Annual Report

2022

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 especially 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

1. Prof. S.D. Jayaratne (Chairman/NMRA)
2. Dr. Vijith Gunasekera (Chief Executive Officer/NMRA)
3. Dr. Asela Gunawardena (DGHS)
4. Prof. Pradeep de Silva
5. Mr. M.M. Chathura Parakrama Mohottigedara
6. Dr. Kosala Karunaratne
7. Mr. S.A.N Priyantha Serasinghe
8. Mr. Manoj Gamage
9. Mr. Supul Wijesinghe
10. Dr. Pradeep Kumarasinghe
11. Prof. Priyadarshani Galappaththi
12. Dr. Duminda Ariyarathne
13. Prof. Hemantha Dodampahala

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

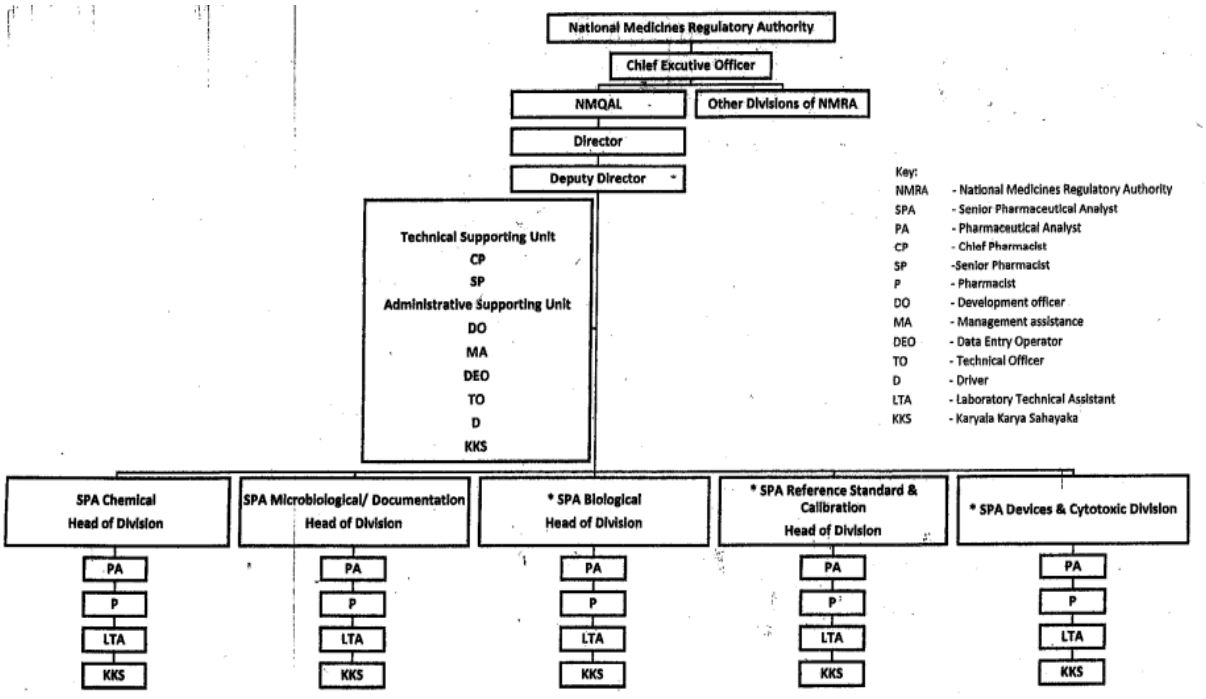
National Drug Quality Assurance Laboratory (NDQAL) was the National Laboratory established in Sri Lanka for testing Cosmetics, Devices and Drugs. It was established in 1990 under Cosmetics Devices and Drug Act No.27 of 1980, with Norwegian consultancies and NORAD funds with the vision of ensuring Quality,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

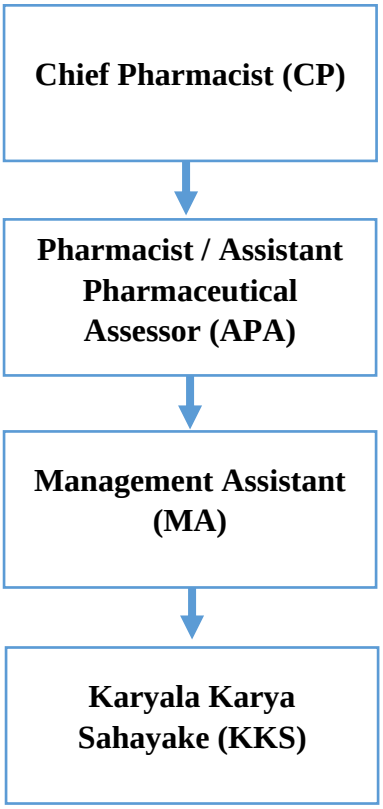
- To coordinate with laboratories local or overseas when their services are deemed necessary as decided by the NMRA.

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;

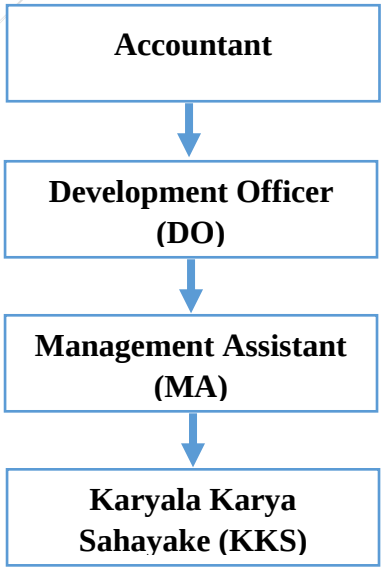
- Evaluation, and make arrangements to register and give recommendation for issuing of import license for medicines, medical devices, cosmetics and borderline products.
- Regulation of Pharmaceutical manufacturing sites locally and internationally.
- Price Regulation
- Regulation of Island wide Pharmacies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

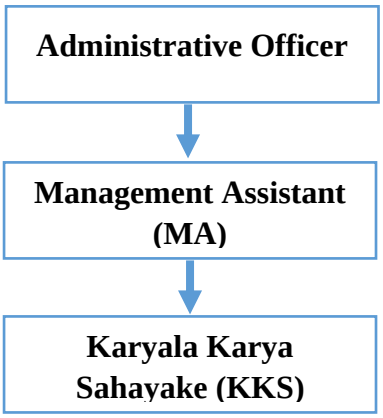
1.4.4 Administration Division

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

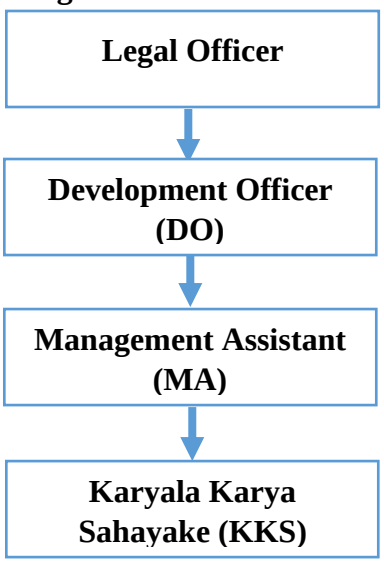
1.4.5.1 Introduction

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

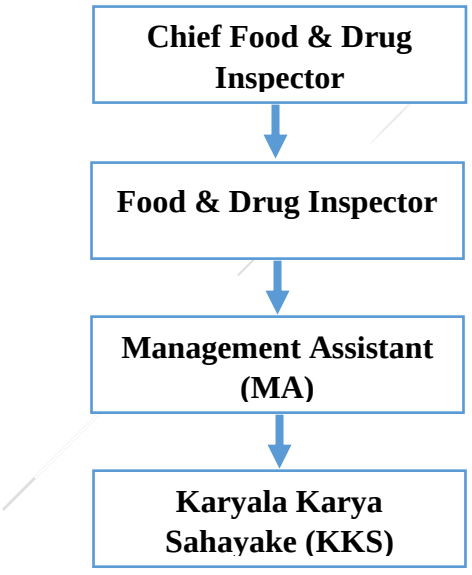
1.4.6.1 Introduction

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

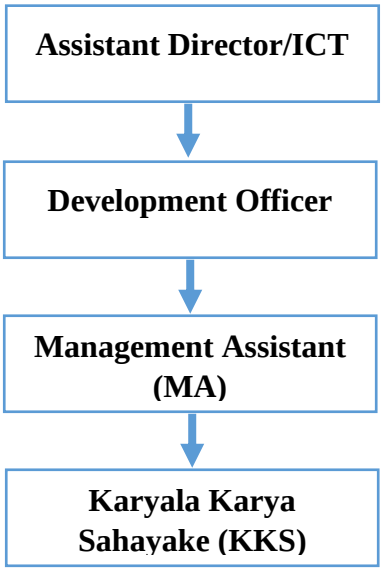
- Investigating & initiate legal actions on the detentions made by the SSFFC & smuggled products
- Investigating the availability of state-owned drugs in the private market
- Inspecting & recommending of dangerous drugs applications
- Organizing & conducting educational programs
- Conducting prosecutions 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

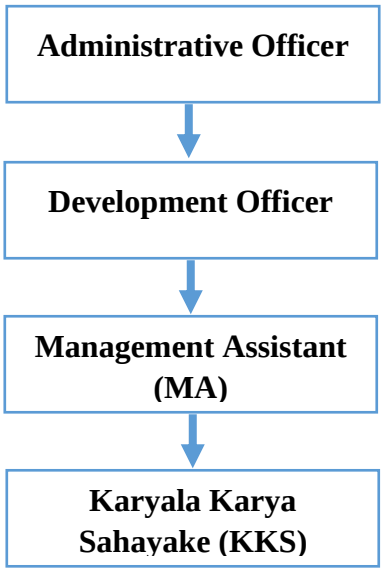


1.4.8 Human Resource Division

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)

Performance of the Division:

1) Total Number of reports issued : 477

2) Total number of sample received in the month the year :374

2.1) Breakdown of the samples received:	
Registration	43
NMQAL Surveillance	138
MSD Surveillance	23
Complaints	63
Food & Drug Inspectors	69
Court Samples	26
SPC tender	7
Others	5
Total	**374**

2.2) Number of reports issued from above samples : 241

2.3) Number of samples still remains in the laboratory received from 01-01-2020 to 31-12-2022 as at 01.01.2023 : 165

3) Summary of products analysed

3.1) Samples tested as per request categories

TYPE	LOCAL PRODUCTS		IMPORTED PRODUCTS		TOTAL	
1) PRE MARKETING	**PASS**	**FAIL**	**PASS**	**FAIL**	**PASS**	**FAIL**
A) REGISTRATION	24	3	10	7	34	10
B) STATE PHARMACEUTICALS CORPORATION	0	1	6	0	6	1
C) OTHER REQUESTS (SPECIFY)	0	0	0	0	0	0
2) POST MARKETING						
A) POST MARKETING						
i. NMQAL SURVEILLANCE	83	21	42	18	125	39
ii. COMPLAINT	2	10	11	35	13	45
iii. MEDICAL SUPPLIES DIVISION	5	0	3	2	8	2
iv. STATE PHARMACEUTICALS CORPORATION	0	0	0	0	0	0
B) FOOD & DRUG INSPECTOR						
i. INFORMAL	9	0	23	1	32	1
ii. FORMAL	12	1	26	1	38	2
C) OTHER REQUESTS SPECIFY	0	0	1	2	1	2
GRAND TOTAL	135	36	122	66	257	102

3.2) Total No. of reports issued

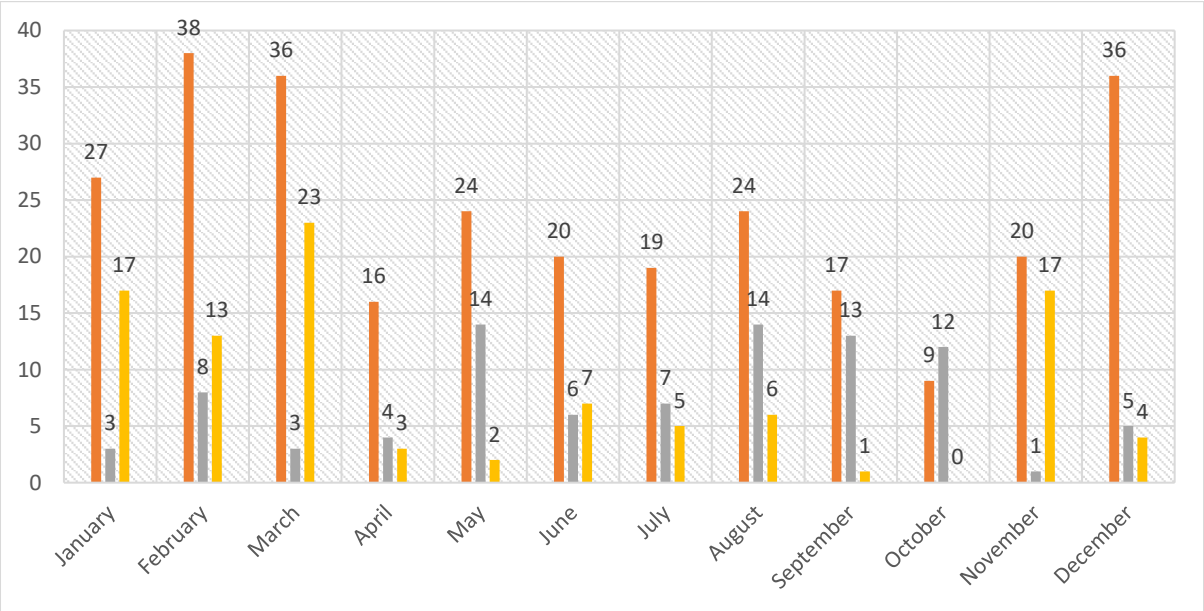
Product Category	Pass	Fail	Total	Failure % of the category
Imported	122	66	188	**35**
Local	135	36	171	**21**
Court Samples			43	
Other products (specify) Hand Sanitizer, cosmetics,samples with comments			75	
Total report issued			**477**	

3.3) Number of reports issued within 90 days from the above reports : **268**

3.4) Breakdown of failures as per market status

Product Category			Pass	Fail	Total	% Failure of the category
Pre market			40	11	51	22
Post market			217	91	308	30

4) Progress of analysis



Month	Pass	Fail	Others (Cosmetic, Hand Sanitizers,courts & etc)
January	27	3	17
February	38	8	13
March	36	3	23
April	16	4	3
May	24	14	2
June	20	6	7
July	19	7	5
August	24	14	6
September	17	13	1
October	9	12	0
November	20	1	17
December	36	5	4

5) Staff situation

Position	Cadre	in position	% availability
Director	1	0	0
Deputy Director	1	0	0
Pharmaceutical Analysts	26	6	23
Pharmacists	29	13	45
Laboratory Technical Assistants	7	0	0

6) Other activities (e.g. QMS, purchasing, GMP inspections & etc)

6.1 GMP Inspections = 37

No:	Site name & address
1	Himata Pvt Ltd, Homagama
2	Emergen Life Sciences - Kelaniya
3	Glaxo Smithkline - Ratmalana
4	Ceylon Oxygen Ltd - Kurunegala
5	Newgen Lanka Healthcare Pvt Ltd, Kurunegala
6	Ace Healthcare Pvt Ltd, Horana
7	Astron Ltd, Ratmalana
8	Navesta Pvt Ltd, Horana
9	Isolez Biotec Pharma - Katunayake
10	Morison Limited- Homagama
11	Diyatha Pharmaceuticals Ltd -Ja-ela
12	Schithra Pharmaceuticals - Bandaragama
13	Yaden Laboratories - Ja - Ela
14	Newgen Lanka Healthcare Ltd- Colombo 05
15	Plastica International Pvt Ltd-Malabe
16	Reliance Life Science Pvt Ltd - India
17	Theon Pharmceutical Pvt Ltd - India
18	LDLS Manufacturing Pvt Ltd - India
19	Ajantha Pharmaceuticals Pvt Ltd - India
20	MWJ Lifescience - Nugegoda
21	Ace Healthcare Pvt Ltd, Kandana, Horana
22	Treffor Pharmaceuticals - India
23	Halewood Laboratories - India
24	ACE Pharmaceuticals - Horana
25	Lina Manufacturing Ltd - Kadawatha
26	Uniliver Ltd - Horana

27	Suraksha Pharmaceuticals - Homagama
28	Sands Active Pvt Ltd - Ja-Ela
29	ACE healthcare Pvt Ltd - Horana
30	Celogen Lanka Pvt Ltd - Kandy
31	Himata Pvt Ltd - Homagama
32	Navesta Pharmaceuticals - Horana
33	CIC Life Sciences - Ragama
34	Karnataka Antibiotics & Pharmaceuticals - India
35	Belco Pharma - India
36	Swedeshi Industry PLC - Kandana
37	Kelun Life Science - Horana

