Annual Report

2021

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
PV	Pharmacovigilance
SCCT	Sub Committee of Clinical Trial
SDG	Sustainable Development Goals
SSFFC	Substandard/Spurious/Falsely-Labeled/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 Present Chairman

I am pleased to present the Annual Report for the year 2022 of the National Medicines Regulatory Authority, which is an independent body of the Ministry of Health. The main function of the Authority is to assume the quality, safety, efficacy, and affordability of all kind of medicines, medical devices, borderline products, and cosmetics, for the public by following the National Medicine Policy, in Sri Lanka.

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 and specially inadequate human resources. The National Medicines Regulatory Authority is proud of having the National Medicines 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, for becoming financially stable by 2017 and being 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, and developing human resources wisely.

Prof. S.D. Jayaratne
Chairman
National Medicines Regulatory Authority

Message of the Present Chief Executive Officer

I, being the CEO of one of the fast-growing Medicine Regulatory Authorities in South-East Asia, the NMRA, feel very proud to present its Annual Report for the year 2022. 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.

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.

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 and I feel very proud that the National Medicines 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 the Authority. I am fully committed to achieving that goal by improving operational productivity, financial performance and independence, developing the human capital base, and using the latest methods in IT systems.

Dr. Vijith Gunasekera
Chief Executive Officer
National Medicines Regulatory Authority

Board of Directors - 2021

1. Dr. Rasitha Indula Wijewantha (Chairman)
2. Dr. Saveen Semage (Chief Executive Officer)
3. Dr. Asela Gunawardena (DGHS)
4. Prof. Sisira Siribaddana
5. Dr. Ananda Wijewickrama
6. Ms. K.Sajeewani Dayarathne
7. Dr. Nissanka Jayawardena
8. Dr. Sanath Lanerolle
9. Mrs. W.M.G.M. Wijesuriya
10. Prof. Sudheera Jayasinghe
11. Dr. Sewwandi Subasinghe
12. Mr. Raja Goonaratne

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 - government 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.

Accordingly, to ensure smooth functioning of NMRA activities the following divisions have been established and activated.

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

Further, there are several committees comprising with number of expertise in the relevant fields to assist for the decision making process namely;

- Medicine Evaluation Committee (MEC)
- Medical Devices Evaluation Committee (MDEC)
- Sub Committee of Clinical Trials (SCCT)
- Cosmetic Evaluation Committee (CEC)

All those committees are responsible for evaluation of Medicines, Medical Devices, Borderline Products, Clinical Trial items and Cosmetics items to ensure safety, quality & efficacy of all those products available within the country.

In addition, Pricing Committee for regulating the market price to ensure the availability of all those medicinal items at an affordable price for the public.

Also, there is an Appeal Committee open to the public and Advisory Committee to oversee the implementation of NMRA Act.

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

1.2 Vision, Mission, and Objectives of the Authority

1.2.1 Vision of the Authority

‘Improve access to quality medicines, healthcare products and cosmetics’

1.2.2 Mission of the Authority

‘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 Objectives 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 Divisions under the NMRA

For the smooth functioning of the NMRA, following divisions have been established.

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

1.4.1 National Medicines Quality Assurance Laboratory (NMQAL)

1.4.1.1 Introduction

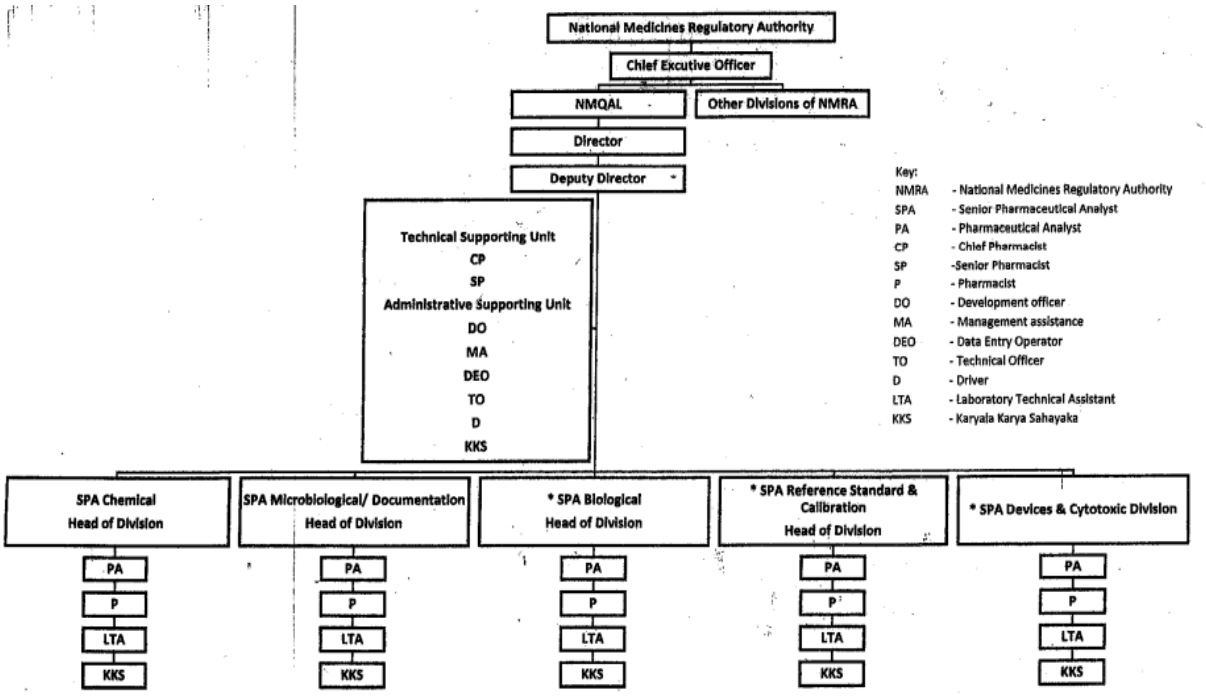
National Drug Quality Assurance Laboratory (NDQAL) was the National Laboratory established in Sri Lanka for testing Cosmetics, Devices and Drugs. It was established in 1990 under Cosmetics Devices and Drug Act No.27 of 1980, with Norwegian consultancies and NORAD funds with the vision of ensuring Quality,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

The National Medicine 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.

1.4.1.2 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.

1.4.1.3 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

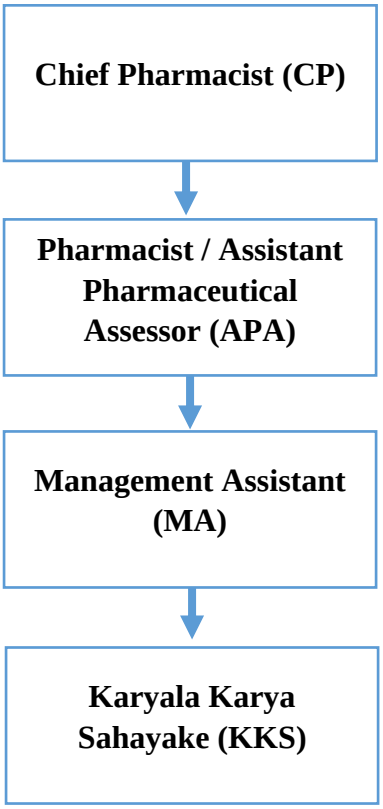
- To coordinate with laboratories local or overseas when their services are deemed necessary as decided by the NMRA.

1.4.2 Medicines Regulatory Division

1.4.2.1 Introduction

This could be identified as one of the main functions of NMRA and responsible for ensuring safety, efficacy and quality of medicinal products and cosmetics at an affordable price for the public. Accordingly, the division is engaged in regulating medicines, medical devices and borderline products used within Sri Lanka to protect the interests of patients using the products. 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.

1.4.2.2 Divisional Chart of the Medicines Regulatory Division



1.4.2.3 Functions of Medicines Regulatory Division

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

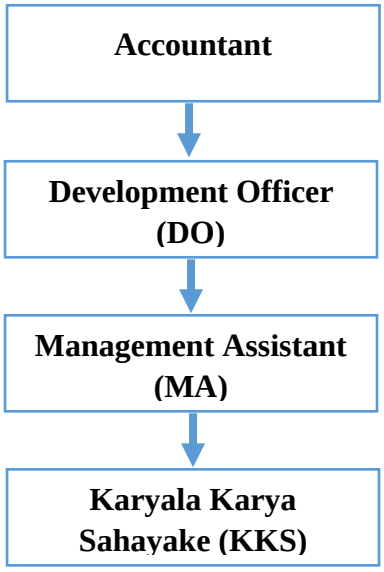
- Evaluation, and make arrangements to register and give recommendation for issuing of import license for medicines, medical devices, cosmetics and borderline products.
- Regulation of Pharmaceutical manufacturing sites locally and internationally.
- Price Regulation
- Regulation of Island wide Pharmacies
- Pharmacovigilance

1.4.3 Finance Division

1.4.3.1 Introduction

Controlling of all the monetary activities within the authority is handled by the Finance Division. Accordingly, all the revenue sources are identified, received and handled the cash flow in an effective manner. Submitting the final accounts on time is the main task of the Finance Division while preparing annual budget forecast including all expenses. In addition, all the procurement activities which are required to ensure smooth functions of the other divisions of NMRA are handled by the finance division.

1.4.3.2 Divisional Chart of the Finance Division



1.4.3.3 Functions of the Finance Division

- Receiving revenue through eighteen revenue streams.
- Preparing final accounts
- Preparing the budgets 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 activities
- Procurement activities

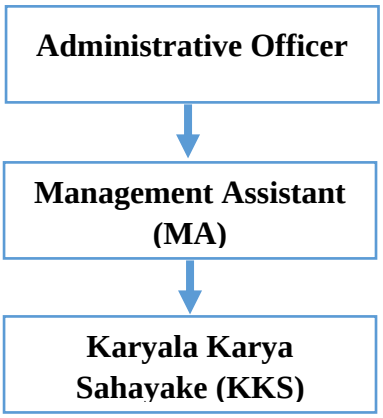
1.4.4 Administration Division

1.4.4.1 Introduction

From the beginning of NMRA, the Administration Division is playing a key role for the Authority. 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 and cosmetics 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 are handled. It helps the organization to deliver a high-quality service to its clients, by establishing the formal communications with other institutes as well.

1.4.4.2 Divisional Chart of the Administration Division



1.4.4.3 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 of staff ID cards

1.4.5 Legal Division

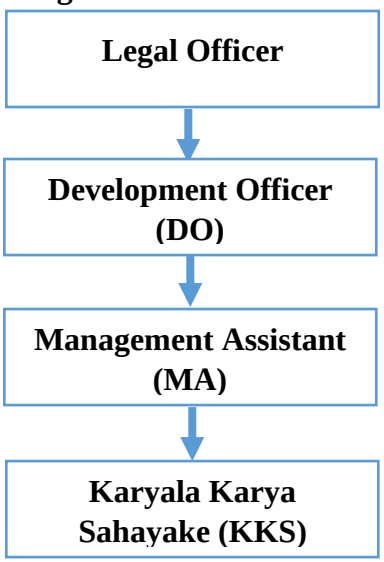
1.4.5.1 Introduction

Legal Division established with effect from 21st of April 2017, which plays a pivotal role for the Authority in rendering advice to the Authority on all legal & regulatory issues including all litigation matters in which NMRA is a party.

The role of the legal division is necessary for the regulatory functions of the NMRA.

Legal Division has the responsibility to provide legal opinion in terms of the National Medicines Regulatory Authority Act No. 05 of 2015 and other directly related legislations in the regulatory activities carried out by the NMRA.

1.4.5.2 Divisional Chart of the Legal Division



1.4.5.3 Main Functions of the Legal Division

- Drafting of Agreements, Gazettes, Cabinet Memorandum, Memorandum Of Understandings and any other legal documentations.
- Amending, advising and reviewing primary and secondary legislations.
  e.g.: laws, rules, regulations, guidelines and Standard Operating Procedures are the responsibilities and functions of the Legal Division in NMRA.
- Conducting, Monitoring and processing of applications for agency transfer matters and any other matters relating to the legal division.
- Legal Division also provides legal opinions on matters referred by other divisions of NMRA as well as licensees, stakeholders, ministries/ divisions and other forums.
- Take necessary steps pertaining to the parliamentary affairs.
- Legal Division also advises the Authority in the cases requiring legal input on various regulatory matters and initiation of legal proceedings under the National Medicines Regulatory Authority Act No. 05 of 2015.
- It is also responsible for handling cases filed in Courts of Law such as Supreme Court, Court of Appeal, Magistrate Court, Commercial High Court, High Court, Labour Tribunal and Human Rights Commission, Commission of Right to Information etc., where NMRA has been cited as a party.
- Attending any commission inquires/CID inquires where necessary.
- Handling all applications received under the Right to Information Act No. 12 of 2016.
- Coordinating the Board Meetings
- Any other matters relating to the legal division.

1.4.6 Inspectorate and Enforcement Division

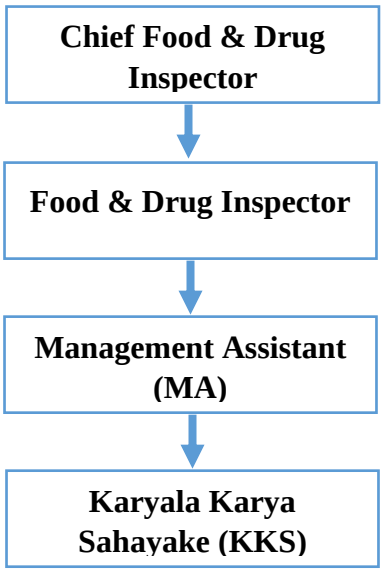
1.4.6.1 Introduction

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.

1.4.6.2 Divisional Chart of the Inspectorate and Enforcement Division



1.4.6.3 Functions of Inspection and Enforcement Division

- Functioning as Authorized Officers under the NMRA Act
- Conducting Post marketing surveillance
- Obtaining formal and informal samples when necessary
- Inspecting & recommending medicines handling establishments to issue licenses
- Inspecting & recommending medicine transport vehicles to issue licenses
- Ensuring the implementation of product recall procedure

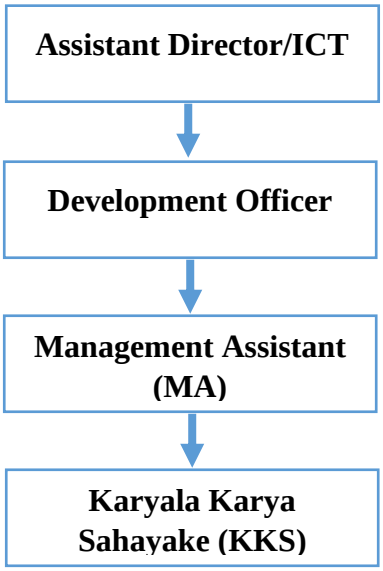
- Investigating & initiate legal actions on the detentions made by the SSFFC & smuggled products
- Investigating the availability of state-owned drugs in the private market
- Inspecting & recommending of dangerous drugs applications
- Organizing & conducting educational programs
- Conducting prosecutions against the violations committed under the Act
- Coordinating & corporation with other law enforcement agencies

1.4.7 Information and Communication Technology (ICT) Division

1.4.7.1 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.

