audit, it was observed that the licences were not issued according to the serial numbers and the weaknesses found in the process from the handing over of the relevant payment receipt by the applicant to the Authority up to the issue of licence had given rise to the above situation.

### 3.4 Staff Administration

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The following observations are made.

(a) The approved cadre of the Authority as at the end of the year under review stood at 232 while the actual cadre was 122. Accordingly, the number of vacancies was 111 and excess was 01. Ninety officers of the Ministry of Health, Nutrition and Indigenous Medicine had been

employed in the Authority and the relevant approval had not been obtained in accordance with Section 17 of the National Medicines Regulatory Authority Act, No.5 of 2015 for the employment of 34 officers out of the above officers. Further, three retired officers had been recruited for a non-executive post included in the approved cadre and one officer had been recruited on contract basis to the post of Stenographer which had not been included in the approved cadre. Although a period of 03 years had elapsed from the establishment of the Authority by 21 September 2018, Authority had failed to fill the posts on permanent basis.

(b) As 8 officers comprising 06 Development Officers and two Laboratory Assistants of the Ministry of Health, Nutrition and Indigenous Medicine employed in the Authority as at 31 December 2017 had been released to the Ministry of Health, Nutrition and Indigenous Medicine upon termination of the period of employment in the Authority, those posts further remained vacant by 10 August 2018, the date of audit. Moreover, for the purpose of recruiting 10 officers to the post of Development Officer and one officer to the post of Information and Communication Technical Assistant, a newspaper advertisement had been published on 06 August 2017. Nevertheless, it had been failed to recruit relevant officers by conducting a written competitive examination and/ or through an interview board in terms of Paragraph 5.4 of the Scheme of Recruitment even by 21 September 2018, the date of audit.

(c) The officer who had been selected for the post of Director (Human Resources) by calling for applications through a newspaper advertisement published on 12 June 2016 had refused the acceptance of the said post on 24 November 2016, whereas action had not been taken to recruit a new officer on permanent basis even by 21 September 2018 and an officer had been recruited on acting basis instead.

(d) For the purpose of recruiting one officer to the post of Administrative Officer and 41 officers to the post of Management Assistant, newspaper advertisements had been published on 12 June 2016 and 22 November 2016 respectively. Nevertheless, relevant recruitments had not been made even by 21 September 2018 and 19 officers had been recruited to the post of Management Assistant on contract basis.

(e) It had been failed either to prepare a scheme of recruitment or revise the approved cadre relating to 06 posts –Assistant Director/Deputy Director, Internal Auditor, Drugs Analyst, Expenditure Officer, Pharmacologist and the Pharmacist included in the approved cadre of the Authority even by 21 September 2018.

(f) Duty lists had not been properly given to 97 officers employed in the Authority as at 31 December 2017.

### 3.5 Procurement and Contract Process

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The following observations are made.

(a) A Procurement Timetable in accordance with the Guideline 4.2.2 (b) of the Government Procurement Guidelines had not been prepared relating to the Procurement Plan prepared for the year under review.

(b) The Authority had purchased 6 items totaled Rs.1,351,167 under the shopping method during the year under review. Nevertheless, a suitable specimen in the standard bids calling documents had not been used as required by Guideline 5.3.1 of the Government Procurement Guidelines.

(c) Although an air-conditioner costing Rs.182,850 had been procured and installed in the above procurement, conditions on maintenance and services had not been included in the bid documents in calling for bids and as such, the Authority had to get the maintenance and services done under whatever the rate prescribed by the relevant company. Further, the air-conditioner purchased had not been entered in the inventory even by 14 July 2018.

(d) In the above procurement, a formal agreement had not been entered into according to Guideline 8.9.1(b) of the Government Procurement Guidelines in connection with the purchase of 05 Laptops costing Rs.670,000.

(e) A total cost estimate had not been prepared for the procurement of planning, procuring and establishing a record room with movable shelves costing Rs.13,972,626 by following national competitive bids calling method and due to the deficiencies occurred in the preparation of specifications, instead of curved staircase constructed at a cost of Rs.325,000 another staircase had to be constructed again at a cost of Rs.275,000, thus resulting in an uneconomic expenditure of Rs.325,000.

## 4. Sustainable Development Goals

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### 4.1 Achievement of Sustainable Development Goals.

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Every institution shall take steps in compliance with the Agenda 2030 of the United Nations Sustainable Development Goals. Nevertheless, it was not established as to whether the Authority had been aware of the manner in which it should take steps in connection with the functions coming under purview of the Authority.

## 5. Systems and Controls

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Deficiencies observed in systems and controls during the course of the audit were brought to the notice of the Chairman of the Authority from time to time. Special attention is needed in respect of the following areas of systems and controls.