6.2 Staff Trainings

2022/01/03	Implementation of monitoring environmental conditions conducted by Mrs. Amara Pinnawala / Deputy Director - NMQAL
2022/01/07	Training on measurement uncertainty calculation conducted by Measurement units, Standards & Service Depatment
2022/01/26	Estimation of uncertainty measurement conduct by Mrs. I.P. Edussuriya/ Pharmaceutical Analyst - NMQAL
2022-02-01	Development & validation of dissolution procedure by USP Education Center (Virtual Training)
2022-02-21	Competency assessment on pH Test - Knowledge on SOP in house training at NMQAL
2022-02-24	Audit Fundamentals by USP Education Center (Virtual Training)
2022-03-23 & 24	Virtual training: Planning & conduct of Bioequivalence Studies conducted by Sun Pharma

6.3 Other Matters

Management Review Meeting held on 24th Feb. 2022

6.4

1. Evaluation of Analytical Test Methods: 22

2. Replies to manufacturers on quality failures: 11

2.2 Progress of Pharmaceutical 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, Pharmacovigilance 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

1. Medicines dossier evaluations

Type of applications	Number of applications received	Number of applications evaluated
New Medicines applications	999	1643 + 939 RR
MEDREG applications	482	
Re-Registration applications	571	
Additional	608	
Variations	346	90

2. **Number of MEC –Subcommittee meetings for dossier evaluation =** 28

3. **Review of applications for New Molecular Entity (NME)**

Total of submitted NCEs in 2022	No. of accepted NCEs	No. of rejected NCEs	Pending at MEC
19	15	03	01

4. 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
206	203	03

5. Evaluation of applicaions for sample import license

Medicines Sample License - 2022	
No of application received	1272
No of application rejected	210
No of applications approved by the MEC	505
No of application pending due to the incomplete documents (already informed to L/A but didn't receive any response)	120
No of sample license issued	422

6. Number of MEC meetings conducted = 12 (12minutes were written)

7. No of MEC Subcommittee = 28 Sub committee

8. Applications for controlled substances

Number of applications received	Total number of applications received	Total number of issued from the received requests
Number of import authorizations	159	155
Number of letters for monthly quota approval	20	20
Number of letters for authorized person	19	19

9. Issuing Waiver of registration

Type of application	Accepted applications in 2022	Number of Approved	Number of not approved	Decision Pending
WOR (Special Pathway	358	196	13	149
WOR (Normal pathway)	284	116	129	39
Donations	332	332	-	-

Number of WOR meetings for review WOR appliactions = 11

10. Review applications for shipment clearance approval

Number of applications received	Number of applications reviewed and approved	Number of applications reviewed and reject
3416	3281	135

11. Update medicines database

Number of received registration certificates from Admin	Number of entered certificates to data base	Number of pending to enter
4912	Extended certificates - 2904 New certificate - 2008	0

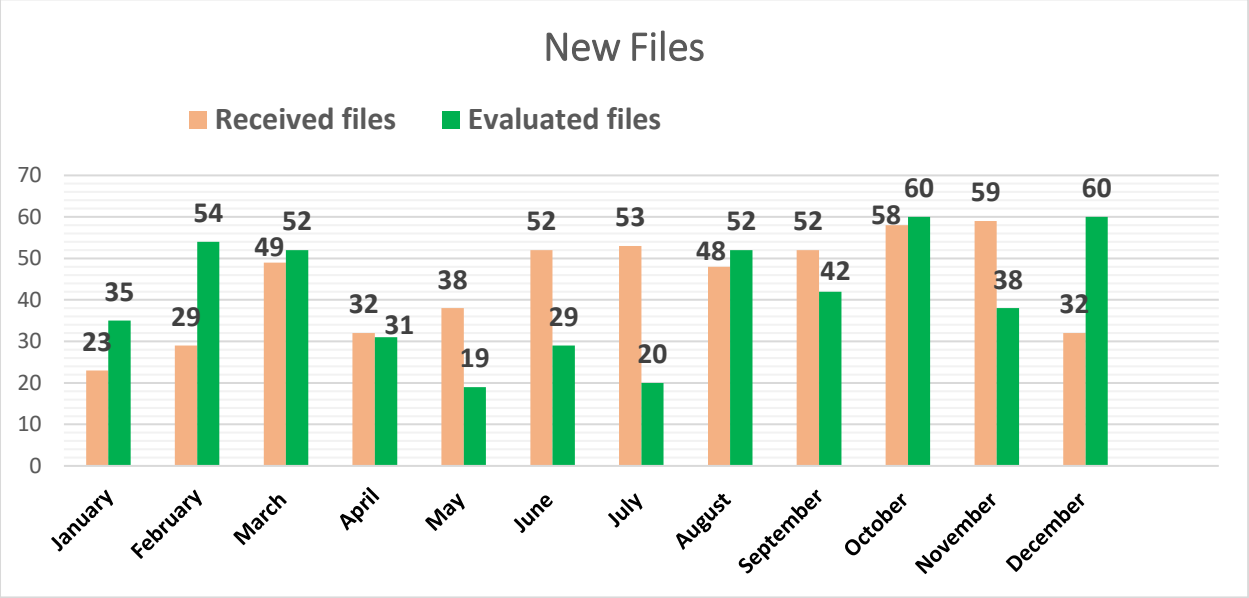
2.2.2 Medical Devices Regulatory Division

1. Evaluation of Medical Device Applications (Dossiers)

1-1 New Files

Format 1-1

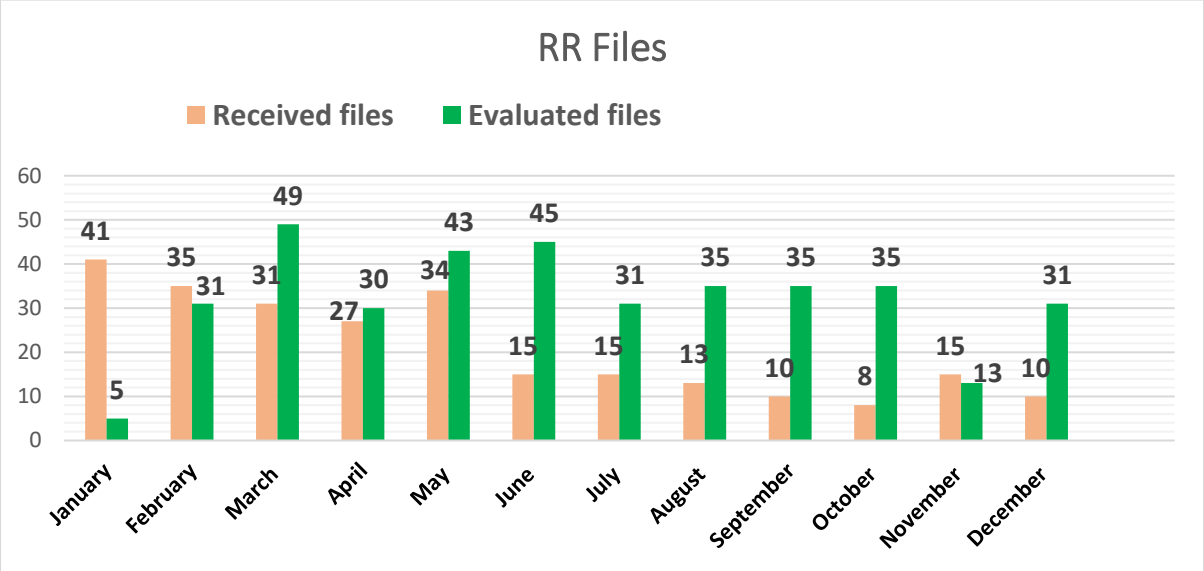
Month	No of Received files	No of Evaluated files
January	23	35
February	29	54
March	49	52
April	32	31
May	38	19
June	52	29
July	53	20
August	48	52
September	52	42
October	58	60
November	59	38
December	32	60



1-2 Re -Registration Files

Format 1-2

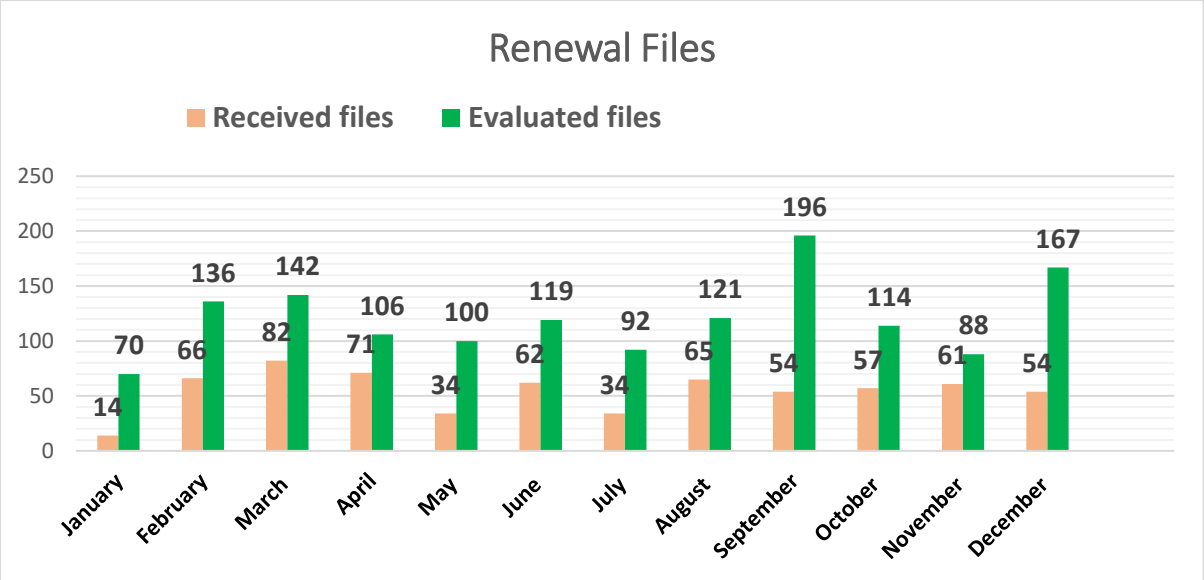
Month	No of Received files	No of Evaluated files
January	41	05
February	35	31
March	31	49
April	27	30
May	34	43
June	15	45
July	15	31
August	13	35
September	10	35
October	8	35
November	15	13
December	10	31



1-3 Renewal Files

Format 1-3

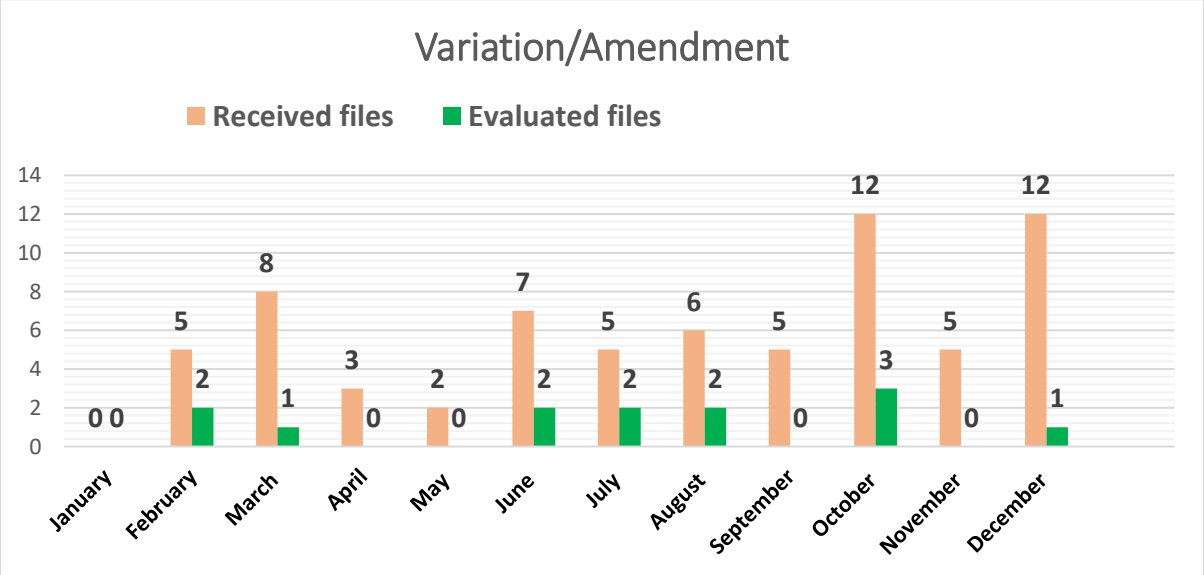
Month	No of Received files	No of Evaluated files
January	14	70
February	66	136
March	82	142
April	71	106
May	34	100
June	62	119
July	34	92
August	65	121
September	54	196
October	57	114
November	61	88
December	54	167



1-4 Variations/Amendments

Format 1-4

Month	No of Received files	No of Evaluated files
January	00	00
February	05	02
March	08	01
April	03	00
May	02	00
June	07	02
July	05	02
August	06	02
September	05	00
October	12	03
November	05	00
December	12	01



1-5 Rejected Files

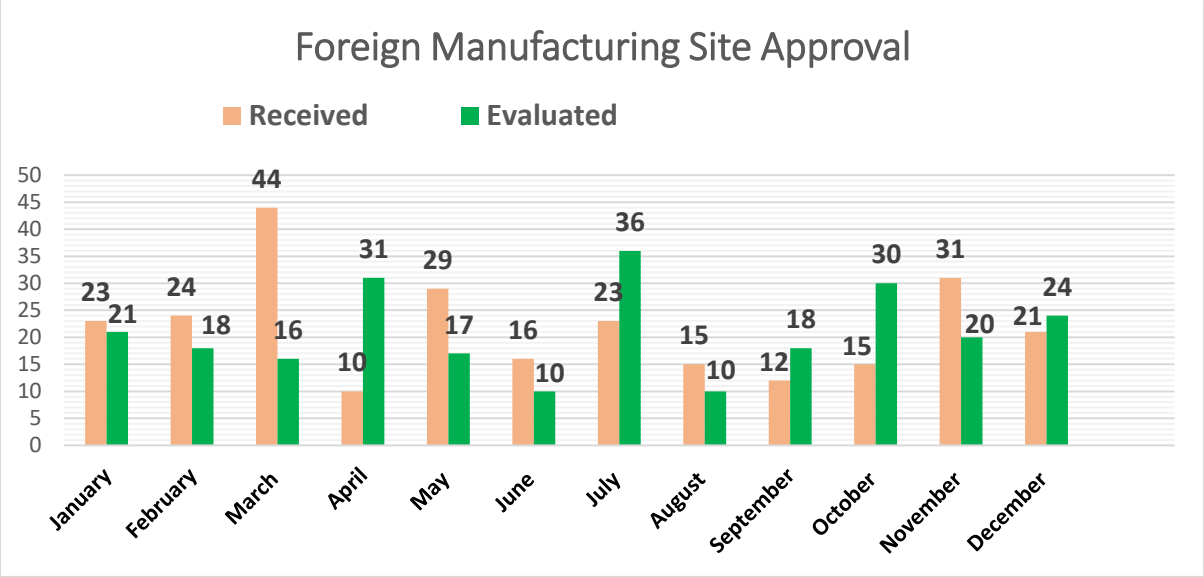
Format 1-5

Month	No of Rejected files
January	07
February	10
March	16
April	03
May	02
June	01
July	02
August	03
September	02
October	04
November	00
December	04

2. Foreign Manufacturing Site Approval files

Format 2-1

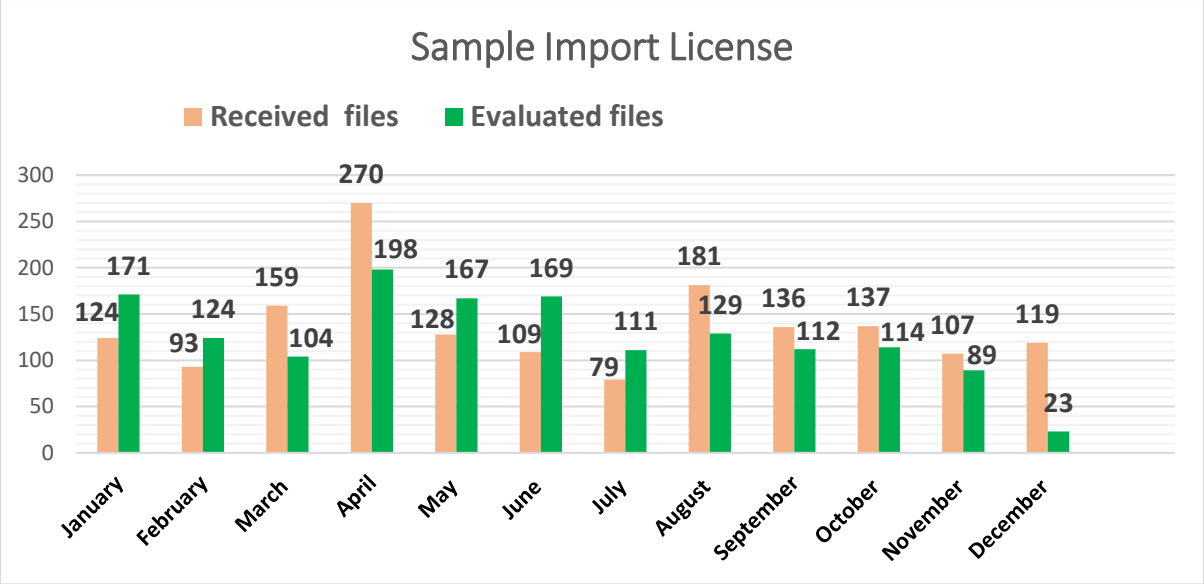
Month	No of Received files	No of Evaluated files
January	23	21
February	24	18
March	44	16
April	10	31
May	29	17
June	16	10
July	23	36
August	15	10
September	12	18
October	15	30
November	31	20
December	21	24



