Annual Report

2020

NMRA
NATIONAL MEDICINES REGULATORY AUTHORITY

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 2020 of the National Medicines Regulatory Authority, which is an independent body of the Ministry of Health and Indigenous Medicine Services. The main function of this institute is to check the quality, safety, efficacy, and affordability of All drugs, medical devices, borderline products, and cosmetics following the National Drug Policy that has been consumed by the public.

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

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

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

Prof Asita de Silva

Chairman

National Medicine Regulatory Authority

Message of the Chief Executive Officer

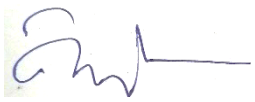
I being the CEO of one of the fastest growing Drug Regulatory Agencies in South - East Asia, the NMRA, feel very proud to present its Annual Report 2020. From the beginning we have recognized, understood and shared our vision, mission and goals among the members of our team which was the invaluable strength 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. Minister of Health, Pavithra Wanniarachchi, Prof. Asita De Silva, the Chairman, NMRA and the Board of members of the Authority.

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

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

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

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



Dr. Kamal Jayasinghe

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

Chief Executive Officer/ Director General

National Medicines Regulatory Authority

Board of Directors

1. Prof. Asita De Silva - Chairman
2. Dr. Kamal Jayasinghe
3. Mrs. C. Herath
4. Ms. K.S Dayaratne
5. Dr. Asela Gunawardena
6. Dr. Lakkumar Fernando
7. Dr. Kapila Ranasinghe
8. Dr. Nissanka Jayawardana
9. Dr. Sanath Lanerolle
10. Dr. Ananda Wijewickrama
11. Dr. Palitha Abeykoon
12. Dr. (Mrs) Nithushi Samaranayake
13. Mr. M.K Harshan Karunarathna

Chapter 1

Corporate Profile / Executive Summary

1.1 Introduction

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

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

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

At the start of NMRA, organization structure was not properly recorded but, following divisions were identifiable in it.

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

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

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

1.2 Vision, Mission, Objectives of the Organization

1.2.1 Vision of the Organization

"Improve access to quality assured medicines and healthcare products"

1.2.2 Mission of the Organization

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

1.2.3 Objects of the Authority

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

1.3 Main Functions

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

1.4 Cadre Availability

Category of employees	Post	Approved Cadre	Actual Cadre	Vacancies / Excess
Senior level	Director General	01	01	-
	Director	04	01	03
	Director (Human Resources)	01	-	01
	Medical Officer	04	-	04
	Accountant	01	01	-
	Internal Auditor	01	-	01
	Assistant Director/Deputy Director	06	01	05
	Assistant Director/Deputy Director (ICT)	01	01	-
	Cost Accountant	01	-	01
	Legal Officer	01	01	-
	Pharmaceutical Analyst	13 (contract 12)	06	-

Tertiary Level	Administrative Officer	01	-	01
	Assistant Pharmaceutical Assessor	40	-	40
	Costing Officers	05	-	05
Secondary Level	Pharmacists	-	45	-
	Development Officers	10	07	03
	Drug Inspector	20	03 (temporary basis)	20
	Technical Officer (Civil)	01	-	01
	ICT Assistant	01	-	01
	Management Assistant	43 + (contract basis 10)	22 (02 Contract Basis)	23
Primary	Driver	10	07 (01 Secondment/ temporary 02/ 04 Permanent)	06
	Plumber	01	-	01
	Electrician	01	01	-
	Lab Assistant	08	-	08
	Karyala Karya Sahayaka	30	23	07
	Total	**257**	**120**	**131**

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

1.5.1 National Medicines Quality Assurance Laboratory (NMQAL)

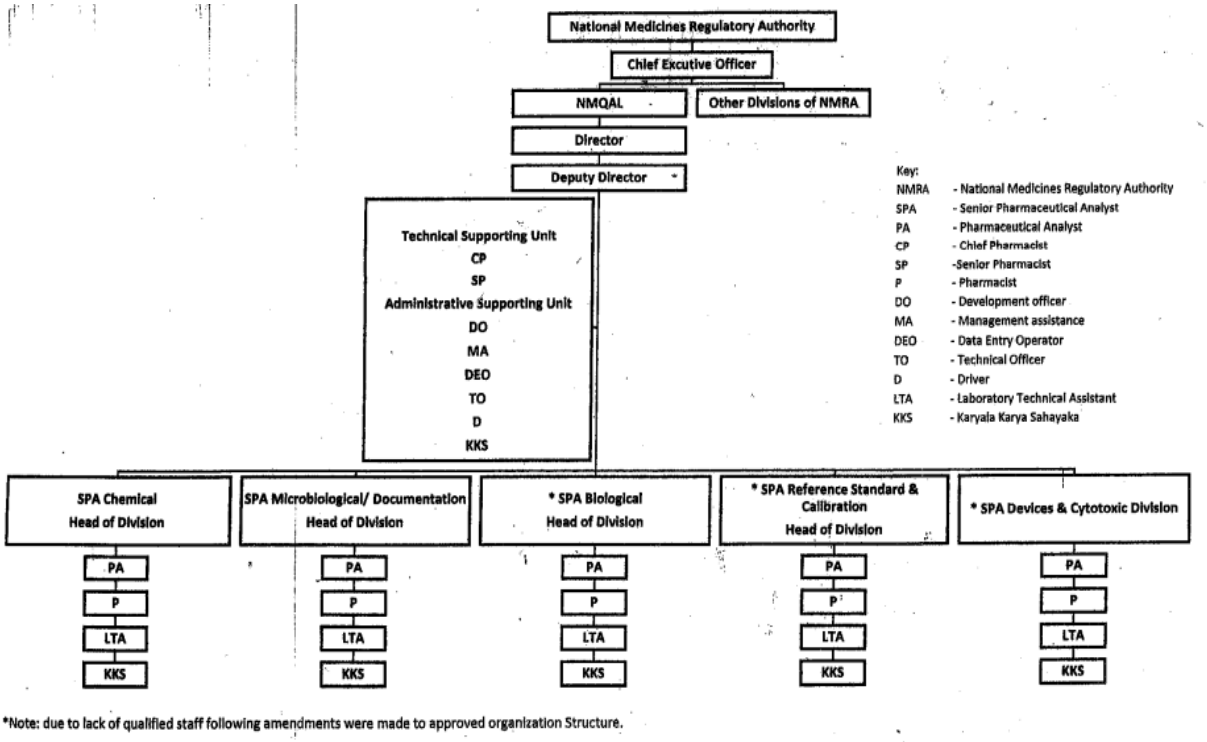
National Drug Quality Assurance Laboratory (NDQAL) was the National Laboratory established in Sri Lanka for testing Cosmetics Devices and Drugs. It was established in 1990 under Cosmetics Devices and Drug Act No.27 of 1980, with Norwegian consultancies and NORAD funds with the vision of ensuring Quality,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

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

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

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

1.5.1.2 Divisional Chart of NMQAL:



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

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

1.5.1.3 Main functions of NMQAL

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

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

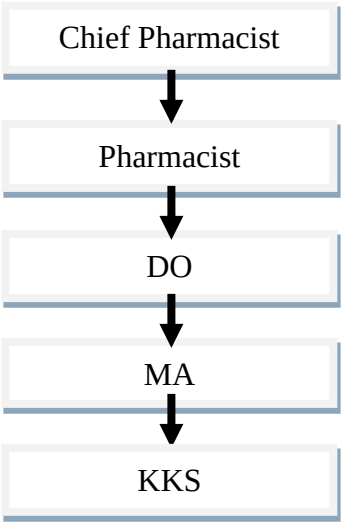
- Conduct training programs on quality assurance system
- To coordinate with laboratories local or overseas when their services are deemed necessary as decided by the NMRA.

1.5.3 Pharmaceutical Regulatory Division

1.5.2.1 Introduction

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

1.5.2.2 Divisional Chart of the Pharmaceutical Regulatory Division



1.5.2.3 Functions of Pharmaceutical Regulatory Division

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

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

1.5.3 Inspectorate and Enforcement Division

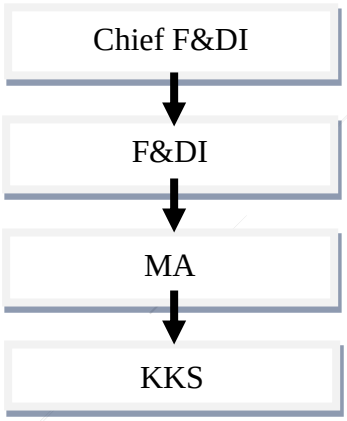
1.5.3.1 Introduction

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

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

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

1.5.3.2 Divisional Chart of the Inspectorate and Enforcement Division



1.5.3.3 Functions of Inspection and Enforcement Division

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

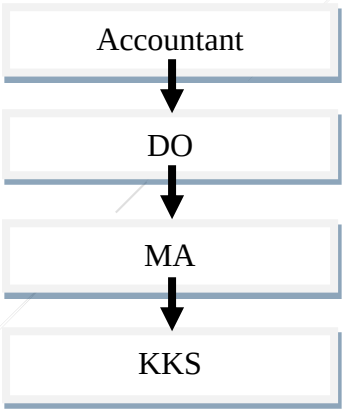
9. Inspecting & recommending of dangerous drugs applications
10. Organizing & conducting educational programs
11. Conducting prosecutions against the violations committed under the Act
12. Coordinating & corporation with other law enforcement agencies

1.5.4 Finance Division

Finance division of NMRA has commenced its activities from the 01.01.2016. Currently finance division has operated with sixteen members as Accountant, two development officers, eight management assistants, three trainees, one contract basis member and one KKS.

