Annual Report

2023

NMRA

NATIONAL MEDICINES REGULATORY AUTHORITY

NATIONAL MEDICINES REGULATORY AUTHORITY (NMRA)

No. 120, Norris Canal Road, Colombo 10.

Table of Contents

Page No.

List of Abbreviations

BPEC	Borderline Products Evaluation Committee
CDD Act	Cosmetic, Device and Drugs Act
CEC	Cosmetics Evaluation Committee
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
ICT	Information Communication 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
SCCT	Sub Committee of Clinical Trial
SDG	Sustainable Development Goals
SSFFC	Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Programme
WD	Withdrawal
WH	Withhold
WHO	World Health Organization

Message of the Chairman

National Medicines Regulatory Authority (NMRA), which was established in 2015 by an Act of Parliament, is an independent body coming under the Ministry of Health, Sri Lanka. It is entrusted with the task of regulating all medicines, medical devices and borderline products in Sri Lanka and it has the responsibility of ensuring that these products meet the applicable standards of safety, quality, and efficacy.

2023 was a year of turbulence for the NMRA during which it had to face many challenges. The strong parliamentary Act and the resilience of the staff of the NMRA prevented a total collapse of the regulatory system of medicines in Sri Lanka. Now, the NMRA is recovering from this situation due to correct political decisions, lack of political interference, commitment of the staff and the support from the medical specialists. Processes are now being laid down with the hope that functioning of the NMRA will be smooth.

For more than 8 years, the NMRA has been financially independent. Furthermore, the NMRA helps the government by paying a significant Treasury Levy and Income Tax.

The NMRA is committed to fulfill its responsibility as the regulator of all medicines and related products so that high quality medicines and related products are available for the citizens of Sri Lanka for an affordable price.

Dr. Ananda Wijewickrama
Chairman
National Medicines Regulatory Authority

Message of the Chief Executive Officer

National Medicines Regulatory Authority of Sri Lanka (NMRA), an independent organization coming under the Ministry of Health, is the only government entity which regulates all medicines, medical devices, borderline products and cosmetics that are imported as well as manufactured in the country.

As the Chief Executive Officer of the NMRA, I am pleased to present the Annual Report of the Authority for the year 2023.

During the year 2023, even amidst the post-Covid situation and the economic crisis in the country, the NMRA has achieved a significant growth of its turnover.

NMRA income is based on the fees charged for issuing licenses for manufacturing, imports, etc, and granting registration for medicinal and related products. Achieving a high turnover clearly shows that NMRA activities have progressed significantly. By achieving a high turnover, NMRA was able to contribute significantly to the country's economy, by paying Treasury Levy and income tax.

We are in the process of strengthening our workforce and our operating framework with the target of improving our efficiency, financial status, and in all other operations which will help us to maintain our independency. Further, we are planning to increase the employee benefits leading to enriching the morale of our workforce and as a result and to achieve a high output.

Dr. Saveen Semage
Chief Executive Officer
National Medicines Regulatory Authority

Board of Directors as at 01.01.2023

1. Prof. S.D. Jayaratne (Chairman/NMRA)
2. Dr. Vijith Gunasekera (Chief Executive Officer/NMRA)
3. Dr. Asela Gunawardena (DGHS)
4. Dr. Pradeep de Silva
5. Mr. Chathura Parakrama Mohottigedara
6. Dr. Kosala Karunaratne
7. Dr. Priyantha Serasinghe
8. Mr. Manoj Gamage
9. Mr. Supul Wijesinghe
10. Dr. Pradeep Kumarasinghe

Board of Directors as at 31.12.2023

1. Dr. Ananda Wijewickrama - Chairman
2. Ms. Deepika Bulathsinhala - CEO (Acting)
3. Dr. Asela Gunawardane - DGHS
4. Prof. Priyadarshani Galappatthy
5. Dr. Pradeep Kumarasinghe De Silva
6. Dr. Kosala Karunaratne
7. Dr. Duminda Ariyaratne
8. Dr. Banukie Jayasuriya
9. Dr. Priyantha Serasinghe
10. Mr. Chathura Mohottigedara
11. Mr. Supul Wijesinghe
12. Mr. Manoj Gamage

Present Board of Directors

1. Dr. Ananda Wijewickrama - Chairman
2. Dr. Saveen Semage - CEO
3. Dr. Asela Gunawardena - DGHS
4. Prof. Priyadarshani Galappatthy
5. Dr. Sanath Akmeemana
6. Dr. Pradeep Kumarasinghe de Silva
7. Dr. Kosala Karunaratne
8. Dr. Duminda Ariyaratne
9. Dr. Banukie Jayasuriya
10. Ms. Tamara Adikari
11. Mr. Palitha Mendis Kumarasinghe
12. Mr. Susantha Kahawatta
13. Mr. Sujeewa Mudalige

Chapter 1
Corporate Profile

1.1 Introduction

National Medicines Regulatory Authority (NMRA) is the only government agency established in Sri Lanka to regulate 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 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 and cabinet approval was granted in 2004. 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 July 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 assuring safety, quality, efficacy and accessibility of 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
- Inspectorate and Enforcement Division
- Finance Division
- Human Resources and Administration Division
- Legal Division
- ICT Division

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

- Medicine Evaluation Committee (MEC)
- Medical Devices Evaluation Committee (MDEC)
- Borderline Product Evaluation Committee (BPEC)
- Sub Committee of Clinical Trials (SCCT)
- Cosmetic Evaluation Committee (CEC)
- Pharmacy Evaluation Committee
- Advertisement evaluation committee

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, healthcare products and cosmetics to ensure their Safety, Quality and Efficacy for the benefit of people of Sri Lanka’

1.2.3 Objectives of the Authority

1. 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;
2. 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;
3. 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;
4. Encourage the manufacturing of good quality medicines in Sri Lanka with a view to assuring the availability of essential medicines at affordable prices;
5. Promote the safe and rational use of medicines, medical devices and borderline products by health care professionals and consumers;
6. Recommend appropriate amendments to relevant laws pertaining to medicines, medical devices and borderline products;
7. Educate the general public, health care professionals and all stakeholders on medicines, medical devices and borderline products;
8. Regulate the promotion and marketing of medicines, medical devices and borderline products;
9. Regulate the availability of the medicines, medical devices and borderline products;
10. Conduct post marketing surveillance on quality, safety and adverse reaction of the medicines, medical devices and borderline products;
11. Regulate all matters pertaining to the conduct of clinical trials in Sri Lanka.