3. Sample Import Licence Approval

Format 3-1

Month	No of Received files	No of Evaluated
January	124	171
February	93	124
March	159	104
April	270	198
May	128	167
June	109	169
July	79	111
August	181	129
September	136	112
October	137	114
November	107	89
December	119	23

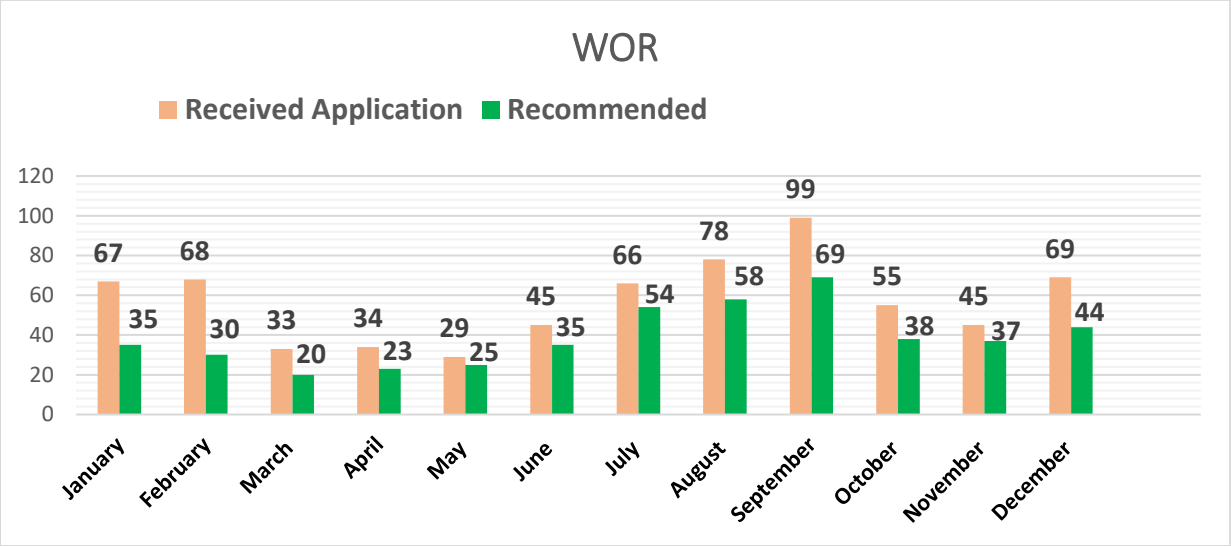


4. Issuing Waiver of Registration

Format 4-1

Month	No of applications received	Recommended	Not Recommended
January	67	35 (Donation-21)	29
February	68	30 (Donation-22)	05
March	33	20 (Donation-16)	00
April	34	23 (Donation-16)	07
May	29	25	04
June	45	35	10
July	66	54 (Donation-34)	12
August	78	58 (Donation-34)	11
September	99	69 (Donation-24) (SPC/ICL-41) (CEO Minute-04)	00
October	55	38 (Donation-32) (SPC/ICL-05)	01

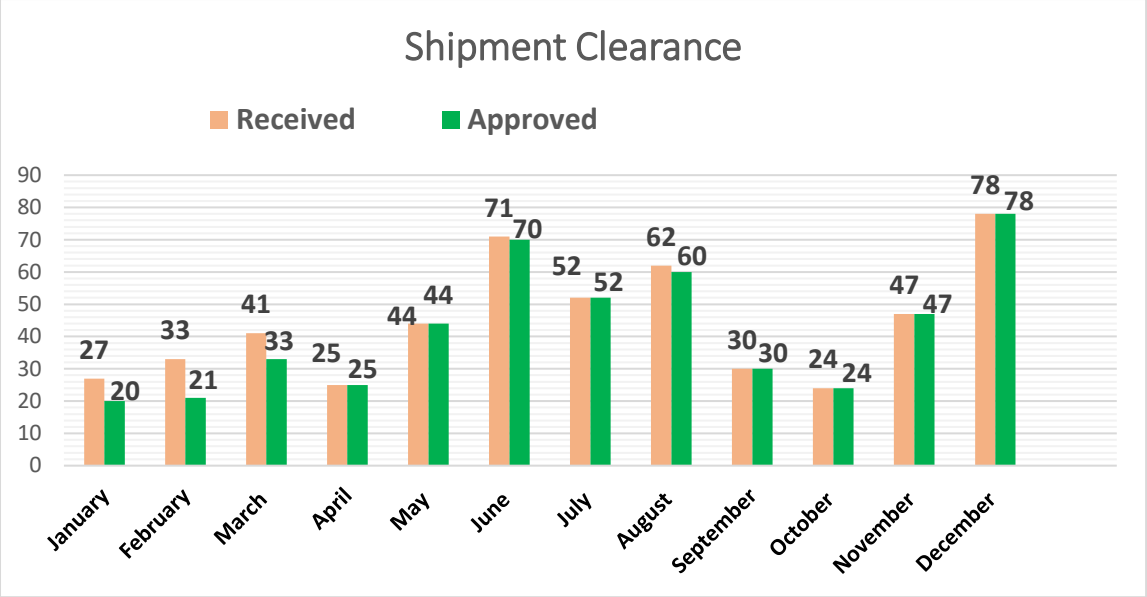
November	45	37 (Donation-26) (SPC/ICL-02)	03
December	69	44 (Donation-31) (SPC/ICL-09) (CEO Minute-04)	Next Committee -25



5. Issuing Shipment clearance

Format 5-1

Month	Received applications	Approved	Not Approved
January	27	20	07
February	33	21	12
March	41	33	08
April	25	25	00
May	44	44	00
June	71	70	01
July	52	52	00
August	62	60	02
September	30	30	00
October	24	24	00
November	47	47	00
December	78	78	00



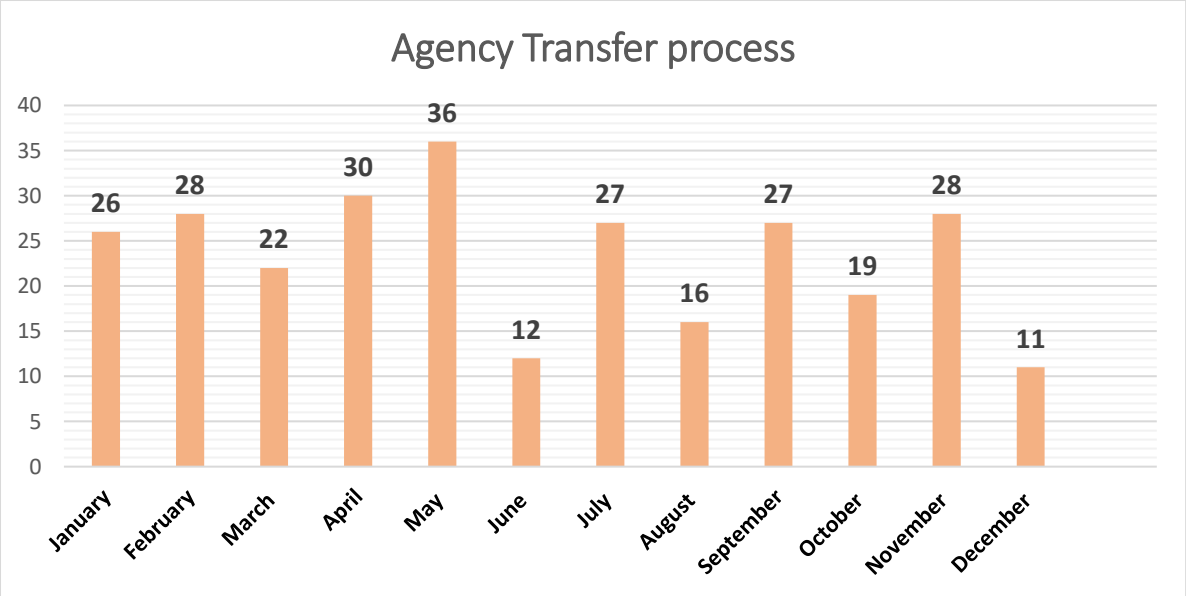
6. Handling Quality issues / Complaints

Month	No of complaints received	No of Batch Withhold	No of Batch Withdrawal	No of Product Withhold	No of Product Withdrawals
January	04	NIL	NIL	03	NIL
February	08	04	NIL	NIL	NIL
March	NIL	NIL	01	NIL	NIL
April	NIL	NIL	NIL	NIL	NIL
May	02	NIL	NIL	NIL	NIL
June	01 (File Ref : QF/01/2022)	NIL	NIL	NIL	NIL
July	NIL	01(File No.QF/07/CP/P 7/2020)	NIL	NIL	NIL
August	01(IV set)	NIL	NIL	NIL	NIL
September	02 (IV set – Unregistered Product and Surgical Suture)	NMRA/MD/QF /05/CP/P7/2022 NMRA/UR-MD/03/2022	NIL	NIL	NIL
October	Not reported	NIL	NIL	NIL	NIL
November	Not reported	NIL	NIL	NIL	NIL
December	02	NIL	NIL	NIL	NIL

7. Agency Transfer Process

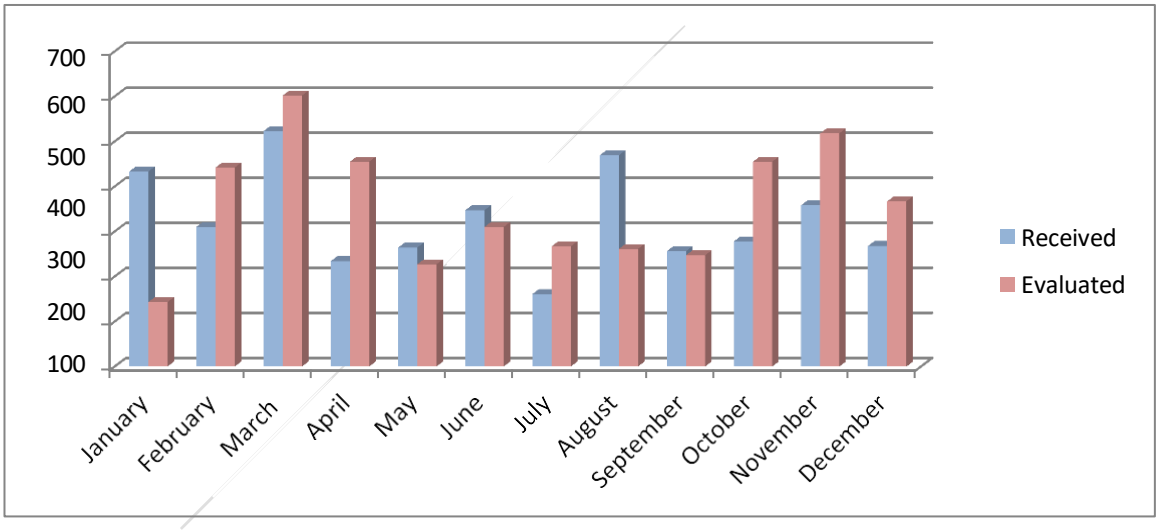
Format 7-1

Period	No of files sent to legal department with comments
January	26
February	28
March	22
April	30
May	36
June	12
July	27
August	16
September	27
October	19
November	28
December	11



2.2.3 Cosmetics Regulatory Division

	Received			Sample Licence	Total	Evaluated			Sample Licence	Total
Month	New	Additional	RR			New	Additional	RR		
January	224	29	4	176	433	73	61	3	6	143
February	130	98	16	66	310	126	121	3	192	442
March	235	207	4	77	523	323	163	10	106	602
April	103	37	1	93	234	242	119	1	93	455
May	90	113	8	53	264	61	132	0	34	227
June	204	80	1	62	347	204	64	8	34	310
July	94	31	0	36	161	60	115	0	92	267
August	269	113	14	73	469	98	78	14	71	261
September	202	44	0	10	256	176	56	7	8	247
October	125	104	24	25	278	302	118	10	25	455
November	186	97	1	74	358	206	205	23	84	518
December	119	111	2	36	268	141	210	2	14	367
Total	**1981**	**1064**	**75**	**781**	**3901**	**2012**	**1442**	**81**	**759**	**4294**



	Evaluation Decisions					Sample Licence Decisions			Total
Month	FR	PR	Awaiting	Reject	Variation	Approved	Reject	Awaiting	
January	24	84	26	3	0	6	0	0	143
February	48	177	24	1	0	189	2	1	442
March	60	382	39	2	13	95	11	0	602
April	45	253	53	1	10	93	0	0	455
May	68	101	16	2	6	34	0	0	227
June	26	210	32	1	7	34	0	0	310
July	29	88	36	7	15	92	0	0	267
August	8	162	19	0	1	68	3	0	261
September	19	207	9	0	4	8	0	0	247
October	60	351	8	7	4	24	1	0	455
November	110	299	16	2	7	84	0	0	518
December	127	211	15	0	0	14	0	0	367
Total	**624**	**2525**	**293**	**26**	**67**	**741**	**17**	**1**	**4294**

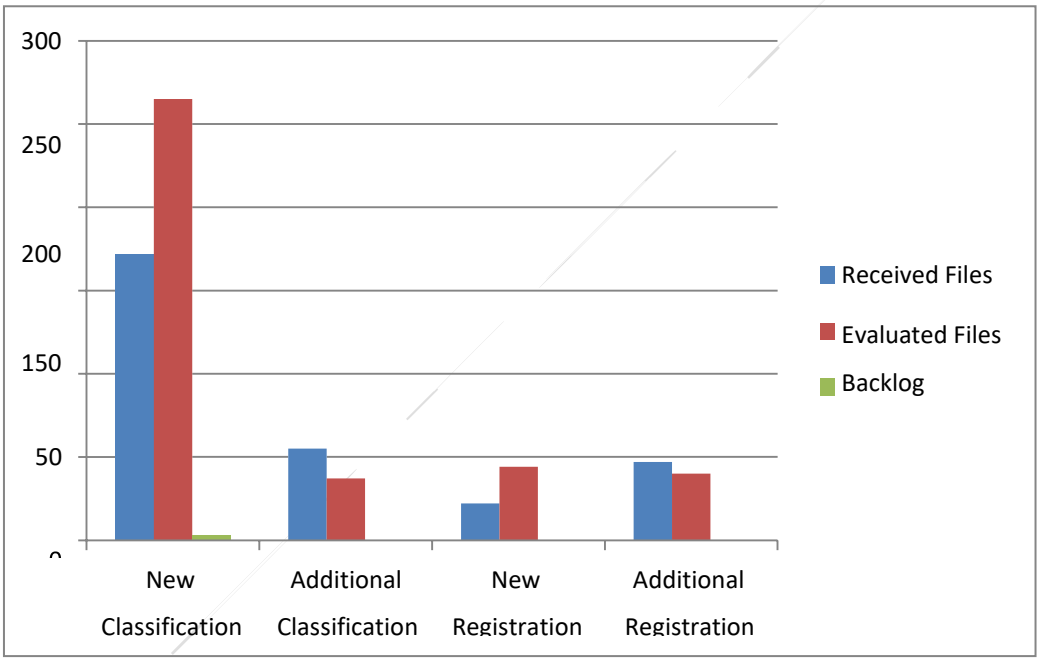
2.2.4 Borderline Product Regulatory Division