1.4.7.2 Divisional Chart of the ICT Division

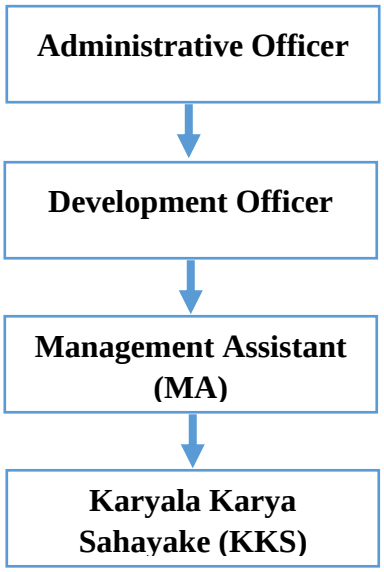


1.4.8 Human Resource Division

1.4.8.1 Introduction

Human Resources Division of the National Medicines Regulatory Authority handles the recruitment, development, retention and firing processes of the Authority staff. Accordingly, the purpose of the division is to maximize the utilization of the employees to achieve Authority objectives efficiently and effectively.

1.4.8.2 Divisional Chart of the Human Resources 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)

What is done in 2021:

SLAB conducted initial assessment (online) for obtaining ISO 17025 status.
ISO 9001 initial audit conducted by a consultant.
Following Training programs were planned and conducted for NMQAL staff. All training programs were done as virtual meeting.

- Method Validation 1st - 08th January 2021 - Conducted by WHO Consultant
- Method Validation 2nd - 12th January 2021 - Conducted by WHO Consultant
- Outsourcing testing activities of NMQAL - Conducted by WHO Consultant
- Quality control of medicinal products & preparation of reference materials- Conducted by WHO Consultant
- Key performance indicators - Conducted by WHO Consultant
- Advanced Good Manufacturing Practices (GMP) Inspections - Conducted by WHO Consultant

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
6) (Equipment, chemicals, solvents, reagents, primary and other standards, glassware and other accessories etc.)
7) Strengthen the internal communications/procedures/support for a better service.
8) Develop the laboratory activities to achieve ISO 17025 accreditation and/or to obtain WHO prequalification states.

Performance of the Division:

During 2021 NMQAL analyzed about 389 samples and failures were detected in 86 samples/batches and recommendations on failures were given accordingly.

Please refer Annex II

Performance to achieve SDG's:

01.01.2021 - 31.12.2021

No. of certificate of Quality issued = 485-96

= 389

Sample Type	Pass	Fail/WH/ WD	Already WD	Not Done	Total
Complaint	57	39	2	35	133
Formal	25	10	-	52	87
Informal	44	3	-	5	52
Lab Request	7	3	-	-	10
Manu. Request	1	-	-	-	1
Registration	36	8	-	-	44
SPC Tender	5	1	-	4	10
Others	27	14	-	-	41
Surveillance	83	8	-	-	91
Sanitizers					16
	285	**86**	**2**	**96**	**485**

No. of failure report issued = 86

Percentage (%) of quality failure from the Report issued in 2020 = 22

2.2 Progress of Medicines Regulatory Division

Pharmaceutical Regulatory Division is comprising of sub divisions such as; Medicine Regulatory Division, Device Regulatory Division, Cosmetic Regulatory Division, Borderline Regulatory Division, Manufacturing Regulatory Division, Pharmacy Regulatory Division, Pharmocovigilance Division, Pricing Unit, Clinical Trail Regulatory Division, HS Codes Clearance Unit, Information, Education, Communication and Research Division, Market Control & Advertising Unit, and QMS Unit.

Routine duties of are completed with maximum efficiency by regulatory pharmacists with multiple job roles to carry out the responsibilities of NMRA.

Plans for future

1) Introducing subdivision of the division to create teams of similar job roles to improve efficiency
2) Electronic system requirement to be fulfilled to reduce over processing and improve the efficiency of the respective divisions.

2.2.1 Medicines Regulatory Division

Medicines dossier evaluations

Type of applications	Number of applications received	Number of applications evaluated
New Medicines applications	239	562
MEDREG applications	413	
Re-Registration applications	125	
Additional	1251	

Number of MEC - Subcommittee meetings for dossier evaluation

Total evaluated dossiers	Number of applications reviewed by MEC - sub committee	Number of applications send to CEO signature
682	682	0

Review of applications for New Molecular Entity (NME)

Total applications received for (NME)	Number of applications reviewed and approved	Number of applications reviewed and reject
69	46	23

Evaluation of applications for personal use authorization

Total applications received for personal user authorization letters	Number of applications reviewed and approved	Number of applications reviewed and reject
145	136	09

Evaluation of applicaions for sample import license

Number of applications recived for sample import license	Number of applications reviewd and approved (From 29.5.2021)	Number of applications reviewd and rejected.
693	633	60

Number of MEC meetings conducted = 10 (10 minutes were written)

No of MEC Subcommittee - 13 Sub committees

Applications for import authorizations for controlled substances

Number of applications received	Total number of applications evaluated and approved	Total number of applications evaluated and rejected
125	125	0

Requests for approval of monthly quota of narcotic drugs for private hospitals

Number of applications received	Number of applications reviwed and approved	Number of applications reviwed and rejected.
34	34	0

Requests for approval of authorized person to handle narcotic drugs in private hospitals

Number of applications received	Number of applications reviewd and approved	Number of applications reviewd and rejected
23	23	0

Issuing Waiver of registration

Number of WOR meetings for review WOR appliactions =

Total number applications received	Total number applications reviewed and approved	Total number applications reviewed and reject
351	254	97

Review of quality failure reports

Number of NMQAL reports received	Number communicated to relevant stake holders	Number pending
65	65	0

Review applications for shipment clearance approval

Number of applications received	Number of applications reviewed and approved	Number of applications reviewed and reject
55	55	0

Extension of registration certificates and import license

Number of applications received	Number of applications reviewed and approved	Number of applications reviewed and reject
3892	2355	1537

Extension of import license

Number of applications received	Number of applications reviewed and approved	Number of applications reviewed and reject
4067	3742	325

Update medicines database

Number of received registration certificates from Admin	Number of entered certificates to data base	Number of pending to enter
1336	1336	0

2.2.2 Medical Devices Regulatory Division

Sample Import License Applications

Total No. of applications received	Total No. of applications Approved	Total No. of applications Rejeced
873	477	396

Medical Device Application

Total No. of applications received	Total No. of applications Evaluated	Decisions
New - 259 Re-Registration - 101 Renewal - 826	New - 681 Re-Registration - 63 Renewal - 375	FR - 207 PR - 777 RJ - 58 Awaiting Data/ Sample - 103 Certificate Amendment - 56

Waiver of Registration

Total No. of applications received	Total No. of applications Approved	Total No. of applications Rejected
1312	766	546

Certificate / License Extensions	
Total No. of applications received	Total No. of Certificate / License Extended
2357	1724

Officers	Number of Applications Evaluated						
	Medical Device Applications			Sample Import License Applications	WORs	A/T Files	Certificate / License Extensions
	New	RR	Renewal				
P3	46	02	45	NIL	N/A	-	
P8	49	03	18	-	1312	-	
P7	84	10	47	831	-		
P27	84	05	37	-	-	-	
P25	30	04	56	-	-	-	
P24	93	05	22	-	-	-	
P9	75	09	19	05	-	-	
P33	74	10	57	24	-	-	
P39	60	01	NIL	13	-	-	-
P37	12	01	11			-	
P28	75	16	63	-	-	-	

2.2.3 Cosmetic Regulatory Division

Type of Application	Number of files received	Total number s evaluated
Total Applications received with the year 2021	4232	4035
Total New Applications	2413	2367
Total Renewal Applications	1681	1530
Total Re-registration Applications	138	138

Type of Application	Types of registration granted	Number of applications evaluated	Total Applications evaluated during year
New Applications	Provisional Registration	1940	2367
	Full Registration	-	
	Awaiting Data	394	
	Reject	33	
Renewal Applications	Provisional Registration	710	1530
	Full Registration	634	
	Awaiting Data	170	
	Reject	16	
Re registration Applications	Provisional Registration	67	138
	Full Registration	53	
	Awaiting Data	13	

2.2.4 Borderline Product Regulatory Division

Performance of the BPR Division in 2021

Performance of the Borderline Products Regulatory Division	
Classification New Applications	
Number of Classification Applications accepted in year 2021	232
Number of Classification Reports issued in year 2021	57
Number of Classification Report issued as at 19.05.2022(From the applications accepted in year 2021 only)	153
Total Number of Classification Application rejected in year 2021	9
Registration Applications	
Number of Registration Applications accepted in year 2021	45
Number of Registration Evaluation Reports issued in year 2021	48
Total Number of Registration Application rejected in year 2021	4
Consignment Clearance Request	

Number of Consignment Clearance Requests submitted in 2021	42
Number of Consignment Clearance Issued in 2021	29
Number of Consignment Clearance submissions rejected	13
Sample Import License	
Number of Sample Import License submitted	54
Number of Sample Import License issued	64
Number of Sample Import License rejected	28

2.2.5 Manufacturing Regulatory Division (MFRD)

1) GMP inspection of local manufacturers

Medicines manufacturers - 23
Devices manufacturers - 48
Cosmetic manufacturers - 103
Total - 174

NB: Includes follow up inspections of the same manufacturer

2) Applications for approval of foreign manufacturing sites

Number of applications received - 51
Number approved - 41
Awaiting deficient data/GMP inspection - 09
Number rejected - 04

3) Formulation approvals

Number of applications received - 540
Number approved - 533
Number rejected - 7

4) Processing of certificates and licenses

i) GMP certificates - 34
ii) Free Sales Certificates - 12
iii) Certificates of a Pharmaceutical Product - 03
iv) Manufacturing Licenses - 288
v) Clarification letters for customs clearance of material and equipment required by local manufacturers - 289

5) Publication of guideline
    i. Guideline on approval of an overseas manufacturing plant
6) Preparation of SOPs

    Preparation of annual training plan for the Manufacturing Regulatory Division

2.2.6 Pricing Unit

Output and Deliverables
Dossiers
Number of Evaluation Sheets Received = 232
Number of Dossiers Received from Admin Office = 112
There were total applications (New/RR/ Additional) reviewed - 516 applications. (Including appeals & queries)
Approved: - 319 applications
25 applications under communication with local agents to negotiate the MRP
Back log of dossiers: - 25 Applications.
Import licenses.
There were total applications reviewed - 130 applications.
Committee approved - 95 applications
35 applications under communication with local agents to negotiate the MRP

2.2.7 Clinical Trial Regulatory Division

Number of meetings for Clinical Trials Evaluation Committee (CTEC) held : 12

Target: Minimum 10 meetings per year (target achieved)

Summary of clinical trial applications submitted for review

Total number of applications received from 01.01.2021to 31.12.2021	: 09
Number of trial applications on Investigational New Drugs (INDs)	: 5
*Total number of applications reviewed for year 2021	: 11
Total number of applications on which decisions were pending	: 02

*Includes 02 application carried over from year 2020

Clinical trial applications according to the type of the investigational product

Type of product	Approved	Not approved	Pending	Other	Total
Medicine	8	1	2	-	11
Medical device	-	-	-	-	-
Borderline product	-	-	-	-	-
Total	**8**	**1**	**2**	**-**	**11**

NMRA reference number	Application received date	Date of letter notifying the decision	Time for final decision (with stop-clocks)	Remarks
CLITRI/2020/0043	30.10.2020	22.01.2021	56 days	-
CLITRI/2021/0044	18.11.2021	25.01.2021	49 days	-
CLITRI/2021/0049	17.05.2021	30.08.2021	36 days	-
CLITRI/2021/0050	04.06.2021	12.07.2021	19 days	-
CLITRI/2021/0051	07.06.2021	09.07.2021	58 days	Appeal is submitted to the board
CLITRI/2021/0052	09.06.2021	13.07.2021	22 days	-
CLITRI/2021/0053	28.06.2021	14.07.2021	10 days	-
CTM/022/2021	01.09.2021	12.11.2021	43 days	-
CTM/023/2021	01.09.2021	15.11.2021	47 days	-
CTM/024/2021	17.09.2021	29.09.2021	-	PI did not response to the queries raised by NMRA.
CTM/025/2021	04.10.2021	-	-	Under Review

Average time for review* : 37 days

Percentage of reviews carried out within timeline of 75 days : 100%

Training/ workshop conducted

i. GCP Inspection work shop conducted by WHO - 22nd September to 24th September 2021

ii. Participated for FERCSL GCP Workshop conducted by Sri Lanka Medical Association – 28th June 2021 & 05th July 2021

2.2.8 Pharmacovigilance Division

No	Activity performed	Details/Nos	Remarks
1.	Developing and publishing guidelines	12 Nos	These guidelines were drafted with the expert consultant assigned by the WHO for PV division
2.	Developing the SOPs	09 Nos	Developed with the WHO consultant
3.	Meeting conducted with the WHO expert	21 Nos	For developing guidelines and SOPs
4.	Participation at training program	03 Nos	Conducted by the WHO
5.	Developing electronic reporting form	01 Nos	
6.	Conducting training program for stakeholders	03 Nos	
7.	Drafting regulations (for amendment) pertaining to the PV	Based on the directions of WHO consultant provided the suggestions for amendment	
8.	Preparing and circulating communication letters on quality failures	65 Nos	
9.	Conducting Safety and Risk Evaluation Sub Committee (SAFRESC) meeting	03 Nos	

The following list of activities are required to be performed according to the WHO benchmark assessment by the Pharmacovigilance (PV) division and currently we are developing the system.