1.3 Main Functions

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

1.4 Main Divisions of 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. Inspectorate and Enforcement Division
4. Finance Division
5. Human Resources and Administration Division
6. Legal Division
7. ICT Division

1.4.1 National Medicines Quality Assurance Laboratory (NMQAL)

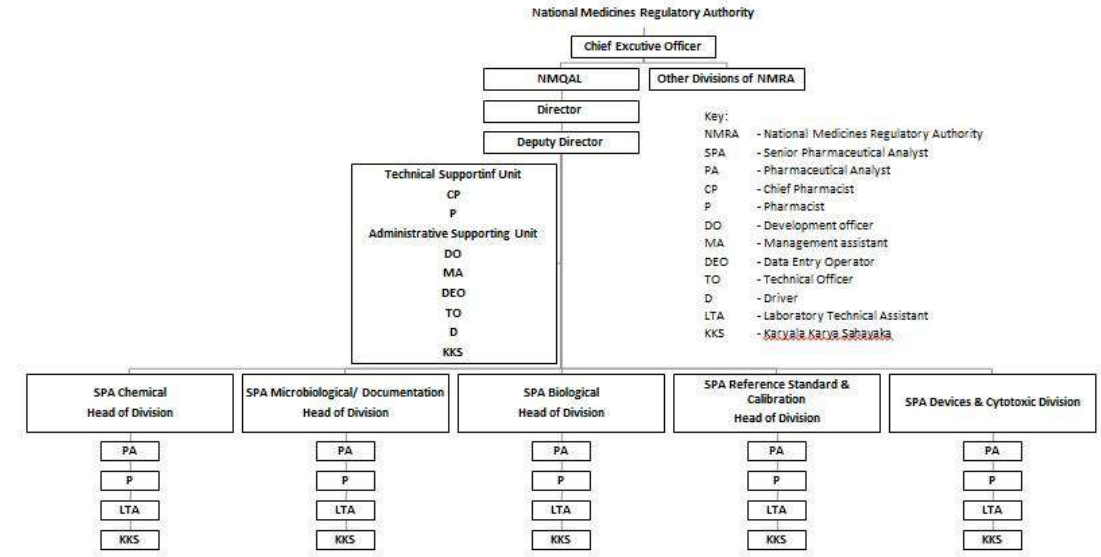
1.4.1.1 Introduction

National Medicines Quality Assurance Laboratory (NMQAL) provides the technical support needed to operate the quality assurance system on Medicines and Medical Devices. At present existing facility of NMQAL consists of 4 story building constructed in 1990 with NORAD funds and consultancy. Main divisions of NMQAL are Chemical, Microbiological, Biological, Reference Standard & Calibration and Devices & Cytotoxin divisions. The primary function of the NMQAL is to conduct laboratory tests necessary for determining compliance with product quality, safety and efficacy requirements. NMQAL follows the test procedures in standard pharmacopoeias and other accepted (validated) test procedures in the assessment of quality safely and efficacy.

At present analysis is carried out for medicines and limited number of medical devices.

NMQAL Quality Management System is established to meet the requirements of ISO/IEC 17025. At present NMQAL accreditation process is halt due to ongoing process of staff recruitment and renovation of laboratory building.

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 mane of 'Biological Division'. Accordingly, Chemical tests, Physical tests, Particulate Matter tests are conducted by this division.

1.4.1.3 Main functions of NMQAL

1. Analysis of locally manufactured and imported Medicines and Medical Devices at different points in the distribution chain. (Premarketing and Post marketing stages) Samples for analyses are submitted as registration samples, complaints samples, tender samples and surveillance samples collected from government and private institutions.
2. Function as an additional approved analyst when the circumstances so require.
3. Participate in GMP inspections
4. Evaluate the validated In-house analytical procedures at registration
5. Participate in external quality assurance assessment scheme (proficiency testing)
6. Conduct training programs on quality assurance system for BPharm, BSc (Pharmacy) and Chemical Pathologist (PGIM)
7. To coordinate with laboratories local or overseas when their services are deemed necessary as decided by the NMRA.

1.4.2 Pharmaceutical Regulatory Division

1.4.2.1 Introduction

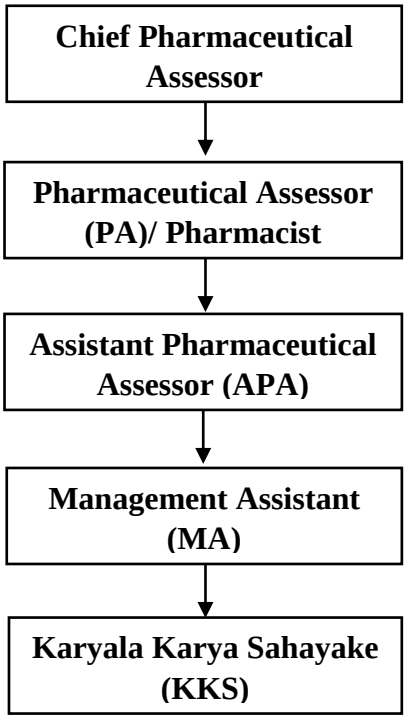
Pharmaceutical Regulatory Division is comprising of sub divisions such as; Medicine Regulatory Division, Medical Device Regulatory Division, Cosmetic Regulatory Division, Borderline Regulatory Division, Manufacturing Regulatory Division, Pharmacy Regulatory Division, Pharmacovigilance Division, Pricing Unit, Clinical Trial Regulatory Division, HS Codes Clearance Unit, Information, Education, Communication and Research Division, market Control & advertising Unit, and QMS Unit.

Routine duties are completed with maximum efficiency by pharmaceutical Assessors, Assistant Pharmaceutical Assessors and pharmacists with multiple job roles to carry out the responsibilities of NMRA.

Plans for future

1. Electronic system requirement to be fulfilled to reduce over processing and improve the efficiency of the respective divisions.
2. Digitalized systems to process to ensure the transparency and security.
3. Recruitment of approved carder
4. Implementation of post market surveillance
5. Achieving benchmark maturity level

1.4.2.2 Divisional Chart of the Pharmaceutical Regulatory Division



1.4.2.3 Main Functions of Pharmaceutical Regulatory Division

Regulate and ensure safety, and quality of medicines, medical devices, cosmetics and borderline products under NMRA act to make them available for the public at an affordable price including;

1. Evaluation, and make arrangements to register and give recommendation for issuing of import license for medicines, medical devices, cosmetics and borderline products.
2. Regulating, Inspecting and control of pharmaceutical manufacturing facilities and processes, both for local manufacturers and overseas manufacturers
3. Price Regulation
4. Regulation of Island wide Pharmacies
5. Pharmacovigilance activities
6. HS code clearance of medicinal products through the ASYCUDA system.
7. Regulation and control of all aspects pertaining to clinical trials

1.4.3 Inspectorate and Enforcement Division

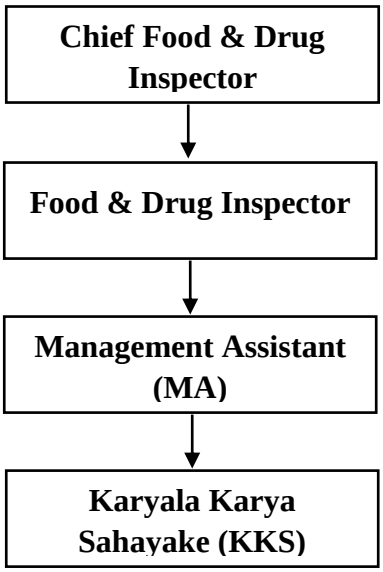
1.4.3.1 Introduction

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

The main function of the Inspectorate & Enforcement Division of the NMRA is inspecting and investigating issues pertaining to proper implementation of the provisions of the NMRA Act as may be authorized and directed by the Authority. Two senior Food & Drugs Inspector officers have been appointed to this unit to carry out these functions as Authorized Officers under the NMRA Act. 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.