Due to the COVID 19 pandemic situation country has on lockdown for few times. Day to day essential activities were carried out with limited number of staff members.

1.5.4.2 Divisional Chart of the Accounts Division



1.5.4.3 Functions of the finance division

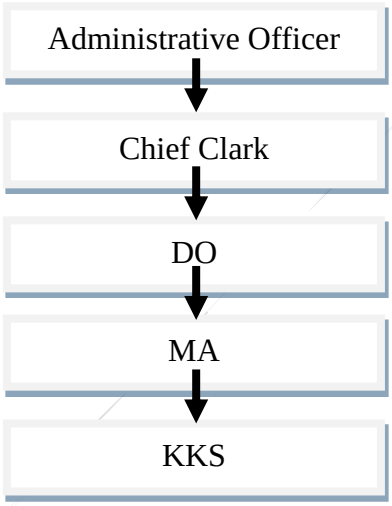
- Receiving all revenue through eighteen revenue streams.
- Preparing final accounts
- Preparing the budget for the coming year and obtaining the approval
- Maintaining all the supplies required to run the day-to-day activities of the authority
- All monetary controlling matters
- Procurement activities

1.5.5 Administration Division

1.5.5.1 Introduction

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

1.5.5.2 Divisional Chart of the Administration Division



1.5.5.3 Functions of Administration Division

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

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

- License Issuing after evaluations of Dossiers - Drugs (Manufacturing and Import License), Device (Manufacturing and import License), Sample License and Registration license issuing (Drugs and Devices) Registration Certificates and Licenses typing, and email the evaluation sheets.

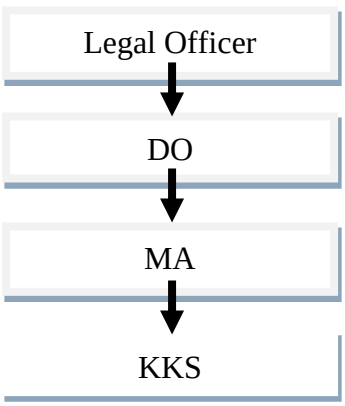
- Supervising the license and the registration certificates issuing process
- Personnel Management within the Authority
- Supervise all the activities related to maintenance of the office premises
- Maintaining utility services
- Making relevant reports in relation to the section
- Vehicle and transport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

1.5.7 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

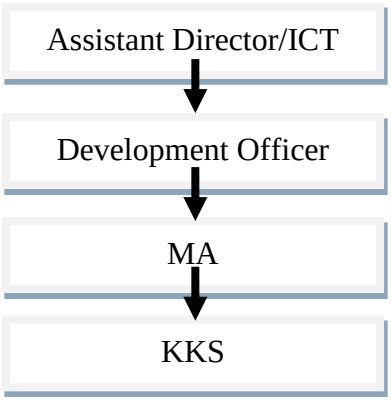
1. Recommend appropriate amendments to the NMRA Act No 5 of 2015 pertaining to medicines, medical devices, borderline products and cosmetics
2. Review emerging guidelines/ regulations and adopt to suit to the Sri Lankan context
3. Improve/amend the current regulations in order to achieve an effective 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

1.5.7 Information and Communication Technology (ICT) Division

1.5.7.1 Introduction

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

1.5.7.2 Divisional Chart of the ICT Division



Chapter - 2

Progression and Vision

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

2.1 Progress of National Medicines Quality Assurance Laboratory (NMQAL)

Participated External Quality Assurance Assessment Scheme Phase 10 conducted by WHO
Following Training programs were planned for NMQAL staff.

- Conformity Assessment Body (CAB) Forum 2020 – Virtual meeting for Technical Staff of NMQAL conducted by SLAB
- Validation & verification of Analytical methods –Virtual meeting for Technical Staff of NMQAL- Conducted by WHO Consultant
- Method validation – Virtual meeting for Technical Staff of NMQAL – WHO Consultant

Management Department has given approval to recruit 12 Pharmaceutical Analysts (Contract basis)

Plans for future:

1) Recruit of highly qualified competent technical staff with various scientific backgrounds and other supportive staff.
2) Develop an organizational chart for NMQAL aligned with the NMRA organizational structure.
3) Re-start the analyses of more samples at the post marketing stage.
4) Develop a maintenance procedure for sophisticated and highly sensitive analytical equipment as the support provided by the local agents are inadequate.

5) Establish a separate purchasing unit at NMRA to procure all laboratory needs (Equipment, chemicals, solvents, reagents, primary and other standards, glassware and other accessories etc.)
6) Strengthen the internal communications/procedures/support for a better service.
7) Develop the laboratory activities to achieve ISO 17025 accreditation and/or to obtain WHO prequalification states.

Sample Type	Pass	Fail /WH /WD	Already WD	Not Done	Total
Complaint	53	70	6	19	148
Formal	40	6	-	24	70
Informal	68	1	-	1	70
Lab Request	-	2	-	-	2
Manu.Request	-	-	-	-	0
Registration	62	11	-	-	73
SPC Tender	-	1	-	-	1
Others	13	28	4	-	45
Surveillance	39	1	5	-	45
Sanitizers					98
Total	**275**	**120**	**15**	**44**	**552**

No. of certificate of Quality issued = 552-44

= 508

No. of failure report issued = 120

Percentage (%) of quality failure from the Report issued in 2020 = 24

2.2 Progress of Pharmaceutical Regulatory Division

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

Plans for future

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

2.3 Progress of Inspection and Enforcement Division

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

Number of the cases filed by Food & Drugs Inspectors island wide & fines collected pertaining to Abusive medicines (Tramadol/Pregablin/Dizepam/Gabapentin)

(From 2015.07.01-2020.06.30 Five years period of NMRA)
It's a well-known fact that, pharmaceutical drugs are being abused by drug addicts and novices by way of student's island wide. And the same time, complaints have been received for several years from various law enforcement agencies and Authorized Officers who perform duties in the island. A commendable assistance has been extended by all the Law Enforcement Agencies (POLICE including STF,PNB) ,NAVY, Excise Department, Customs, Coastal Guard, by way of gathering & providing intelligence information and providing security to FDII. Based on the complaints received, legal actions are being taken

by Food & Drugs Inspectors, who act as the Authorized officers under the NMRA Act. During the past five years, a significant number of court case had been filed by the Authorized officers, after joint operations with other law enforcement agencies and single handedly as well.

From 2015.07.01-2020.06.30 (Five years period of NMRA)

No	***Year***	**No of cases filed**	**Fines collected**
01	*2015*	53	Rs 21,52000.00
02	*2016*	28	Rs 13,65000.00
03	*2017*	70	Rs 36,92500.00
04	*2018*	143	Rs 14,91000.00
05	*2019*	106	Rs 1516500.00
06	*2020 (up to 30.6.2020)*	05	Rs 65000.00
Total			**Rs 102,82,000.00**

2.4 Progress of Finance Division

In this year we were able to introduce distress loan facility to the staff members. Also, activities with the e-NMRA system are further improved in this year.

Plans for the future

1. Accounts to be handled by the NMRA and make use of the revenue effectively to achieve organizational objectives.
2. Increase the contribution to the e-NMRA system by supporting 52 types of revenues and setting up a system to view reports.

2.5 Progress of Administration Division

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

In addition, as the main function of the Administration Division the licenses and Registration Certificates are issued as follows;

No	Certificate Type	2020
1	Medicine Registration	1688
2	Medicine Import	3417
3	Medicine Manufacture	277
4	Medicine Sample	54
5	Device Registration	997
6	Device Import	2354
7	Device Manufacture	24
8	Device Sample	436
9	Cosmetic Registration	1741
10	Cosmetic Import	2036
11	Cosmetic Manufacture	231
12	Cosmetic Sample	611
13	Borderline Registration	36
14	Borderline Import	51
15	Borderline Manufacture	-
16	Borderline Sample	38
	TOTAL	**13991**

Plans for future

1) Human resource is planned to be improved further to improve efficiency of the organization.
2) Organizational structure to be finalized and necessary alterations to be made according to the government guidelines.