1. Number of received vigilance events/ ADR reports per 100,000 persons of the population
2. Number of awareness events conducted for health care providers and patients as per plan
3. Number of adverse events reports satisfactorily handled and sent to Vigibase by the PV department Vs No. of received adverse events reports
4. Number of fatal vigilance events/ADRs reports analyzed within 24 hours of receipt Vs received fatal vigilance events/ADRs reports
5. Number of serious vigilance events/ADRs reports analyzed within 5 days Vs received serious vigilance events/ADRs reports
6. Number of serious vigilance events/ADRs reports acknowledged &/or issued feedback to the reporter Vs received serious vigilance events/ ADRs reports
7. Higher ICSRs completeness score as measured by the WHO-UMC vigiGrade™ (ranges from 0.07 to 1)
8. Number of local potential signals initially evaluated within 5 working days Vs number of local potential signals
9. Number of vigilance inspections conducted as per the inspection program
10. Number of pharmaceutical companies having a functional PV system Vs total number of pharmaceutical companies in the country
11. Number of assessed RMPs by the PV department Vs submitted RMPs
12. Number of additional risk minimization measures requested from pharmaceutical companies which showed effectiveness Vs those additional risk minimization measures approved
13. Number of pharmaceutical companies who submitted PBRERs as per the stipulated submission schedule
14. Number of assessed PBRERs by the PV department Vs submitted PBRERs
15. Number of assessed DHPCs within 3 working days by the PV department Vs submitted DHPCs
16. Number of DHPCs with satisfactory dissemination progress Vs number of the same DPHCs disseminated

17. Number of received vigilance events/ADR reports regarding the medicinal products under additional monitoring Vs number of reports to the others medicinal products
18. Number of appropriate regulatory actions taken as a consequence of the national Pv activities (label changes, safety warnings, withdrawals of medicines, safety communication, risk minimization activities…) Vs number of vigilance activities (processed topics) taken as a random sample for this performance evaluation

Number of appropriate feedback/notification/ communications with stakeholders (internal or external) conducted as a consequence of Pv activities Vs number of vigilance activities (processed topics) taken as a random sample for this performance evaluation

2.2.9 Training and Awareness Programs conducted by the Information, Education, Communication and Research Division of the NMRA during 2021

1. Awareness program on Good Manufacturing Practices for small scale manufacturers (virtual) - 23rd January 2021 (organized the Pharmaceutical Society of Sri Lanka)
2. Awareness program on Pharmacovigilance for Marketing Authorization Holders (Virtual) – 03rd March 2022 (organized the Pharmaceutical Society of Sri Lanka)
3. Awareness program on Good Storage and Distribution Practices - 23rd April 2021
4. Training for Pharmacists of the NMRA on Evaluation of Applications of Generic Medicines for Marketing Authorization - 2nd 3rd and 8th August 2021
5. Training for final year B Pharm undergraduates at the NMRA - Final Year B Pharm undergraduates of the General Sir John Kotelawala Defence University (Virtual) - 05 .03. 2021
6. MD Medical Administration Part II Training - March 2021

2.3 Progress of Inspection and Enforcement Division

Detail of prosecutions conducted by FDII, attached to NMRA - 2021

Serial No.	Case filled On.	Case No.	Court	Name of Accused	Charge/s	Fine Imposed (Rs.)	Order to publish paper notice
01	2021.01.21	244/21	M. C. Maligakanda	Lithum Malintha Weerasinghe, Sunshine Healthcare (Pvt.) Ltd., Sri Wickrama Mawatha, Colombo 15.	Therapeutic goods were transported without a proper storage facility	10,000	No
02	2021.01.21	245/21	M. C. Maligakanda	W. A. S. Dhanushka Perera, Sri Wickrama Mawatha, Colombo 15.	Therapeutic goods were transported without a proper storage facility	25,000	No
				January Total Fines		**35,000**	
03	2021.03.02	29471	M. C. Gangodawila	H. Manoj Priyantha, Old Kottawa Road, Delkanda	Selling expired drugs	Pending	
04	2021.03.02	29472	M. C. Gangodawila	W. M. T. Priyadarshani, Old Kottawa Road, Delkanda	(i) Storing expired drugs (ii) Storing physicians sample	Pending	
05	2021.03.17	5233/17	M. C. Mahara	H. M. Nadeeshan Madushanka Perera, siyambalawatta,	(i) In possession of restricted drugs (Tramadol X ^{225} 200 tabs)	Pending	

				Delgoda	(ii) Smuggles drug transport (Tramadol X ^{225})		
06	2021.03.20	11235/20	M. C. Maligakanda	K. P. Lahiru Nayanapriya, Kadiranawatta, Mattakkuliya	Drugs storing without a licence	4,000	No
07	2021.03.24	27424/18	M. C. Maligakanda	K. A. Charitha Lakmal, Dematagoda, Kalipulla Estate	Storing of medicines without a licence (18 Pregabalin Capsules)	7,500	No
08	2021.03.24	22753/19	M. C. Maligakanda	(1) Raveendran Ragu Aravindan, Ginigathhena (2) Shanmugaraja Prasandan, Bodhiraja Mawatha, Maligakanda	Transport of medicines without licence by van	25,000 25,000	No
09	2021.03.24	18191/20	M. C. Maligakanda	Mohamad Iqbal Mohamad Miran, State Road, Colombo 14	Storing of medicines without a licence (400 Pregabalin Capsules)	20,000	No
10	2021.03.24	18346/20	M. C. Maligakanda	Kalisan Hemamali, Weheragodalla, Wellampitiya	Storing of medicines without a licence (25 Pregabalin Capsules)	7,500	No
11	2021.03.24	18347/20	M. C. Maligakanda	W. A. Rasika Sandamali, No. 104/221, Wellampitiya	Storing of medicines without a licence (70 Pregabalin Capsules)	10,000	No

12	2021.03.24	23069/20	M. C. Maligakanda	Rajkumar Roshan Kumar, No. 140/1, Sri Dharmarama Road	Storing of medicines without a licence (16 Pregabalin Capsules)	7,500	No
13	2021.03.24	24511/20	M. C. Maligakanda	(1) Shanmuga Thangaraja, Wedikanda, Rathmalana (2) T. A. Siranjan, Yatapola, daraniyagala (3) A. Mohamed Nazar, wadulwatha	Transport of medicines without a licence by lorry (18900 Caps)	50,000 50,000 50,000	No
14	2021.03.24	42/21	M. C. Maligakanda	Mohomed Ameer Mohomed lham, P. R. 130, Sri Dharmarama Road, Dematagoda	Storing of medicines without a licence (07 Pregabalin Capsules)	5,000	No
15	2021.03.24	148/21	M. C. Maligakanda	R. Naween Christeen, Muwadora Uyana, Colombo 15	Storing of medicines without a licence (21 Pregabalin Capsules)	Open Warrant	
16	2021.03.24	2740/21	M. C. Maligakanda	Mohomed Ameer Mohomed lham, P. R. 130, Sri Dharmarama Road, Dematagoda	Storing of medicines without a licence (30 Pregabalin Capsules)	10,000	No
				March Total Fines		**271,500**	

17	2021.06.30	B/1870/21	M. C. Mount-Lavinia	Matrics Lifecare (Pvt.) Ltd., Rubber watta Road, Nikape, Dehiwala (1) M. N. M. Salman (2) M. M. M. Jubran (3) M. N. M. Rizan	(i) Repacking of "Enova" (ii) Importing unregistered medicines	Pending	
				June Total Fines		**Pending**	
18	2021.07.22	14302/21	M. C. Maligakanda	(1) Chamath Kamil Joshep De Silva Wijayarathne (2) Medi Diag (Pvt.) Ltd., No. 16, Gothami Road, Colombo 08	Unregistered, Smuggled Medical devices storing	40,000	Yes
				July Total Fines		**40,000**	
19	2021.09.08	16768/21	M. C. Maligakanda	Mohamed Rizo Mohomed, 61/1/1, Masenger Street, Colombo 12	Unregistered Devices (Pulse Oximeters) transporting.	75,000	Yes
20	2021.09.08	16769/21	M. C. Maligakanda	Abdul Sathor Mohomed Ishaq, Hampdo Lane, Colombo 06	Unregistered Devices (Pulse Oximeters) transporting.	75,000	Yes
21	2021.09.08	16770/21	M. C. Maligakanda	Abdul Azees Fazal Mohomed, Dhawalasinharama Mawatha, Colombo 15	Unregistered Devices (Pulse Oximeters) transporting.	75,000	Yes
				September Total Fines		**225,000**	

22	2021.11.30	24688/21	M. C. Maligakanda	Murugesu Paraneedaran, Baseline Mawatha, Colombo 09	Smuggled drugs storing (Tozilusumab)	Pending	
23	2021.11.30	24689/21	M. C. Maligakanda	Mohamed Asmir Mohamed Yasin, Maligawaththa, Colombo 10.	Smuggled medical devices storing. (Antigen Kits 420)	15,000	
24	2021.11.30	24690/21	M. C. Maligakanda	Mohamed Asmir Mohamed Yasin, Maligawaththa, Colombo 10.	Smuggled medical devices storing. (Pulse Oximeters 1610)	15,000	
25	2021.11.30	24691/21	M. C. Maligakanda	Badurdeen Mohamed Mohamed Azeer, Colombo 12.	Smuggled medical devices storing. Antigen Kits 46)	20,000	
26	2021.11.30	24692/21	M. C. Maligakanda	Badurdeen Mohamed Mohamed Azeer, Colombo 12.	Smuggled medical devices storing. (Pulse Oximeters 198)	25,000	
				November Total Fines		**75,000**	
2021 Total fines						**646,500**	

Annual Inspection - Retail Pharmacies, Wholesale Pharmacies, Medicine Transportation Vehicles - 2021

Month	Retail Pharmacies	Wholesale Pharmacies	Medicine Transportation Vehicles	Total
January	0	0	48	48
February	0	0	63	63
March	04	0	117	121
April	08	07	182	197
May	15	05	129	149
June	17	10	119	146
July	26	08	201	235
August	40	10	129	179
September	39	14	364	417
October	36	06	254	296
November	09	04	163	176
December	07	05	121	133
Total	201	69	1890	2160

Number of court appearance: - 61

Number of complaints: - 14

Number of samples collected: - 16

Number of cases filed: - 26

Total fines collected: - Rs. 646,500.00

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	Category		Total License
1	Registration	Medicine	352
2		Device	1099
3		Borderline	42
4		Cosmetic	3236
5	Import	Medicine	483
6		Device	3164
7		Borderline	76
8		Cosmetic	4061
9	Sample	Medicine	385
10		Device	474

11		Borderline	35
12		Cosmetic	1150
13	Manufacture	Medicine	288
14		Device	74
15		Borderline	1
16		Cosmetic	273
17	Retail		31
18	Transport		2490
19	Wholesale		7
	Total		**17,721**

2.6 Progress of Legal Division

Number of opening files in year 2021	241
Closed files 2021 (01.01.2021 Up to 31.12.2021)	221
Total Pending Files Up to 31.12.2021	384
Agency Transfer Closed Files (01.01.2021 up to 31.12.2021)	
Number of Free of charges files from (01.01.2021 – 31.12.2021)	19
Number of Payment Basic files from (01.01.2021 – 31.12.2021)	88
Total	107
Agency Transfer Total Income (From 01.01.2021 - 31.12.2021)	Rs. 38,375,062.88/-

Regulations/ Gazettes issued under the NMRA Act from 01.01.2021 to 31.12.2021.

No.	Gazette No	Gazette Name
01	2241/43 - 19.08.2021	*The Medicines (Celling on Prices) Regulations of 2019 published in the Gazette Extraordinary No.2123/35 of May 15, 2019 amended by the repeal of the Schedule. *The Medical Devices Pricing Regulations No. l of 2017 published in the Gazette Extraordinary No.2006/45 of February 17, 2017 as amended by regulations published in the Gazette Extraordinary No.2114/54 of March 15, 2019 amended by the repeal of the Schedule *The Medical Devices (Pricing) Regulations of 2018 published in the Gazette Extraordinary No.2086/37 of August 31, 2018 as amended by regulations published in the Gazette Extraordinary No.2114/54 of March, 15,2020 amended by the repeal of the Schedule *The Medical Devices Pricing Regulations No.5 of 2017 published in the Gazette Extraordinary No.2030/47 of August 4, 2017 as amended by regulations published in the Gazette Extraordinary No.2114/54 of March 15,2019 amended by the repeal of the Schedule.
02	2243/20 - 04.09.2021	The Medical (Pricing of Medical Devices) Regulations, No. 1 of 2021.

Pending Court Cases (up to 31.12.2021) - Filed by the NMRA

No.	LO Number	Case	Status	Position of the NMRA
01	NMRA/LO/10/2017	Negambo Magistrate Court Case bearing No. J93933	Pending	Plaintiff
02	NMRA/LO/11/2017	Minuwangoda Magistrate Court Case bearing 70066	Pending	Plaintiff
03	NMRA/LO/15/2017	Wattala Magistrate Court Case bearing No.45379/09	Pending	Plaintiff
04	NMRA/LO/16/2017	Pandura Magistrate Court Case bearing No.07875	Pending	Plaintiff
05	NMRA/LO/434/2018	Panadura Magistrate Court Case bearing No.53946	Pending	Plaintiff
06	NMRA/LO/439/2018	Nuwaraeliya Magistrate Court Case bearing No.62475	Pending	Plaintiff
07	NMRA/LO/465/2018	C.A Writ/400/2018 -Markss HLC (Pvt) Ltd	Pending	Plaintiff
08	NMRA/LO/494/2019	Ampara Magistrate Court Case bearing No.90068	Pending	Plaintiff
09	NMRA/LO/590/2019	Ampara Magistrate Court Case bearing No.92792	Pending	Plaintiff
10	NMRA/LO/726/2019	Gampaha Magistrate Court Case bearing No.82460	Pending	Plaintiff
11	NMRA/FDI/Investi/2019	Pharmace Case bering No.28329/05/20	Pending	Plaintiff
12	NMRA/LO/1088/2021	Mount Lavinia Magistrate Court Case bearing No. 14280/S/21	Pending	Plaintiff

Pending Court Cases (up to 31.12.2021) - Filed against the NMRA

No.	LO Number	Case	Status	Position of the NMRA
01	NMRA/LO/24/2017	SC/FR/102/2016 Lionel Guruge, CPA VS. NMRA	Pending	Respondent
02	NMRA/LO/411/2018	C.A./Writ/285/18 Nawaloka Hospitals PLC & Others Vs. Hon.Dr.Rajitha Senarathne & Others	Pending	Respondent