1.4.3.2 Divisional Chart of the Inspectorate and Enforcement Division



1.4.3.3 Main Functions of Inspection and Enforcement Division

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

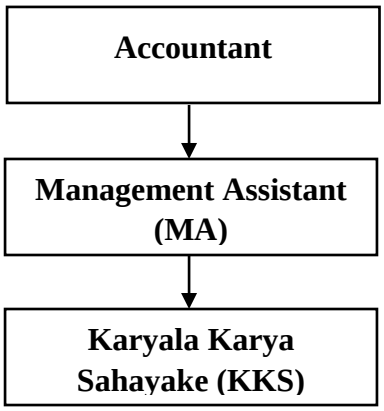
7. Investigating & initiate legal actions on the detentions made by the SSFFC & smuggled products
8. Investigating the availability of state-owned drugs in the private market
9. Inspecting & recommending of dangerous drugs applications
10. Organizing & conducting educational programs
11. Conducting prosecutions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

1.4.4 Finance Division

1.4.4.1 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.

1.4.4.2 Divisional Chart of the Finance Division



1.4.4.3 Main Functions of the Finance Division

1. Receiving revenue through eighteen main revenue streams.
2. Preparing final accounts
3. Preparing the budgets for the coming year and obtaining the relevant approvals
4. Maintaining all the supplies required to run the day-to-day activities of the authority
5. All monetary controlling activities
6. Procurement activities

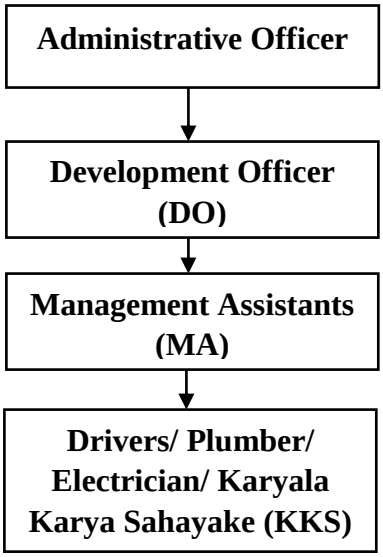
1.4.5 Human Resources and Administration Division

1.4.5.1 Introduction

From the beginning of NMRA, the Human Resources and Administration Division is playing a key role for the Authority. Main functions of the Human Resources and Administration Division are engaging all activities related to Human Resources and issue the import /sample 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 of bills and other payments, maintain leave and other staff arrangements, and make arrangements to enhance staff welfare are handled by the Human Resources and Administration Division. It helps the organization to deliver a high quality services to its clients, by establishing the formal communications with other institutes as well.

1.4.5.2 Divisional Chart of the Human Resources and Administration Division



1.4.5.3 Main Functions of Human Resources and Administration Division

This division is established to cover all the Human Resources functions, administrative and maintenance functions at NMRA and specifically maximize the utilization of the employees to achieve Authority objectives efficiently and effectively and issuing licenses and registration certificates of Medicines, Medical Devices, Cosmetics and Borderline items.

Accordingly, main activities functioned in Human Resources and Administration Division is as follows;

1. Handles the recruitment, development, retention and firing processes of the Authority staff.
2. License Issuing after evaluations of Dossiers - Medicines (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.
3. Supervising the license and the registration certificates issuing process
4. Personnel Management within the Authority
5. Supervise all the activities related to maintenance of the office premises
6. Maintaining utility services
7. Making relevant reports in relation to the section
8. Vehicle and transport management
9. Coordinating the activities related to staff leave (official/local/foreign)
10. Certifying the attendance of the permanents staff and training staff
11. 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
12. Supervising external and internal record rooms
13. Issuing of staff ID cards

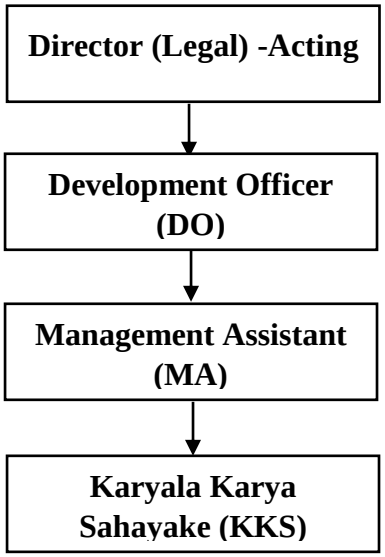
1.4.6 Legal Division

1.4.6.1 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.

1.4.6.2 Divisional Chart of the Legal Division



1.4.6.3 Main Functions of the Legal Division

Drafting of Agreements, Gazettes, Cabinet Memorandum, Memorandum of Understandings and any other legal documentations. Legal Division responsible for 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. Legal Division also conducting, monitoring and processing of applications for agency transfer matters and any other matters relating to the NMRA. Legal Division provides legal opinions on matters referred by other divisions of NMRA as well as licensees, stakeholders, ministries/ divisions and other forums and take necessary steps pertaining to the parliamentary affairs.

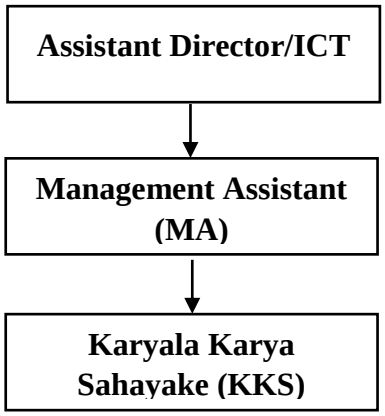
Legal Division also advises the Authority in the cases requiring legal input on various regulatory matters and initiation of legal proceedings under the National Medicines Regulatory Authority Act No. 05 of 2015. It is also responsible for handling cases filed in Courts of Law such as Supreme Court, 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 and attending any commission inquires/CID inquires where necessary. Legal Division also handling all applications received under the Right to Information Act No. 12 of 2016, and any other matters relating to the legal division.

1.4.7 Information and Communication Technology (ICT) Division

1.4.7.1 Introduction

The Information & Communication Technology (ICT) Division is responsible for management of the Information and communication including website, Local Area Network, Databases and Computer Hardware and Software. This includes updating the website in regular basis, attend to network issues, taking backups, troubleshooting Hardware and Software issues and providing technical support.

1.4.7.2 Divisional Chart of the ICT Division



1.4.7.3 Main Functions of the ICT Division

1. Drafting Updating and maintaining the NMRA official website.
2. Providing assistance in maintaining the data in the NMRA. This includes taking backups, creating forms, maintaining Google sheets and providing technical support in maintaining other databases used within the NMRA.
3. Maintenance of the computers and Network of the NMRA
4. Troubleshooting the internet and network issues and contacting the service providers regarding the failures and other issues.
5. Provisioning email and Internet service to the staff of the NMRA
6. Installing software and troubleshooting the hardware and software issues.
7. Arranging virtual meetings, providing technical support during the meetings, recording virtual meetings as per the requests.
8. Monitoring the CCTV camera system and contacting the service provider regarding the issues and maintenance of the CCTV camera system.