3) Separate divisions to be established for Human Resources.

2.6 Progress of Legal Division

- **Total Closed Files (up to 31.12.2020)**

Closed files 2017 (21.04.2017-31.21.2017)	69
Closed files 2018 (01.01.2018 Up to 31.12.2018)	166
Closed files 2019 (01.01.2019 Up to 31.12.2019)	225
Closed files 2020 (01.01.2020 Up to 31.12.2020)	102
Total	562

- **Agency Transfer Closed Files** **96**

Number of Free of charges files from (01.01.2020 – 31.12.2020)	12
Number of Payment Basic files from (01.01.2020 – 31.12.2020)	84
Total	96

- **Agency Transfer Total Income**

(From 01.01.2020 – 31.12.2020) **Rs. 34,054,388.94**

Performance of the division in 2020

The performance summary of Legal Division is undermentioned.

No.	Gazette No	Gazette Name
1	2160/28 - 29.01.2020	Pricing of Medical Devices Regulations, No.1 of 2020
2	2167/01 - 16.03.2020	Amendment to the Pricing of Medical Devices Regulations, No.1 of 2020
3	2167/16 -20.03.2020	Amendment to the Pricing of Medical Devices Regulations, No.1 of 2020
4	2167/17 – 20.03.2020	Medical Devices (Availability within Sri Lanka) Regulations, No.2 of 2020
5	2170/09 – 11.04.2020	Rescinded the Medical Devices (Availability within Sri Lanka) Regulations, No.2 of 2020

6		The Pricing of Medical Devices Regulations, No. ….. of 2020. Prepared.
7		The Medical (Pricing of Medicines) Regulations, No… of 2020. Prepared.
8		The Medical (Pricing of Medical Devices) Regulations, No… of 2020. Prepared.

Regulations/ Gazettes issued under the NMRA Act from 01.01.2020 to 31.12.2020.

Pending Court Cases (up to 31.12.2020) – 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/LO/13/2017	මතුගම මහේස්ත්‌රාත් අධිකරණය අංක 71118/11 (MTS /FDI / Legal /2014)	**Pending**	**Plaintiff**
5	NMRA/LO/15/2017	වත්තල මහේස්ත්‌රාත් අධිකරණයේ විභාග වන අංක: 45379/09 දරණ නඩුව (LO/213/14)	**Pending**	**Plaintiff**
6	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**
7	NMRA/LO/434/2018	පානදුර අධිකරණයේ M/C 53946	**Pending**	**Plaintiff**
8	NMRA/LO/439/2018	බටහිර ඖෂධ නඩුව නඩු අංක : 62475 නුවරඑළිය මහේස්ත්‌රාත් අධිකරණය	**Pending**	**Plaintiff**
9	NMRA/LO/494/2019	අම්පාර අධිකරණයේ M/C 90068	**Pending**	**Plaintiff**
10	NMRA/LO/590/2019		**Pending**	**Plaintiff**

		අම්පාර අධිකරණයේ M/C 92792		
11	NMRA/LO/726/2019	Case No.82460 Gampaha MC	**Pending**	**Plaintiff**

Pending Court Cases (up to 31.12.2020) – 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**
2	NMRA/LO/411/2018	Nawaloka Hospitals PLC & Others Vs Hon.Dr.Rajitha Senarathne & Others C.A. (Writ) Application No.285/18	**Pending**	**Respondent**
3	NMRA/LO/412/2018	Asiri Hospital Holdings PLC & Others Vs Hon.Dr.Rajitha Senarathne & Others C.A. (Writ) Application No.284/2012	**Pending**	**Respondent**
4	NMRA/LO/465/2019	C.A Writ/400/2018 -Markss HLC (Pvt) Ltd	**Pending**	**Respondent**
5	NMRA/LO/707/2019	C.A. Writ/499/2019 Markss HLC (Pvt) Ltd against SPC & 4	**Pending**	**Respondent**
6	NMRA/LO/720/2019	C.A/ Writ/517/2019	**Pending**	**Respondent**
7	NMRA/LO/731/2019	CA/Writ/501/2019	**Pending**	**Respondent**
8	NMRA/LO/817/2020	CA Writ Application bearing no.101/2020	**Pending**	**Respondent**
9	NMRA/LO/823/2020	CA/Writ /78/2020	**Pending**	**Respondent**

Chapter - 3

Overall Financial Performance

National Medicines Regulatory Authority

Financial Statements for the year ended
31 December 2020

NATIONAL MEDICINES REGULATORY AUTHORITY
STATEMENT OF FINANCIAL POSITION

As at 31 December,	Note	2020 Rs.	2019 Rs.
Assets			
Non current assets			
Property, plant and equipment	2	49,892,359	50,226,858
Working on Progress	2.1	5,600,619	5,472,075
Total non current assets		**55,492,978**	**55,698,933**
Current assets			
Inventory	3	1,655,865	1,992,864
Deposits and other receivable	4	22,544,810	980,863
Short term investments	5	3,149,130,138	2,479,226,476
Cash and cash equivalents	6	129,108,499	412,220,462
Total current assets		**3,302,439,312**	**2,894,420,664**
Total assets		**3,357,932,290**	**2,950,119,597**
Equity and liabilities			
Equity			
Accumulated Fund		2,404,402,488	1,745,743,546
Total equity		**2,404,402,488**	**1,745,743,546**
Non Current liabilities			
Capital grant	7	157,364	1,500,266
Deferred tax	8	7,102,486	2,971,330
Total non current liabilities		**7,259,850**	**4,471,596**
Current liabilities			
Advance receipts	9	76,702,510	271,932,395
Provision for Income tax	19	575,361,535	619,465,553
VAT payable	10	68,856,674	63,915,809
Stamp duty payable	11	22,747,938	6,181,736
Provision for Treasury levy	12	146,929,966	160,486,545
Accrued expenses and other payables	13	55,671,329	77,922,417
Total current liabilities		**946,269,952**	**1,199,904,455**
Total equity and liabilities		**3,357,932,290**	**2,950,119,597**

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

K.M.Y.K Karunarathna
Accountant

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

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

Dr. Rasitha Wijewantha
Chairman

Dr.Kamal Jayasinghe
Chief Executive Officer

23rd Augest 2021

Dr. Rasitha Wijewantha
MBBS, MD
Chairman
National Medicines Regulatory Authority
Sri Lanka.

Dr. Kamal Jayasinghe
MBBS, DFM, MSc. Med Admin, MBA, DIPPCA, MCMA
Director General / CEO
National Medicines Regulatory Authority
120, Norris Canal Road, Colombo 10.

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NATIONAL MEDICINES REGULATORY AUTHORITY
STATEMENT OF COMPREHENSIVE INCOME

For the year ended 31 December,	Note	2020 Rs.	2019 Rs.
Revenue	14	1,059,441,826	1,191,761,598
Interest income		177,652,925	167,504,937
Other income	15	1,239,604	374,570
Administrative expenses	16	(93,984,429)	(131,991,135)
Salaries and wages	17	(146,730,584)	(107,099,244)
Other expenses	18	(58,605,113)	(17,061,320)
Amortization of capital grant		1,342,902	1,342,902
Net income before taxation		**940,357,130**	**1,104,832,308**
Income tax for the year	19	(266,752,264)	(309,137,517)
Net income after taxation		**673,604,866**	**795,694,791**

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,	2020 Rs.	2019 Rs.
Cash Flows from Operating Activities		
Net income before taxation	940,357,130	1,104,832,308
Adjustment for :		
Depreciation	17,515,637	11,628,106
Interest income	(177,652,925)	(167,504,937)
Amortization of capital grant	(1,342,902)	(1,342,902)
Gratuity Expense	1,257,060	893,668
Treasury levy		-
Operating Profit before Working Capital Changes	**780,134,001**	**948,506,243**
Changes in items of working capital		
(Increase)/Decrease in Inventory	336,999	396,263
(Increase)/Decrease in Deposits and other receivable	(21,560,582)	(803,364)
(Increase)/Decrease in Advance receipts	(183,249,343)	174,943,415
(Increase)/Decrease in VAT payable	5,653,112	(115,815,380)
(Increase)/Decrease in Stamp duty payable	16,566,202	(33,958,668)
(Increase)/Decrease in Provision for treasury levy		50,687,109
(Increase)/Decrease in Accrued expenses and other payables	5,801,201	38,939,056
(Increase)/Decrease in Short Term Investment Increase	-	(1,117,504,935)
		900,468,913
Cash generated from operations	**603,681,589**	**845,858,652**
Tresury levy Paid	(80,917,066)	
Tax Paid	(306,965,632)	
Net Cash from /(Used in) Operating Activities	**215,798,891**	**845,858,652**
Cash flows from investing activities		
Acquisition of Property plant and equipment	(6,935,359)	(33,173,495)
WIP Changes	(128,543)	-
Investment in short term deposits	(669,499,875)	(1,117,504,935)
Interest income	177,652,925	167,504,937
Net Cash from / (Used in) Investing Activities	**(498,910,853)**	**(983,173,493)**
Net increase/ decrease in Cash & cash equivalents	(283,111,962)	(137,314,840)
Cash and cash equivalents at the beginning of the year	412,220,462	549,535,302
Cash and cash equivalents at the ending of the year	**129,108,499**	**412,220,462**

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

ICMY
9/2/2022

K. M. Y. K. Karunarathne
Accountant
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10'

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09/02/2022

Dr. Rasitha Wijewantha
MBBS, MD
Chairman
National Medicines Regulatory Authority
Sri Lanka.