03	NMRA/LO/412/2018	C.A./Writ/284/2012 Asiri Hospital Holdings PLC & Others Vs. Hon.Dr.Rajitha Senarathne & Others	Pending	Respondent
04	NMRA/LO/465/2019	C.A/Writ/400/2018 Markss HLC (Pvt) Ltd	Pending	Respondent
05	NMRA/LO/707/2019	C.A./Writ/499/2019 Markss HLC (Pvt) Ltd Vs. SPC & 4	Pending	Respondent
06	NMRA/LO/720/2019	C.A./Writ/517/2019 SLCPI 3 others VS. Hon. Pavithra Wanniarachchi & 8 others.	Pending	Respondent
07	NMRA/LO/731/2019	C.A./Writ/501/2019 SLCPI Vs. Hon. Pavithra Wanniarachchi & 2 others.	Pending	Respondent
08	NMRA/LO/823/2020	C.A./Writ/78/2020 Hemas Pharmaceuticals (Pvt) Ltd Vs. Dr. Anil Jayasinghe & others	Pending	Respondent
09	NMRA/LO/949/2021	C.A./Writ/417/2020 Ace Healthcare (Pvt) Ltd and 2 others Vs. Director General of Customs and 15 others.	Pending	Respondent
10	NMRA/LO/1007/2021	SC/FR/108/2021 People's Movement for the Right of Patients & 2 others Vs. Mrs. Pavithra Wanniarachchi, Hon Minister of Health & 23 others.	Pending	Respondent
11	NMRA/LO/1109/2021	SC/FR/321/2021 Dr. Darini Rajasingham & 2 others Vs. Hon. Keheliya Rambukwella, Minister of Health & 4 others.	Pending	Respondent
12	NMRA/LO/1116/2021	2/1130/2021 - LT Case F.R.Gafoor Vs. Chairman, NMRA	Pending	Respondent
13	NMRA/LO/1153/2021	Human Right Commission Complaint No. HRC-HO-2244-21	Pending	Respondent

2.7 Progress of Human Resources Division

Cadre Information as at: 2021.12.31

Designation	Salary Code	Service Level	DMS Approved Cadre			Existing Cadre			
			Permanent	Contract	Casual	Permanent	Contract	Secondment	Ministry of Health employees
Director General/ CEO	HM 2-1-2016	1	1	-	-	1	-	-	-
Director	HM 1-1-2016	1	4	-	-	-	-	-	1
Director (HR)	HM 1-1-2016	1	1	-	-	-	-	-	-
Medical Officer	MM 1-3-2016	1	4	-	-	-	-	-	-
Accountant	MM 1-1-2016	1	1	-	-	1	-	-	-
Internal Auditor	MM 1-1-2016	1	1	-	-	-	-	-	-
Assis. Director/Deputy Director	MM 1-1-2016	1	6	-	-	-	-	-	1
Assis. Director/Deputy Director (ICT)	MM 1-1-2016	1	1	-	-	1	-	-	-
Cost Accountant	MM 1-1-2016	1	1	-	-	-	-	-	-
Legal Officer	MM 1-1-2016	1	1	-	-	1	-	-	-
Pharma. Analyst	MM 1-1-2016	1	13 *	12	-	-	-	-	6
Pharmaceutical Assessor	MM 1-1-2016	1	30	-	-	-	-	-	-
Assis. Pharmaceutical Assessor	JM 1-1-2016	2	40	-	-	28	-	-	-
Administrative Officer	JM 1-1-2016	2	1	-	-	1	-	-	-
Costing Officer	MA 5-2 2016	2	5	-	-	-	-	-	-
Pharmacist	MA 5-1 2016	3	- **	-	-	-	-	1	37
Development officer	MA 3- 2016	3	10	-	-	7	-	-	-
Drug Inspector	MA 5-1 2016	3	20	-	-	-	-	-	3
Tech. Officer (Civil)	MA 2-2-2016	3	1	-	-	-	-	-	-
ICT Assistant	MA 2-1-2016	3	1	-	-	-	-	-	-
Management Assistant	MA 1-1-2016	3	43	10	-	42	-	-	-
Driver	PL 3-2016	4	10	-	-	4	-	-	1
Plumber	PL 2-2016	4	1	-	-	-	-	-	-
Electrician	PL 2-2016	4	1	-	-	1	-	-	-
Lab Assistant	PL 2-2016	4	8	-	-	-	-	-	-
K.K.S	PL 1-2016	4	30	-	-	23	-	-	-
Total			**235**	**22**	**-**	**110**	**0**	**1**	**49**

* The 13 posts of Pharmaceutical Analyst are abolished after their retirement.

** The post of Pharmacist has been suppressed with effect from 2020.11.03 and instead of that the Pharmaceutical Assessor (PA) and Assistant Pharmaceutical Assessor (APA) posts have been established. However, the Pharmacists under Ministry of Health are employed at NMRA until the completion of recruitments for these new posts (PA and APA).

Human Resource Profile

Service Level	Approved Cadre	Existing Cadre	Vacancy
Senior	76	12	64
Tertiary	46	29	17
Secondary	85	90 (including Pharmacists from MOH, not in the approved cadre)	
Primary	50	29	21
Total	**257**	**160**	

Performance of HR Division

- Recruitment Details for the year 2021

Position	Appointed Date	Number of positions filled
Chief Executive Officer	2021.11.10	01
Director HR	2021.02.25	01
Administrative Officer	2021.04.29	01
Assistant Pharmaceutical Assessor	2021.12.15	15
	2021.12.16	09
	2021.12.20	01
	2021.12.27	03
Management Assistant	2021.16.15	17
	2021.06.21	01
	2021.06.28	02
	2021.07.05	02
	2021.08.02	01
	2021.12.01	02
	2021.12.07	01
Total positions filled		**57**

- In addition, the vacancy advertisements were published for recruitment for the posts of Director HR, Internal Auditor, and Pharmaceutical Assessor.
- Provided Training opportunities to seventeen (17) undergraduates.
- Submitted drafted Scheme of Recruitments for DMS approval and obtain approval for the posts of;

  Pharmaceutical Analyst (Contract) - resubmit for amendment

  Pharmaceutical Assessor

  Assistant Pharmaceutical Assessor
- Confirm the service of NMRA employees after completing their three years probation periods.

  Legal officer (1)

  Karyala Karya Sahayaka (23)
- Appointed Food & Drug Inspectors for strengthening post-market surveillance.
- Hold an Efficiency Bar Examination for NMRA staff.
- Bonus payment to all employees as per the PED circular 03/2020
- Issued service letters and miscellaneous letters as requested by employees and other institutions.
- Payment of Annual increments of Authority staff and recommend annual increments of Ministry staff.
- Conducted two-days workshop (02 workshops) for NMRA staff regarding Establishment Code and Financial Regulations.

Chapter - 3

Overall Financial Performance

National Medicines Regulatory Authority

Financial statement for the year ended 31 December 2021

NATIONAL MEDICINES REGULATORY AUTHORITY
STATEMENT OF FINANCIAL POSITION

As at 31 December,	Note	2021 Rs.	2020 Rs.
Assets			
Non current assets			
Property, plant and equipment	2	114,561,686	49,892,359
Capital Working Progress	2.1		5,600,619
Total non current assets		**114,561,686**	**55,492,978**
Non Current Assets			
Distress Lone Balance		5,125,570	
Current assets			
Inventory	3	1,947,084	1,655,865
Deposits and other receivable	4	16,561,415	22,544,810
Short term investments	5	2,141,652,055	3,149,130,138
Cash and cash equivalents	6	1,624,514,939	129,108,499
Total current assets		**3,784,675,492**	**3,302,439,312**
Total assets		**3,904,362,748**	**3,357,932,290**
Equity and liabilities			
Equity			
Accumulated Fund		2,994,730,451	2,404,402,488
Capital Gain		64,275,375	
Total equity		**3,059,005,826**	**2,404,402,488**
Non Current liabilities			
Provision for Gratuity		2,834,700	
Capital grant	7	5,920,019	157,364
Deferred tax	8	13,488,345	7,102,486
Total non current liabilities		**22,243,064**	**7,259,850**
Current liabilities			
Advance receipts	9	87,185,512	76,702,510
Provision for Income tax	19	151,836,233	575,361,535
VAT payable	10	52,463,719	68,856,674
Stamp duty payable	11	30,299,888	22,747,938
Provision for Treasury levy	12	400,000,000	146,929,966
Accrued expenses and other payables	13	101,328,507	55,671,329
Total current liabilities		**823,113,858**	**946,269,952**
Total equity and liabilities		**3,904,362,748**	**3,357,932,290**

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

K.M.Y.K Karunarathna
Accountant

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

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

Dr. Rasitha Wijewantha
Chairman
..... 2022

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

Dr.Saveen Semage
Chief Executive Officer

Dr. Saveen Semage
MBBS, MSc, MD
Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

NATIONAL MEDICINES REGULATORY AUTHORITY
STATEMENT OF COMPREHENSIVE INCOME

For the year ended 31 December,	Note	2021 Rs.	2020 Rs.
Revenue	14	1,252,757,342	1,059,441,826
Interest income		148,182,620	177,652,925
Other income	15	8,853,050	1,239,604
Administrative expenses	16	(119,812,930)	(93,984,429)
Salaries and wages	17	(152,382,467)	(146,730,584)
Other expenses	18	(12,182,753)	(58,605,113)
Amortization of capital grant			1,342,902
Net income before taxation		**1,125,414,862**	**940,357,130**
Income tax for the year	19	(158,222,092)	(266,752,264)
Net income after taxation		967,192,769	673,604,866
Provision for treasury levy		(400,000,000)	
Net Income for 2021		567,192,769	**673,604,866**

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

NATIONAL MEDICINES REGULATORY AUTHORITY
STATEMENT OF CHANGES IN EQUITY

For the year ended,	Accumulated Fund Rs.
Balance as at 31 December 2018	**1,047,449,960**
Prior year correction	(17,831,726)
Restated balance as at 31 December 2018	**1,029,618,234**
Profit for the year	795,694,791
Provision for treasury levy	(79,569,479)
Balance as at 31 December 2019	**1,745,743,546**
Prior year correction	52,414,563
Restated balance as at 31 December 2020	**1,798,158,109**
Profit for the year	673,604,866
Provision for treasury levy	(67,360,487)
Balance as at 31 December 2020	**2,404,402,488**
Prior year correction	23,135,193
Restated balance as at 31 December 2021	**2,427,537,681**
Profit for the year	567,192,769
Provision for treasury levy	-
Balance as at 31 December 2021	**2,994,730,451**

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,	2021 Rs.	2020 Rs.
Cash Flows from Operating Activities		
Net income before taxation	1,125,414,862	940,357,130
Adjustment for :		
Depreciation	21,870,537	17,515,637
Interest income	(148,182,620)	(177,652,925)
Amortization of capital grant		(1,342,902)
Gratuity Expense	683,972	1,257,060
Adjustment on prior year	(51,820,238)	
Operating Profit before Working Capital Changes	**947,966,513**	**780,134,001**
Changes in items of working capital		
(Increase)/Decrease in Inventory	(291,219)	336,999
(Increase)/Decrease in Deposits and other receivable	(857,825)	(21,560,582)
(Increase)/Decrease in Advance receipts	10,483,002	(183,249,343)
(Increase)/Decrease in VAT payable	(14,608,754)	5,653,112
(Increase)/Decrease in Stamp duty payable	7,551,950	16,566,202
(Increase)/Decrease in Provision for treasury levy		
(Increase)/Decrease in Accrued expenses and other payables	45,241,658	5,801,201
(Increase)/Decrease in Short Term Investment Increase		-
Cash generated from operations	**995,485,324**	**603,681,589**
Treasury levy Paid	(146,929,966)	(80,917,066)
Tax Paid	(536,936,978)	(306,965,632)
Net Cash from /(Used in) Operating Activities	**311,618,380**	**215,798,891**
Cash flows from investing activities		
Acquisition of Property plant and equipment	22,396,988	(6,935,359)
WIP Changes	5,600,619	(128,543)
Investment in short term deposits	1,007,478,083	(669,499,875)
Interest income	148,182,620	177,652,925
Net Cash from / (Used in) Investing Activities	**1,183,658,310**	**(498,910,853)**
Net increase/ decrease in Cash & cash equivalents	1,495,276,690	(283,111,962)
Cash and cash equivalents at the beginning of the year	129,108,499	412,220,462
Cash and cash equivalents at the ending of the year	**1,624,385,189**	**129,108,499**

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

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS
For the year ended 31 December 2021

1. Accounting policies

1.1 Reporting entity

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

1.2 Principal activity and nature of the operation

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

2. Basis of preparation

2.1 Statement of compliance

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

2.2 Responsibility for financial statements

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

2.3 Basis of measurement

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

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

2.4 Functional and presentation currency

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

2.5 Use of estimates and judgments

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

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

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

Retirement benefit obligation
Useful life time of the depreciable assets

2.6 Materiality and aggregation

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

2.7 Comparative information

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

3. Summary of significant accounting policies

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

3.1 Plant and equipment

3.1.1 Recognition and measurement

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

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

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

3.1.2 Subsequent costs

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

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

3.1.3 Depreciation

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

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

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

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

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

3.1.4 De-recognition

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

3.2 Financial Instruments

3.2.1 Initial recognition and subsequent measurement

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

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

3.2.2 Subsequent measurement

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

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

3.2.3 Financial assets at amortized cost (debt instrument)

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

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

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

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

3.2.4 Derecognition of financial assets

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

3.3 Trade & other receivables

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

3.4 Cash & cash equivalents

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

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

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.