Chapter - 2

Progress of the respective Divisions

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, borderline 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)

Current staff situation at NMQAL

	Position	No. of staff members
1	Act. Director (Sec. Head/ Micro Division)	01
2	Act. Deputy Director (Sec. Head/ Chemical Division)	01
3	Pharmaceutical Analyst	04
4	Pharmacists	05
5	Development officers	01
6	Management Assistants	03
7	LTA	00
8	KKS	08

Sample Situation

Sample Type	* No. of samples in hand 2023.01.01	No. of samples received within year	No.of Reports issued in within year	Balance of samples in hand 31.12.2023
Registration	21	57	46	32
NMQAL Surveillance	51	31	70	12
MSD Surveillance	7	23	20	10
Lab request	2	2	2	2
Complaints	16	281	152	145
Food & Drug Inspectors	44	107	59	92
Court Samples	36	86	79	43
SPC Tender / Pre shipment	0	7	4	3
SPMC	0	1	1	0
Others	0	21	14	7
Total	**177**	**616**	**447**	**346**

***** From 1st Jan 2013 -31st March 2023

Samples tested as per request categories

Type	Local products		Imported products		Total	
1) Pre Marketing	**Pass**	**Fail**	**Pass**	**Fail**	**Pass**	**Fail**
Registration	16	3	21	6	37	9
State Pharmaceuticals Corporation	0	0	1	3	1	3
Other requests (specify)	0	0	0	0	0	0
2) post marketing						
A) post marketing						
NMQAL surveillance	46	8	11	6	57	14
Complaint	13	28	49	44	62	72
Medical supplies division	8	5	0	7	8	12
State pharmaceuticals corporation	0	0	0	0	0	0
B) Food & Drug Inspector						
Informal	10	1	9	2	19	3
Formal	1	2	26	1	27	3
C) Other requests specify (SPMC & etc)	2	3	3	7	5	10
Grand total	96	50	120	76	216	126

Total No. of reports issued

Product Category	Pass	Fail	Total	Failure % of the category
Imported	120	76	196	**39**
Local	96	50	146	**34**
Court Samples			79	
Other products (specify) Hand Sanitizer, cosmetics			26	
Total report issued	216	126	**447**	**28**

Breakdown of failures as per market status

Product Category	Pass	Fail	Total	% Failure of the category
Pre market	38	12	50	24
Post market	178	114	292	39

No. of Evalaution of inhouse analytical test methods	No. of Replies manufactures explanations on quality failures
17	6

GMP Inspections

	Site name & address
1	ACE Healthcare Pvt Ltd - Horana
2	ACI Pharmaceuticals Ltd - Bangladesh
3	Appasamy Occular Devices Pvt Ltd -
4	CPCI Pharmaceuticals - Vietnam
5	Dream Life Science Pvt Ltd - Bandaragama
6	Emergen Life Sciences
7	Farbe Firma Pvt Ltd - India
8	Felxicare Pvt Ltd - Bandarawela
9	ICL Brands - Ekala
10	Isolez Biotech Pharma
11	Kelun Life Science Pvt Ltd- Kandy
12	Kwality Pharmaceuticals - India
13	Laugh Life Sciences - Koggala
14	Lina Spiro Pvt Ltd - Sri Lanka
15	Lupin Ltd - India

16	MCI Manufactures - Sri Lanka
17	Medicom Pvt Ltd- Dehiwala
18	Navesta Pharmaceuticals Ltd - Sri Lanka
19	Newgen Lanka Healthcare - Kurunegala
20	Panacea Medical
21	Phoenix Industries Ltd
22	PT Merk - Indonesia
23	Sands Active- Ja - Ela
24	Schitra Medicare Services Pvt Ltd- Bandaragama
25	SPMC- Rathmalana
26	Surgi Pharma - Kelaniya
27	Swiss Parenterals - India
28	Vimphaco, Vietnam
29	Yaden Pvt Ltd - Katunayake

2.2 Progress of Pharmaceutical Regulatory Division

2.2.1 Medicines Regulatory Division

Medicines dossier evaluations

Type of applications	Number of applications received	Number of applications evaluated
New Medicines applications	990	502
MEDREG applications	26	142
Re-Registration applications	466	624
Additional	662	453
Variations	567	173

Number of MEC –Subcommittee meetings for dossier evaluation = 21

Review of applications for New Molecular Entity (NME)

Total of submitted NCEs in 2023	No. of accepted NCEs	No. of rejected NCEs	Pending at MEC
71	52	19	-

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
236	233	3

Evaluation of applications for sample import license

Medicines Sample License -2023	
No of application received	1516
No of application rejected	246
No of applications approved by the MEC	919
No of application pending due to the incomplete documents (already informed to L/A but didn't receive any response)	128
No of sample license issued	1135

Number of MEC meetings conducted =12

No of MEC Subcommittee = 21

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	-	119
Number of letters for monthly quota approval	-	33
Number of letters for authorized person	-	39

Issuing Waiver of registration

Type of application	Accepted application in 2023	Number of approved	Number of not approved/Decision Pending
WOR (Special pathway)	216	75	141
WOR (Normal pathway)	99	72	27
Donations	50	194	06

Number of WOR meetings for review WOR applications = 11

Review applications for shipment clearance approval

Number of applications received	Number of applications reviewed and approved	Number of applications reviewed and reject
4436	3503	190

Update medicines database

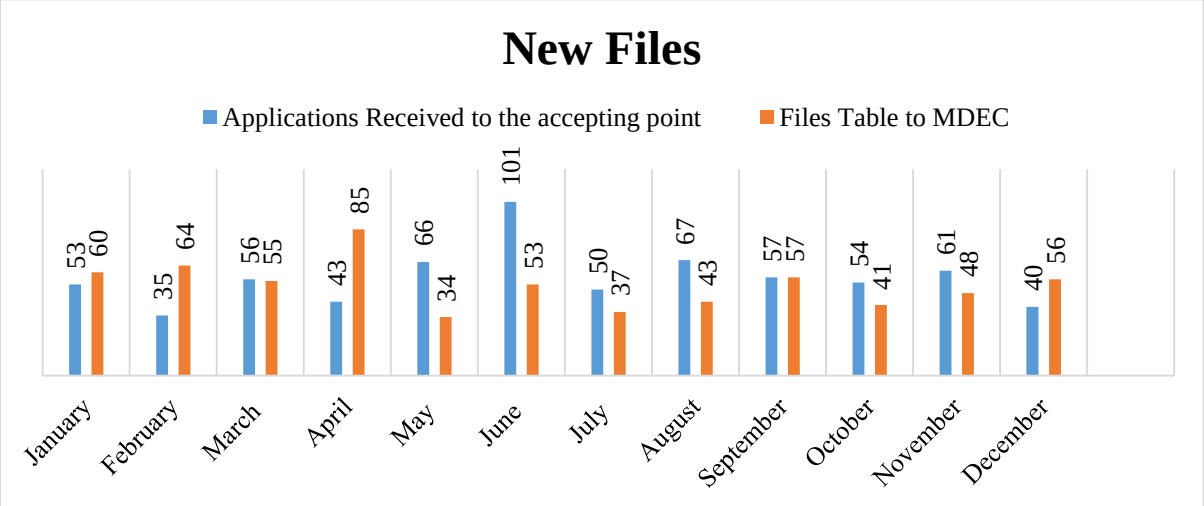
Number of received registration certificates from admin	Number of entered certificates to data base	Number of pending to enter
1771	Extend certificates - 21	0
	New certificates - 1750	