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS
For the year ended 31 December 2020

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 2020

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 2020

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

For the year ended 31 December,		2020 Rs.	2019 Rs.
2.1	**Capital Working Progress**		
	On going Public Finger Print Scanners	-	269,359
	On going cost Public Addressing System	543,591	499,589
	On going cost CCTV Systems	4,658,794	4,658,794
	On going cost Narahenpita building	215,484	44,333.31
	On going cost Security Access	182,750	-
		5,600,619	**5,472,075**
3	**Inventory**		
	Opening Inventory	1,992,864	2,389,127
	Purchased for year	1,773,231	1,995,957
		3,766,095	4,385,084
	Consumption	2,110,230	2,392,220
	Closing Inventory	**1,655,865**	**1,992,864**
4	**Deposits and other Receivable**		
	Deposit for Fuel	50,000	50,000
	Other Receivables	5,550	194,083
	Prepayments	62,000	736,780
	Festival Advance	126,000	-
	Advance Receivables	5,000	-
	Building Rent	13,500,000	-
	Distress Loan Receivable	8,796,260	-
	Total deposits and prepayments	**22,544,810**	**980,863**
5	**Short term investments**		
	Opening Balance	2,479,226,476	1,361,721,541
	Invest for the Year	492,250,737	949,999,998
	Interest for the year	177,652,925	167,504,937
		3,149,130,138	**2,479,226,476**
6	**Cash and cash equivalents**		
	BOC Current Account	129,108,496	412,220,462
	Petty Cash	3	-
	Total cash and cash equivalents	**129,108,499**	**412,220,462**
7	**Capital grant**		
	Capital grant	1,500,266	2,843,168
	Amortization of capital grant	(1,342,902)	(1,342,902)
	Total Capital grant	**157,364**	**1,500,266**
8	**Deferred tax liability**		
	Accounting written down value of Property plant and equipment	49,892,359	50,226,858
	Tax base of Property plant and equipment	24,526,336	29,091,550
	Taxable Temporary deference	25,366,023	21,135,309
	Tax @ 28%	7,102,486	5,917,886
	Deferred Liability at the end of the year	**7,102,486**	**5,917,886**
	Deferred Liability as at beginning of the year	2,971,330	2,946,556
	Charge as deferred tax during the year	**4,131,156**	**2,971,330**

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NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2020 Rs.	2019 Rs.
14	**Revenue**		
	Drug Sample License Income	889,460	18,760,318
	Device Sample License Income	7,956,394	18,345,905
	Cosmetic Sample License Income	278,800	463,400
	Borderline Sample License Income	747,821	1,103,156
	Drug Import License Income	65,457,634	96,156,458
	Device Import License Income	44,851,068	63,870,299
	Cosmetic Import License Income	4,344,000	6,726,500
	Borderline Import License Income	767,295	654,214
	Drug Manufacturing License Income	4,937,907	5,859,540
	Device Manufacturing License Income	382,264	960,327
	Cosmetic Manufacturing License Income	334,000	217,000
	Drug Registration Income	82,769,330	115,165,232
	Device Registration Income	48,962,225	62,057,397
	Cosmetic Registration Income	6,147,500	7,863,500
	Borderline Registration Income	1,231,297	1,272,716
	Labotary Test	8,519,342	7,921,631
	Drug Processing Fees	83,960,364	239,968,215
	Device Processing Fees	122,948,986.14	147,981,580.00
	Cosmetic Processing Fees	976,500	983,000
	Borderline Processing Fees	3,247,209	11,193,119
	Clinical Trial Processing Fees	93,958	-
	Drug Advertising Fees	372,257	2,164,703
	Retail Pharmacy License Income	1,873,949	26,665,061
	Wholesale Pharmacy License Income	375,784	6,108,897
	Transport Pharmacy License Income	17,806,634	19,135,314
	Drug WOR	28,463,728	9,643,738
	Device WOR	15,614,479	-
	Borderline WOR	93,399	-
	GMP	-	89,841,166
	Device GMP - Local / Foreign	588,194	-
	Drug GMP - Local / Foreign	23,966,690	-
	Drug WHO Inspection	245,365	-
	Device WHO Inspection	74,798	-
	Drug COPP Certificate	261,557	162,533
	Submission of Additional Documents	-	51,670,640
	Additional Drug	126,286,003	83,961,047
	Additional Device	90,134,252	-
	Additional Borderline	3,118,960	-
	Agency Transfer	31,933,754	41,196,078
	Device Free sale Certificates	46,288	54,454
	Clarification	-	13,830,962
	Device Clarification	719,174	-
	Drug Clarification	48,699	-
	Category A/B processing fees	-	4,202,362
	Fees for Variation Review	-	3,679,155
	Company Profile	-	27,740,076
	Approval for Repacking	-	820,443
		831,827,317	**1,188,400,136**

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2020 Rs.	2019 Rs.
16	**Administrative expenses**		
	Depreciation	17,515,637	11,628,106
	Water	252,597	611,710
	Electricity	6,913,019	8,633,989
	Telephone	1,339,143	913,710
	Postage	181,705	368,925
	Stationery	2,110,230	1,995,957
	Travelling - Local	5,967,566	45,641
	Travelling - Foreign	32,823	33,549,596
	Training and development expenses	1,054,847	17,935,115
	Fuel expense	2,449,145	948,494
	Security charges	3,998,503	3,524,619
	Document handling charges	1,474,015	1,142,262
	Publication, Translation and advertisement charges	5,485,127	2,373,271
	Cleaning service	3,883,700	2,924,475
	Vehicle maintenance	3,251,319	1,863,140
	Maintenance of Laboratory equipment	6,453,384	24,830,467
	Maintenance of fire extinguisher	12,500	33,201
	Maintenance of Air-conditioning	566,235	6,371,486
	Maintenance of building	1,599,802	6,371,486
	Maintenance of computer items and other	6,880,627	875,563
	Maintenance of website	458,200	559,085
	Maintenance of Office Equpments	619,709	88,230
	Maintenance of Software & Packages	232,563	-
	Expenses for Good Manufacturing Practice visits	7,178,988	-
	WHO meeting expenses	-	1,862,297
	Reservation of Conference Hall	1,134,920	-
	Rates and taxes	475,999	-
	Audit fee	1,200,000	1,023,000
	Forensic Audit Fee	3,200,000	-
	Sample Testing Expenses	23,204	-
	Books, Journals & Information	3,308,791	1,350,237
	Consultation Fee	23,301	167,073
	Sanitary Items Expense	29,115	-
	Building Rent	2,700,000	-
	Consumable Expenses	531,190	-
	Covid 19 Expenses	819,485	-
	Interview Fees	26,400	-
	Vehicle Insurance	573,784	-
	Vehicles Parking Fee	26,855	-
	Total	**93,984,429**	**131,991,135**

Income Tax computation
Year of Assement 2020

Net income before taxation	940,357,130
Add : Disallowable expense	
Depreciation	17,515,637
	-
	957,872,767
Less : Allowable expenses	
Capital allowance	(18,597,332)
Less : income not subject to income tax	-
Amortization of capital grant	(1,342,902)
Adjusted net profit for the year	937,932,533
Taxable profit trade and	**937,932,533**
Tax Loss:	-
Total statutory income	937,932,533
Tax expense for the period, @ 28%	262,621,109
Tax expense for the period	262,621,109
Tax Credit	
Income Tax payable	**262,621,109**
Deffreed tax computation	
Accounting written down value of PPP	49,892,359
Tax base of PPP	24,526,336
Taxable Temporary deference	25,366,023
Tax @ 28% rate	7,102,486
Deferred Liability as at beginning of the year	2,971,330
Charge as deferred tax during the year	4,131,156

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Report of the Auditor General on the affairs of the National Medicines Regulatory Authority including the Financial Statements for the year ended 31 December 2020 in terms of Article154(6) of the Constitution of the Democratic Socialist Republic of Sri Lanka.

1. Financial Statements

1.1 Qualified Opinion

The audit of the financial statements of the National Medicines Regulatory Authority for the year ended 31 December 2020 comprising the statement of financial position as at 31 December 2020 and the statement of comprehensive income, statement of changes in equity and cash flow statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, was carried out under my direction in pursuance of provisions in Article 154 (1) of the Constitution of the Democratic Socialist Republic of Sri Lanka read in conjunction with provisions of the National Audit Act No. 19 of 2018 and Finance Act, No.38 of 1971. My comments and observations which I consider should be tabled in Parliament appear in this report.