3.9 Revenue

3.9.1 Services

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

3.9.2 Interest income

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

3.10 Government Grants

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

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

3.11 Expenses

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

3.12 Foreign currency transaction

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

3.13 Tax expenses

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

3.13.1 Current tax

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

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

3.13.2 Deferred taxation

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

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

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

3.14 Statement of cash flows

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

3.15 Commitment and contingencies

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

3.16 Related party transaction

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

3.17 Events after the reporting date

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

As at,31/12/2021

2 Property, plant and equipment

Cost	Filng store Rs.	Lab equipment Rs.	Furniture and fittings Rs.	Office equipment Rs.	Computer equipment Rs.	Computer Software Rs.	Total Rs.
Restated Balance as at 01 January 2019	15,257,976	9,451,740	2,084,965	5,319,876	7,915,653	224,400	40,583,935
Correction - Working Progress	-	-	-	-	-	-	(329,325)
Additions during the year	-	31,436,266	714,659	852,070	170,500	-	33,173,495
Balance as at 31 December 2019	15,257,976	40,888,006	2,799,624	6,171,946	8,086,153	224,400	73,428,105
Restated Balance as at 01 January 2020	15,257,976	40,888,006	2,799,624	6,171,946	8,086,153	224,400	73,428,105
Correction - Working Progress							-
Additions during the year	-	9,789,666	1,602,640	1,988,433	3,853,610	549,000	17,783,349
Balance as at 31 December 2020	15,257,976	50,677,672	4,402,264	8,160,379	11,939,763	773,400	91,211,454
Restated Balance as at 01 January 2021	15,257,976	50,677,672	4,402,264	8,160,379	11,939,763	773,400	91,211,454
Correction - Working Progress		64,275,375			(123,120)		64,152,255
Additions during the year	-		6,881,019.25	9,088,839	149,250	6,277,880	22,396,988
Balance as at 31 December 2021	15,257,976	114,953,047	11,283,283	17,249,218	11,965,893	7,051,280	177,760,697
Accumulated depreciation							
Balance as at 31 December 2020	9,765,104	17,806,655	2,054,421	4,252,765	7,188,694	251,456	41,319,095
Restated Balance as at 01 January 2021	9,765,104	17,806,655	2,054,421	4,252,765	7,188,694	251,456	41,319,095
Prior Year Correction				16,211	(6,831)		9,380
Charge for the year	3,051,595	11,473,871	2,023,543	2,559,425	2,058,353	703,749	21,870,537
Balance as at 31 December 2021	12,816,699	29,280,526	4,077,964	6,828,400	9,240,216	955,205	63,199,011
Carrying value							
As at 31 December 2021	**2,441,277**	**85,672,521**	**7,205,319**	**10,420,818**	**2,725,677**	**6,096,075**	**114,561,686**

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

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

For the year ended 31 December,		2021 Rs.	2020 Rs.
2.1	**Capital Working Progress**		
	On going Public Finger Print Scanners		-
	On going cost Public Addressing System		543,591
	On going cost CCTV Systems		4,658,794
	On going cost Narahenpita building		215,484
	On going cost Security Access		182,750
		-	**5,600,619**
3	**Inventory**		
	Opening Inventory	1,655,865	1,992,864
	Purchased for year	3,960,087	1,773,231
		5,615,952	3,766,095
	Consumption	(3,668,868)	2,110,230
	Closing Inventory	1,947,084	**1,655,865**
4	**Deposits and other Receivable**		
	Deposit for Fuel	50,000	50,000
	Other Receivables		5,550
	Prepayments	1,019,375	62,000
	Festival Advance	(1,500)	126,000
	Advance Receivables		5,000
	Building Rent	13,500,000	13,500,000
	Distress Loan Receivable	1,926,540	8,796,260
	Deposit for Drinking water	67,000	
	Total deposits and prepayments	**16,561,415**	**22,544,810**
5	**Short term investments**		
	Opening Balance	3,149,130,138	2,479,226,476
	Invest for the Year	299,999,999	492,250,737
	Interest for the year	148,182,620	177,652,925
	Maturiry Investment	(1,455,660,702)	
		2,141,652,055	**3,149,130,138**
6	**Cash and cash equivalents**		
	BOC Current and Savinngs Account(ZIBA)	1,624,514,939	129,108,496
	Petty Cash	-	3
	Total cash and cash equivalents	1,624,514,939	**129,108,499**
7	**Capital grant**		
	Capital grant	5,920,019	1,500,266
	Amortization of capital grant		(1,342,902)
	Total Capital grant	**5,920,019**	**157,364**
8	**Deferred tax liability**		
	Accounting written down value of Property plant and equipn	114,561,684	49,892,359
	Tax base of Property plant and equipment	(66,389,022)	24,526,336
	Taxable Temporary deference	48,172,661	25,366,023
	Tax @ 28%	13,488,345	7,102,486
	Deferred Liability at the end of the year	13,488,345	**7,102,486**
	Deferred Liability as at beginning of the year	(7,102,486)	2,971,330
	Charge as deferred tax during the year	6,385,859	**4,131,156**

13

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2021 Rs.	2020 Rs.
9	**Advance receipts**		
	Fees received in advance	72,972,666	72,972,666
	Deposit to be Classified	11,894,247	2,628,262
	Over Payment	2,318,598	1,101,582
	Total advance receipts	87,185,512	**76,702,510**

		2021 Rs.	2020 Rs.
10	**VAT payable**		
	Opening Balance	68,856,674	63,915,809
	VAT for the year	100,323,931	-
	Input VAT for the year	(3,089,222)	72,768,399
	Input VAT		(3,199,478)
	Other Adjustment	303,335	29,051,265
	Paid for the year	(113,931,000)	(92,967,074)
	Prior Year Correction		(712,247)
	VAT Payable	52,463,719	**68,856,674**
11	**Stamp duty payable**		
	Opening Balance	22,747,938	6,181,736
	Stamp Duty for the year	45,019,763	22,747,938
	Paid for the year	(37,467,813)	(6,978,956)
	Prior Year Corrections		797,220
	Stamp duty payable	30,299,888	**22,747,938**
12	**Provision for Treasury levy**		
	Net income after taxation	967,735,433	673,604,866
	Provision [illegible]% for year	400,000,000	67,360,487
	Opening Balance	146,929,966	79,569,479
	Paid for the year	(146,929,966)	
		400,000,000	**146,929,966**
13	**Accrued expenses and other payables**		
	Accounts Payables	9,636,600	9,198,979
	Accrued expenses	4,180,765	129,950
	Other Payables	1,794,043	-
	Retention Deposit	108,646	14,977
	EPF Payable		13,607
	ETF Payable		2,041
	Payee Payable		-
	Pension Payable		104,087
	Secondment Allowances Payable	21,235	79,794
			2,150,728
	Audit Fees Payable	2,400,000	2,223,000
	Committees & Evaluation Payable	117,475	179,475
	Contribution for MOH Staff Salary	83,069,743	41,500,000
	Salary Payable		62,543
	W & OP Payable		12,148
	Total Accrued expenses	**101,328,507**	**55,671,329**

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2021 Rs.	2020 Rs.
14	**Revenue**		
	Drug Sample License Income	7,835,689	889,460
	Device Sample License Income	9,702,717	7,956,394
	Cosmetic Sample License Income	468,800	278,800
	Borderline Sample License Income	598,164	747,821
	Drug Import License Income	128,877,215	65,457,634
	Device Import License Income	95,323,161	44,851,068
	Cosmetic Import License Income	8,012,734	4,344,000
	Borderline Import License Income	1,388,942	767,295
	Drug Manufacturing License Income A	10,894,168	4,937,907
	Drug Manufacturing License Income B	161,990	
	Device Manufacturing License Income A	1,147,073	382,264
	Device Manufacturing License Income B	415,305	
	Cosmetic Manufacturing License Income	401,000	334,000
	Drug Registration Income FR Local A	686,488	82,769,330
	Drug Registration Income FR Local B	20,289	
	Drug Registration Income FR Foreign	10,511,017	
	Drug Registration Income PR Local A	4,885,524	
	Drug Registration Income PR Local B	61,069	
	Drug Registration Income PR Foreign	103,457,358	
	Device Registration Income FR Local A	823,018	48,962,225
	Device Registration Income FR Local B	81,072	
	Device Registration Income FR Foreign	15,491,862	
	Device Registration Income PR Local A	687,715	
	Device Registration Income PR Local B	593,769	
	Device Registration Income PR Foreign	102,588,782	
	Cosmetic Registration Income FR Foreign	3,120,500	6,147,500
	Cosmetic Registration Income FR Local	48,000	
	Cosmetic Registration Income PR Foreign	7,217,344	
	Cosmetic Registration Income PR Local	547,500	
	Cosmetic Registration Income Renewal	57,500	
	Borderline Registration Income PR Foreign	1,470,583	1,231,297
	Borderline Registration Income PR Local	19,987	
	Laboratory Test	10,483,170	8,519,342
	Drug Processing Fees Local A	9,346,269	83,960,364
	Drug Processing Fees Local B		
	Drug Processing MP Foreing	10,464,835	
	Drug Processing Combined	913,496	
	Drug Processing New Dosage	304,019	
	Drug Processing Foreing	28,718,995	
	Drug Processing Fees Renewal Local A	1,930,959	
	Drug Processing Fees Renewal Foreign	29,505,191	
	Drug Processing Fees Therapeutic	16,224,433	
	Drug Processing Fees NCE	6,944,235	
	Drug Processing Fees NCE int	3,343,032	
	Device Processing Fees Local A	3,326,424	122,948,986.14
	Device Processing Fees Local B	2,015,922	
	Device Processing Fees MP Foreign	21,941,608	
	Device Processing Fees Foreign	34,849,066	
	Device Processing Fees Renewal Local A	98,310	
	Device Processing Fees Renewal Local B	9,459	

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NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

14	**Revenue Cont.....**		
	Device Processing Fees Renewal Foreig	17,379,972	
	Cosmetic Processing Fees	1,356,000	976,500
	Borderline Processing Fees Foreing	10,718,145	3,247,209
	Borderline Processing Fees Local	447,808	
	Borderline Processing Fees Ini for	16,973,578	
	Clinical Trial Processing Fees	1,361,039	93,958
	Drug Advertising Fees	805,313	372,257
	Retail Pharmacy License Income	43,174,597	1,873,949
	Wholesale Pharmacy License Income	36,125,829	375,784
	Transport Pharmacy License Income	18,041,828	17,806,634
	Drug WOR	3,167,994	28,463,728
	Device WOR	21,055,896	15,614,479
	Borderline WOR		93,399
	GMP Device Local Repac	40,427	-
	Device GMP - Local A	442,903	588,194
	Device GMP - Local B	944,952	
	Drug GMP - Local A	560,702	23,966,690
	Drug GMP - Local B	179,238	
	Drug WHO Inspection	486,887	245,365
	Device WHO Inspection	383,507	74,798
	Drug COPP Certificate	49,902	261,557
	Additional Drug Foreing	85,536,487	126,286,003
	Additional Drug Local A	5,588,762	90,134,252
	Additional Drug Local B	1,477,119	
	Additional Drug Variation	14,504,402	
	Additional Drug MP	2,285,117	
	Additional Device Foreing	89,334,411	
	Additional Device Local A	1,774,416	
	Additional Device Local B	472,763	
	Additional Device Variation	2,894,477	
	Additional Borderline Foreign	5,644,946	3,118,960
	Additional Borderline Local	80,574	
	Agency Transfer	35,581,888	31,933,754
	Device Free sale Certificates	152,249	46,288
	Clarification		-
	Device Clarification	1,476,411	719,174
	Drug Clarification	963,678	48,699
	Device Amendment	1,118,013	1,007,820
	Drug Amendment	1,333,413	3,911,282
	Cosmetic Amendment	65,000	98,000
	Borderline Amendment	79,495	
	Drug Formulation Approval	2,644,301	850,679
	Borderline Formulation Approval		112,914
	Borderline Advertisement	399,740	
	Device Advertisement	2,032,505	
	Device Duplicate Certificate	99,361	
	Drug Free Sale		36,697
	Cosmetic Renewal		150,000
	Automation Income	125,505,536	71,277,943
	2018 · Advance Receipts Income	-	20,307,230
	2019 · Advance Receipts Income	-	129,861,944
	Total Income	**1,252,757,342**	**1,059,441,826**

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NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2021 Rs.	2020 Rs.
15	**Other Income**		
	Tender Application Fees	12,000	15,000
	Other Income	39,901	-
	Supplier Registration	285,000	444,000
	Exam Fees Income		594,000
	Distress Loan Interest	311,289	186,604
	Savings A/C Interest	8,204,860	-
		8,853,050	**1,239,604**
16	**Administrative expenses**		
	Depreciation	21,870,537	17,515,637
	Water	483,928	252,597
	Electricity	6,691,499	6,913,019
	Telephone	1,944,800	1,339,143
	Postage	138,763	181,705
	Stationery	3,668,868	2,110,230
	Travelling - Local	15,662,199	5,967,566
	Travelling - Foreign		32,823
	Training and development expenses	1,259,700	1,054,847
	Fuel expense	1,452,280	2,449,145
	Security charges	6,362,757	3,998,503
	Document handling charges	1,559,470	1,474,015
	Publication, Translation and advertisement charges	3,765,858	5,485,127
	Cleaning service	3,603,950	3,883,700
	Vehicle maintenance	5,630,350	3,251,319
	Maintenance of Laboratory equipment	9,257,490	6,453,384
	Maintenance of fire extinguisher	113,800	12,500
	Maintenance of Air-conditioning	108,100	566,235
	Maintenance of building	7,782,372	1,599,802
	Maintenance of computer items and other	2,463,240	6,880,627
	Maintenance of website	45,920	458,200
	Maintenance of Office Equpments	541,947	619,709
	Maintenance of Software & Packages	3,931,022	232,563
	Expenses for Good Manufacturing Practice visits		7,178,988
	WHO meeting expenses		-
	Reservation of Conference Hall	429,910	1,134,920
	Rates and taxes	495,670	475,999
	Audit fee	1,200,000	1,200,000
	Forensic Audit Fee		3,200,000
	Sample Testing Expenses	16,072	23,204
	Books, Journals & Information	929,200	3,308,791
	Consultation Fee		23,301
	Sanitary Items Expense		29,115
	Building Rent	16,200,000	2,700,000
	Consumable Expenses	227,338	531,190
	Covid 19 Expenses	1,390,212	819,485
	Interview Fees	24,210	26,400
	Vehicle Insurance	545,495	573,784
	Vehicles Parking Fee	15,975	26,855
	Total	**119,812,930**	**93,984,429**

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2021 Rs.	2020 Rs.
17	**Salaries and wages**		
	Salaries and wages	35,621,594	32,089,561
	Other allowances	49,042,457	14,360,516
	MOH Staff Salary	51,727,213	82,675,993
	Overtime & 1/20 payment	8,236,021	7,319,886
	Secondment allowance	187,721	1,326,781
	Contribution for Pension	73,553	1,217,983
	Contribution for Employee Provident Fund	3,896,579	3,556,390
	Contribution for Employee Trust Fund	974,145	889,097
	Contribution for W & OP		-
	National Insurance Trust Fund E		-
	Gratuity Expense	683,972	1,257,060
	Staff Bonus	1,939,213	2,037,317
	Total	152,382,467	**146,730,584**
18	**Other expenses**		
	Refreshment and other expenses	2,331,483	1,175,826
	Bank Charges		500
	Staff Tea	2,237,601	1,662,271
	Legal Expenses	1,061,500	1,733,570
	Payment for Committees	4,703,734	1,820,033
	Miscellaneous Expenses	99,748	104,726
	Expert for Reviewing of Dossiers		1,534,966
	Surcharges	13,216	-
	Donation for COVID 19 Fund		50,000,000
	Valuation Fee		488,220
	Clinical Control A\C		85,000
	Corporate Plan Expenses	1,519,987	
	Expences for Basic requarment on poposed Narahenpita Bu	215,484	
	Total	**12,182,753**	**58,605,113**

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NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2021 Rs.	2020 Rs.
19	**Income tax for the year**		
19.2	Income tax expense for the year	151,836,233	262,621,108
	Deferred tax expense for the year	6,385,859	4,131,156
	Tax expense for the year	158,222,092	**266,752,264**
19.2	Net income before taxation	1,125,414,862	940,357,130
	Add : Disallowable expense	24,202,020	24,202,020
	Less : Allowable expense	(65,072,359)	(65,072,359)
	Less : Income not subject to income tax		-
	Adjusted profit for the year	1,084,544,523	899,486,791
	Other profit and income liable to tax		-
	Total statutory income/ Taxable income	1,084,544,523	899,486,791
	Income tax for the year	151,836,233	251,856,301
	Tax Credits:		-
	Notional Tax		-
	Prior Year Correction	(38,424,557)	240,506
	Income tax expense for the year	151,836,233	262,621,108
	Opening Balance	575,361,535	312,499,921
	Paid for the year	(536,936,978)	
	Total tax payable as at the year end	**151,836,233**	**575,361,535**
20	**Prior year adjustment**	**23,135,193**	**52,414,563**
	Prior year adjustment was made to rectify the following matters:		
	Advance		-
	Other		-
	2018 Notional Tax Correction		(5,666,983)
	Distress loan		15,900
	Income Tax	38,424,557	5,426,477
	Festival Advance		(13,500)
	Advance		966
	Salary Reimbursement		440,455
	EPF		521,790
	ETF		240,832
	PAYEE		170,312
	NITF		(375)
	W & OP		(6,960)
	Pension Payable		13,998,017
	Secondment Payable		11,162,236
	Accrued	(7,274,029)	2,994,615
	Fixed Assets	(123,120)	10,847,990
	Depreciation		(602,212)
	Retention		(242,906)
	Advance Receipts		11,980,542
	VAT	(1,305,021)	712,247
	Short Terms Investment		403,787
	WHT		31,333
	Cash Book	(951,159)	
	Audit Fee	108,000	
	Capital Grant	(5,762,655)	
	Acc .Dip.	(9,380)	
	Prepayment	(0)	
	Accounts Payable	28,000	
		23,135,193	**52,414,563**

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

21 Revenue and Expenditure for the year 2021 have been analyzed and presented indetail as compared to the year 2020

22 **Events after the reporting date**
The NMRA identified the unavailability of supporting documents for the applications on the e-NMRA System on July 9th, 2021.
For the incident, NMRA made a complaint to the Criminal Investigation Department (CID) on 22nd July 2021 and the investigation was started by the CID.
The e-nmra System data recovery operation was started by Epic Lanka Technologies to recover the lost data and is currently continuing with the supervision of a technical expert committee, which was appointed by the Secretary to the State Ministry of Production, Supply, and Regulation of Pharmaceuticals.