2.2.2 Medical Devices Regulatory Division

Monthly Evaluation of Medical Device Applications (Dossiers)

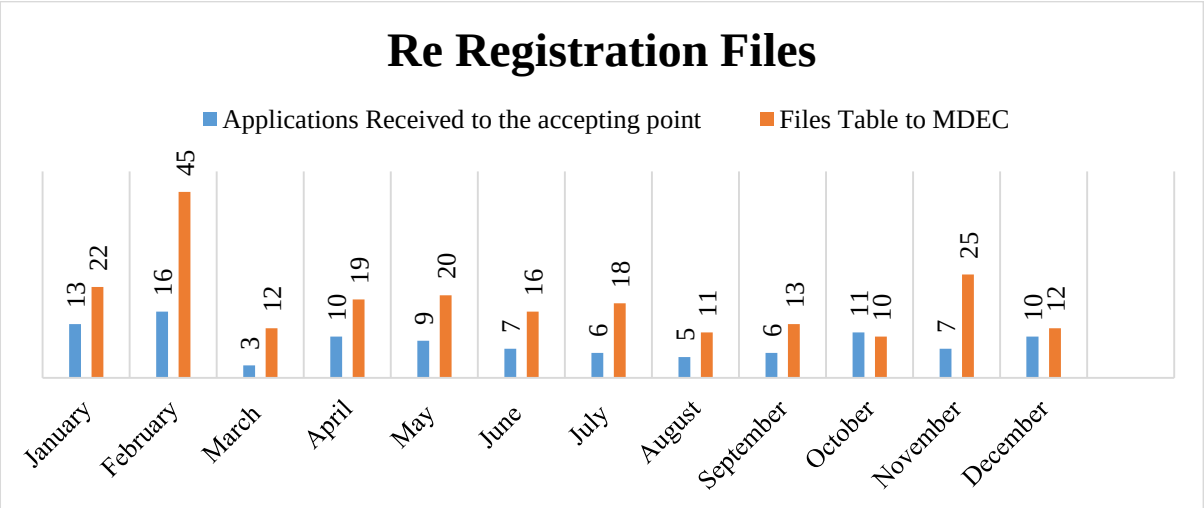
Monthly Evaluated New Dossiers

Month & Year	New	
	Received applications to Accepting point	Evaluation Completed Dossiers
Jan-23	53	60
Feb-23	35	64
Mar-23	56	55
Apr-23	43	85
May-23	66	34
Jun-23	101	53
Jul-23	50	37
Aug-23	67	43
Sep-23	57	57
Oct-23	54	41
Nov-23	61	48
Dec-23	40	56
Total	**683**	**633**



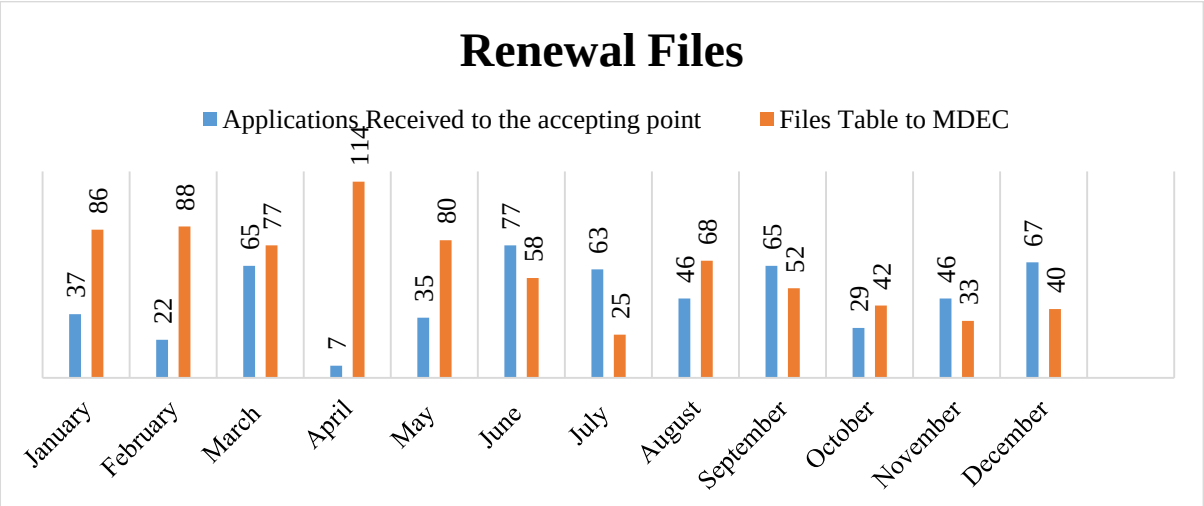
Monthly Evaluated RR Dossiers

Month & Year	RR	
	Received applications to Accepting point	Evaluation Completed Dossiers
Jan-23	13	22
Feb-23	16	45
Mar-23	3	12
Apr-23	10	19
May-23	9	20
Jun-23	7	16
Jul-23	6	18
Aug-23	5	11
Sep-23	6	13
Oct-23	11	10
Nov-23	7	25
Dec-23	10	12
Total	**103**	**223**