In my opinion, except for the effects of the matters described in Paragraph 1.5 of this report, the financial statements give a true and fair view of the financial position of the Authority as at 31 December 2020, and of its financial performance and its cash flows for the year then ended in accordance with Sri Lanka Sector Accounting Standards.

1.2 Basis for Qualified Opinion

My opinion is qualified based on the matters described in paragraph 1.5 of this report.

I conducted my audit in accordance with Sri Lanka Auditing Standards (SLAS). My responsibilities, under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of my report. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my qualified opinion.

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

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

In preparing the financial statements, management is responsible for assessing the Authority's ability to continue as a going concern, disclosing, as applicable, matters related to going

concern and using the going concern basis of accounting unless management either intends to liquidate the Authority or to cease operations, or has no realistic alternative but to do so.

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

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

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

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

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

- Appropriate audit procedures were designed and performed identify and assess the risks of material misstatement in financial statements whether due to fraud or errors in providing a basis for the expressed audit opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

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

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

- Conclude on the appropriateness of the management's use of the going concern basis of accounting and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Authority's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the

related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my auditor's report. However, future events or conditions may cause the Institute to cease to continue as a going concern.

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

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

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

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

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

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

1.5 Audit Observations on the preparation of Financial Statements

1.5.1 Internal Control over the preparation of financial statements

The Authority is required to "devise and maintain" a system of internal accounting controls sufficient to provide reasonable assurance that , transactions are executed in accordance with management's general or specific authorization, transactions are recorded as necessary to permit preparation of financial statements in conformity with the applicable reporting standards , and to maintain accountability for assets, access to assets is permitted only in accordance with management's general or specific authorization, and the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

1.5.2 Non-compliance with reference to Sri Lanka Accounting Standards

	Non-compliance with reference to the Relevant Standard	Comment of the Management	Recommendation
(a)	Instead of being classified as current assets and non-current assets the distress loan of Rs. 8,796,260 issued to the officers in terms of Paragraphs 60 and 66 of Sri Lanka Accounting Standard 1, it had been stated as current assets. Likewise, provision for employees' gratuity of Rs. 2,150,728 to be disclosed as anon-current liability in terms of Paragraph 69 of the Standard had been shown as a current liability.	Corrections and disclosures will be made through the final accounts of the ensuing year.	Action should be taken in keeping with the accounting standard.
(b)	In order to correct the errors occurred during the preceding years, a sum of Rs.52,414,563 had been adjusted to the balance of the Statement of Changes in Equity at the beginning of the year. Nevertheless, the nature of the errors had not been disclosed in terms of Section 49 of the Sri Lanka Accounting Standard 8.	- Do-	- Do-
(c)	In terms of Sri Lanka Accounting Standard 10, if the events after the reporting date of the financial statements pose a material influence, it should be disclosed in the financial statements. Nevertheless, the deletion of data and confidential information of the Documents and Workflow Management System and an estimate of the resultant financial impact or in case such estimate could not be prepared, a statement to that effect had not been disclosed in the financial statements.	- Do-	- Do-
(d)	In terms of Paragraph 55 of Sri Lanka Accounting Standard 19, the accounting policy adopted in the calculation of employees' gratuity had been disclosed, whereas calculation of employees' gratuity had not been carried out based on that policy. Further, a distinguishable Plan Asset	- Do-	- Do-

had not been prepared in relation to the non-defined benefit plan of Rs. 2,150,728 of the Authority.

1.5.3 Accounting Deficiencies

	Audit Observation	Comment of the Management	Recommendation
(a)	Although non-current assets including 03 vehicles belonging to the Presidential Secretariat, 06 vehicles belonging to the Ministry of Health and the National Medicines Quality Assurance Laboratory functioned under the Ministry and its assets had been permanently given to the Authority, action had not been taken to assess and account for those assets and to recognize the depreciation expenses relating to them.	Measures are being taken on the transfer of 06 vehicles belonging to the Ministry of Health and other assets will be included in the final accounts for the year 2021.	All the assets of the Authority which have not been brought to account should be assessed and accounted for.
(b)	Without being taken action to identify and properly adjust in the accounts a sum of Rs. 2,628,262 directly received by the bank as at 31 December 2020, it had been stated as unidentified deposits in the financial statements. Hence, the current liabilities had been increased by similar value.	Being the deposits directly received by the bank, these unidentified balances occur every month and due to setting these balances in the following month, this value has to be accounted for as unidentified deposits.	Income related to the accounting period should be correctly identified and necessary adjustments thereto should be made.
(c)	As accrued expenditure of Rs. 7,113,732 as at 31 December 2020 had not been brought to account, profit of the year and current liabilities had been overstated and understated by that amount in the financial statements respectively.	Corrections will be made through the final accounts of the ensuing year.	Expenditure relating to the period of accounts should be correctly identified.
(d)	As provision for Income Tax had been excessively made by Rs.41,648,456 for the year under review, the after tax profit for the year under review and provision for Income Tax as at 31 December 2020 had been understated and overstated in the financial statements respectively.	- Do-	Provision for Income Tax relating to the period of accounts should be correctly made.

1.5.4 Unauthorized Transactions

Description on the Unauthorized Transactions	Comment of the Management	Recommendation
Although the Board of Directors had granted approval to hire 03 vehicles per day to transport the officers due to prevailing Covid 19 epidemic and to pay Rs.20,000 per day for the 03 vehicles, contrary to that 06 vehicles had been so hired and Rs.49,500 had been paid per day. Accordingly, a sum of Rs. 4,344,280 had been overpaid for the period of 10 months from March to December 2020 contrary to the approval of the Board of Directors.	Initially 02 busses were deployed on the approval of the Board of Director for the transport of staff due to Covid 19 epidemic and subsequently, the facility was increased by deploying 03 busses and 02 vans on the requirement of staff's reporting for service.	Action should be taken either to obtained approval of the Board of Directors for the overpaid amount or to recover that amount from the officers who should be held responsible.

1.5.5 Lack of Documentary Evidence for Audit

Item	Amount	Audit Evidence not Furnished	Comment of the Management	Recommendation
	Rs.			
Receipt of advances	72,972,666	Detailed schedules and details on receipts relating to a sum of Rs. 72,972,666 received as advances as at 31 December 2020 were not furnished to audit.	Relevant schedules will be furnished to audit without delay.	Relevant schedules and details on receipts should be furnished to audit.

1.6 Non-compliance with Laws, Rules, Regulations and Management Decisions

Reference to Laws, Rules, Regulations etc.	Non-compliance	Comment of the Management	Recommendation
(a) National Medicines Regulatory Authority Act, No.05 of 2015.			
(i) Sections 43(2) (a) and (b)	Although the Medicines Evaluation Committee should carry out a technical evaluation of the medicines forwarded for registration and submit a report in respect thereof specifying the benefits and risks attached to such medicines and the quality, efficacy, safety, need and cost of such medicines with pharmacoeconomic analysis where necessary in keeping with the National Medicines Policy, no request whatsoever had been made to the Medicines Evaluation Committee consisting of specialist physicians representing the fields such as general medicine, general surgery, paediatrics, gynaecology and obstetrics and professors in Pharmacology to carry out such evaluation and submit a report on the medicines forwarded for the registration. Instead, action had been taken to issue a provisional certificate or full registered certificate after evaluating the relevant applications by a Pharmacist and thereafter examining that evaluation again by another three Pharmacists, and the details on such registrations had been submitted to the Medicines Evaluation Committee following the issue of registration certificate to the relevant company.	Applications made for registration will be forwarded to the Medicines Evaluation Committee and evaluated and submitted recommendations with effect from 05 October 2020.	Action should be taken in accordance with provisions of the Act.