Number of applications evaluated										Number of applications sumbited to CEO's Approval									
Month	New		Additional		RR	Variations	Formulation Approvals	S.I.L.	Site Master Files	New		Additional		RR	Variations	Formulation Approvals	S.I.L.	Site Master Files
	Classification	Registration	Classification	Registration						Classification	Registration	Classification	Registration					
January	15	_	_	1	_	1	_	8	3	15	_	_	1	_	1	_	5	3
February	26	2	_	5	_	_	_	3	2	12	3	_	3	_	_	_	3	2
March	27	1	3	3	_	_	_	13	_	17	1	_	1	_	_	_	8	_
April	25	7	2	5	_	_	_	11	_	27	8	_	6	_	_	_	11	_
May	27	6	_	5	_	_	_	6	1	12	3	_	5	_	_	_	5	1
June	18	5	3	3	4	1	_	11	_	11	5	2	7	1	1	_	9	_
July	15	2	2	3	3	_	_	22	_	13	1	3	2	6	_	_	22	_
August	29	3	5	2	1	_	1	_	1	_	3	_	1	1	_	1	_	1
September	12	4	3	2	_	_	_	9	1	27	3	2	2	1	_	_	2	1
October	23	2	6	5	_	_	2	6	1	12	6	2	6	_	_	2	6	1

November	24	6	8	3	_	_	_	7	1	16	3	4	6	_	_	_	3	1
December	21	6	6	3	_	_	_	5	_	15	4	_	3	_	_	_	5	_
Total	265	44	37	40	13	2	3	101	10	177	40	13	43	9	2	3	79	10

Total = 505

	Received Files	Evaluated Files	Backlog
New Classification	172	265	3
Additional Classification	55	37	_
New Registration	22	44	_
Additional Registration	47	40	_
Total	296	386	3



2.2.5 Manufacturing Regulatory Division (MFRD)

1) GMP Audits

A. GMP audit of local manufacturing sites		
Category	Number of Requests	Number of Inspections
Medicine manufacturers	35	48
Medical devices manufacturers	24	21
Cosmetics manufacturers	40	41
Borderline product manufacturers	01	01
Total	90	112*

* Includes follow up inspections & allocations from previous year

New local manufacturing sites/ production lines approved in year 2022

1. Ace Healthcare (Pvt) Ltd, Horana – oral solid and liquid dosage forms , topical products
2. Kelun Life Sciences (Pvt) Ltd, Pallekele, Kandy – new glass vial and ampoule line
3. Navesta Pharmaceuticals (Pvt) Ltd – penicillin oral solid dosage forms
4. Yaden Laboratories (Pvt) Ltd, Katunayake – small volume parenteral products

B. GMP audit of overseas manufacturing sites (all medicine manufacturers)			
Number of Requests	Teams approved	Approval pending	Inspections conducted
24	11	13	08

2) Approval of Foreign Manufacturing Sites

Applications for Approval of Foreign Manufacturing Site					
Application type	Received	Evaluated	Approved	Awaiting	Rejected
New	33	37*	18	19	Nil
Additional	22	36*	26	10	Nil

*Includes applications from previous year

3) Formulation Approvals

Applications for formulation approval				
Received	Evaluated	Approved	Rejected	Pending
474	414	404	10	60

4) Processing of Certificates and Licenses

	GMP certificates	**CPPs**	**Free Sales Certificates**
Requests	44	10	148
Issued	42	08	65
Pending	02	02	Nil*

*Payments not made/rejected – 83 (see annex I for summary)

Manufacturing licences for products

1. Number of applications received - 741
2. Recommended and forwarded for typing - 739

5) Miscellaneous Activities

Activity	Requests	Letters issued	Pending
Issuing of clarification letters	544	527	07
Recommendations for VAT/PAL exemption	752	751	01

I. Document Formats:

The updated formats relevant to approval of overseas manufacturing sites were published.

- Checklist for accepting applications for approval of an overseas manufacturer of medicines. (Revision 01)
- Application for approval of an overseas manufacturer of medicines. (Revision 02)
- Assessment form for evaluation of an overseas pharmaceutical manufacturing site. (Revision 02)

II. Training

Training was confined to online participations.

- Training on GMP inspection report writing; 18.02.2022; conducted virtually by WHO appointed consultant, Dr. Engy Al Hosary
- Training on desk review of manufacturing sites; 11.03.2022; conducted virtually by WHO appointed consultant, Dr. Engy Al Hosary
- "Advanced Good Manufacturing Practices (GMP) Inspections" e-learning course; 07.11.2022 – 25.11.2022; MFDS Korea/WHO. (Participant – Ms. Prabha Dayawansa)
- PMDA ATC GMP Inspection Webinar; 25th and 26th October 2022; PMDA Japan (Participant – Ms. S. S. Shobia)

III. Achievements:

- Successful completion of annual risk-based GMP audit plan for year 2022
- Re-initiation of overseas GMP audits which were held due to COVID 19 pandemic situation
- Initiation of peer review of GMP audit reports

Annex I

Free Sale Certificate Summary

Manufacturer	Submitted requests count	Rejected/Not paid	Issued certificates count
4Ever Skin Naturals (Pvt) Ltd.	54	40	14
The Swadeshi Industrial Works PLC	44	42	2
Eco Envi Lanka (Pvt) Ltd.	1	1	0
Unilever Sri Lanka (Pvt) Ltd.	19	0	19
Pure Herbs Inventions (Pvt) Ltd.	2	0	2
Janet Lanka (Pvt) Ltd.	13	0	13
Ansell Lanka (Pvt) Ltd.	14	0	14
Flexicare Lanka (Pvt) Ltd.	1	0	1
Total	**148**	**83**	**65**

2.2.6 Pricing Unit

DOSSIERS		
Total Discussed		1605
Approved Dossiers		1482
Negotiation Going on		123

IMPORT LICENSE		
Total Received		1785
Total Discussed		1464
Approved Import License		1383
Negotiation Going on		81

2.3 Progress of Inspection and Enforcement Division (IED)

Handling of Public complaints

Total number received in 2022-66

- No to be investigated-50%
- No investigated- 39%
- No under investigation-11%

Area	No. received	No. investigated	No pending	No.under investigation	Remarks
NMRA	29	13	11	05	
Colombo	06	01	05	-	
Gampaha	07	-	07	-	
Kalutara	02	-	02	-	
Kandy	05	03	02	-	
Nuwara-eliya	02	02	-	-	Investigated by C-FDI
Galle	05	02	02	01	Investigated by NMRA
Matara	01	01	-	-	
Kegalle	02	01	01	-	
Anuradapura	03	01	01	01	
Puttalam	01	01	-	-	
Kurunegala	01	01	-	-	
Matale	01	-	01	-	
Badulla	01	-	01	-	
	66	**26**	**33**	**07**	

Recommended vehicles for Drug Transportation

Types of vehicle							
Car		Van		Freezer truck		Total	
No checked	No recomm	No checked	No recomm	No checked	No recomm	No checked	No recommen
1706	1622	156	137	139	130	2001	1889

Submitting of Samples by FDII

Serial No.	District	Samples submitted							
		2020		2021		2022		Total	
		Formal	Informal	Formal	Informal	Formal	Informal	Formal	Informal
01.	NMRA	13	18	19	06	13	-	45	24
02.	NIHS	-	-	-	-	-	-	-	-
03.	Colombo		20	03	-	-	-	03	20
04.	Gampaha	-	06	02	-	07	-	09	06
05.	Kalutara	02	14	-	-	-	-	02	14
06.	Kandy	04	05	04	-	06	-	14	05
07.	Matale	-	-	-	-	-	-	-	-
08.	NuwaraEliya	-	-	-	-	-	-	-	-
09.	Galle	01	04	-	-	-	-	01	04
10.	Matara	-	14	-	-	-	-	-	14
11.	Hambantota	-	06	-	-	-	-	-	06
12.	Jaffna	-	-	-	-	-	-	-	-
13.	Mannar	-	-	-	-	-	-	-	-
14.	Vavuniya	-	07	01	-	-	-	01	07
15.	Mullaitive	-	-	-	-	-	-	-	-
16.	Kilinochchi	-	-	-	-	-	-	-	-
17.	Batticaloa	-	06	-	-	-	-	-	06
18.	Ampara	02	17	-	16	-	10	02	43
19.	Kalmunai	-	-	-	-	-	-	-	-
20.	Trincomalee	03	-	08	-	08	-	19	-
21.	Kurunegala	-	-	-	-	-	-	-	-
22.	Puttalam	-	-	-	-	-	-	-	-
23.	Anuradhapura	06	-	-	-	-	01	06	01
24.	Polonnaruwa	-	-	-	01	-	-	-	01
25.	Badulla	02	11	03	-	03	02	08	13
26.	Moneragala	-	01	03	01	-	01	03	03
27.	Ratnapura	-	17	01	14	-	06	01	37
28.	Kegalle	-	16	-	06	-	-	-	22
		33	**162**	**44**	**44**	**37**	**20**	**114**	**226**

Number of recommendations of Retail/Wholesale applications-NMRA.

Type of application		No received	No recommended	No rejected
New locations	Retail		61	03
	wholesale		25	-
Renewal	Retail		49	-
	wholesale		37	-
Routine inspections			80	-
Total			252	03

Court procedures- NMRA-2022

- Number of court appearances - 118
- Number of cases handled - 404

Summary of Prosecution, conducted by FDII/NMRA-2022

No of appearances at the courts-118
Total collection of fines- Rs 1,389,600.00 *(out of 34 cases)*
Number of cases convicted-34 Number of cases pending-62

Serial No.	Charge	No. of Charges
01	Carrying on a pharmacy without a licence	04
02	Issuing medicines without a pharmacist	01
03	Selling medicines without a prescription	01
04	Selling smuggled medicines	02
05	Storing smuggled medicines [106(1)]	03
06	Selling unregistered medical devices	01
07	Storing medicines without a valid licence	05
08	Storing smuggled medical devices	02
09	Violations identified with regard to abusive medicines (Tramadol & Pregabalin)	83
	Total Charges	**102**
	Total number of cases filed	**96**

Surprise inspections conducted/NMRA-2022

Month	Places visited	No of places visited	Defects identified	Defects corrected
January	Meegoda, Wattala, Anuradapura	12	15	10
February	Galle, Elpitiya	10	14	09
March	Kandy Wennappuwa Nawala	12	08	05
May	Sunshine HealthCare warehouse Emerchemie warehouse Hemas warehouse etc	06		
November	Mawanella Kandy	06	06	04
December	Moratuwa Panadura Galle Matara	10	05	04

August

- No of raids conducted-02
  No of places raided-04

1.An unregistered brand of "Redline" anti-biotic was detected at

i. Union Chemist Pvt Ltd,Wattala
ii. Union Chemist Pvt Ltd, Col 02
iii. Essess Pharmacy Pvt Ltd, Col 04

2. Seizure of "Alprazolam tbs" at DHL warehouse, Col 02 with Custom officials.
The sender was trying to send the medicine to UK via Parcel Post while hiding inside a

Cont... Raids conducted by NMRA-2022

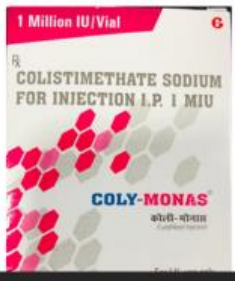
March-

- ✓ ***Gampola***-Detection of fake "Dettol"repacking
- ✓ ***Pundalu-Oya***-arrest of 2 pharmacy owners for prescribing medicines.
- ✓ ***Moratuwa***-nabbing of assistant for issuing medicines without a prescription
- ✓ **Battaramulla-**

September

A courier company, who had been carrying out advertisements over the social media, for home delivering Medicines from India, was apprehended after carrying out surveillance.

A prescription was produced to the courier to bring down an antibiotic. The unreasonable amount they claimed was deposited at the nominated bank, following their invoice. Upon arrival of the medicine, the warehouse of the courier company was raided where another medicine was also detected.



It was revealed that, the medicine had been hand carried to Sri Lanka ignoring the storage conditions mentioned.

Our data base indicate that the medicine smuggled, is not a registered brand.

December

Destructions of Pharmaceuticals supervised by NMRA

Serial No.	Description	2021	2022
01	Number of destructions recommended	23	47
02	Number of destructions supervised	23	47
03	Method of destructions		
(i)		23	46
(ii)	Incineration at high temperature	-	-
(iii)	Crush & bury	-	-
(iv)	Landfill	-	01
(v)	Mix with Sewer by WS&DB Inert sation	-	-
04	Quantity disposed (Metric Tons)	39.605	28.363

2.4 Progress of Finance Division

Finance Division of the National Medicines Regulatory Authority (NMRA) has made significant progress in streamlining its financial operations and enhancing its overall efficiency. Over the past few years, the division has implemented several key initiatives to better manage financial resources, improve transparency, and ensure compliance with regulatory standards.

Additionally, the Finance Division has been successful in establishing strong partnerships with relevant stakeholders, such as the Ministry of Health, external auditors, and other government agencies. These collaborations have allowed for a better exchange of information and best practices, contributing to the division's continuous improvement.

Plans for the future

1. Making use of the revenue effectively to achieve organizational objectives.
2. Completion of taking over the three vehicles given by the President's Office to the Authority.
3. Conducting the annual good survey.

2.5 Progress of Administration Division

Total License Issued for the Year 2022

No	Catogary		Total License
1	Medicines	Registration	2009
2		Import	1214
3		Manufacture	424
4		Sample	786
5	Medical Device	Registration	2036
6		Import	1492
7		Manufacture	92
8		Sample	891
9	Borderline	Registration	53
10		Import	34
11		Manufacture	1
12		Sample	40
13	Cosmetic	Registration	2703
14		Import	1673
15		Manufacture	868
16		Sample	805
Total			**15121**

2.6 Progress of Legal Division

Total Opening Files from 21.04.2017 up to 31.12.2022 1335

Number of opening files in year 2022 168

Total Closed Files (up to 31.12.2022)

Closed files 2017 (21.04.2017-31.21.2017) 69

Closed files 2018 (01.01.2018 Up to 31.12.2018) 166

Closed files 2019 (01.01.2019 Up to 31.12.2019) 225

Closed files 2020 (01.01.2020 Up to 31.12.2020)	102
Closed files 2021 (01.01.2021 Up to 31.12.2021)	221
Closed files 2022 (01.01.2022 Up to 31.12.2022)	238
Total	1021
Total Pending Files Up to 31.12.2022	324

Agency Transfer Closed Files (01.01.2022 up to 31.12.2022)

- Number of Free of charges files from (01.01.2022 – 31.12.2022) 5
- Number of Payment Basic files from (01.01.2022 – 31.12.2022) 77
- Total **82**

Regulations/ Gazettes issued under the NMRA Act from 01.01.2022 to 31.12.2022

No.	Gazette No	Gazette Name & Description
01	2269/11- 2022.02.28	The Medicines (Pricing of Paracetamol Tablets/Capsules 500mg) Regulations, 2022. Revised retail price by thirty-five per centum (35%). Fixed MRP Rs. 2.30/-
02	2271/23- 2022.03.15	Amendment to the Medicines (Ceiling on Prices) Regulations, 2019. The Medicines (Pricing of Paracetamol Tablets/Capsules 500mg) Regulations, 2022 published in Gazette Extraordinary No. 2269/11 of February 28, 2022 is hereby rescinded & Amendment to the Ceiling on Pricing Regulation 29% increase 60 Medicinal Products.
03	No. 2273/04 - 2022.03.28	• Further amendment to the Medical Devices Pricing Regulations, No. 01 of 2017. (Lances)

		• Further amendment to the Medical Devices Pricing Regulations, No. 05 of 2017 (Stent) • Further amendment to the Medical Devices (Pricing) Regulations, 2018 (Blood Glucose Monitoring System) • Amendment to the Medical (Pricing of Medical Devices) Regulations No. 1 of 2021 Revised retail price by a total twenty-nine per centum (29%)
04	No. 2277/55 – 2022.04.29	The Medicines (Ceiling on Prices) Regulations, 2019 published in the Gazette Extraordinary No. 2123/35 of May 15, 2019, as amended by regulations published in Gazette Extraordinary No. 2241/43 of August 19, 2021 and regulations published in Gazette Extraordinary No. 2271/23 of March 15, 2022 are further amended. Revised retail price by a total forty per centum. (40%).
05	No.2295/18 2022.09.01	• Further amendment to the Medical Devices Pricing Regulations, No. 01 of 2017. (Lances) • Further amendment to the Medical Devices Pricing Regulations, No. 05 of 2017 (Stent) • Further amendment to the Medical Devices (Pricing) Regulations, 2018 (Blood Glucose Monitoring System) • Amendment to the Medical (Pricing of Medical Devices) Regulations No. 1 of 2021 Revised retail price by a total forty per centum. (40%)

Pending Court Cases (up to 31.12.2022)-Filed by the NMRA

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

Pending Court Cases (up to 31.12.2022)-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	CA/Writ/285/18 Nawaloka Hospitals PLC & Others	Pending	Respondent

		Vs. Hon.Dr.Rajitha Senarathne & Others		
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
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