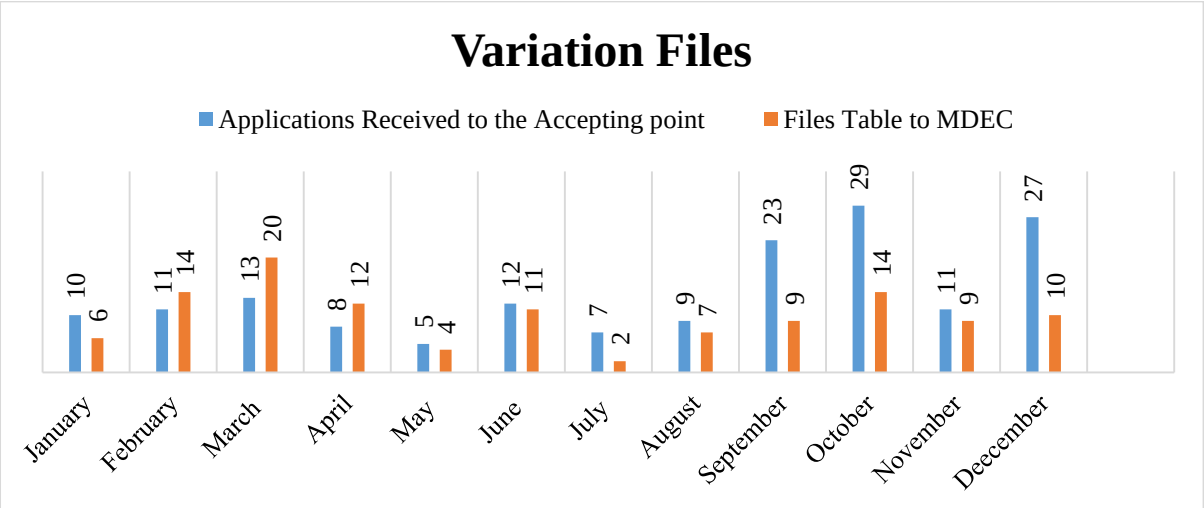
Monthly Evaluated Renewal Dossiers

Month & Year	Renewal	
	Received applications to Accepting point	Evaluation Completed Dossiers
Jan-23	37	86
Feb-23	22	88
Mar-23	65	77
Apr-23	7	114
May-23	35	80
Jun-23	77	58
Jul-23	63	25
Aug-23	46	68
Sep-23	65	52
Oct-23	29	42
Nov-23	46	33
Dec-23	67	40
Total	**559**	**763**



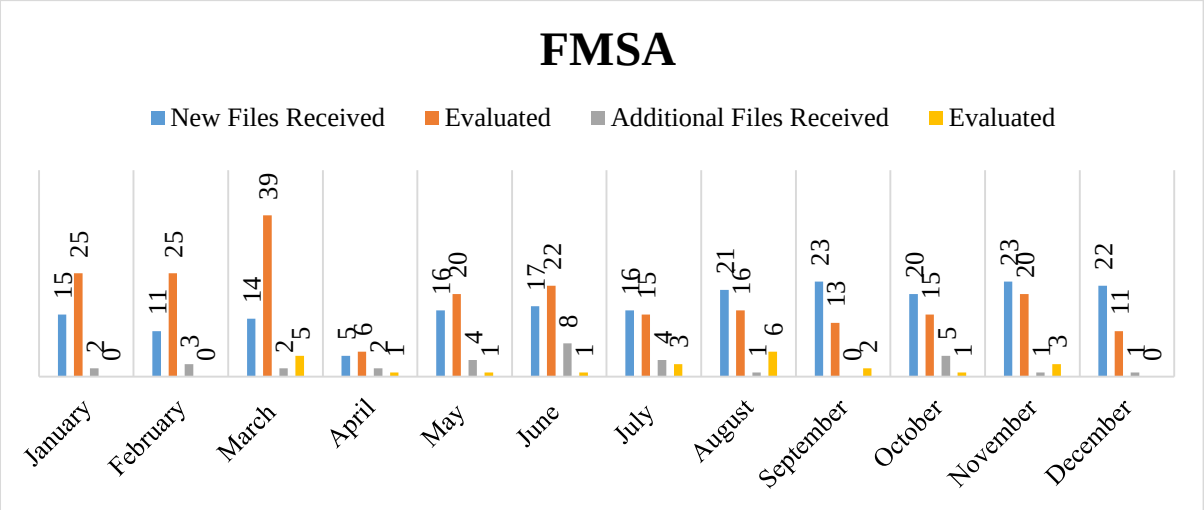
Monthly Evaluated Variation Dossiers

Month & Year	Variation	
	Received applications to Accepting point	Evaluation Completed Dossiers
Jan-23	10	6
Feb-23	11	14
Mar-23	13	20
Apr-23	8	12
May-23	5	4
Jun-23	12	11
Jul-23	7	2
Aug-23	9	7
Sep-23	23	9
Oct-23	29	14
Nov-23	11	9
Dec-23	27	10
Total	**165**	**118**



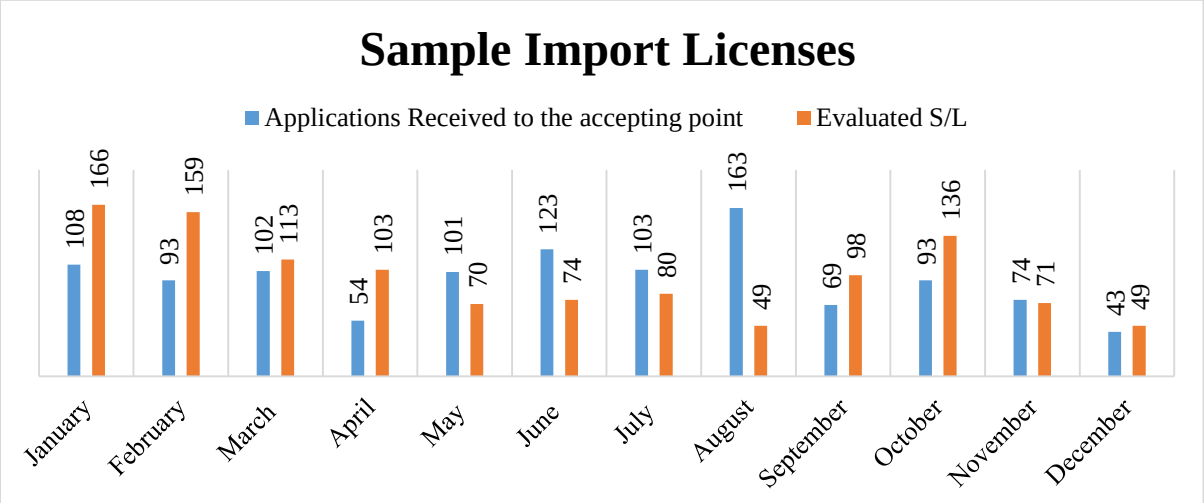
Foregin Manufacturing Site Registration file Evalution

Month & Year	New		Additional	
	Received applications to Accepting point	Evaluation Completed Files	Received applications to Accepting point	Evaluation Completed Files
Jan-23	15	25	2	0
Feb-23	11	25	3	0
Mar-23	14	39	2	5
Apr-23	5	6	2	1
May-23	16	20	4	1
Jun-23	17	22	8	1
Jul-23	16	15	4	3
Aug-23	21	16	1	6
Sep-23	23	13	0	2
Oct-23	20	15	5	1
Nov-23	23	20	1	3
Dec-23	22	11	1	0
Total	**203**	**227**	**33**	**23**