(ii) Section 59(4)(b)	Although medicines should be submitted to the National Medicines Quality Assurance Laboratory (NMQAL) for testing of the quality thereof before registration of the medicines, without being so taken steps to test the quality of the medicine, 1,055 registration certificates had been issued during the year under review, including 1,035 temporary registration certificates and 20 fully registered certificates issued for a period of 05 years only upon the evaluation of documented information of the medicine by a Pharmacist. According to the data of the National Medicines Quality Assurance Laboratory, the total number of medicine samples tested for issuing registration certificates was 33 during the year under review.	Testing for quality of all the medicines is not practically performed, only medicines selected according to the guidance on providing samples to the Medicines Registration and Quality Test Division are tested, and registration certificates for the medicines of Meropenem For Injection, Erythromycin (All Dosage Forms), Thyroxin (All Dosage Forms) will be issued upon necessarily receipt of the quality assurance certificates.	Action should be taken in accordance with provisions of the Act.
(iii) Section 74(1)	The medical devices permitted for the purpose of the Act had not been listed from time to time by the Minister.	It is practically difficult to make such list and publish in the Gazette and it will be taken into account in making amendments to the Act.	Action should be taken in accordance with provisions of the Act.
(iv) Section 109	During the year under review, 81 letters of exemption from registration had been issued due to the reasons such as cancellation of registration, lack of registered suppliers, not presenting the registered bidders which were not come under the category of 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. One of the above letters had been issued to a	In terms of Section 109 of the Act and recommendations of the Ministry of Health, the applications submitted are referred to the subcommittee of experts established by the Authority and the letter of exemption from	Letters of exemption from registration should be issued only for the special circumstances specified in the Act.

	private company to release the stock of 6,000 bottles of Furosemide syrup costing Rs. 2,563,080 from the Custom that is used for the diseases such as cardiac, liver, renal diseases and hypertension. It was revealed at a laboratory test conducted after the use of 98 per cent of the above medicine in the hospitals including Lady Ridgeway Hospital for Children that the drug had failed in quality. It was observed that these types of quality failed medicines had been received to the country due to issue of letters of exemption from registration without evaluating documents on the quality of the relevant medicine or the samples, accordingly the medicines without assurance of the quality had been issued to the patients and the resultant damages to the patients could not be measured.	registration is issued only for the relevant stock of medicines upon the recommendation of that committee.	
(v) Regulation issued in terms of Section 142 relating to the registration of medicines and issue of licences.			
❖ Regulation No, 4	A common register had not been maintained to document every request made for the registration of medicines. As a result, details such as date of receipt of the application for registration of medicines, application number, name of the manufacturer, country of manufacturer, authorized importer, generic name; if the medicine is a combination product, the generic name of the active ingredients, brand name, the dosage, strength of the medicine, type of the application (new application or an application for renewal), type of medicine as well as details on money received for each application, date of	All applications made for the registration of medicines are documented separately and the use of computerized common register for the activities relating to the new applications and the renewal of registration was commenced from 01 November 2021.	Action should be taken in accordance with the directives.

		submission of each application to the Medicines Regulatory Division for evaluation, number of applications rejected and approved by each division, the number of applications further being processed in each division and the time taken by each division for the registration could not be obtained by the audit. Accordingly, it was observed that the registration of medicines and licensing process had not been carried out transparently.		
	❖ Regulation No. 133 (5)	Although a data base together with the necessary information relating to the applications received, approved, rejected and suspended by the Authority or the withdrawn applications should be maintained, such data base had not been maintained by the Authority.	Action will be taken to maintain a data base in the future.	- Do-
	❖ Paragraph 08 of Schedule XXIII in Regulation No134	An information system had not been maintained to ensure that the registration certificates would be issued within the targeted processing period specified in the paragraph and to examine to that effect.	Action will be taken to maintain an information system in the future.	Action should be taken in accordance with the regulation.
(b)	Section 40 of the National Audit Act, No.19 of 2018.	An Internal Audit Division had not been established for the Authority.	Action is being taken to make relevant recruitment to the post of Internal Auditor and an Internal Audit Division will be established on completion of those activities.	Action should be taken in accordance with provisions indicated in the Act.
(c)	Paragraph 10.1 of the Establishments Code of the Democratic Socialist Republic of Sri Lanka.	Although a staff officer entitled to a 1/20 allowance is not entitled to overtime pay for his performing duties during weekends and public holidays, staff officers serving in the Authority had obtained both 1/20 allowance and an overtime allowance.	These payments were made with the approval specified in the letter No. MH / AD / 01/04/12/2016 dated 09 September 2016 issued by the	Action should be taken either to recover overpaid allowances or to recover the money from

			Ministry of Health, Nutrition and Indigenous Medicine.	the officers who acted contrary to the provisions of the Establishments Code.
(d)	Financial Regulations of the Democratic Socialist Republic of Sri Lanka.			
	(i) Financial Regulation 237(b)	It was observed at an audit test check that 10 payment vouchers worth Rs.1,896,284 in which specific certificates relating to each expenditure had not been attached had been certified.	The relevant officials were instructed to pay attention to ensure the certification of those payments including all certificates.	Action should be taken in accordance with the Financial Regulations.
	(ii) Financial Regulations 371 (2) (b) and Public Finance Department Circular No. 03/2015 dated 14 July 2015	Even though the maximum amount of ad hoc sub-imprests that can be given to a staff officer is Rs. 100,000, ad hoc sub-imprests of Rs.1,329,200 had been issued on 12 occasions exceeding that limit and in most cases the ad hoc sub-imprests had been re-issued before settling the sub iprests obtained. Further, ad hoc sub-imprests of Rs. 1,961,700 had been settled after a delay of 03 days to 185 days from the completion of the relevant work.	Having been attached an officer to the subject necessary internal awareness was made to rectify those deficiencies.	Action should be taken in accordance with Financial Regulations and circular provisions.
	(iii) Financial Regulations 128 (1)(e), 507,756, 757,758, 770 and Paragraph 3.1.6 of Public Finance Circular No. 05/2016 dated 31 March 2016.	Although the Accounting Officer should make arrangements to appoint the Board of Surveys before 15 December of each financial year and submit its reports to the Auditor General with a copy to the Chief Accounting Officer before 17 March of the following year, non-current assets totalling Rs. 55,492,978 had not been surveyed and reports thereof had not	Arrangements are being made to conduct the Board of Survey for the year 2021 and the survey reports for the year 2022 will be submitted to the Auditor General as	Action should be taken in accordance with Financial Regulations and circular provisions.

		been submitted to the Auditor General since the establishment of the Authority in 2015.	soon as possible	
	(iv) Financial Regulation 1645 (a) and 14647(e)	Log entry books had not been maintained for 09 vehicles used by the Authority and a vehicle inventory had also not been maintained.	At present, measures are being taken to maintain vehicle log entry books and a vehicle inventory.	Action should be taken in accordance with Financial Regulations.
(e)	Guideline 4.2 of the Government Procurement Guidelines	Authority had not prepare a Procurement Plan for the year under review.	The procurement plan will be formally prepared focusing on the Government Procurement Guidelines in the future.	Action should be taken in accordance with the Government Procurement Guidelines.
(f)	Treasury Circular			
	(i) Circular No.842 dated 19 December 1978.	No Register of Fixed Assets had been maintained in respect of Property, Plant and Equipment costing Rs. 91,211,454 as at 31 December 2020.	A Register of Fixed Assets is being prepared at present.	Action should be taken in accordance with Circular Provisions..
	(ii) Assets Management Circular No.01/2017 dated 28 June 2017.	Every public institution is required to submit accurate information on all assets under its control to the Comptroller General, and each institution should appoint an appropriate official to coordinate such activities, whereas the Authority had not taken steps accordingly.	Action will be taken to submit accurate information on all assets existed during the years 2020/2021 to the Comptroller General and to appoint a Coordinating Officer.	-Do-
(g)	Public Enterprises Circular, No. 95 dated 14 June 1994.	An incentive scheme relating to Covid-19 had been implemented for the staff without being approved by the Treasury. Irrespective of the normal working days or holidays, allowances had been calculated in a manner equivalent to one and half days per working day, thus paying a sum totalling Rs. 17,843,781 to the staff of the Authority as allowance for the year under review.	Considering all the matters relating to those payments, such payments were suspended with effect from November 2021.	Action should be taken either to obtain Treasury approval on the allowances already paid or recover the sum from the officers responsible.

(h)	Paragraph 5.2.5 of the Public Enterprises Circular, No. PED/12, dated 02 June 2003.	A copy of the budget report approved by the Board of Directors, should have been sent to the Line Ministry, Department of Public Enterprises, the Treasury, and the Auditor General prior to 15 days from the beginning of the year. However, it had not been so done.	Action has been taken to prepare the annual budget for the year 2022 and thereby forwarding a copy thereof after being approved by the Board of Directors.	Do.
(i)	Public Finance Circular, No. PED/03/2015 dated 17 June 2015.	Contrary to provisions of circulars and without any approval , a sum totalling Rs.250,886 had been paid to the Chairman of the Authority as Covid-19 allowances.	Considering all the matters relating to those payments, such payments were suspended with effect from November 2021.	Action should be taken either to obtain Treasury approval on the allowances already paid or recover the sum from the officers responsible.
(j)	Paragraph 3.1 of the Public Administration Circular, No. 30/2016 dated 29 December 2016.	A fuel consumption test should be carried out after a period of 12 months following each fuel consumption test, running 25,000 kilo meters or a major overhaul on the engine, whichever occurs first. However, it had not been so done with respect to 09 vehicles being used by the Authority.	Instructions have already been given to conduct fuel consumption tests on all the vehicles.	Provisions of Circulars should be followed.