Right to Information Act

2022									
RTI No.	**Name of the Applicant**	**Address**	**Telephone No.**	**Information requesting letter date**	**Information requesting letter received date**	**Acknowledgment letter Date**	**Reply date**	**If Appeal submitted, appeal letter date**	**File States**
78	SLCPI	No.50, Nawam Mawatha, Colombo 02.	5588800/2421745 slcpi@chamber.lk	2022.01.05	2022.01.05	2022.01.11	2022.02.11 Sent the Decision on 14th February 2022 by post and via email. Rejection of information request under section 5(1) (a) of the No.16 of 2016 RTI Act & Pending case before the Court.	-	Closed
79	A. M. M. Rauf Director	kalpentyn Syndicate Pvt Ltd	kalpentyn@yahoo.com	2022.01.25	2022.01.25	2022.01.31	2022.03.04		Closed
80	N.M. I.B Nawaratthne	No.55, Nawamorape, Maswella.	0773425427	2022.01.25	2022.01.27	2022.01.31	2022.03.04	-	Closed
81	Maithree Pitawala	No.139, "Sirisevena", Kanduboda	0777058519 maithpit@sltne	2022.02.08	2022.02.10	2022.02.12 By post	Third party information. Test report request is sent &		Closed

		, Delgoda.	t.lk/maithpit@gmail.com			on 14.02.2022	requesting the time period to provide information till 23rd May 2022. 2022.05.05		
82	Dr. Darini Rajasingham,	No.12, Sir Marcus Fernando Mawatha, Colombo 7.	0777288393 darini.raj.sen@gmail.com	2022.03.07	2022.03.11	2022.03.18	2022.05.04 5 (ii) (a), (b) & (c) –is not coming under the preview of NMRA 5 (ii) (d) & (f) – exempted information covered by Sec.5 (1) (i) 5 (ii) (f) - NMRA didn't carry out any Clinical Trials		Closed
83	Mr. Sandran Rubatheesan	No. 08, Hunupitiya Cross Road, Colombo 02.	0112447931 5 srtheesa@hotmail.com	2022.01.26	2022.03.11	2022.03.18			Pending
84	Mrs. B.H. Tharika Virajini	Girithalana (North), Hettipola, Kurunegala		2022.06.01	2022.06.09	2022.06.10			Pending
85	Ms. Namini Nimilamalee Wijedasa	No. 63/1, Ekwatte Road, Mirihana, Nugegoda	0777380158 nwijedasa@gmail.com	2022.06.10	2022.06.10	2022.06.10	2022.11.16		Closed
86	Paralogaraja Sobiya	No.54/15, Karuvapulam Lane, Kokuvil East,	0768079231 sobisobiya48@gmail.c	2022.09.27	2022.10.28	2022.10.31	2022.11.15	2022.11.11 Already	Closed

		Kokuvil	om					provided the requested information.	
87	Mr. Ajith P. Perera	**Home –** No. 169 A/2, School Lane, Bandaragama **Office –** No.39/3, Dias Building, Susantha Mawatha, Panadura.	0777668993 0382245518 ajithpperera@yahoo.com	2022.10.25	2022.10.28	2022.11.02	2022.11.16	2022.11.16	Closed
88	Paralogaraja Sobiya	No.54/15, Karuvapulam Lane, Kokuvil East, Kokuvil	0768079231 sobisobiya48@gmail.com	2022.10.28	2022.11.02	2022.11.03			Pending
89	Mr. Indika Rajakaruna	Director, Innomedsys International (Pvt) Ltd, 55-1F, Buthgamuwa Road, Welikada, Rajagiriya.	sales@innomedsys.com info@innomedsys.com	2022.11.17	2022.11.17	2022.11.21	2022.12.15		Closed
90	Thisara Edirithilaka	No.370/2D, Lake Round Road, Ihala Biyanwila, Kadawatha	thisara_himaranga@ymail.com	2022.12.01	2022.12.06	2022.12.06			Pending

91	N.M.I.B. Nawarathne	No.55, Nawamorape, Maswella	0773425427	2022.11.28	2022.12.15	2022.12.16	2023.01.03		Closed
92	Ms. Yakshitha Yoganath	No. 74/1, Polpathi Road, Kokuvil East, Kokuvil.	0775103180 k.lakshy@gmail.com	2022.11.26	2022.12.22				Pending
93	Mr. Selvarasa Kajendren (Member of Parliament)	No.56/7, Manal Tharai Lane, Kandhar Madam, Jaffna.	0773024316 skajendren@yahoo.com	2022.11.04	2022.12.22	2022.12.23			Pending
94	Mr.W.O. Manoj Fernando	No. 1b, 1st Lane, Pagoda Road, Nugegoda	0777263460	2022.12.21	2023.01.02	2023.01.03			Pending

Address/Name Change from Local Agents

Address Change				
No	**Name of the Company**	**Previous Address**	**Present Address**	**Date**
1	Reckitt Benckiser (Lanka) Ltd	No.41, Laurie's Road, Colombo 04	No.25, Shrubbery Garden, Colombo 04	13.08.2021
2	Leader Pharma Agency (Pvt) Ltd	No.117/15, Pierise Terrace, Off Peiris Mawatha, Kalubowila, Dehiwala	No.120/3/D. Colombo Road, Raththamapitiya, Boralesgamuwa	01.10.2021

3	Medinex (Pvt) Limited	No.175/06, Nawala Road, Narahenpita, Colombo 05	No.175/08, Lake Viewe Drive, Nawala Road, Narahenpita, Colombo 05	05.10.2021
4	SMM Halcyon (Pvt) Ltd	No.100/08, Nawala Road, Narahenpita, Colombo 05	No.274, Thimbirigasyaya Road, Colombo 05	06.10.2021
5	Lanka Therapeutics (Pvt) Ltd	No.854/8C, Aluthmawathe Road, Colombo 15 & No.50A, Park Road, Hendala, Wattala	No.70, Bangalawatta Road, Hendala, Wattala	18.10.2021
6	AV Global Implex (Private) Limited	Level 08, East Tower, World Trade Center, Colombo 01	No.14 1/1, Sri Priyadarshana Mawatha, Colombo 10	23.11.2021
7	Micro Healthcare (Pvt) Ltd	No.112, Nawala Road, Narahenpita,Colombo 05	No.274, Thimbirigasyaya Road, Colombo 05	07.12.2021
8	Lanka Therapeutics (Pvt) Ltd	No.854/8C, Aluthmawathe Road, Colombo 15 & No.50A, Park Road, Hendala, Wattala	No.70, Bangalawatta Road, Hendala, Wattala	10.12.2021
9	Hemsons International (Private) Limited	No.36, Bristol Street, Colombo 01	No.34-2/1, 2nd Floor, Hemas Building, Sir Razik Fareed Mawatha, (Previously knows as "Bristol Street") Colombo 01	23.02.2022
10	Somerfield Pharmaceuticals Private Limited	No.47/2, 1st Lane, New Jayaweera Mawatha, Ethulkotte	No.06, Bogola Court, Dickmans Road, Colombo 04	10.03.2022
11	Diligence Healthcare (Pvt) Ltd	No.175, Parakum Mawatha, Bangalawatta, Kottawa	No.92. Thalawathogoda Road, Pitakotte	21.03.2022
12	Hyena Pharmaceuticals (Pvt) Ltd	No.32/4, Siyane Road, Gampaha	Bo.351/17, Kerewalapitiya Road, Hendala, Wattala	28.04.2022
13	Med Solutions (Pvt) Ltd	No.69/8A, Old Road, Nawala, Rajagiriya	No.4-1/1, Chandra De Silva Mawatha, Off Pagoda Road, Nugegoda	01.06.2022
14	Fresenius Medical Care Lanka (Pvt) Ltd	No. 102, Union Place, Colombo 02	No. 67A, Gregory's Road, Colombo 07	14.09.2022
15	Infuxion Lanka (Private) Limited	No. 216, De Saram Place, Colombo 10	No. 51/4A, Ward Place, Colombo 07	07.10.2022
16	Tropical Pharma (Private) Limited	No. 501 F, 3rd Floor, Unity Plaza, Galle Road, Colombo 04	No. 143/2, Veediya Bandara Mawatha, Off Ambatale Road, Mulleriyawa North, Mulleriyawa, 10620	18.10.2022
17	Cliniqon Biotech Private Limited	No. 43B, Dharmapala Mawatha, Madiwela, Kotte, Maharagama	No. 941/1, Jayanthi Mawatha, Kotte Road, Ethul Kotte	17.11.2022

18	Zenith Impex (Pvt) Ltd	No. 61/1, M.D.H.Jayawardena Mawatha, Madinnagoda, Rajagiriya	No. 404/4, Kaduwela Road, Thalangama North, Battaramulla	17.11.2022
19	Alpha & Omega Diagnostics (Pvt) Ltd	No. 32, Nanda Mawatha, Kandawaththa, Nugegoda	No. 404/4, Kaduwela Road, Thalangama North, Battaramulla	17.11.2022
20	Reckitt Benckiser (Lanka) Ltd	No. 41, Laurie's Road, Colombo 04	No. 25, Shrubbery Gardem, Colombo 04	25.11.2022
21	SMM Halcyon (Pvt) Ltd	No. 100/08, Nawala Road, Narahenpita, Colombo 05	No. 274, Thimbirigasyaya Road, Colombo 05	29.11.2022
22	Associated Laboratories (Private) Limited	No. 73, Isipathana Mawatha, Colombo 05	No. 65, Jetawana Road, Colombo 14	05.12.2022
23	Shield Medical (Pvt) Ltd	No. 240/32, Densil Kobbekaduwa Mawatha, Battaramulla	No. 228/1, Green Side, Thalawathugoda Road, Hokandara South, Hokandara	16.12.2022
24	Micro Healthcare (Pvt) Ltd	No.112, Nawala Road, Narahenpita,Colombo 05	No.274, Thimbirigasyaya Road, Colombo 05	12.12.2022
25	Mansel (Ceylon) (Private) Limited	No. 73, Isipathana Mawatha, Colombo 05	No. 65, Jetawana Road, Colombo 14	12.12.2022
26	AV Global Implex (Private) Limited	Level 08, East Tower, World Trade Center, Colombo 01	No. 14 1/1, Sri Priyadarshana Mawatha, Colombo 10	05.01.2023
27	Nextgen Healthcare (Pvt) Ltd	No.17, Parakum Mawatha, Jayanthipura, Battaramulla	No.15, Rathnayaka Mawatha, Pelawatta, Battaramulla	24.01.2023
28	Zydus Lanka (Private) Limited	Level 26 & 34, World Trade Centre, Echelon Square, Colombo 01	Level 12, Parkland Building, No 33, Parl Street, Colombo 02	07.02.2023

Name Change

No	Request Name of the Company	Previouss Name	Present Name	Date
1	M/S Micro Healthcare (Pvt) Ltd	**Kamazu (Pvt) Ltd**, No.135, 16th Lane, College Street, Kotahena, Colombo 13	**M/S Micro Healthcare (Pvt) Ltd,** No.112, Nawala Road, Narahenpita, Colombo 05	26.11.2020
2	Softlogic Pharmaceuticals (Pvt) Ltd	**Lifeline Pharmaceuticals (Pvt) Ltd**, No.2, Andarewatta Road, Kirulapone, Colombo 05	**Softlogic Pharmaceuticals (Pvt) Ltd**, No.14, De Fonseka Place, Colombo 05	11.06.2021
3	Morrison PLC	M S J Industries (Ceylon) (Private) Limited	Morrison PLC	30.01.2019
4	Morison Limited	**Morison Plc**, No.620, Biyagama Roada, Pethiyagoda, Kelaniya	**Morison Limited,** "Hemas House", No.75, Braybrooke Place, Colombo 02	22.06.2022

5	George Steuart Ethicals (Pvt) Ltd	Seri Naturals (Pvt) Ltd	George Steuart Ethicals (Pvt) Ltd	28.04.2022
6	SQ Marketing (Pvt) Ltd	SQ Marketing	SQ Marketing (Pvt) Ltd	24.05.2022
7	Morrison Limited	Morrison PLC, No.620, Biyagama Road, Pethiyagoda, Kelaniya	Morrison Limited, "Hemas House", No.75, Braybrooke Place, Colombo 02	20.06.2022
8	Softlogic Pharmaceuticals (Pvt) Ltd	**Lifeline Pharmaceuticals (Pvt) Ltd**, No.2, Andarewatta Road, Kirulapone, Colombo 05	**Softlogic Pharmaceuticals (Pvt) Ltd**, No.14, De Fonseka Place, Colombo 05	12.08.2022
9	Diligence Global (Pvt) Ltd	Diligence Healthcare (Pvt) Ltd	Diligence Global (Pvt) Ltd	07.09.2022

2.7 Progress of Human Resources Division

Cadre Information as at: 2022.12.31

Table 01

Designation	Salary Code	Service Level	DMS Approved Cadre		Existing Cadre				
			Permanent	Contract	Permanent	Contract	Secondment	Ministry of Health employees	Multi Task Force
Director General	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	-	-	-	-	-	-
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 **		3	-	-	-	-	1	36	-
Development officer	MA 3- 2016	3	10	-	6	-	-	-	-
Drug Inspector	MA 5-1 2016	3	20	-	-	-	-	2	-
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	41	-	-	-	-
Driver	PL 3-2016	4	10	-	4	-	-	2	-
Plumber	PL 2-2016	4	1	-	-	-	-	-	-
Electrician	PL 2-2016	4	1	-	-	-	-	-	-
Lab Assistant	PL 2-2016	4	8	-	-	-	-	-	-
K.K.S	PL 1-2016	4	30	-	23	-	-	-	3
			235	**22**	**105**	**0**	**1**	**49**	**3**

* The post of Pharmaceutical Analyst has been approved to be abolished when the Pharmaceutical Analysts who are currently in service leave the Authority.

** The post of pharmacist has been suppressed with effect from 2020.11.03 and the pharmaceutical Assessor and Asst. pharmaceutical assessor posts are established instead of that suppressed post. But pharmacists under the Ministry of Health are employed until recruited for these new posts.

Table 02

Service Level	Approved Cadre	Existing Cadre
Senior	76	11
Tertiary	46	29
Secondary	85	86
Primary	50	32
Total	**257**	**158**

- Recruitment Details for the year 2022

Position	**Appointed Date**	**Number of positions filled**
Chief Executive Officer	2022.07.18	01
Assistant Pharmaceutical Assessor	2022.01.05	01
Management Assistant	2022.01.03	01
Driver (Multipurpose development Task force)	2022.03.18	02
Karyala Karya Sahayaka (Multipurpose development Task force)	2022.03.18	07
		12

- Published advertisements for recruitments

Position	Number of Vacancies
Legal Officer	01
Driver	
Electrician	01
Plumber	01
Karyala Karya Sahayaka	

- Interviews held

Position	Date
Director (HR)	24.08.2022
Internal Auditor	24.08.2022
Legal Officer	31.08.2022
Development Officer	29.08.2022 30.08.2022
Technical Officer	12.09.2022 13.09.2022

- Identify the necessities of staff of the Authority in relation to restructuring the positions of the Authority and developing an organogram for the National Medicines Regulatory Authority.
- Provided Training opportunities to fourteen (40) students referred by institutes.
- Confirm the service of NMRA employees after completing their probation periods.