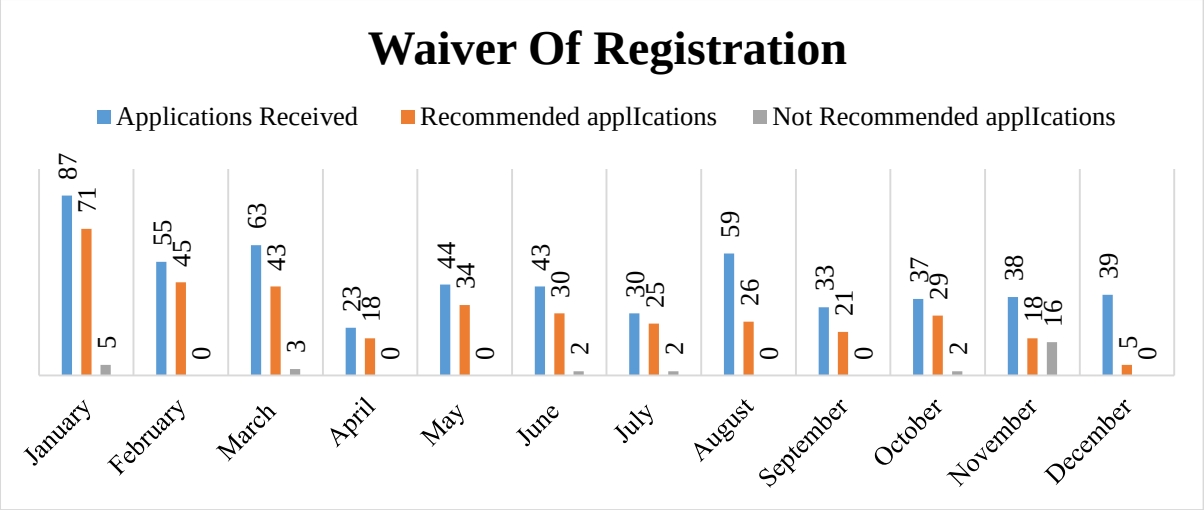
Sample Import Licenses Evaluation

Month	Received applications to Accepting point		Evaluation Completed Files	
Jan-23	108	New = 75 Additional = 33	166	Approved = 123 Reject = 43
Feb-23	93	New = 64 Additional = 29	159	Approved = 137 Reject = 22
Mar-23	102	New = 86 Additional = 16	113	Approved = 93 Reject = 20
Apr-23	54	New = 48 Additional = 06	103	Approved = 89 Reject = 14
May-23	101	New = 96 Additional = 05	70	Approved = 63 Reject = 7
Jun-23	123	New = 118 Additional = 05	74	Approved = 69 Reject = 5
Jul-23	103	New = 103	80	Approved = 63 Reject = 17
Aug-23	163	New = 163	49	Approved = 46 Reject = 03
Sep-23	69	New = 69	98	Approved = 84 Reject = 13
Oct-23	93	New = 93	136	Approved = 91 Reject = 45
Nov-23	74	New = 74	71	Approved = 63 Reject = 08
Dec-23	43	New = 43	49	Approved = 40 Reject = 09
Total	**1126**		**1168**	



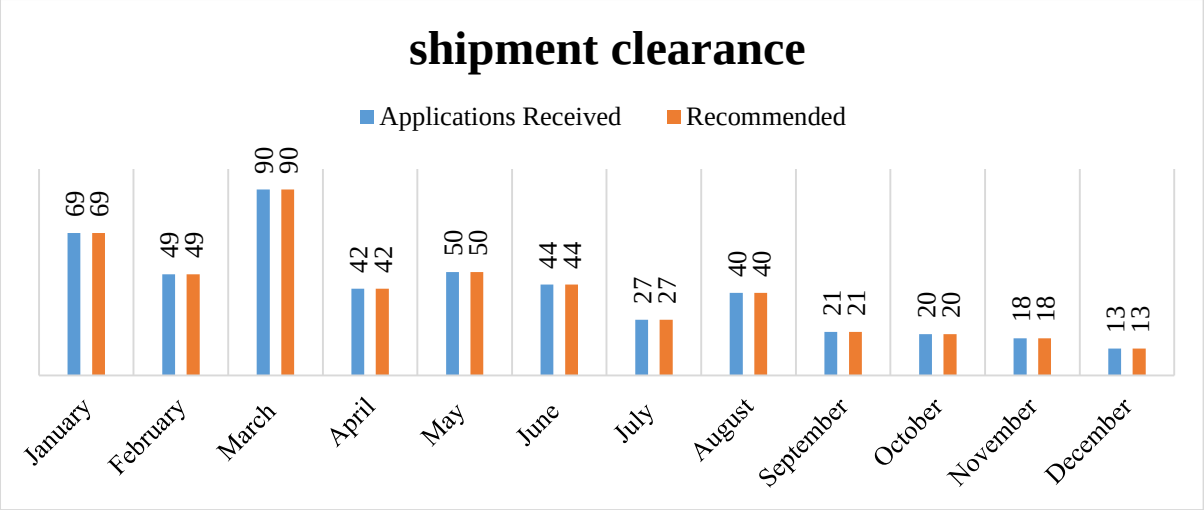
Issuing Waiver of Regsitration

Month & Year	No of applications Received	Recommended applications	Not Recommended applications
Jan-23	87	71 (Donation-65/ ICL-5 / Other-1)	05
Feb-23	55	45 (Donation-37/ ICL-7 / Other-1)	00
Feb-23	63	43 (Donation-24/ ICL-3 / Other-16)	03
Mar-23	23	18 (Donation-15/ ICL-00 / Other-03)	00
Apri-23	44	34 (Donation-24/ ICL-00 / Other-10)	00
May-23	43	30 (Donation-29/ ICL-00 / Other-01)	02
June-23	30	25 (Donation-22/ ICL-00 / Other-03)	02
Aug-23	59	26 (Donation-26/ ICL-00 / Other-03/ To next WOR committee -33)	00
Sep-23	33	21 (Donation-17/ ICL-00 / Other-02/CEO Minute-2/ To next WOR committee -12	00
Oct-23	37	29 (Donation-27/ ICL-00 / Other-02/CEO Minute-0/ To next WOR committee -06	02
Nov-23	38	18 (Donation-12/ ICL-00 / Other-06/CEO Minute-0/ Pending dicision -04	16
Dec-23	39	05 (Donation-02/ ICL-00 / Other-03/CEO Minute-0/ Next Committee -34	00
Total	**551**	**365**	**30**