1.7 General Administration of Information Technology Infrastructure

Audit Observation	Comment of the Management	Recommendation
The contract for automating the information system of the Authority had been awarded to a private company on 03 May 2018 for a period of 05 years at a contract value of Rs. 29 million. An agreement had been entered into in order to implement the Documents and Workflow Management System under the model of Operational Expenditure Financing; and, a sum of Rs. 12,253,328 had been paid to the contractor during the period from June 2019 up to May 2021. Nevertheless, some of the	Following the instructions given by the Board of Directors, this project will be implemented under an accurate methodology in due course.	All the activities such as, implementation of the project, supervision, and consultancy should be done with transparency, effectively and productively in an accurate methodology. The agreement entered into should be extended

information maintained in the information system had been deleted either deliberately or due to negligence of the said company. As of 30 November 2021, the service of the system remained non-functional until the end of the investigations conducted by the Criminal Investigation Department in that connection. Furthermore, a Memorandum of Understanding had been entered into with the Information and Communication Technology Agency on 25 June 2018 for a period of one year in order to obtain consultancy, management and technical assistance for the said system, but no action had been taken to extend that agreement in parallel with the 05 year contract period. Moreover, contrary to the contract agreement, action had not been taken to draw attention on the confidentiality of the information, change the passwords, and avoid the misuse of information. Once the completion of automation process, an audit trial had not been carried out with the manual and automated systems being executed parallelly. Furthermore, the management had not been concerned with the matters such as, the possibility of management and conservation of files with copies of the documents being safely stored along with the relevant data up to a period of 05 years, obtaining copies automatically daily, weekly and monthly, and obtaining insurance policy on professional liability; and, payments had been made to the company without obtaining secured copies of the data and annexures. The assets in the system costing Rs.7,558,128 should have been capitalized though, that amount had been written off against the profit instead.

by the end of each year, and action should be taken in accordance therewith.

2. Financial Review

2.1 Financial Results

The operating result of the year under review was a profit of Rs. 673,604,866 as compared to the corresponding profit of Rs. 795,694,791 for the preceding year, thus observing a deterioration of Rs. 122,089,925 in the financial result. This deterioration had mainly been attributed by the decrease in total revenue by Rs. 132,319,772 and the grant of Rs. 50,000,000 made to the Covid Fund.

3. Operating Review

3.1 Management Inefficiencies

	Audit Observation	Comment of the Management	Recommendation
a)	A private company had been entrusted with the contract on 01 December 2015 to transport, safely store and maintain the completed files. A sum of Rs. 4,503,080 had been paid to the contractor during the 05 year period from the date of awarding the contract up to 31 December 2020. However, it was not verified as per the file that the payments were made after verifying in terms of Paragraphs 3.3 and 3.4 of the agreement that necessary storage facilities were available and the standard procedure to avert fire hazards was followed. Information such as, locations of storing the files, security provided for the documents, and the manner in which such documents were stored, was not known to the Authority even by 23 October 2021. Having stated that some of the files under custody of the then contractor had been damaged by floods in the year 2016, making payments to the contractor for the period of one year from May 2016 to April 2017 had been suspended, but no formal inquiry had been conducted on the damaged files. Furthermore, an agreement had not been entered in to with the contractor for the year 2021 even by 23 October 2021 but his services were being obtained even by the date of this report. The Authority had not brought their attention on establishing an own record room by analyzing the cost incurred in that connection over a period of 06 years.	After the damage caused by floods in 2016, those files had been transferred to two other stores. Action had been taken to take copies of the damaged files. Audit trial will be carried out as soon as possible in this year thus taking action to ensure safety of the files. Attention has been drawn by the Authority to maintain a record room.	Attention should be drawn on the possibility of constructing a record room for the Authority. It is necessary to ensure the facilities of the stores, safety from the fire hazards, and the standard practice is followed.
b)	When a sample of 19 dossiers, under which registration certifications on medical devices had been issued, was examined in	Not commented	A formal inquiry should be conducted in that

	the year 2020, it was observed that some of those dossiers had been handed over by the relevant companies in the years 2016 and 2017, and a period ranging from 150 to 1,395 days had been spent to issue certificates after evaluating those dossiers. Matters further observed included : the Chief Executive Officer had taken 15 – 181 days to provide 451 dossiers for evaluation; external evaluators had been entrusted with evaluation after a period of one year; and, action had not been taken to obtain the evaluation reports or take follow up action.		connection.
c)	Requests had been made for registration of 583 new medical devices in the year under review, but registration certificates had been issued only for 149 devices even by 01 April 2021 whereas 04 of them had been turned down with decisions pending on 02 other devices. Registration could not be given for the rest of the 428 medical devices.	- Do.	- Do.
d)	Contrary to Sections 41 (2), 66(2), and 87(2) of the National Medicines Regulatory Act, No. 05 of 2015, officers holding a recognized degree in Medicine, Pharmacology, Pharmacy or any other related discipline, had not been appointed to the Medicine Regulatory Division, Medical Devices Regulatory Division and the Borderline Production Regulatory Division.	Highly experienced Pharmacists in the health sector are officiating in those Divisions. Officers qualified enough among the ones absorbed into the permanent staff of the authority, would be appointed as Heads of the Divisions relating to regulating activities.	It is necessary to make sure that provisions of the Circular are adhered to.
e)	Contrary to Sections 60 (2), 61, 84 (2), 85, 103(2), and 104 of the National Medicines Regulatory Act, No. 05 of 2015, the Authority should have informed the public trough the Gazette on the refusal to register medicines, medical devices, and borderline products. Nevertheless, it had not been so done.	It is acknowledged that the said process had not taken place regularly, and this will be done on regular basis in due course.	Provisions of the Circular should be followed.

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3.2 Operating Inefficiencies

	Audit Observation	Comment of the Management	Recommendation
a)	The National Medicines Quality Assurance Laboratory had submitted an application to the Sri Lanka Accreditation Board on 06 February 2020 in order to obtain a certificate of conformity. However, that certificate could not be obtained even by the date of audit on 31 December 2021. Furthermore, it was not verified that the Authority had obtained other certificates on standard.	Conversions required by the Sri Lanka Accreditation Board is being done at present. Once the process is completed, the laboratory will again be evaluated by the Sri Lanka Accreditation Board.	Certificate of conformity on the standard of the laboratory should be obtained.
b)	In terms of Sections 72(1), and 93(1) of the National Medicines Regulatory Authority Act, No. 05 of 2015, the Authority should prepare guidelines on the medical devices and borderline products presented for evaluation, and such guidelines should be provided for the Medical Devices and Borderline Evaluation Committee. As per Section 142, regulations should be made relating to the issue of licenses and registration of medical devices and borderline products. Nevertheless, such guidelines had not been prepared and published in the Gazette, nor had the regulations on the registration and issue of licenses been made.	All of the general guidelines have been prepared (by each Division) for the evaluation of medicines, medical devices, borderline products and other relevant items; and, such guidelines have been published on the webpage of the Authority. Instructions issued by the World Health Organization from time to time, and the evaluation activities of the evaluation committee also belong to the said regulation process. Having considered the possibility of issuing guidelines separately, corrective measures will be taken in due course.	General guidelines on the evaluation of medical devices and borderline products, and regulations for the registration of products and issue of certificates, should be made.

c)	Contrary to Section 123 of the National Medicines Regulatory Authority Act, No. 05 of 2015, an Appeals Committee had not been appointed to hear and determine appeals presented to the Authority.	As the Appeals Committee should be appointed by the Minister, the Minister has been informed in that connection.	Provisions of the Act should be followed.
d)	The number of samples tested by the National Medicines Quality Assurance Laboratory in the preceding year in terms of Section 39 of the National Medicines Regulatory Authority Act, No. 05 of 2015, represented 60 per cent of the total number of samples presented in that year. Furthermore, only 334 of the 468 samples presented during the year under review had been tested showing the progress of 71 per cent.	Testing all the samples received by the laboratory within the same year is difficult. This is a process taking part in every year. Quality reports on the samples remaining in the year would be issued later, and reports on 443 of the 468 samples received in the year 2020 have been issued representing 95 per cent.	Action necessary to increase the number of samples being tested, should be taken.
e)	Revenue totalling Rs.6,464,208 had been refunded in 107 instances during the years 2019 and 2020 due to reasons such as, overcharge of Value Added Tax by the Authority from external institutions, double payments being made owing to negligence and errors of the officers, collection of revenue in excess of the specified fee, non-issue of import licenses following the expiration of registration, and failure in issuing transport licenses owing to changes in names and expiration of the validity period of stocks licenses. However, of the	The collected revenue is refunded to the parties responsible due to miscellaneous reasons. There were 107 instances of refund only in the years 2019 and 2020. External parties as well as internal officers were apprised from time to time in the year 2021 to avoid this situation. As a result, the instances of refund could be reduced to 18 in the year 2021.	Action should be taken to identify the unjustifiable reasons that prompted to refund the revenue, thereby identifying and recovering the overpaid income tax and Treasury levy.

	matters based on which the revenue had been refunded, the effect of the negligence and errors of the officers had not been recognized thereby failing to take action to recover the overpaid income tax and taxes of the Treasury, surcharge the responsible officers, and bring remedial measures to minimize the refund of revenue by maintaining a register containing all the information in that connection.		
f)	The number of pharmacies registered as at 31 December 2020 had not been made available to the Audit. During the year under review, only 48 pharmacies had been inspected by the Authority whereas offices of the provincial health officers had inspected only 23 pharmacies.	Cases had been filed against 48 pharmacies after being inspected. The number of pharmacies inspected was higher than that. The reasons that caused the reduction in the number of cases filed included : curfew imposed in the year 2020, pharmacies had to be closed, and lack of attention drawn to take legal action in the context that the pharmacies had to be open under any circumstance following instructions of the Government to avert a shortage of medicines. Measures have been taken to inspect the pharmacies under a proper plan and targets during this year.	A methodology suitable to inspect the pharmacies and take legal action whenever necessary, should be introduced.