  Accountant (1)
  Development Officer (07)
  Management Assistant (12)
  Driver (01)
- Bonus payment to all employees as per the PED circular
- Issued service letters and miscellaneous letters, cadre reports as requested by employees and other institutions.
- Payment of Annual increment of Authority staff and recommend annual increment of ministry staff.
- Conducted an attitude development outdoor training program for the NMRA staff 31.12.2022

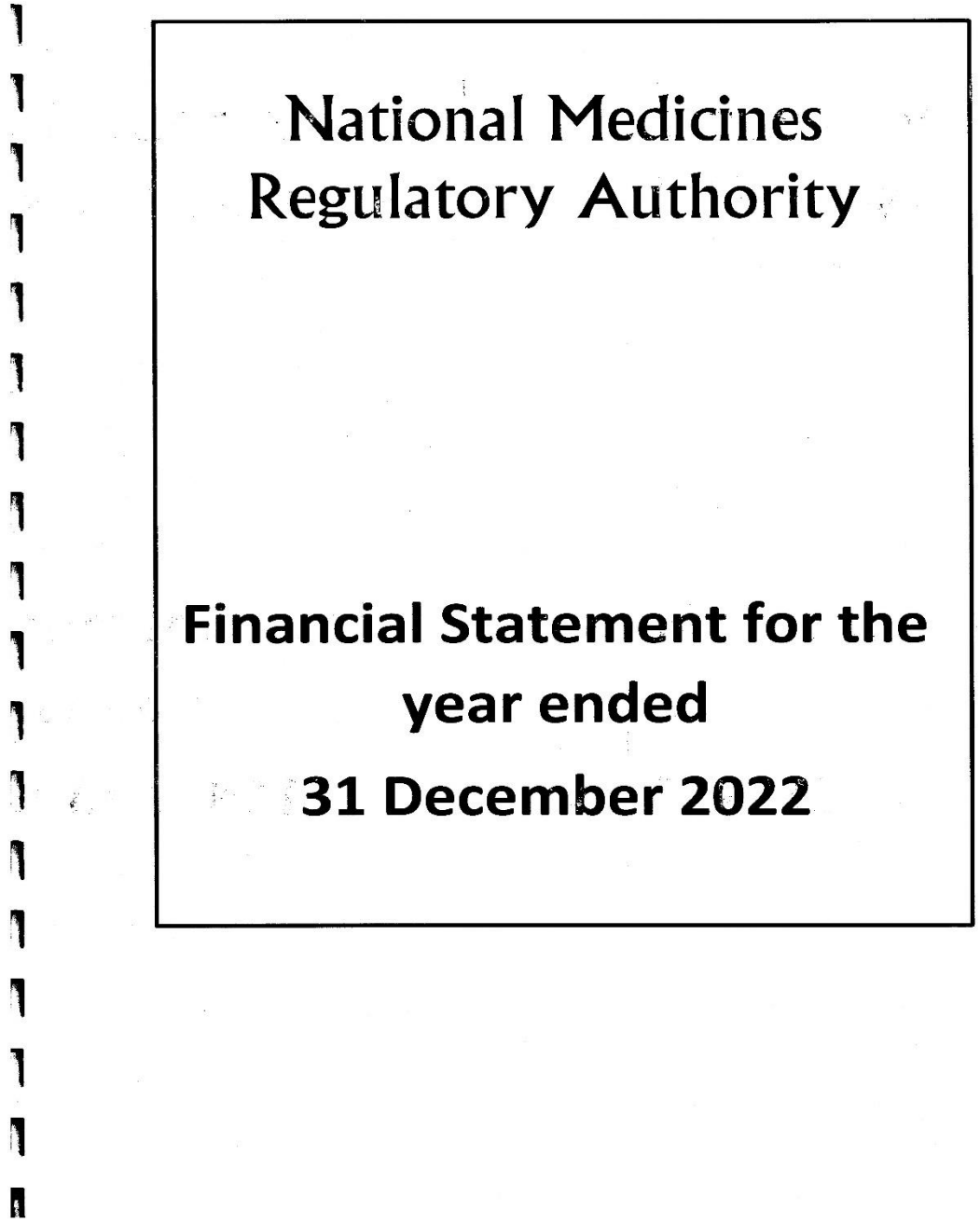
2.8 Progress of ICT Division

Summary of the of Tasks Completed

No	Tasks	No of Tasks Completed during the period
01	Printer issues	179
02	Software Installations	30
03	Network Troubleshooting	138
04	Web Site updates	36
05	Systems testing (Medicine Database, Licence and Certificated Issuing System etc.)	16
06	Laptops, Desktop PC repairing and hardware troubleshooting.	133
07	Technical support for the virtual meetings	107

Chapter - 3

Overall Financial Performance



NATIONAL MEDICINES REGULATORY AUTHORITY
STATEMENT OF FINANCIAL POSITION

Column1	Column2	Column3	Column4
As at 31 December,		2022	2021
	Note	Rs.	Rs.
Assets			
Non current assets			
Property, plant and equipment	2	93,422,394	114,561,686
Total non current assets		93,422,394	**114,561,686**
Non Current Assets			
Distress Lone Balance		8,683,610	5,125,570
Current assets			
Inventory	3	14,179,700	1,947,084
Deposits and other receivable	4	19,906,528	16,561,415
Fix Deposits		2,750,000,000	
Cash and cash equivalents	5	2,515,746,487	3,766,166,994
Total current assets		**5,299,832,715**	**3,784,675,493**
Total assets		**5,402,138,719**	**3,904,362,748**
Equity and liabilities			
Equity			
Accumulated Fund		4,498,490,257	2,994,730,451
Capital Gain		64,275,375	64,275,375
Total equity		**4,562,765,632**	**3,059,005,826**
Non Current liabilities			
Capital grant	6	5,920,019	5,920,019
Deferred tax	7	2,638,603	13,488,345
Provision for Gratuity	8	4,697,072	2,834,700
Total non current liabilities		**13,255,694**	**22,243,064**
Current liabilities			
Advance receipts	9	100,593,163	87,185,512
VAT payable	10	33,810,117	52,463,719
Stamp duty payable	11	11,960,316	30,299,888
Provision for Treasury levy	12	645,817,300	400,000,000
Accrued expenses and other payables	13	22,953,627	101,328,507
Provision for Income tax	20	10,982,871	95,836,233
Total current liabilities		**826,117,394**	**767,113,858**
Total equity and liabilities		**5,402,138,719**	**3,848,362,748**

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.

Prof. S D Jayarathna
Chairman
2023

Prof. S.D. Jayaratne
MBBS (Col), MD (Col), FRCP (Lond), FCCP, FRCGP
Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road, Colombo 10.

Dr. Vijith Gunasekera
Chief Executive Officer

Dr. Vijith Gunasekera
MBBS, MSc, MScon, 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,

Column1	Column2	Note Column4	2022 Rs. Column6	2021 Rs. Column7
Revenue		**14**	2,041,175,151	1,252,757,342
Interest income		**15**	397,823,366	156,698,769
Other income		**16**	539,664	336,901
Administrative expenses		**17**	(145,429,428)	(119,812,930)
Salaries and wages		**18**	(126,232,660)	(152,382,467)
Other expenses		**19**	(15,151,757)	(12,182,753)
Provision for treasury levy			**(645,817,300)**	(400,000,000)
Net income before taxation			**1,506,907,035**	**725,414,862**
Income tax for the year		**20**	**(212,482,517)**	(158,222,092)
Net income after taxation			1,294,424,519	567,192,769

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

National Medicins Regulatoty Authority
Statement of Changes in net Assets/ Equity
For the Ended December 31 2022

Column1	Gov Grant	Capital Gain	Net surplus/(deficit)	Gratuity Provition	Differd Tax	Total
Balance as at December	5,920,019	64,275,375	2,994,730,451	2,834,700	13,488,345	3,081,248,890
						-
Gratuity Provition				1,862,373		1,862,373
						-
Capital Gain						-
						-
Capital Grant						-
						-
Priear year adjustment			209,335,287			209,335,287
						-
Amatization						-
Adjustment					10,416,052	10,416,052
Differd Tax					433,690	433,690
						-
Net surplus/(deficit) for the period			1,294,424,519			1,294,424,519
						-
Balance as at 31 December	**5,920,019**	**64,275,375**	**4,498,490,257**	**4,697,073**	**2,638,603**	**4,597,720,811**

NATIONAL MEDICINES REGULATORY AUTHORITY
STATEMENT OF CASH FLOW

Column1	Column3
As at 31 December,	2022
	Rs.
Cash Flows from Operating Activities	
Net income before taxation	1,506,907,035
Adjustment for :	
Depreciation	34,756,957
Interest income	(397,823,366)
Amortization of capital grant	
Gratuity Expense	2,031,998
Adjustment on prior year	26,579,455
Operating Profit before Working Capital Changes	**1,172,452,079**
Changes in items of working capital	
(Increase)/Decrease in Inventory	(12,232,616)
(Increase)/Decrease in Deposits and other receivable	(3,345,113)
(Increase)/Decrease in Advance receipts	13,407,651
(Increase)/Decrease in VAT payable	(18,653,602)
(Increase)/Decrease in Stamp duty payable	(18,339,572)
(Increase)/Decrease in Provision for treasury levy	245,817,300
(Increase)/Decrease in Accrued expenses and other payables	(78,374,880)
Cash generated from operations	**128,279,168**
Treasury levy Paid	(400,000,000)
Tax Paid	(151,836,233)
Gratuity paid	(169,625)
Net Cash from /(Used in) Operating Activities	**(552,005,858)**
Cash flows from investing activities	
Acquisition of Property plant and equipment	(13,778,676)
WIP Changes	
Investment in short term deposits	(1,599,999,928)
Investment in short term Maturity	1,693,603,900
FD	(2,750,000,000)
Interest income	397,823,366
Net Cash from / (Used in) Financing Activities	**(2,272,351,338)**
Net increase/ decrease in Cash & cash equivalents	**(1,523,625,949)**
Cash and cash equivalents at the beginning of the year	1,624,514,939
Cash and cash equivalents at the ending of the year	**100,888,990**

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NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS
For the year ended 31 December 2022

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.

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS
For the year ended 31 December 2022

3.9 Revenue

3.9.1 Services

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

3.9.2 Interest income

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

3.10 Government Grants

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

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

3.11 Expenses

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

3.12 Foreign currency transaction

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

3.13 Tax expenses

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

3.13.1 Current tax

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

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

3.13.2 Deferred taxation

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

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

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

3.14 Statement of cash flows

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

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

3.15 Commitment and contingencies

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

3.16 Related party transaction

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

3.17 Events after the reporting date

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

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

As at,31/12/2022

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 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
Balance as at 01 January 2022	15,257,976	114,953,047	11,283,283	17,249,218	11,965,893	7,051,280	177,760,697
Additions during the year	-	-	1,800,798	3,117,118	8,860,760	-	13,778,676
Balance as at 31 December 2022	15,257,976	114,953,047	13,084,081	20,366,336	20,826,653	7,051,280	191,539,373
Accumulated depreciation							
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
Balance as at 01 January 2022	12,816,699	29,280,526	4,077,964	6,828,400	9,240,216	955,205	63,199,011
Charge for the year	2,441,276	22,156,612	2,171,322	3,442,906	2,838,120	1,706,720	34,756,957
Adjustment				161,010			161,010
Balance as at 31 December 2022	15,257,976	51,437,138	6,249,287	10,432,317	12,078,336	2,661,925	98,116,979
Carrying value							
As at 31 December 2022	**(0)**	**63,515,909**	**6,834,795**	**9,934,019**	**8,748,317**	**4,389,355**	**93,422,394**

NATIONAL MEDICINES REGULATORY AUTHORITY

NOTES TO THE FINANCIAL STATEMENTS

For the year ended 31 December,

		2022 Rs.	2021 Rs.
3	**Inventory**		
	Opening Inventory	1,947,084	1,655,865
	Purchased for year	16,421,587	3,960,087
		18,368,671	5,615,952
	Consumption	4,188,970	(3,668,868)
	Closing Inventory	14,179,700	1,947,084
4	**Deposits and other Receivable**		
	Deposit for Fuel	100,000	50,000
	Other Receivables	50,000	
	Prepayments	2,288,578	1,019,375
	Festival Advance		(1,500)
	Advance Receivables	100,000	
	Building Rent	14,512,500	13,500,000
	Distress Loan Receivable	2,752,200	1,926,540
	Deposit for Drinking water	103,250	67,000
	Total deposits and prepayments	**19,906,528**	**16,561,415**
	Short term investments		
	Tresury Bills and Bonds		
	Opening Balance	2,141,652,055	3,149,130,138
	Invest for the Year	1,599,999,928	299,999,999
	Recivable Interest for the year	366,809,414	148,182,620
	Maturiry Investment	(1,693,603,900)	(1,455,660,702)
		2,414,857,497	**2,141,652,055**
5	**Cash and cash equivalents**		
	BOC Current and Savinngs Account(ZIBA)	100,888,990	1,624,514,939
	Tresury Bills and Bonds	2,414,857,497	2,141,652,055
	Total cash and cash equivalents	**2,515,746,487**	**3,766,166,994**
6	**Capital grant**		
	Capital grant	5,920,019	5,920,019
	Total Capital grant	**5,920,019**	**5,920,019**

		2022 Rs.	2021 Rs.
7	**Deferred tax liability**		
	Accounting written down value of Property plant and equipmer	93,422,394	114,561,684
	Tax base of Property plant and equipment	(74,575,231)	(66,389,022)
	Taxable Temporary deference	18,847,163	48,172,661
	Tax @ 14%	2,638,603	13,488,345
	Deferred Liability at the end of the year	2,638,603	13,488,345
	Deferred Liability as at beginning of the year	(13,488,345)	(7,102,486)
	Adjustment for after applied currect rates	10,416,052	
	Charge as deferred tax during the year	(433,690)	6,385,859

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2022 Rs.	2021 Rs.
8	**Provision for Gratuity**		
	Opening Balance	2,834,700	2,150,728
	Expence for the year	2,031,997	683,972
	Paid Amount	(169,625)	
	Provision for the year	**4,697,072**	**2,834,700**

		2022 Rs.	2021 Rs.
9	**Advance receipts**		
	Fees received in advance	72,972,666	72,972,666
	Deposit to be Classified	25,420,629	11,894,247
	Over Payment	2,199,867	2,318,598
	Total advance receipts	**100,593,163**	87,185,512

		2022 Rs.	2021 Rs.
10	**VAT payable**		
	Opening Balance	52,463,719	68,856,674
	VAT for the year	248,225,346	100,323,931
	Input VAT for the year	(4,144,228)	(3,089,222)
	Other Adjustment		303,335
	Paid for the year	(262,734,720)	(113,931,000)
	VAT Payable	33,810,117	52,463,719
11	**Stamp duty payable**		
	Opening Balance	30,299,888	22,747,938
	Stamp Duty for the year	36,373,220	45,019,763
	Paid for the year	(54,712,792)	(37,467,813)
	Stamp duty payable	11,960,316	30,299,888
12	**Provision for Treasury levy**		
	Net income before taxation	2,152,724,336	967,735,433
	Provision 30% for year	645,817,301	400,000,000
	Opening Balance	400,000,000	146,929,966
	Paid for the year	(400,000,000)	(146,929,966)
		645,817,300	**400,000,000**

		2022 Rs.	2021 Rs.
13	**Accrued expenses and other payables**		
	Accounts Payables	7,108,861	9,636,600
	Accrued expenses	5,088,990	4,180,765
	Other Payables	2,185,893	1,794,043
	Retention Deposit	142,304	108,646
	EPF Payable	10,080	
	ETF Payable	1,512	
	Secondment Allowances Payable		21,235
	Bank TFR - Sal. Payable	74,343	
	Audit Fees Payable	1,248,000	2,400,000
	Committees & Evaluation Payable	47,475	117,475
	Contribution for MOH Staff Salary	7,046,169	83,069,743
	Total Accrued expenses	**22,953,627**	**101,328,507**

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NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2022 Rs.	2021 Rs.
14	**Revenue**		
	Drug Sample import License Income	20,259,036	7,835,689
	Device Sample import License Income	28,837,583	9,702,717
	Cosmetic Sample import License Income	330,900	468,800
	Borderline Sample import License Income	1,260,123	598,164
	Drug Import License Income	107,404,406	128,877,215
	Device Import License Income	103,521,803	95,323,161
	Cosmetic Import License income	8,157,000	8,012,734
	Borderline Import License Income	2,553,747	1,388,942
	Drug Manufacturing License Income A	20,746,583	10,894,168
	Drug Manufacturing License Income B	109,426	161,990
	Device Manufacturing License Income A	1,794,620	1,147,073
	Device Manufacturing License Income B	709,296	415,305
	Cosmetic Manufacturing License Income	1,019,000	401,000
	BorderlineManufacturing License Income	57,012	
	Drug Registration Income FR Local A	8,505,735	686,488
	Drug Registration Income FR Local B	218,306	20,289
	Drug Registration Income FR Foreign	201,813,637	10,511,017
	Drug Registration Income PR Local A	12,121,241	4,885,524
	Drug Registration Income PR Local B		61,069
	Drug Registration Income PR Foreign	10,204,979	103,457,358
	Device Registration Income FR Local A	703,388	823,018
	Device Registration Income FR Local B	278,304	81,072
	Device Registration Income FR Foreign	127,916,234	15,491,862
	Device Registration Income PR Local A	610,705	687,715
	Device Registration Income PR Local B	501,992	593,769
	Device Registration Income PR Foreign	62,646,422	102,588,782
	Cosmetic Registration Income FR Foreign	2,016,500	3,120,500
	Cosmetic Registration Income FR Local	133,000	48,000
	Cosmetic Registration Income PR Foreign	7,232,000	7,217,344
	Cosmetic Registration Income PR Local	437,500	547,500
	Cosmetic Registration Income Renewal	35,000	57,500
	Borderline Registration Income FR Foreign	525,533	
	Borderline Registration Income PR Foreign	2,767,179	1,470,583
	Borderline Registration Income PR Local	57,012	19,987
	Laboratory Test	15,353,144	10,483,170
	Drug Processing Fees Local A	48,844,931	9,346,269
	Drug Processing Fees Local B	-	-
	Drug Processing MP Foreing	24,713,084	10,464,835
	Drug Processing Combined	5,575,371	913,496
	Drug Processing New Dosage	738,811	304,019
	Drug Processing Foreing	209,814,180	28,718,995
	Drug Processing Fees Renewal Local A	4,007,969	1,930,959
	Drug Processing Fees Renewal Foreign	138,499,630	29,505,191
	Drug Processing Fees Therapeutic	22,415,812	16,224,433
	Drug Processing Fees NCE	8,016,605	6,944,235
	Drug Processing Fees NCE int	3,212,559	3,343,032
	Device Processing Fees Local A	2,676,033	3,326,424
	Device Processing Fees Local B	753,151	2,015,922
	Device Processing Fees MP Foreign	99,945,393	21,941,608
	Device Processing Fees Foreign	171,313,920	34,849,066
	Device Processing Fees Renewal Local A	369,811	98,310
	Device Processing Fees Renewal Local B	40,600	9,459