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தேசிய கணக்காய்வு அலுவலகம்
NATIONAL AUDIT OFFICE
NAOSL

| | Area of control | Observation |
|---|---|---|
| (a) | Revenue Accounting | Failure in classifying and accounting the revenue |
| (b) | Issuance of Waiver of Registration Letters | Not taking action to maintain the issue of Waiver of Registration Letters at minimum level. |
| (c) | Recruitment of the Staff | Failure to attach the staff in terms of the Act. |
| (d) | Fixed Assets Control | Failure to take over the assets from the Ministry. |
| (e) | Issuance of Pharmacy Licences | Not taking action to maintain a formal data system. |
| (f) | Financial Control | Not properly preparing the bank reconciliation statements and existence of delays in their preparation. |
| (g) | Procurement | Failure in appointing the bid opening committees and not recording the details on opening bids in a prescribed form. |

Sgd./ H.M. GAMINI WIJESINGHE
Auditor General

H.M.Gamini Wijesinghe

Auditor General

**National Medicine Regulatory Authority – 2017**

The audit of financial statements of the National Medicine Regulatory Authority for the year ended 31 December 2017 comprising the statement of Financial Position as at 31 December 2017 and the statement of Comprehensive Income, statement of changes in equity and statement of cash flows for the year then ended and notes to the financial statements and 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 Section 13 (1) of the Finance Act, No 38 of 1971 and Section 20 of the National Medicine Regulatory Authority Act No. 5 of 2015. My comments and observations, which I consider should be published with the Annual Report of the Authority in terms of Section 14 (2) (c) of the Finance Act appear in this report and the transaction report submitted to the Chairman of the Authority on 15 October 2018.

**1.2 Management Responsibility for the Financial Statements**

Management is responsible for the preparation fair presentation of these financial statements in accordance with Sri Lanka Accounting Standards and for such internal control as the management determines is necessary to enable the preparation of financial statements that are free from material misstatements, whether due to fraud or error.

**1.3 Auditor's Responsibilities for the Audit of the Financial Statements**

My responsibility is to express an opinion on these financial statements based on my audit. I conducted my audit in accordance with Sri Lanka Auditing Standard consistent with International Auditing Standards of Supreme Audit Institutions (ISSAI 1000-1810).

**1.4 Basis for Qualified Opinion**

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

**2. Financial statements**

**2.1 Qualified Opinion**

In my Opinion , except for the matters described in paragraph 2.2 of this report, the financial statements give true and fair view of the financial position of National Medicine Regulatory Authority as at 31 December 2017 and its financial performance and cash flows for the year then ended in accordance with Sri Lanka Accounting Standards.

**2.2 Comments on the Financial statements**

**2.2.1 Sri Lanka Accounting Standard**

The following observations are made

(a) Sri Lanka Accounting Standard 1

(i) According to the paragraph 113 of the standard, notes had not been presented for the items i.e. Inventory, short term investments, provision for income tax, Payable value added tax, payable stamp duty, provisions for Treasury remittance included in the financial position statements and interest income and other income included in the statement of Comprehensive income.

(ii) According to the paragraph 117 of the standard, even though significant accounting policies which need to understand the financial statements should be disclosed, related party transactions had not been disclosed by the Authority.

(b) Sri Lanka Accounting Standard 20

According to the paragraph 31 of the standard, it had not been disclosed that Government Grant for recurrent expenditure not being received during the year under review compared with the previous year.

**2.2.2 Accounting Deficiencies**

The following observations are made

(a) Laboratory testing charges amounting to Rs.2,913,051 and license fees amounting to Rs.217,672 relating to previous years which had been received during the year under review had been taken into accounts considering as revenue for the year under review.

(b) Revenue from registration of drugs and revenue of medical equipment processing fees relating to the year under review had been understated by Rs.3,078,000 and Rs.489,846 respectively in the accounts.

(c) Income tax for the year under review and the liability of tax as at 31 December 2017 had been overstated by Rs.2,723,519.

(d) Although the value of Value Added Tax paid in the year 2018 relating to the year under review and the previous year was Rs.106,949,434, the payable value of Value Added Tax as at 31 December 2017 had been taken into accounts as Rs.105,462,594.

(e) Although the stamp fees paid in the year 2018 relating to the year under review and the previous year was Rs.31,201,280, the payable stamp fees as at 31 December 2017 had been taken into accounts as Rs.36,111,233.

**2.2.3 Unreconciled Control Accounts**

There were differences of Rs.310,800 and Rs.46,473 between the value of the financial statements and the schedules relating to the income of medical equipment importation charges and income of testing charges of good manufacturing practice (local) respectively.

**2.2.4 Lack of Evidence for Audit**

Schedules and age analysis had not been presented to audit relating to advance received amounting to Rs.85,643,656 as per the financial statements for the year under review. Hence the said value could not be affirmed.

**2.2.5 Assets not being Accounted**

Assets belonged to the National Drug Quality Assurance laboratory which was implemented under the Ministry had not been taken into accounts even as at 31 May 2019.

**3. Financial Review**

**3.1 Financial Result**

According to the financial statements presented, operations of the year under review had resulted a profit of Rs.288,823,697 and the corresponding profit for the previous year was Rs.57,557,675. Accordingly an improvement of Rs.231,266,022 was observed in the financial result. Increase of registration income by 385 per cent had mainly affected to this improvement.

**3.2 Trend Analysis of Main Expenditure Items**

Administration expenditure for the year under review and the previous year were Rs.25,497,060 and Rs.60,759,242 respectively and the said expenditure had increased by 138 per cent in the year under review compared with the previous year. Increase of foreign travel expenses by 2516 per cent and expenses for testing good manufacturing practice by 1635 per cent had mainly affected to it.

# 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 | - | 06 |
| Secondary Level | 155 | 74 | 81 |
| Primary Level | 50 | 34 | 16 |
| TOTAL | **245** | **120** | **125** |