23 **Contingent Liabilities**
There is no any commitment and contingencies as at the reporting date.

24 **Litigation and claims**
In 2021 26 cases have been filed by FDII for the violations identified. No of cases pending 05. Total collection of fiacs - Rs.646,500.00.Detail of prosecutions conducted by provincial FD II - 2021. No of Cases 16 .No of cases pending 02. Total collection of fiacs Rs 473,000.00

B.J International (Pvt) Ltd filed a case against the NMRA at Commercial High-Court of Colombo, bearing Case no. HC.CIVIL 425/2017/MR, Challenging non-issuance of renewing certificates of registration and asking total sum of rupees Rs.497,700,000/=. The order was given on 11.11.2021. Now, B.J International (Pvt) Ltd appealed to section 755 (1) of the civil procedure code. Further, up to the year 2019, 13 cases were pending before the court filed by NMRA, and 11 cases were pending before the court filed against NMRA. Up to 2020, 11 cases were pending before the court filed by NMRA, and 9 cases were pending before the court filed against NMRA. The above all cases are handled by Legal Division. No of 20 cases were pending up to 31st of December 2020.

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

26 **Approval of financial statements**
These Financial statements were approved by the Board of members and authorized for issue on .... 2022.

27 **Nature of the Prior year adjustment**
Nature of the Prior year adjustment is currection of the opening balances.

20

Income Tax computation
Year of Assement 2021

Net income before taxation	1,125,414,862
Add : Disallowable expense	
Depreciation	21,870,537
Refreshment expenses	2,331,483
	1,149,616,881
Less : Allowable expenses	
Capital allowance	(65,072,359)
Less : income not subject to income tax	-
Amortization of capital grant	
Adjusted net profit for the year	1,084,544,522
Taxable profit trade and	**1,084,544,522**
Tax Loss:	-
Total statutory income	1,084,544,522
Tax expense for the period, @ 14%	151,836,233
Tax expense for the period	151,836,233
Tax Credit	
Income Tax payable	**151,836,233**
Deffreed tax computation	
Accounting written down value of PPP	114,561,686
Tax base of PPP	(66,389,022)
Taxable Temporary deference	48,172,664
Tax @ 28% rate	13,488,346
Deferred Liability as at beginning of the year	7,102,486
Charge as deferred tax during the year	6,385,860

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தேசிய கணக்காய்வு அலுவலகம்
NATIONAL AUDIT OFFICE

මගේ අංකය
எனது இல
My no
MSU/B/NMRA/1/21/17

දිනය
திகதி
Date
09 September 2022

The Chairman
National Medicines Regulatory Authority

Report of the Auditor General on the Financial Statements and Other Legal and Regulatory Requirements of the National Medicines Regulatory Authority for the year ended 31 December 2021 in terms of Section 12 of the National Audit Act, No. 19 of 2018.

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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 2021 comprising the statement of financial position as at 31 December 2021 and the statement of comprehensive income, statement of changes in equity and the cash flow statement for the year then ended, and the notes in relation with 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 report to Parliament in pursuance of provisions in Article 154 (6) of the Constitution will be tabled in due course.

In my opinion, except for the effects of the matters described in the basis for Qualified Opinion section of my report, the accompanying financial statements give a true and fair view of the financial position of the Authority as at 31 December 2021 and of its financial performance and its cash flows for the year then ended in accordance with Sri Lanka Accounting Standards.

1.2 Basis for Qualified Opinion

(a) Although the statement of changes in equity should be prepared as included all components of the equity in accordance with Paragraphs 106 and 108 of Sri Lanka Accounting Standard 1, capital grants amounting to Rs.5, 920,019 and capital gain amounting to Rs.64, 275,375 as at 31 December 2021 had not been disclosed in the statement of changes in equity.

(b) As a result of the cash flow statement prepared for the year under review was not prepared in accordance with the provisions of Sri Lanka Accounting Standard 7, understatement of net cash flow from operating activities by Rs.35,614,587, overstatement of net cash flow from investment activities by Rs.34,533,678, overstatement of the value of cash and cash equivalents as at 01 January 2021 by Rs.951,159 and overstatement of the value of cash and cash equivalents as at 31 December 2021 by Rs. 129,750 were shown.

(c) Although changes in accounting estimates should be adjusted in the statement of comprehensive income of the current year in accordance with Paragraph 36 of Sri Lanka Accounting Standard 8, overprovision of audit fees amounting to Rs.108, 000 and under-provision of value added tax amounting to Rs.270, 777 had been adjusted to the retained earnings in the statement of changes in equity.

(d) Although an explanation on changes in applicable tax rates compared to previous accounting periods should be disclosed in the financial statements for the year under review in terms of Paragraph 81 (d) of Sri Lanka Accounting Standard 12, the change in the tax rate of 28 per cent applied by the Authority in previous years to 14 per cent in the year under review had not been disclosed in the financial statements.

(e) Although the useful life of property, plant and equipment should be annually reviewed as per the Paragraph 61 of Sri Lanka Accounting Standard 16 and if the expected conditions differ from the estimates, actions should be taken to revise those changes in accordance with Sri Lanka Accounting Standard 8, as a result it was not so done, a number of 187 asset items cost at Rs.7,233,052 with a zero book value as at 31 December 2021 were still being used and actions had also not been taken with regard to that to disclose in terms of Paragraph 76 of this Standard.

(f) Actions had not been taken to transfer, assess and account for the office building and the land where the Authority is located, the National Medicine Quality Assurance Research Laboratory building and the land and 06 vehicles, to the Authority and actions had not been taken to assess and account for the 03 vehicles which were taken over to the Authority.

(g) A sum of Rs. 11,894,247 received to the bank by 31 December 2021 had been shown in the financial statements an unidentified deposits which were directly without being identified and adjusted in the accounts properly. The profit for the year and the current liabilities as at 31 December 2021 had been understated and overstated respectively in the financial statements.

(h) As a result of not considering the matters such as revision of the number of years for which capital allowance is granted by Schedule 04 of the Act in terms of Section 16 of the Inland Revenue Act No. 24 of 2017 in calculating income tax from the year 2018 to the year 2021 by the Authority, the fact that the reduce of tax levied on receipts and profits from the provision of health care services to 14 per cent with effect from 01 January 2020 in terms of Section 51(2) (4) (h) of the Inland Revenue (Amendment) Act No. 10 of 2021, applying of opening balance incorrectly in calculating deferred tax expense for the year 2020 and calculation of capital allowance wrongly in the reviewing year with accounting errors, the total income tax expenditure had been overstated and accounted due to by Rs. 138,139,464 current income tax amounting to Rs.124,779,725 and deferred income tax amounting to Rs.13,359,739. Further, the income tax payable under current liabilities

amounted to Rs. 124,779,725 and the deferred income tax under non-current liabilities amounted to Rs.10, 413,183 had been overstated in the statement of financial position as at 31 December 2021. Accordingly, although the accurate income tax payable as at 31 December 2021 was Rs.27,056,510, as a result of paying Rs.151,836,233 as income tax on 16 June 2022, by the authority a sum of Rs.124,779,723 had been overpaid as income tax.

(i) Although a sum of Rs. 692,031 from the income received in the year 2019, 2020 and 2021 had been approved to refund by the authority had not been released as at 31st December 2021 and had not been accounted for an expenses payable on that date.

(j) Although the expenditure of Rs. 527,065 related to the outdoor training program held by the Authority should be accounted for as training and development expenses, a sum of Rs.65, 025 and Rs. 45,290 had been accounted for other expenses and local travelling expenses respectively. Further, a sum of Rs.138,250 payable for souvenirs had also not been accounted for.

(k) Detailed schedules and receipt details pertaining to the balance of Rs.72,972,666 in advance receivable account as at 31 December 2021 were not submitted to the audit.

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

1.3 Other Information Included in the Annual Report 2021 of the Authority

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The other information comprises the information included in the Annual Report 2021 of the Authority, but does not include the financial statements and my auditor's report thereon, which I have obtained prior to the date of this auditor's report. The Management is responsible for these other information.

My opinion on the financial statements does not cover the other information and I do not express any form of assurance conclusion thereon.

In connection with my audit of the financial statements, my responsibility is to review the other information identified above and, in doing so, consider whether the other information is materially inconsistent with the financial statements or my knowledge obtained in the audit or otherwise appears to be materially misstated.

When reading the Annual Report 2021 of the Authority on the financial statements, if I conclude that there are material misstatements, the same should be communicated to the controlling parties for correction. If there are uncorrected misstatements appeared furthermore, they will be included in the report tabled by me in Parliament in due course in terms of Article 154 (6) of the Constitution.

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

---

Management is responsible for determine the internal control measurements required for preparation of financial statements with true and fair view in accordance with Sri Lanka Accounting Standards, and which 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 and it is also the responsibility of Management to keep accounts on a going concern basis and to disclose matters related to the going concern of the Authority except for the Management intends to liquidate the Authority or cease operations in the absence of any other alternative.

The governance are responsible for overseeing the Authority's financial reporting process.

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

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

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

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

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

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

- Evaluated the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Management.
- Concluded 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 my opinion, should be modified. However, future events or conditions may cause to cease to continue as a going concern.

- Evaluated 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.

I communicate with those charged with governance regarding, among other matters, significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

2. Report on Other Legal and Regulatory Requirements

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2. 1 Special provisions for following requirements are included in the National Audit Act, No. 19 of 2018.

2.1.1 I have obtained all the information and explanation that required for the audit and as far as appears from my examination except for the impact of the matters described in the section on the Basis for the Qualified Opinion in my report and proper accounting records had been kept by the Authority as per the requirement of Section 12 (a) of the National Audit Act, No. 19 of 2018.

2.1.2 The financial statements presented by the Authority is consistent with the preceding year as per the requirement of Section 6 (1) (d) (iii) of the National Audit Act, No. 19 of 2018.

2.1.3 The financial statements presented includes all the recommendations made by me in the previous year as per the requirement of Section 6 (I) (d) (iv) of the National Audit Act No. 19 of 2018, except for the observations in Paragraph (k) of this report.

2.2 Based on the procedures performed and evidence obtained were limited to matters that are material, nothing has come to my attention to make declaration on following;

2.2.1 To state that any member of the governing body of the Authority has any direct or indirect interest in any contract entered into by the Authority which are out of the normal cause of business as per the requirement of Section 12 (d) of the National Audit Act, No. 19 of 2018 .

2.2.2 To state that the Authority has not complied with any applicable written law, general and special directions issued by the Governing Body of the Authority as per the requirement of Section 12 (f) of the National Audit Act, No. 19 of 2018 except for the observations appear below;

	Reference to Laws, Rules and Regulations	**Non-compliance**
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(a)	National Medicines Regulatory Authority Act No. 05 of 2015	

(i)	Sections 58,59,82,83 and 109	Any medicine or medical device should not be manufactured or imported without being registered with the Authority and obtained a license from the Authority. The Authority was given powers to issue letters of exemption from registration only in special cases such as to save a life, to prevent the

		spread of infectious diseases or epidemics, at national interest and national security. But the letters of exemption from registration had been issued to the State Pharmaceutical Corporation and Private Institutions for the 67 medicines and 140 medical equipment during the reviewing year on the reasons such as cancellation of registration, lack of registered suppliers, etc., which do not fall under such circumstances.
(ii)	Sections 60 (2), 61, 84(2), 85, 103(2) and 104 and Sub-sections	Although the Authority should inform the public in cases of the Registration of Medicines, Medical Devices and Border Line Productions as well as the refusal of registration through the terms published in the Gazette, actions had not been taken to publish 2,948 Medicines Registration Certificates issued by the Authority and 991 rejected applications, 315 Medical Devices Registration Certificates and 23 rejected applications in the Gazette during the year under review and instead, it had been posted on the website of the Authority.