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NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2022 Rs.	2021 Rs.
14	**Revenue Cont.....**		
	Device Processing Fees Renewal Foreig	53,232,412	17,379,972
	Cosmetic Processing Fees	995,000	1,356,000
	Borderline Processing Fees Foreing	9,073,016	10,718,145
	Borderline Processing Fees Local	550,621	447,808
	Borderline Processing Fees Ini for Foreign	16,387,056	16,973,578
	Clinical Trial Processing Fees	1,161,905	1,361,039
	Drug Advertising Fees	359,999	805,313
	Retail Pharmacy License Income	46,058,454	43,174,597
	Wholesale Pharmacy License Income	12,439,863	36,125,829
	Transport Pharmacy License Income	29,266,658	18,041,828
	Drug WOR	13,445,367	3,167,994
	Device WOR	18,290,251	21,055,896
	Borderline WOR	-	-
	GMP Device Local Repac		40,427
	Device GMP - Local A	726,901	442,903
	Device GMP - Local B	278,020	944,952
	Drug GMP -Foreing SAARC	27,655,599	
	Drug GMP - Local A	1,909,696	560,702
	Drug GMP - Local B	140,819	179,238
	Drug WHO Inspection	748,768	486,887
	Device WHO Inspection	245,188	163,507
	Drug COPP Certificate	148,433	49,902
	Additional Drug Foreing	68,220,321	85,036,487
	Additional Drug Local A	10,818,351	5,588,762
	Additional Drug Local B	350,040	1,477,119
	Additional Drug Variation	23,139,961	14,504,402
	Additional Drug MP	4,611,473	2,285,117
	Additional Device Foreing	114,702,756	89,334,411
	Additional Device Local A	696,921	1,774,416
	Additional Device Local B	626,880	472,763
	Additional Device MP	1,767,775	-
	Additional Device Variation	5,015,173	2,894,477
	Additional Borderline Foreign	6,058,558	5,644,946
	Additional Borderline Local	-	80,574
	Additional Borderline Variation	201,899	-
	Agency Transfer	51,454,105	35,581,688
	Device Free sale Certificates	196,839	152,749
	Borderline Clarification	3,712	-
	Device Clarification	605,757	1,476,471
	Drug Clarification	11,910,570	963,678
	Device Amendment	259,310	1,118,613
	Drug Amendment	-	1,333,413
	Cosmetic Amendment	26,000	65,000
	Borderline Amendment	114,433	79,495
	Cosmetic Amendment Certificates	55,000	-
	Device Amendment Certificates	2,838,236	-
	Drugs Amendment Certificates	5,863,495	-
	Phar. & Trans.Amended License	478,723	-

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NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

	2022 Rs.	2021 Rs.
Drug Formulation Approval	3,856,063	2,644,301
Borderline Formulation Approval	530,125	-
Borderline Advertisement	202,999	399,740
Device Advertisement	1,679,446	2,032,505
Device Duplicate Certificate	-	99,361
Drug Free Sale	-	-
Cosmetic Renewal	-	-
Automation Income	-	125,505,536
Total Income	**2,041,175,151**	**1,252,757,342**

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2022 Rs.	2021 Rs.
15	**Interest Income**		
	Tresury Bills and Bond Int.	366,809,414	
	Distress Loan Interest	363,032	311,289
	Savings A/C Interest	30,650,920	8,204,860
		397,823,366	**8,516,149**
16	**Other Income**		
	Tender Application Fees	242,000	12,000
	Other Income	33,583	39,901
	Supplier Registration	216,000	285,000
	Accomandation fee	48,081	-
		539,664	**336,901**
17	**Administrative expenses**		
	Depreciation	34,756,957	21,870,537
	Water	503,462	483,928
	Electricity	7,065,813	6,691,499
	Telephone	1,580,700	1,944,800
	Postage	300,155	138,763
	Stationery	4,188,970	3,668,868
	Travelling - Local	5,777,333	15,662,199
	Travelling - Foreign	26,015,991	-
	Training and development expenses	1,828,308	1,259,700
	Fuel expense	2,229,611	1,452,280
	Security charges	6,681,014	6,362,757
	Document handling charges	2,206,598	1,559,470
	Publication, Translation and advertisement charges	1,249,123	3,765,858
	Cleaning service	6,399,870	3,603,950
	Maintenance of Vehicle	4,255,527	5,630,350
	Maintenance of Filling Stores	1,184,500	-
	Maintenance of Laboratory equipment	4,034,973	9,257,490
	Maintenance of fire extinguisher	-	113,800
	Maintenance of Air-conditioning	321,650	108,100
	Maintenance of building	2,679,177	7,782,372
	Maintenance of computer items and other	224,250	2,463,240
	Maintenance of website	18,150	45,920
	Maintenance of Office Equpments	1,230,438	541,947
	Maintenance of Software & Packages	3,955,504	3,931,022
	Reservation of Conference Hall		439,910
	Rates and taxes	475,999	495,670
	Audit fee	1,236,000	1,200,000
	Sample Testing Expenses	20,923	16,072
	Books, Journals & Information	6,883,347	929,200
	Consultation Fee	81,109	-
	Sanitary Items Expense	177,469	-
	Building Rent	16,402,500	16,200,000
	Consumable Expenses	361,675	227,338
	Mask Expenses	501,770	1,390,212
	Interview Fees	20,625	24,210
	Vehicle Insurance	561,111	545,495
	Vehicles Parking Fee	18,825	15,975
	Total	**145,429,428**	**119,812,930**

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NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2022 Rs.	2021 Rs.
18	**Salaries and wages**		
	Salaries and wages	77,739,135	35,621,594
	Other allowances	2,885,577	49,042,457
	MOH Staff Salary	28,768,736	51,727,213
	Overtime & 1/20 payment	4,918,202	8,236,021
	Secondment allowance	136,025	127,721
	Contribution for Pension		73,553
	Contribution for Employee Provident Fund	6,316,020	3,896,579
	Contribution for Employee Trust Fund	1,579,005	974,145
	Gratuity Expense	2,031,998	683,972
	Staff Bonus	1,857,963	1,939,213
	Total	**126,232,660**	**152,382,467**
19	**Other expenses**		
	Refreshment and other expenses	6,112,973	2,331,483
	Bank Charges	192,497	-
	Staff Tea	4,503,103	2,237,601
	Legal Expenses	653,975	1,061,500
	Payment for Committees	2,562,000	4,703,734
	Miscellaneous Expenses	527,209	99,748
	Expert for Reviewing of Dossiers	600,000	-
	Surcharges	-	13,216
	Corporate Plan Expenses	-	1,519,987
	Expences for Basic requarment on poposed Narahenpita Buil.	-	215,484
	Total	**15,151,757**	**12,182,753**

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NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2022 Rs.	2021 Rs.
20	**Income tax for the year**		
20.1	Income tax expense for the year	212,916,207	151,836,233
	Deferred tax expense for the year	(433,690)	6,385,859
	Tax expense for the year	212,482,517	158,222,092
20.2	Net income before taxation	1,506,907,035	725,414,862
	Add : Disallowable expense	45,373,033	24,202,020
	Less : Allowable expense	(31,450,020)	(65,072,359)
	Adjusted profit for the year	1,520,830,048	684,544,523
	Other profit and income liable to tax		
	Total statutory income/ Taxable income	1,520,830,048	684,544,523
	Income tax for the year	212,916,207	95,836,233
	Adjustment		(38,424,557)
	Pre payment	(201,933,336)	
	Income tax expense for the year	212,916,207	95,836,233
	Opening Balance	151,836,233	575,361,535
	Paid for the year	(151,836,233)	(536,936,978)
	Total tax payable as at the year end	**10,982,871**	**95,836,233**

21 Revenue and Expenditure for the year 2022 have been analyzed and presented indetail as compared to the year 2021

22 **Calculation of Income tax**

Opening balances have been restated and presented from the year 2016 onwards with all adjustment.

Income tax calculated as per Circular No. SET-F-2020/2021 issued by Inland Revenue Department
b) Health care services - 14 %

23 **Contingent Liabilities**

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

24 **Litigation and claims**

The Inspectorate & Enforcement division is responsible for the proper implementations of the provisions of the NMRA Act.

In the year 2022 – Ninety-six (96) cases have been filed by the IED alone, for the various violations identified under the act by 02 Food & Drugs Inspectors (Authorized officers) who are attached to the NMRA. 155 cases have been filed by regional FDII island wide.

Rs 2329600.00 has been imposed for the 96 cases filed officials of the NMRA while Rs 43,43,000.00 has been fined for the cases filed by regional FDII.

Altogether, 251 cases have been files and total fines imposed were Rs 66,67,600.00 for the year 2022.

Number of pending cases are 15.

25 **Approval of financial statements**

These Financial statements were approved by the Board of members and authorized for issue on .... 2023.

26 **Nature of the Prior year adjustment**

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

27 The total interest given under Note No. 15 for the year 2021 includes Treasury bills and bonds interest , Distress loan interest and saving A/C Interest.

MSU/B/NMRA/1/22/10

31 May 2023

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 2022 in terms of Section 12 of the National Audit Act, No. 19 of 2018.

The above Report is sent herewith.

W.P.C. Wickramarathne

Auditor General.

Copies – 01. Secretary , Ministry of Health

02. Secretary , Ministry of Finance, Economic Stabilization and National Policy

MSU/B/NMRA/1/22/10

31 May 2023

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 2022 in terms of Section 12 of the National Audit Act, No. 19 of 2018.

1. Financial Statements

1.1 Adverse Opinion

The audit of the financial statements of the National Medicines Regulatory Authority for the year ended 31 December 2022 comprising the statement of financial position as at 31 December 2022 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, because of the significance of the matters discussed in the basis for Adverse Opinion section of my report, the accompanying financial statements do not give a true and fair view of the financial position of the Authority as at 31 December 2022 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 Adverse Opinion

(a) Although the comparative information for the previous year for all figures shown in the financial statements for the year under review should be presented in terms of Paragraphs 38 and 38A of Sri Lanka Accounting Standard 01, the Authority had not submitted comparative information of the previous year for the statement of changes in equity and cash flow statement of the year under review. Further, the comparative statement of financial position remained unbalanced and showed a difference of Rs. 56,000,000 .

(b) As a result of the capital grant balance which should be shown under the equity as per Paragraphs 54 and 57 of Sri Lanka Accounting Standard 01 amounting to Rs. 5,920,019 was shown under non-current liabilities, the total equity and non-current liability balances of the Authority had been understated and overstated respectively in the statement of financial position as at 31 December 2022 .

(c) Due to inclusion of Treasury tax amounting to Rs.645,817,300 in the year under review in the statement of comprehensive income instead of including in the statement of changes in equity in terms of Paragraph 106 (d) (iii) of Sri Lanka Accounting Standard 01, the net income of the year under review had been understated by an equal amount to that.

(d) Although the statement of changes in equity should be prepared to include only the components of the equity in accordance with Paragraphs 106 and 108 of Sri Lanka Accounting Standard 01, post-employee benefits and deferred tax liability balances amounting to Rs. 4,697,073 and Rs. 2,638,603 respectively had been included in the statement of changes in equity of the Authority as at 31 December 2022. As a result, the total equity had been overstated by Rs.7,335,676 at the end of the year under review in the statement of changes in equity .

(e) The basis of preparation of the financial statements and information on the specific accounting policies should be presented in the Notes in terms of Paragraph 112 of Sri Lanka Accounting Standard 01 . Nevertheless, the false statements which were not reconciled with the financial statements of the year under review had been included in the Notes.

(f) Although only investments maturing within 03 months or less from the date of investment should be considered as cash equivalents in terms of Paragraph 07 of Sri Lanka Accounting Standards 07, five Treasury Bills and Treasury Bond investments totalling to Rs.2,414,857,497 with maturities longer than that period had been shown by the Authority under cash equivalents.

(g) Due to non-preparation of cash flow statement in accordance with Paragraphs 18(b) and 20 of Sri Lanka Accounting Standard 07, the operating profit before changes in working capital had been understated by Rs. 643,640,666 and the difference in working capital items and net cash flow generated by operating activities had been overstated by Rs. 245,817,300 and Rs. 397,823,366 respectively and the net cash flow from investing activities had been understated by Rs.397,823,366.

(h) The prior year errors amounting to Rs.1,781,077 to be corrected by restating comparative values as per Paragraph 42(a) of Sri Lanka Accounting Standard 08 and the prior year errors amounting to Rs.1,154,844 to be corrected by restating the opening balances of the assets, liabilities and equity accounts in accordance with Paragraph 42(b) had been directly adjusted to the accumulated fund of the year under review.

(i) Although the nature of the corrected prior years' errors and the corrected values of the relevant line items should be disclosed in accordance with Paragraphs 49(a) and 49(b) of Sri Lanka Accounting Standards 08, actions had not been taken by the Authority as above in respect of the prior year adjustments credited to the accumulated fund totalled to Rs.209,335,287 . As a result, the accuracy of the

accumulated fund balance amounting to Rs. 4,498,490,257 stated in the statement of financial position as at 31 December 2022 were not sufficiently ascertained.

(j) Although the cost of assets acquired before the end of the reporting period should be reconciled in the financial statements in determining after the reporting period in terms of Paragraph 9(c) of Sri Lanka Accounting Standard 10, due to failure to adjust the cost of 03 such vehicles estimated on 06 February 2023 at a cost of Rs.17,750,000 in the financial statements of the year under review, the non-current asset balance as at 31 December 2022 had been understated by an equal amount that.

(k) All adjustments recognized in the year under review for income taxes of prior years should be adjusted against the income tax expense of the year under review in terms of Paragraph 80(b) of Sri Lanka Accounting Standard 12. Nevertheless, as a result of the incorrect value of Rs.201,933,336 had been credited to the accumulated fund to correct the overstatement of income tax amounting to Rs.124,779,724 indicated in the audit report of the previous year, the income tax expense had been overestimated by Rs.124,779,724 and the accumulated fund as at 31 December 2022 had been overstated by Rs.77,153,612 .

(l) Although the useful lives of property, plant and equipment should be reviewed annually and if the expected conditions differ from the estimates, those changes should be revised in accordance with Sri Lanka Accounting Standard 8, in terms of Paragraph 61 of Sri Lanka Accounting Standard 16 , as a result of not doing so, a number of 297 asset items with zero book value as at 31 December 2022 with a cost of Rs. 33,242,530 were still being used and actions had also not been taken to disclose in accordance with Paragraph 76 of this Standard.

(m) Although the accurate values of income tax payable as at the opening date and the closing date of the year under review were Rs.27,056,509 and Rs.178,969,934 respectively, due to the fact that it has been incorrectly stated as Rs.151,836,233 and Rs.10,982,871 respectively in the financial statements, the accurate income tax liability payable as at 31 December 2022 had been understated by Rs.167,986,963 .

Further, as a result of deduction of non-qualified payments totalled to Rs. 648,809,646 as Treasury Taxes amounting to Rs.645,817,300, Other Taxes amounting to Rs.475,999, Post-Employee Benefit Allocations amounting to Rs.1,862,372 and Legal Expenses amounting to Rs.653,975 in computing the taxable income of the year under review, the income tax in the year under review had been understated by Rs.90,833,350.

(n) As a result of non-calculation and accounting of fixed deposit interest income of Rs.113,764,932 for the year under review, the net income of the year under review and the current asset balance as at 31 December 2022 had been understated by an equal amount to that.

(o) Although the investments in total value of Treasury Bills and Treasury Bonds as at the opening and closing date of the year under review were Rs.2,144,317,223 and Rs.2,490,867,187 respectively, due to it has been wrongly stated as Rs.2,141,652,055 and Rs.2,414,857,497, the value of financial investments had been understated by Rs.76,009,690 as at 31 December 2022 . Further, the Treasury Bill maturities amounting to Rs.3,193,611,919 and 22 Treasury Bill re-investment transactions amounting to Rs.3,119,059,361 that occurred during the year under review had not been accounted for and although the accurate Treasury Bill interest income for the year under review was Rs.365,601,378, the net income of the year under review had been overstated by an equal amount to that due to the Authority had over-calculated it by Rs.1,208,036 .

(p) The detailed schedules and receipt details related to the balance of advance receipts amounted to Rs.72,972,666 remaining from the last few years were not submitted for audit.

(q) As a result of a sum of Rs. 25,420,629 received directly to the bank by 31 December 2022 was shown in the financial statements as unidentified deposits without properly identifying and accounting, the net income of the year under review and the balance

of current liabilities as at 31 December 2022 had been understated and overstated respectively by an equal amount to that.