3.3 Transactions of Contentious Nature

Audit Observation	Comment of the Management	Recommendation
It had been targeted as per the regulations relating to the registration of medicines and issue of licenses that 300 working days would be spent on the evaluation of a registered dossier, 180 working days would be spent to evaluate a registered dossier on priority basis, and 15 working days would be spent on the initial examination on the completeness of a registered dossier. However, the same Pharmacist, under the knowledge of the Chief Executive Officer, had evaluated within 01-02 days 17 of 93 dossiers presented to obtain certificates to import samples and registration certificates in the year under review by 03 companies located at the same address comprising 02 directors with same names along with another company liaised to that company whereas another 24 dossiers had been evaluated with or without knowledge of the Chief Executive Officer. Moreover, it was confirmed through an independent report of experts that the said dossiers had not been evaluated properly. It was further revealed that the said pharmacist had spent 281-427 days in the year 2019 to evaluate a dossier pertaining to other companies. The applicants who obtained provisional registration, should request for re-registration prior to 06 months before the lapse of the validity period of the provisional registration being 02 years. In 35 instances however, full registration certificate had been issued to the said network of companies within a period of 03 months from the date of issuing the provisional certificates, and evaluation, examining process and approvals of the Chief Executive Officer relating to the said registration had been done within 01-02 days in a manner favourable to that company. Although a period of over one year had elapsed since the Secretary to the Ministry of Health had been informed on the said irregular act, no information was revealed that an investigation had been conducted or a methodology had been put in place to avert such a practice. Instead, 04 responsible pharmacists had been released to the Ministry of Health on administrative grounds on 12 August 2020 with no disciplinary inquiry at all.	Not commented.	A formal inquiry should be conducted in this connection.

3.4 Procurement Management

Audit Observation	Comment of the Management	Recommendation
As for the contracts the value of which exceeds Rs. 500,000, a formal contract agreement should be entered into in terms of Guideline 8.9.1 (b)of the Government Procurement Guidelines. However, no written agreement had been entered into with the suppliers in respect of the contracts for supply and installation of 10 air conditioners costing Rs. 1,122,095 and purchase of 47 Tabs costing Rs. 2,529,540. As such, services for those items such as maintenance activities, could not be provided.	Those deficiencies will be averted in due course, and procurements will be done in accordance with the Procurement Guidelines.	Provisions of the Government Procurement Guidelines should be followed.

3.5 Human Resource Management

Audit Observation	Comment of the Management	Recommendation
The cadre approved for the Authority as at 31 December 2020 was 257 including 235 permanent employees and 22 employees on contract basis. However, the actual cadre as at that date was 120 of whom 59 had been attached to the posts on secondment basis. Especially, 45 pharmacists evaluating the applications for registration of medicines, had been appointed on secondment basis. Furthermore, 182 vacancies existed including 12 posts in the staff grade such as Director, Deputy Director, and Medical Officer. Furthermore, there existed 70 newly approved posts of Pharmaceutical Assessor and Assistant Pharmaceutical Assessor together with 08 approved posts of laboratory assistant. However, action had not been taken even by 07 October 2021 to recruit officers to those posts. It was observed that	A number of 235 posts had been approved on 07 January 2022 for the permanent staff of the Authority, and 161 employees are in service. The Permanent staff is 111 with a pharmacist employed on secondment basis. Twenty nine Assistant Pharmaceutical Assessors for medicines have been recruited.	The process of absorption and recruitment should be expedited.

vacancies in the posts of drug inspector, and pharma analyst would directly affect the functions of the performance of the Authority such as, inspection of pharmacies, issue of licenses, registration of medicines and medical devices, examining the quality of medicines being presented for registration, and inspection and approval of good manufacturing practices(GMP).

4. Accountability and Good Governance

4.1 Presentation of Financial Statements

Audit Observation	Comment of the Management	Recommendation
The annual financial statements should be presented to the Auditor General within a period of 60 days after the end of the year of accounts in terms of Section 6.5.1 of the Public Enterprises Circular, No. PED/12, dated 02 June 2003. However, financial statements of the year 2020 had been presented to the Auditor General on 16 September 2021 after a delay of 07 months.	Agreed with the observation.	Action should be taken in accordance with the Public Finance Circular.

4.2 Tabling the Annual Report in Parliament

Audit Observation	Comment of the Management	Recommendation
An annual report on the activities carried out in the relevant year of finance should be presented by the Authority to the Minister within a period of six months from the end of the year of finance in terms of Section 23 of the National Medicines Regulatory Authority Act, No. 05 of 2015. That report should be annexed to the report of the Auditor	The annual reports prepared for the years 2016 and 2017 have been handed over to the Ministry of Health and the State Ministry of Production Supply and Regulation of Pharmaceuticals, Supply and Regulation. The format of presentation has been	Action should be taken in accordance with provisions of the Act.

General, the report on accounts of the Authority audited for the relevant year, and a report on the affairs for the ensuing year. The said report should be presented to Parliament by the Minister within a period of 06 months since the date of receipt. However, annual reports had not been prepared and presented to the Minister and Parliament since the year 2017.	changed and annual reports are being prepared according to a new format.	

4.3 Corporate Plan

Audit Observation	Comment of the Management	Recommendation
The Corporate Plan, Action Plan, Procurement Plan and the annual budget of the Authority should have been prepared in parallel, but it had not been so done.	Action is taken to properly prepare those plans.	The Corporate Plan, Action Plan, Procurement Plan and the annual budget should be prepared in parallel.

4.4 Annual Action Plan

	Audit Observation	Comment of the Management	Recommendation
a)	According to Paragraph 04 of the Public Finance Circular, No. 01/2014 dated 17 February 2014 issued by the Secretary of the Treasury, Statutory institutions should prepare an annual action plan with a long term vision for the achievement of objectives mentioned in the Act by including organizational structure of the institution, approved and actual cadre, budget for the relevant year, and the internal audit plan. However, the Authority had prepared only a draft of the action plan for the year under review, and the said information had not been included therein.	Action is taken to properly prepare the action plan.	Provisions of the Public Finance Circular should be followed.

b)	Progress of the activities included in the draft action plan prepared for the year under review, had not been made available to the Audit. Five activities for which provision totalling Rs. 576 million had been allocated, were not initiated. The said amount represented 82 per cent of the annual budget estimate totalling Rs. 700 million.	Those programs could not be implemented due to reasons such as, change in the Cabinet approval later, donation of 03 vehicles by the Presidential Secretariat by suspending the purchase of new vehicles, failure of the National Medicines Quality Assurance Laboratory to provide the specifications, and the spread of Corona Pandemic in the year 2020.	Action should be taken to materialize the objectives mentioned in the action plan.

4.5 Sustainable Development Goals

Audit Observation	Comment of the Management	Recommendation
According to "2030 Agenda" of the United Nations on sustainable development and the provisions of Circular, No. NP/SP/SDG/17 issued by the Secretary to the Ministry of National Policies and Economic Affairs on 14 August 2017, the Authority should have recognized targets for achieving the sustainable development goals together with the constraints thereon and performance indicators to measures the progress. However, the Authority had not identified such indicators thus failing to measure the progress of achievements, deviations and the areas requiring attention.	Action is taken to bring attention on the targets to be achieved by the Authority in respect of sustainable development goals.	Action should be taken to identify suitable indicators to measure the progress of achieving the targets relating to the sustainable development goals.

Chapter - 4

Performance Achieving Sustainable Development Goals (SDG)

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

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

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

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

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

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

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

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

Chapter - 5

Human Resource Profile

5.1 Cadre Management

	Approved Cadre	Existing Cadre	Vacancy
Senior Level	76	12	64
Tertiary Level	46	-	46
Secondary Level	85	77	8
Primary Level	50	31	19
TOTAL	**257**	**120**	**137**