(iii)	Sub-section 69 (1)(a)(i)	Although the Head of the Medical Devices Regulatory Division shall act as the Chairman of the Medical Devices Evaluation Committee, the Medical Equipment Evaluation Committee had been chaired by the Chairman or Chief Executive Officer of the Authority due to failure to appoint an officer to the post of Head of Medical Devices Regulatory Division.
(iv)	Medicines Registration and Licensing Orders established by the Special Gazette Notification No. 2145/1 dated 14 October 2019 issued in accordance with Section 142 ❖ Order No.s 4, 133 (5) and Paragraph 08 of Schedule XXIII of Order No. 134	A single common register to document every request for registration of medicines had not been maintained. As a result, the details such as date of application received for registration of medicines, number in the application, name of manufacturer, country of manufactured, authorized importer, medicine name, medicine names of active ingredients if the medicine is a drug compound, brand name of the medicine, dosage form of the medicine, strength of the medicine, whether it is an application for new or renewed application, type of medicine, as well as details of money received for each application, date of submission of each application to the Medicine Regulatory Division for evaluation, number of applications rejected by the each division and number of approved

		applications, the number of applications still in process in the each division, time taken for registration by respective divisions could not able to obtained to audit. As a result, it was impossible to ensure whether the certificates of registration are issued within the targeted processing period. Accordingly, it was observed that it had failure to process the drug registration and licensing process transparently. Although the Chairman had submitted ideas that the Google Sheet will be maintained to cover all the information from November 2021, the passwords required to access that Google Sheet were not submitted for audit even by 31 December 2022.
(b)	Section 40 of the National Audit Act No. 19 of 2018	An Internal Auditor had not been appointed for the Authority.
(c)	Paragraphs 4.1 and 10.1 of Chapter VIII of the Establishments Code of the Democratic Socialist Republic of Sri Lanka.	Although a staff officer entitled to 1/20 allowance is not entitled to overtime allowance for duty on weekends and public holidays, both 1/20 allowance and overtime allowance had been paid as Rs. 2,060,455 for 998 days of holiday and Rs.1,977,619 for 8,520 hours of overtime to 26 staff officers including an Executive Officer working in the Authority.
(d)	**Financial Regulations of**	

the Democratic Socialist Republic of Sri Lanka

(i)	Financial Regulation 237 (b)	It was revealed in an audit test check that the payment vouchers amounting to Rs.578,958 were certified on 08 occasions in the reviewing year without obtaining a certificate that the goods were received and entered in the relevant inventory or stock books.
(ii)	Financial Regulation 371(2) (b) and Public Finance Department Circular No. 01/2020 dated 28 August 2020	Although the maximum ad hoc advances of Rs.100,000 can be issued only to a staff officer, ad hoc advances of Rs. 1,794,000 had been issued to 08 non-staff officers on 17 occasions. Further, there were also cases where advances were re-issued before the settling of advances issued.
(iii)	128 (1) (e), 507, 756, 757, 758, 770 and Paragraph 11.1 of Part I of Public Finance Circular No. 01/2020 dated 28 August 2020	Although the Accounting Officer shall arrange for the appointment of Boards of Survey before the 15th December of each financial year and forward their reports to the Auditor-General with a copy to the Chief Accounting Officer before 31 March of the following year, counting of the non-current assets with a total cost of Rs.114, 561,686 and submission of the reports to the Auditor General had not been made since the establishment of the Authority in 2015.
(iv)	Financial Regulations 1645 (a) and 1647 (e)	The officer in charge of vehicles had not duly completed and updated the

	vehicle log books as per General Format 267 for each vehicle in his custody. Similarly, the officer in charge of vehicles had not maintained a Register of Vehicles on the motor vehicles in his custody.
(e) Treasury Circulars ----------	
(i) Treasury Circular No. 842 dated 19 December 1978	A Register of Fixed Assets had not been maintained in respect of property plant and equipment totaling to a cost of Rs.114, 561,686.
(ii) Assets Management Circular No. 01/2017 dated 28 June 2017 of Ministry of Finance and Mass Media	Every Government institution should submit accurate information about all assets under it to the Comptroller General and although each institution should nominate a suitable officer to coordinate the activities, the Authority had not taken actions accordingly.
(f) Public Enterprises Circulars ----------	
(i) Circular No. 95 dated 14	Implementing a Covid 19 incentive

	June 1994 and No. PED/12 dated 02 June 2003	scheme for staff without obtaining the approval of the Treasury, the allowance totaled to Rs.62, 116,873 had been paid as Rs.17, 843,781 in the preceding year and Rs.44, 273,092 in the year under review by calculating allowances at the rate of 1 ½ days per day reported for duty, without considering as normal duty days and holidays.
(ii)	Paragraphs 5.1.1, 5.1.2 and 5.1.3 of Circular No. PED/12 dated 02 June 2003	Although a Corporate Plan should be prepared as per Paragraphs 5.1.1 and 5.1.2 of the Circular and copies of the same should be submitted to the Line Ministry, Department of Public Enterprises, Treasury and Auditor General 15 days before the commencement of the accounting year as per Paragraph 5.1.3, the Authority had not prepared a Corporate Plan for the year under review.
(iii)	Paragraph 2.5 of Circular No. PED /03 /2015 dated 17 June 2015	A sum of Rs.454, 827 had been paid as Covid 19 allowances during the year under review to the Chairman of the Authority without obtaining any approval in contrary to the Circular provisions.
(g)	**Public Administration Circulars**	

	(i) Paragraphs 02 (b) and (c) of Public Administration	Arrangements should be made to deploy on holidays on prior approval

	Circular No. 21/2013 dated 07 October 2013	and to make payments for a maximum of 02 days per calendar month and although the prior approval of the Secretary of the relevant Ministry should be obtained in person if employment for more than 02 days is required, a sum of Rs.909, 042 had been paid for 415 holidays during the year under review to the 22 staff officers including an Executive Officers of the Authority without obtaining such an approval.
(ii)	Paragraph 3.1 of Public Administration Circular No. 30/2016 dated 29 December 2016	Although a fuel re-check should be carried out after a period of 12 months after each fuel check or after 25,000 km or after a major engine overhaul whichever occurs first, actions had not been taken in the same manner in respect of 09 vehicles which are being used by the Authority.

2.2.3 To state that it had not performed according to Authority's powers, functions and duties as per the requirement of Section 12 (g) of the National Audit Act, No. 19 of 2018.

(a) The Authority had not collected data on the quantity of medicines imported under license by the Authority, Medical Devices, Border Line Productions or Investigational Medicinal Products in terms of Section 14(k) of National Medicines Regulatory Authority Act No. 05 of 2015.

(b) Within a period of six months after the end of the financial year, the Authority should submit an Annual Report to the Minister on the activities carried out during that financial year in terms of Section 23 of the National Medicines Regulatory Authority Act No. 05 of 2015 and the report of audited accounts of the Authority for the relevant year and a report on the proposed activities for the coming year should be attached to that report along with the Auditor General's Report. Although the Minister should submit the report to Parliament within a period of six months from the date of receipt, the Annual Reports have not been prepared and submitted to the Minister and Parliament since 2017.

(c) An officer with a degree in Medicine, Pharmacology, Pharmacy or any other related disciplines had not been appointed as Heads of the Medicine Regulatory Division, Medicine Devices Regulatory Division and Border Line Production Regulatory in terms of Sub-sections 41 (2), 66 (2) and 87 (2) of the National Medicines Regulatory Authority Act No. 05 of 2015.

(d) Although a technical evaluation report specifying the benefits, risks, feasibility, quality , safety, necessity , price and where necessary, the pharmocol-economic analysis of those medicine and medical devices submitted for registration to the Medicines Evaluation Committee and the Medical Devices Evaluation Committee shall be submitted in terms of Sub-sections 43(2) (a) and (b) and 68 (2) (a) and (b) of the National Medicines Regulatory Authority Act No. 05 of 2015, the Medicine Evaluation Committee and the Medical Devices Evaluation Committee had not submitted such a technical evaluation report to the Authority.

(e) Although the Director General of the Sri Lanka Atomic Energy Regulatory Council or his Nominee shall be appointed to the Medical Device Evaluation Committee in terms of Sub-section 69 (1) (b) (v) of the National Medicines Regulatory Authority Act No. 05 of 2015, the appointment had not been made. The necessity to represent the Medical Device Evaluation Committee to the Sri Lanka Atomic Energy Regulatory Council, which has the powers to issue

licenses and regulate the import and use of radioactive equipment and materials, including medical equipment, was not fulfilled.

(f) Although the General Guidelines should be issued to the each evaluation committees for evaluation of Medical Devices and Border Line Productions in terms of Sub-sections 72(1) and 93(1) of the National Medicines Regulatory Authority Act No. 05 of 2015, such Guidelines had not been prepared. Further, the directives relating to Medical Devices and Border Line Productions had also not been prepared to enforce the Guidelines on good manufacturing practices and other relevant guidelines recommended by the Authority, specifying the procedures to be followed including the specific timeframes for conducting the relevant evaluations in terms of Sub-sections 72 (4) and 93 (4).

(g) Authorized Therapeutic Devices and Registered Border Line Productions had not been listed by the Minister from time to time in terms of Sub-sections 74 (1) and 95 (1) of the National Medicines Regulatory Authority Act No. 05 of 2015.

(h) It had not submitted to the National Medicines Quality Assurance Laboratory to check the quality of Medical Devices and Borderline Products furnished for registration in terms of sub-sections 83 (4) (b) and 102(4)(b) of the National Medicines Regulatory Authority Act No. 05 of 2015. The Chairman of the Authority had submitted comments that the necessary facilities for that were not available in the laboratory.

(i) The orders had not been formulated by the Minister, stating specifically the procedure to be followed in the inspection or evaluation process by the Medical Devices and Border Line Productions Committee and the National Medicines Quality Assurance Laboratory, the time limits of the inspection or evaluation process, the manner in which meetings should be held by the Medical Device Evaluation Committee and specifying the procedures to be followed in the meetings and the matters to be included in the reports to be

submitted in terms of Section 83(6) and 102(6) of the National Medicines Regulatory Authority Act No. 05 of 2015.

(j) An Appeals Committee had not been constituted to hear and decide the appeals submitted to the Authority as per the Section 123 of the National Medicines Regulatory Authority Act No. 05 of 2015.

2.2.4 To state that the resources of the Board had not procured and utilized economically, efficiently and effectively within the time frames and in compliance with the applicable laws as per the requirement of Section 12 (h) of the National Audit Act, No. 19 of 2018 except for the observations mentioned below.

(a) The contract was awarded on 17 December 2020 to the bidder who had submitted the lowest bid of Rs. 4,898,750 for the work of partitioning the office rooms in the new office building which had been acquired on rental basis. In this procurement, Guidelines 2.8.1 (b), 2.12, 5.4.8, 6.3.3, 6.3.6 and 8.12.2 of the Government Procurement Guidelines were not followed and advances of Rs.979, 750 had been issued without obtaining advance payment security in terms of 5.4.4 of the Guideline.

(b) Although the furniture had been purchased by following the shopping method at a cost of Rs.6,854,519 and also not less than 05 sealed bids were to be called in terms of 2.14.1 of the Government Procurement Manual, only 03 bids were called and purchase had been made. Further, this purchase was carried out, taking actions in contrary to the Guidelines such as 2.8.1 (b), 6.3.5 (a), (b), (c), 6.3.6, 8.12.3 (a), (b), (c) of the Government Procurement Guidelines.

(c) Although the approval of the Secretary to the Line Ministry should be obtained for the vehicle repairs exceeding Rs.200, 000 in terms of Guideline 9.3.1 (b) of the Government Procurement Guidelines, a total of Rs.

3,676,401 had been spent for the repair of 03 vehicles owned by the Authority beyond that limit and actions had not been taken to obtain the approval for that. Likewise, there were no log records whether the spare parts removed during repair were undertaken. The officer in charge of vehicles had not accepted those spare parts.

2.3 Other Matters

(a) The Authority had awarded the contract to transport and safely store and maintain the completed files to a private company from 01 December 2015. A sum of Rs.6, 062,550 had been paid to the contractor during the period of 06 years from the commencement of the contract to 31 December 2021. Although payment to the contractor was stopped for the year from May 2016 to April 2017 stating that part of the files in the contractor's custody in 2016 were damaged by the flood, a formal investigation had not been conducted regarding the files that were damaged by the flood. Further, the services of the contractor were still being obtained even by 30 June 2022, the Authority itself had not drawn attention to the establishment of an archive after analyzing the costs for this purpose for 06 years.

(b) All the Government institutions shall review and revise the fees charged by their bodies for services rendered to the public every three years subject to a maximum of 15 per cent and submit by the relevant Accounting Officer for the approval of the Secretary to the Treasury or the Deputy Secretary to the Treasury with the recommendation of the Secretary of their Ministry in terms of Paragraph 5.1 of Part II of Public Finance Circular No. 01/2020 dated 28 August 2020. The Authority had revised the charges levied at last on 05 January 2018 for the issuance of registration certificates in respect of medicinal Devices and Border Line Products, granting licenses, granting of approvals such as approval for exemption from registration, approval for packaging, approval for transfer of agency, conduct of inspections and other services provided. Accordingly, although the actions should be taken to review the charges during the year under review and do the relevant revisions and submit for the Treasury approval, as it had not acted accordingly, the fee income had lost by Rs.187, 913,601 in the year under reviewing year.

(c) Although an application was submitted to the Sri Lanka Accreditation Board on 06 February 2020 to obtain the Certificate of Conformity Assessment regarding the quality of the laboratory by the National Medicines Quality Assurance Laboratory, it had failed to obtain the standard certificate by 31 July 2022 and information about other quality certificates obtained was also not submitted for audit.

(d) Although the 2022 – 2026 Five Year Corporate Plan should be prepared 15 days before the commencement of the year 2022, although the Authority had spent Rs. 1,641,600 to prepare it by 04 July 2022, the Corporate Plan had not been prepared even by that date.

(e) Out of the drug samples that were submitted to the National Medicines Quality Assurance Laboratory to check the quality, the information on the number of drug samples whereas the test reports were not submitted by 01 January 2021 had not been submitted to audit in accordance with Section 39 of the National Medicines Regulatory Authority Act No. 05 of 2015. However, test certificates had been issued only for 157 out of 216 drug samples received in 2019 and 2020 and 299 out of 477 drug samples received in the year under review. Accordingly, out of the drug samples received in the 03 years from 2019 to 2021, the number of samples for which test reports had not been issued by 31 July 2022 was 91 and 42 of them were the samples submitted by the court. The opinion that it will cause the related court proceedings to be delayed for a considerable period of time could not be ruled out in audit.

(f) A total income of Rs.1, 620,119 had been refunded on 18 occasions in the reviewing year due to mistakes of officials and various other reasons. Although this situation has existed for several years, adequate steps had not been taken to mitigate it.

(g) Although the requests had been made in the year 2018, to send money to the Employees' Provident Fund with a delay, failure to request for VAT exemption in due time and to recover the VAT paid to the State Pharmaceutical Manufacturing Corporation**,** a total amount of Rs.756, 173 was overpaid to the Inland Revenue Department as surcharges and VAT due to the matters such as rejection of the said request during reviewing year.

(h) Instead of issuing re-registration certificates for the applications submitted for medicines re-registration, a method of extending the existing registration was followed, a formal approval for that had not been obtained. Out of 3,892 applications submitted for re-registration of medicines during the year under review, the existing registration of the 2,904 applications had been extended and 988 applications had been rejected. As a result of following the method of extension of registration, it was observed that the provisions related to medicine evaluation were violated in terms of sub-sections 47(3) and 59(4) of the National Medicines Regulatory Authority Act No. 5 of 2015.