(r) Actions had not been taken to transfer, assess and account for the office building where the Authority is located, the National Pharmaceutical Quality Assurance Laboratory building and the said land and 06 vehicles to the Authority.

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 opinion.

1.3 Other Information Included in the Annual Report 2022 of the Authority

The other information comprises the information included in the Annual Report 2022 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 read 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.

If, based on the other information I have obtained and the work I have performed prior to the date of this audit report, I conclude that this other information is materially misstated, I am required to report that fact. I have nothing to report in this regard.

When reading the Annual Report 2022 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 appear 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 the preparation of financial statements that give a true and fair view in accordance with Sri Lanka Accounting Standards, and for such internal control as Management determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, Management is responsible for assessing the Authority's ability to continue as a going concern 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.

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

As per Section 16 (1) of the National Audit Act No. 19 of 2018, 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

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

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 explanations required for the audit and as far as appears from my examination, proper accounting records have not been kept by the Authority as per the requirements of Section 12(a) of the National Audit Act No. 19 of 2018 .

2.1.2 The financial statements presented by the Authority is not 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 .

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 Institute 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 Directives	**Observation**
(a)	Section 40 of the National Audit Act No. 19 of 2018 and Paragraph 4.4 of Public Enterprises Circular No. 01/2021 dated 16 November 2021	An Internal Audit Division had not been established for the Authority and an Internal Auditor to report directly to the governing body on the affairs of the Authority had not been appointed.
(b)	**Financial Regulations of Democratic Socialist Republic of Sri Lanka**	
(i)	Financial Regulations 128(1)(e), 507, 756, 757, 758, 770 and Paragraph 11 of Public Finance Circular No. 01/2020 dated 28	Although the Accounting Officer shall arrange for the appointment of Survey Boards before 15 December of every financial year and forward their reports to the Auditor General with a copy to the Chief

	August 2020	Accounting Officer before 31 March of the following year, the non-current assets with a total cost of Rs.191,539,373 had not been surveyed and the reports had not been submitted to the Auditor General.
(ii)	Financial Regulation 237(b)	It was revealed at an audit test check carried out that the payment vouchers valued at Rs.1,801,296 had been certified in 07 cases during the year under review without obtaining a certificate that the goods have been received and entered in the relevant bills of lading or stock books.
(iii)	Financial Regulation 257	Payment should be made only for certified vouchers and although it is the duty of every officer endorsing or disbursing vouchers to ensure that the vouchers are duly certified by an authorized certifying officer, payments had been made for uncertified vouchers amounting to Rs.28,873,570 in 15 cases as per the audit test check.
(iv)	Financial Regulations 371 (2) (b) and Paragraph 9.1 (b) of Public Finance Circular No. 01/2020 dated 28 August 2020	Even though the maximum amount of ad hoc sub-imprests that can only be given to a staff officer was Rs. 100,000, the ad hoc sub-imprests valued at Rs. 1,862,050 had been issued to non-staff officers in 90 cases. Further, advances had been issued again before settlement of the issued advances and due to not accurately

		estimating the cost, more than 50 per cent out of cash advance obtained in 19 cases had been settled.
(c)	**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 with the total cost of Rs. 191,539,373 .
(ii)	Assets Management Circular No.01/2017 of Ministry of Finance and Media dated 28 June 2017	Every public institution is required to submit accurate information on all assets under its control to the Comptroller General, and although each institution should appoint an appropriate official to coordinate such activities, the Authority had not taken steps accordingly.
(d)	**Public Enterprises Circulars**	
(i)	--- Public Enterprises Circular No. 95 dated 14 June 1994	A sum of Rs. 26,498,645 as special allowances and Rs. 8,327,000 as attendance allowances had been paid from May 2022 to April 2023 for affiliated staff of National Medicines Regulatory Authority and Ministry of Health without obtaining the Treasury approval.
(ii)	Paragraph 2.3 of Public Enterprises Circular No.	Although the Strategic Plan should be prepared 15 days before the beginning of

	01/2021 dated 16 November 2021	the accounting year and submitted to the Secretary to the Treasury and the Director General of the Department of Public Enterprises or the Director General of the National Budget Department through the Secretary of the Line Ministry, the Authority had not taken actions accordingly and a Corporate Plan for the years 2022 - 2026 had been prepared instead of the Strategic Plan. The efficiency gap and development gap between the objectives of the Authority and the current situation that should be included in the Strategic Plan had not been identified through a Corporate Plan and the necessary strategies to bridge the gap had also not been planned. Further, there were no specific time targets for each activity in the Action Plan prepared by the Authority and the budgeted cash flow statement had not been submitted in the prepared Annual Budget and forecast financial statements .
(iii)	Paragraph 6.6 of the Public Enterprises Circular No. 01/2021 dated 16 November 2021	Although the Annual Financial Statements and Draft Annual Report should be submitted to the Auditor General within 60 days of the end of the accounting year, the financial statements of the year have been submitted for audit on 24 March 2023 with a 24 days delay and the Draft Annual

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		Report was not submitted for audit.
(e)	**Public Administration Circulars** ----------	
	Paragraph 3.1 of the Public Administration Circular, No. 30/2016 dated 29 December 2016.	Although a fuel consumption test should be carried out after a period of 12 months following each fuel consumption test, running 25,000 kilo meters or a major overhaul on the engine, whichever occurs first, it had not been so done with respect to 08 vehicles 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 except for the below mentioned observations,

(a) The Authority had not collected data on the quantity of drugs, medical devices, border line products or investigational medicinal products imported under licence in terms of Sub-section 14 (a) of the National Drug Regulatory Authority Act No. 05 of 2015 .

(b) An Annual Report on the activities carried out in the relevant year of finance should be presented by the Authority to the Minister within a period of six months from the end of the financial year in terms of Section 23 of the National Medicines Regulatory Authority Act, No. 05 of 2015 and the Report should be annexed to the report of the Auditor General, the report on accounts of the Authority audited for the relevant year, and a report on the affairs for the ensuing year. Although the said report should be presented to Parliament by the Minister within a period of 06 months

since the date of receipt, the Annual Report of the year 2021 had not been prepared and presented to the Minister and Parliament even by now.

(c) The officers holding a recognized degree in Medicine, Pharmacology, Pharmacy or any other related subjects had not been appointed to the Medicine Regulatory Division, Medical Devices Regulatory Division and the Borderline Production Regulatory Division in terms of the Sections 41 (2), 66(2), and 87(2) of the National Medicines Regulatory Act.

(d) A Technical Evaluation Report specifying benefits, risks, authenticity, status, safety, need, price of drugs and medical devices submitted for registration to the Drug Evaluation Committee and Medical Device Evaluation Committee and economic analysis of those drugs where necessary had not been submitted to the Authority in terms of Sub-sections 43(2) (a) and (b) and 68 (2) (a) and (b) of the Act.

(e) Any drug or medical device shall not be manufactured or imported without registering with the Authority and obtaining a license from the Authority in terms of Sections 58,59,82 and 109 of the National Medicines Regulatory Act, and the Authority had received powers to issue letters of exemption from registration only in special cases such as to save life, prevent the spread of infectious disease or epidemic disease, national interest and national security. Nevertheless, on other grounds, 286 letters of exemption from drug registration had been issued on behalf of the State Pharmaceutical Corporation and Medical Supplies Division during the year under review. In checking 38 certificates of exemption from registration that were issued to a private company there was a point of contention in the audit waiver of responsibility by the Authority by presenting conditions that the Authority had not evaluated the relevant drugs and therefore the Authority was not responsible for the quality, safety and authenticity of the

relevant drugs and the responsibility should be taken by the Director of the Medical Supply Division.

(f) Although the Authority should informed the public by publishing the rules regarding registration of drugs, medical devices and border line products as well as cases of refusal of registration in the Gazette in terms of Sections 60 (2), 61, 84 (2), 85, 103(2), and 104 of the National Medicines Regulatory Act, it had not been complied with even by now since the date of establishment of the Authority.

(g) Neither the Director General of the Sri Lanka Atomic Energy Regulatory Council nor his nominee had been appointed to the Medical Device Evaluation Committee in terms of Sub-section 69 (1) (b) (v) of the Act. The necessity to represent the Medical Device Evaluation Committee by 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, had not fulfilled.

(h) Although general guidelines should be issued to the respective evaluation committees for the evaluation of medical devices and border line products, such guidelines had not been prepared in terms of Sections 72(1) and 93(1) of the National Medicines Regulatory Authority Act. Further, Directives had also not been prepared for the enforcement of guidelines on good manufacturing practices and other relevant guidelines by specifying the procedure to be followed including the specific time frame for conducting the respective evaluations, in terms of Sub-sections 72(4) and 93(4).

(i) Authorized medical devices and registered border line products had not been listed by the Minister from time to time in terms of Sub-sections 74 (1) and 95(1) .

(j) The medical devices and border line products submitted for registration had not been submitted to the National Drug Quality Assurance Laboratory for checking the quality in terms of Sub-sections 83 (4) and 102 (4) .

(k) The Minister had not formulated the Directives by specifying the procedures to be followed in the inspection or evaluation process by the Medical Device and Border Line Products Evaluation Committees and the National Drug Quality Assurance Laboratory, the time limits of that process, how meetings should be held, the procedures to be followed in the meetings and the facts to be included in the reports to be submitted in terms of Sub-sections 83 (6) and 102 (6).

(l) An Appeals Committee had not been appointed to hear and determine appeals presented to the Authority in terms of Section 123 of the National Medicines Regulatory Authority Act, No. 05 of 2015.

(m) A database had not been maintained to ensure and verify that certificates of registration are issued within the targetted processing period according to Paragraph 08 of Schedule XXIII of Order No. 134 of Special Gazette Notice No. 2145/1 dated 14 October 2019 with regard to the registration and licensing of medicines in Section 142 National Medicines Regulatory Authority Act, No. 05 of 2015.

2.2.4 to state that the resources of the Authority had not been 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 below mentioned observation ,

Even though the contract for Revamping the Medicine Database had been awarded to a private entity on 11 November 2020, a formal contractual agreement had not been entered into in terms of Guideline 8.9.1 (b) of the

Government Procurement Guidelines. Further, even though a sum of Rs. 4,774,752 had been paid by 31 December 2021 without obtaining a certificate of completion of works as per 8.12.2 of the Procurement Guidelines, this system was in idle even by now.

2.3 Other Audit Observations

(a) Although all government institutions are required to review and revise the fees charged for services provided by their institution to the public every three years subject to a maximum of 15 per cent in terms of Paragraph 5.1 of Part II of Public Finance Circular No. 01/2020 dated 28 August 2020, as a result of the Authority had not acted in compliance with that , the fee income of Rs. 306,176,273 had been lost to the Authority during the year under review as well. Further, although it had been emphasized that all government institutions which had not increased their service fees in the years 2020, 2021 and 2022 should increase their fees by 20 per cent and report to the Public Finance Department before 31 March 2023, the Authority had not complied with it even up to now and formal approval had also not been obtained to avoid revision of rates overriding the circular.

(b) Although fees should be charged on making requests for exemption from registration for private supplies of drugs, medical devices and border line products according to the fee orders No. 02, 03 and 04 of the Special Gazette No. 2052/33 dated 05 January 2018, the fee amounted to Rs. 10,686,209 that could have been charged for 123 applications for exemption from registration of medical devices in the private sector which were rejected during the year under review had been lost to the Authority. Even though an internal circular had been issued on 25 January 2023 to rectify this, actions had not been taken in respect of the officers responsible for the huge loss of revenue occurred to the government by acting contrary to the fee order from the year 2018 to the year under review in terms of Finance Regulation 128 (p) .

(c) Fees should be charged as per Schedule vii of the above Fees Order for sample analysis and although the provisions on samples free from analysis fees had not been included, the Authority had not charged for samples submitted by public institutions such as government hospitals, medical supplies and courts. Accordingly, analysis fee had not been charged for 328 out of 378 samples received during the year under review and 421 out of 477 samples received during the previous year for analysis.

(d) Out of the income of Rs. 5,604,061 which was paid back in 80 cases during the year under review, an amount of Rs. 3,021,246 were income related to previous years and the Authority had paid an additional income tax of Rs. 460,573 based on that income. Further, 48 per cent of total income refunds or Rs.2,701,407 were the overcharges made due to the negligence and mistakes of the officers of the Authority.

(e) Even though the National Drugs Quality Assurance Laboratory had submitted an application to the Sri Lanka Accreditation Board on 06 February 2020 to obtain the certificate of conformity assessment regarding the quality of the laboratory, it had failed to get that standard certificate even by now.

(f) Since only 241 samples had been tested out of 378 drug samples submitted to the National Drug Quality Assurance Laboratory during the year under review in terms of Section 39 of the National Medicines Regulatory Authority Act No. 5 of 2015, the progress was only 64 per cent. Further, although the test report should be issued within 90 days as per Section 39(4) of the Act and the Standard Operating Procedures of the laboratory, the reports of 47 samples submitted from 2019 to 2021 had not been issued by the end of the year under review and out of these, reports of 37 samples had not been issued even by 08 May 2023, the date of audit.

(g) The contract for automating the data system of the Authority had been awarded to a private company for a period of 05 years for Rs. 29 million and a sum of

Rs.12,253,328 had been paid by May 2021. Nevertheless, some of the information entered into this data system had been deleted due to the negligence or intentionality of the concerned private company and the service of the Criminal Investigation Department had been disabled until the investigations were completed. The report submitted by the expert committee appointed in this regard on 15 July 2022 informed that the data that had been deleted from the system cannot be restored and actions had not been taken so far to recover the loss or take any action against the respective company.

(h) The total approved staff of the Authority as at 31 December 2022 was 257 with 235 approved permanent staff and 22 on contract basis staff. Although the total actual staff was 159, since 37 of them were an excess number not included in the approved staff, the actual number of vacancies was 135 out of the total approved staff as at 31 December 2022.

(i) Seventy new posts as 30 Drug Evaluation Officer posts and 40 Assistant Drug Evaluation Officer posts had been got approved on 03 November 2020 by abolishing 70 Pharmacist posts in the approved staff of the Authority. However, as only 28 Assistant Drug Evaluation Officers had been recruited by 31 December 2022, the system of absorption or recruitment as recommended by the Management Services Department to fill the vacancies of 30 Drug Evaluation Officers and 12 Assistant Drug Evaluation Officers had not been implemented even by the date of this report. The duties related to these vacant posts are being carried out by 37 officers holding the post of Pharmacist which is now abolished post assigned by the Ministry of Health and although there is an opportunity for those pharmacists to be absorbed in the posts of Drug Evaluation Officers based on the system of absorption for the posts of Drug Evaluation Officers, it was observed that due to the delay in the process, injustice is happening on them and the situation may affect their performance.

(j) Since 18 positions or 71 per cent out of the 21 senior management positions available in the approved staff of the Authority were vacant, it had failed to identify necessary and unnecessary positions and revise the approved staff and it was observed that the vacancies remained in required posts may have an impact on the overall performance of the Authority.

(k) Although the advertisements were published in newspapers and applications for the posts of Director (Human Resource) and Internal Auditor had been called in the last year by incurring Rs. 308,487, those posts had remained in vacant even by 31 December 2022 .

(l) Although 20 posts of drug inspectors were approved for pharmaceuticals and pharmacy regulatory works, 02 food and drug inspectors who were assigned to the Authority from the Ministry of Health had been deployed for the duties of 02 positions out of that. It was observed that these vacancies in the staff can directly affect the performance related to the main functions such as regulation of pharmaceuticals and pharmacies of the Authority.

(m) Although more than 07 years had elapsed since the National Drug Quality Assurance Laboratory was taken over to the National Medicines Regulatory Authority, the staff required for it had not yet been approved.

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	This payroll software package is not used in the Authority.	
4	**Preparation of Annual Action Plan**			
4.1	Preparation of Annual Action Plan	Compliant		
4.2	Preparation of Annual Internal Audit Plan	Compliant		
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	Compliant		
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)	Compliant		
6.2	Having responded to each internal audit within a month of time	Compliant		
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	Compliant		
6.4	Submitting copies of all the internal audit reports to the Auditor General in accordance with the financial regulations 134(3)	Compliant		
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	Compliant		

8.4	Should have made excesses, deficiencies and other recommendations revealed in the annual board of survey during the period mentioned in the circular	Compliant		
8.5	Disposal of the unserviceable items in terms of FR 772	Compliant		
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	Compliant		
12.3	should have settled the outstanding debt balance being for more than one year	Compliant		
13	**General Deposit Account**			
13.1	Should have acted in accordance with FR 571 with regard to the expired deposits	Compliant		
13.2	Updating and maintaining the control account for the general deposit accounts	Compliant		
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	Compliant		
14.2	Interim imprest issued under FR 371,having been settled within one month after the completion of particular work	Compliant		
14.3	Having issued the interim imprest at present not exceeding the approved limit in terms of FR 371	Compliant		
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		