(i) Although the maximum time for completing the evaluation of a file submitted for registration (Dossier) is 300 days, registration certificates had not been issued even by 25 June 2022 for the 146 Dossiers submitted in the year 2020. Although the 02 days were spent for the main evaluation activities of 06 Dossiers and less than a month for the main evaluation activities of 04 other Dossiers in the examination of a sample of 25 Dossiers of Medical Devices registered during the year under review from a period of 01 to 03 years had been spent to complete the registration. The Chief Executive Officer had spent between 01 ½ months and 01 year to transfer them to the pharmacists from the date of receipt of 18 Dossiers to the Authority and the Pharmacists had spent in between 05 months and 01 year and 09 months to submit 11 Dossiers to the relevant College or External Evaluator for performance evaluation. After the performance evaluation, the Pharmacists had spent 05 months to 01 year and 04 months to commence the technical evaluation of 09 Dossiers and from that day, the Chief Executive Officer had spent 14 days to 02 months to give approval for 09 Dossiers approved for registration by Medical Devices Evaluation Committee. However, the Authority

had not taken adequate measures to minimize these delays and make the registration process efficient and speedy.

(j) In the course of maintaining the Dossiers submitted for registration and preparing the relevant documents, incorrect information had been included carelessly or deliberately and the dates on which certain tasks were performed, the information about the officers who had performed and some essential documents had not been included in the Dossiers. Dates of submission and return of Dossier and samples to concerned college for performance evaluation,

Dates of commencement and completion of technical evaluation by pharmacists as well as recommendation, code and signature of pharmacists were not mentioned in certain Dossiers and incorrect information had been entered in the Technical Evaluation Checklist. Within some dossiers, the summary report on the application and Technical Evaluation Checklist where pharmacists perform the technical evaluation and make recommendations had not been included.

(k) Although 20 members were appointed to the Medical Devices Evaluation Committee, the participation of members was as low as 35 per cent in the 10 meetings held during the year under review and due to the fact that 07 members had not participated even in a single meeting, the knowledge in specialist areas such as laboratory services, biomedical engineering, dental services, biochemistry, surgical pathology and radiology had contributed to the decisions of the Committee.

(l) Although the money had been paid on the online system to obtain the pharmacy license, due to crash of online computer automation system in August 2021, instead of issuing a new license, the licenses issued in 2019 and 2020 had been rubber-stamped and the signatures were made on it by extending dates. There were the cases where the date extensions were not documented and also the signatures were not made for the date extensions.

(m) The contract for automating the data system of the Authority had been awarded to a private company on 03 May 2018 for a period of 05 years for a total contract value of Rs. 29 Million. It had been entered into the implementation of this document and workflow management system as a service by obtaining the Operational Expenditure Financing Model and an amount of Rs.12, 253,328 had been paid to the contracted company during the period from June 2019 to May 2021. But some of the information entered into this data system had been deleted due to negligence or intentionality of the concerned private company and the service had become inactive even by 31 August 2022 until the end of the investigations carried out by the Criminal Investigation Department. Likewise, although a Memorandum of Understanding had been entered into with the Sri Lanka Information and Communication Technology Agency for a period of one year on 25 June 2018 to obtain the necessary consultancy, management and technical advice in the implementation of this system, actions had not been taken to extend the agreement parallel to the contract period of 05 years. Further, steps had not been taken to protect the confidentiality of the information, to change passwords or to prevent the misuse of the information in accordance with the contractual agreement and after automating the system, an Audit Trial had not been conducted on the internal workflow of the Authority implementing the both the manual and automation systems in parallel . Similarly, the management was not concerned with the issues of file management, preservation and ability to securely store copies of documents with relevant data for up to 5 years, obtaining automatic copies on a daily, weekly and monthly basis and obtaining a confirmation of professional liability insurance and payments had been made to the company without obtaining securing copies of relevant data and attachment information. As per the terms of the agreement, although the assets in this system cost at Rs.7, 558,128 should be capitalized, instead, the amount had been written off against the profit. According to the report issued on 15 July 2022 by the expert committee appointed to check and restore the deleted data regarding this incident, it had confirmed that the data that had been deleted from the system could not be restored. Although the registration of drugs, equipment etc. is done using a Google application (Google Form) as a temporary solution after the activities of the system is disabled, it was observed that the system was maintained with deficiencies.

(n) Although fees are payable on application for exemption from registration for private supply of drugs, medical devices and limited products, in terms of Free Regulation No. 02, 03 and 04 of 2017 published in Extraordinary Gazette No. 2023/30 dated 14 June 2017 as amended by Extraordinary Gazette No. 2052/33 dated 05 January 2018, due to the fact that the Authority has proceeded to levy fees when granting approval for exemption from registration, the Authority had lost the fee income of Rs. 11,473,421 which could have been charged for 207 applications for exemption from registration of Medical Devices in the private sector which had been rejected. The Authority had lost an incalculable amount of revenue as a result of taking actions so, in respect of the Medicines, Medical Devices and Border Line Productions during the period from 2018 to 22 August 2022.

(o) A total of Rs. 629,030 as participation allowances, Covid allowances and bonuses for various committees held in 2020 and 2021 had been held by the Accountant in his hand for between 159 and 865 days to pay to respective officials or without taking actions to bank again within 14 days in terms of Financial Regulation 271 (2)(a) and (b) . Due to the payment vouchers prepared for the payment of these allowance were not submitted for audit, on the following day that was 08 June 2022 a sum of Rs. 629,030 had directly been banked. In addition to that, it was ascertained in the cash verification carried out on 23 August 2022 a total of Rs.537, 600 as committee participation allowances, bonuses, attendance allowances and overtime allowances of the year 2022 had been held in hand in between 15 days and 228 days. It was observed that this is an illegal use of government funds and although the money remaining unpaid and the documents related to that should be kept locked in a safe or other safe place designated for that purpose, in terms of Financial Regulation 271 (1), the money was kept in the accountant's office desk drawer in an unsecured manner and the safe, secured by two locks and a code, had been kept in idle in the main office building.

(p) The total approved number of staff of the Authority as at 31 December 2021 was 257 with 235 approved permanent staff and 22 on contract basis. Although the total actual staff was 160, because, out of which 38 were the excess number that was not included in the approved staff, the actual number of vacancies out of total approved staff as at 31 December 2021 was 135. Since 16 posts or 84 per cent of the 19 senior management posts in the approved staff were in vacant, it had failed to identify necessary and unnecessary positions and revise the approved staff and it was observed that the vacancy of required posts may have an impact on the overall performance of the Authority. The method of absorption or recruitment as recommended by the Department of Management Services to fill up the vacancies of 30 Medicines Evaluation Officers and 12 Assistant Medicine Evaluation Officers had not been implemented even by the date of this report.

W.P.C. Wickramarathne
Auditor General.

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

Compliance Report

No	Requirement to be applied	Compliance status (compliant / not applicable)	If not applicable - a brief explanation for it	Specific actions that are proposed to prevent non-compliance in future
1	**The following financial statements / accounts have been submitted on time**			
1.1	Annual financial statements	Compliant		
1.2	Advance accounts on public officers	Compliant		
1.3	Business and product advance accounts (commercial advance account	-		
1.4	Store advance accounts	-		
1.5	Special advance accounts	Compliant		
1.6	Other	-		
2	**Maintains of books and documents (FR 445)**			
2.1	Updating and maintaining the fixed asset register as per public administration circular No 267/2018	Compliant		
2.2	Updating and maintaining personal payroll documents / personal payroll cards	Compliant		
2.3	Updating and maintaining the list of audit queries	Compliant		
2.4	Updating and maintaining the internal audit record	Compliant		
2.5	Preparing all monthly account summaries and submitting them to the treasury on time	Compliant		
2.6	Updating and maintaining the cheque and cash order register	Compliant		

2.7	Updating and maintaining inventory	Compliant		
2.8	Updating and maintaining the stock inventory	Compliant		
2.9	Updating and maintaining the register on loss and damage	Compliant		
2.10	Updating and maintaining the list of liabilities	Compliant		
2.11	Updating and maintaining the sub paper book register (GA-N20)	Compliant		
3	**Representation of function for financial control**			
3.1	Delegating financial powers within the organization	Compliant		
3.2	Should have made the institution aware about the delegating financial powers	Compliant		
3.3	Delegating authority where two or more officers could approve each transaction	Compliant		
3.4	Acting under the control of the Accountant in using the Government payroll software package as per government accounts circular No.171/204 dated 11.05.2014	Not Applicable		
4	**Preparation of Annual Action Plan**			
4.1	Preparation of Annual Action Plan	Compliant		
4.2	Preparation of Annual Internal Audit Plan	Not Applicable		
4.3	Preparing the annual estimate and submitting it to the Public Enterprise Department on the due date	Compliant		
4.4	Submitting the annual cash flow statement to the treasury operations department on time	Not applicable		
5	**Audit Quarries**			
5.1	Having answered for all the audit queries mentioned by the auditor general on the due date which has been fixed by him	Compliant		
6	**Internal Audit**			

6.1	Having prepared the Internal Audit Plan after consultation with the Auditor General at the beginning of the year as per DMA/1-2019-FR 134(2)	Applicable - Not done		Planned to implement
6.2	Having responded to each internal audit within a month of time	Applicable - Not done		Planned to implement
6.3	Submitting copies of all the internal audit reports to the Department of Audit Management ,in terms of sub-sections -40 (4) of the National Audit Act No.19 of 2018	Applicable - Not done		Planned to implement
6.4	Submitting copies of all the internal audit reports to the Auditor General in accordance with the financial regulations 134(3)	Applicable - Not done		Planned to implement
7	**Audit and Management Committees**			
7.1	Should have conducted at least 04 Audit and Management committees during the relevant year as per DMA circular No 1-2019	Compliant		
8	**Asset Management**			
8.1	Submitting information on acquisition and disposal of assets to the Comptroller Generals Office as per chapter 07 of asset management circular No 01/2017	Compliant		
8.2	Appointing a coordinating officer to coordinate the implementation of the provision of that circular in chapter 13 of the above and reporting the information about that officer to the comptroller general's office	Compliant		
8.3	Should have conduct board of survey in accordance with Public Finance Circular No.05/2016 and submitted the relevant reports to the Auditor general on the due date	Applicable - not done		Planned to implement

8.4	Should have made excesses, deficiencies and other recommendations revealed in the annual board of survey during the period mentioned in the circular	Applicable - not done		Planned to implement
8.5	Disposal of the unserviceable items in terms of FR 772	Applicable - not done		Planned to implement
9	**Vehicle Management**			
9.1	Preparing daily running charts and monthly summery reports for the pool vehicles and submitting them to the Auditor General on the due date	Compliant		
9.2	Should have been disposed unserviceable vehicles not less than the period of 06 months, upon becoming unnerved.	Compliant		
9.3	Maintaining and updating the log entry of vehicles	Compliant		
9.4	Taking actions according to the FR 103,104,109 and 110 with regard to the every vehicle accident	Compliant		
9.5	Re-inspecting the fuel combustion of vehicles in accordance with the provisions of paragraph 3.1 of public Administration circular No.2016/30 dated 29.12.2016	Compliant		
9.6	Having taken over full ownership of the leased vehicles log books after the leasing period	Not Applicable		
10	**Bank Account Management**			
10.1	Should have prepared and certified the bank reconciliation statements on the due date and submitted them for audit	Compliant		
10.2	Should have settled inactive bank accounts brought forward during or before the reviewing year	Compliant		
10.3	Should have acted in accordance with the financial regulations regarding the	Compliant		

	balances revealed and adjusted in the bank reconciliation statements and settled those balances within a period of one month.			
11	**Utilization of funds**			
11.1	Incurring expenditure not exceeding the provision which had been made	Compliant		
11.2	Reaching liabilities at the end of the year after utilization of the provision provided in accordance with section 94 (1),not exceeding the limit	Compliant		
12	**Advance Accounts of Public Officers**			
12.1	Compliance with the limits	Not applicable		
12.2	Having done an age analysis of the outstanding loan balances	Not applicable		
12.3	should have settled the outstanding debt balance being for more than one year	Not applicable		
13	**General Deposit Account**			
13.1	Should have acted in accordance with FR 571 with regard to the expired deposits	Not applicable		
13.2	Updating and maintaining the control account for the general deposit accounts	Not applicable		
14	**Imprest Account**			
14.1	Should have forwarded the cash book balance to the treasury operations department, at the end of the year under review	Not applicable		
14.2	Interim imprest issued under FR 371,having been settled within one month after the completion of particular work	Not Applicable		
14.3	Having issued the interim imprest at present not exceeding the approved limit in terms of FR 371	Not applicable		
14.4	Doing reconciliation of imprest account's balance with treasury book, monthly	Not applicable		

15	**Revenue Account**			
15.1	Should have made repayments from the income collected in accordance with the relevant regulations	Compliant		
15.2	Having credited the collected revenue directly to the revenue income without depositing to the deposit account	Compliant		
15.3	Having submitted the outstanding revenue reports to the auditor general, as per FR 176	Compliant		
16	**Human Resource Management**			
16.1	Maintaining Staff within the approved cadre limit	Compliant		
16.2	Should have provided duty lists in writing to all staff members	Compliant		
16.3	submitting all reports to the department of Management Services in terms of MSD circular no. 04/2017 dated 20.09.2017	Compliant		
17	**Providing information to the public**			
17.1	Appointing an information officer in accordance with the right to information act and regulations and updating and maintaining an document consist of such information provided	Compliant		
17.2	Providing information about the organization through its website and having made facilities for the public to put their comments/allegations about the organization, through the website or alternative channels	Compliant		
17.3	Should have submitted reports twice or once a year as per section 8 and 10 of right to information act	Compliant		
18	**Implementation of the citizens charter**			
18.1	Should have formulated and implemented a citizen's / clients' charter in accordance	Compliant		

	with the provisions of the circular No.05/2018 and 05.2018 (1) of the Ministry of Public Administration and Management			
18.2	A methodology should have been developed by the organization to monitor and evaluate the matter of preparation and implementation of citizen's / clients' charter , in terms of the paragraph 2.3 of said circular	Compliant		
19	**Preparation of Human Resource Plan**			
19.1	Preparing human resource plan based on the Public Administration circular No.02/2018 annexure 02 dated 24.01.2018	Compliant		
19.2	Should have ensured at least 12 hours of training per year for each member of the staff , in the above HR plan	Compliant		
19.3	Should have signed annual performance agreement for the entire staff based on the format given in annexure 01 of the above circular	Applicable - Not done		Planned to implement
19.4	Should have appointed senior officer with the responsibility of preparing human resource development plan, capacity development programs implementing skills development program in accordance with paragraph 6.5 of the above circular	Compliant		
20	**Responding to the audit queries**			
20.1	Having corrected the deficiencies pointed out though the audit paragraphs of the Auditor General for the previous year	Compliant		