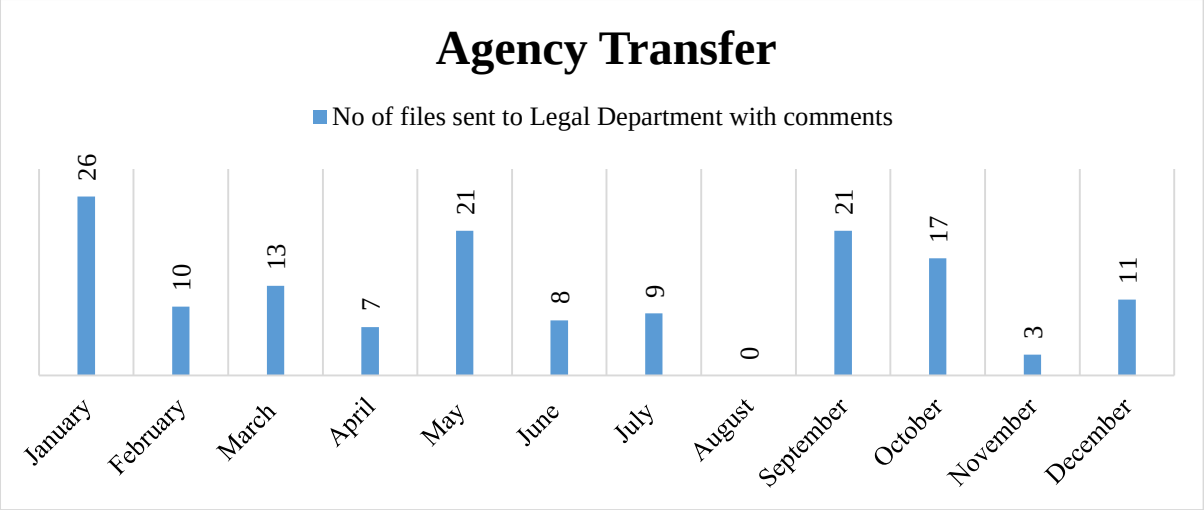
Issuing Shipment Clearance Process

Month & Year	Received to the accepting point	Recommended shipment clearance
Jan-23	69	69
Feb-23	49	49
Mar-23	90	90
Apr-23	42	42
May-23	50	50
Jun-23	44	44
Jul-23	27	27
Aug-23	40	40
Sep-23	21	21
Oct-23	20	20
Nov-23	18	18
Dec-23	13	13
Total	**483**	**483**



Agency Transfer Process

Month & Year	No of files sent to legal department with comments
Jan-23	26
Feb-23	10
Mar-23	13
Apr-23	07
May-23	21
Jun-23	08
Jul-23	09
Aug-23	00
Sep-23	21
Oct-23	17
Nov-23	03
Dec-23	11
Total	**146**

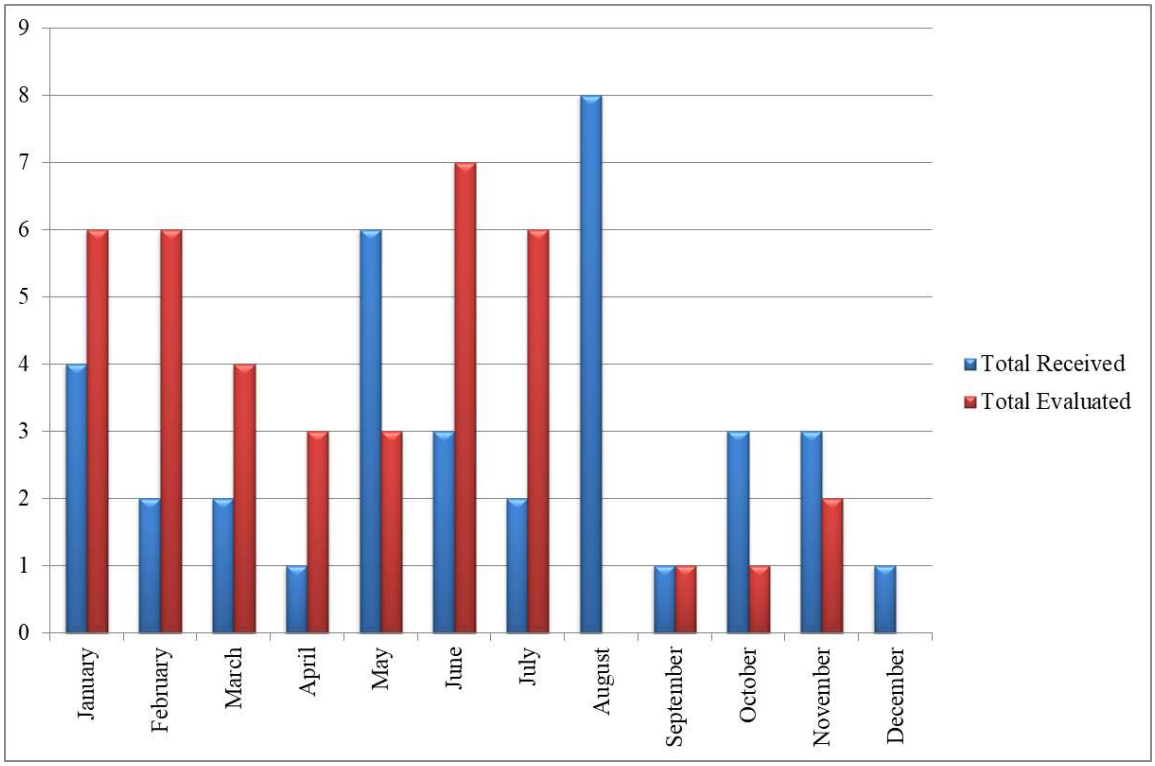


2.2.3 Borderline Product Regulatory Division

Registration Applications

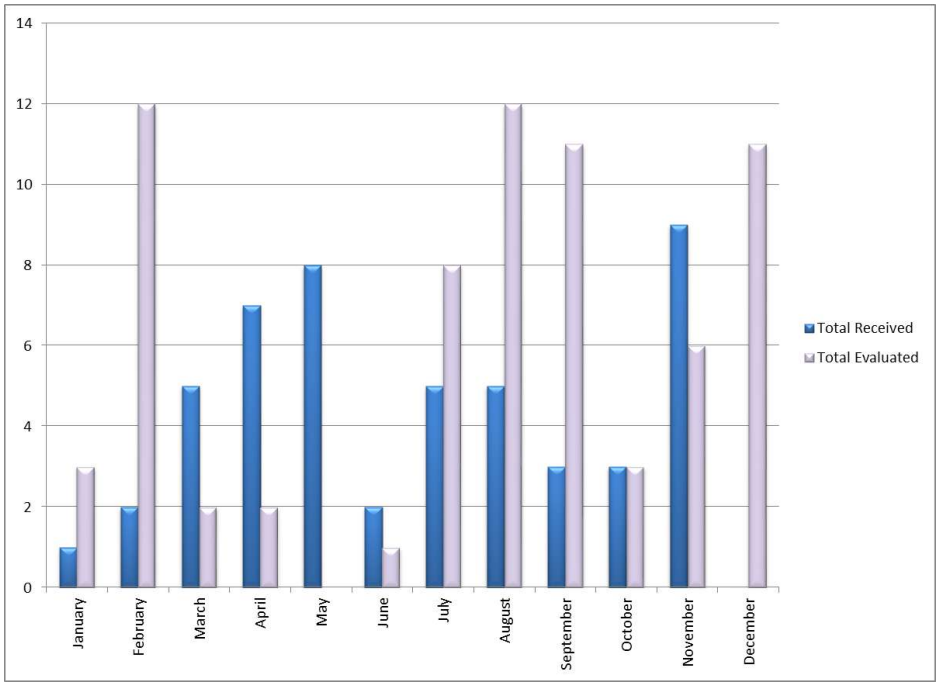
New Applications

Month	Total Received	Total Evaluated
January	04	06
February	02	06
March	02	04
April	01	03
May	06	03
June	03	07
July	02	06
August	08	-
September	01	01
October	03	01
November	03	02
December	01	-
Total	**36**	**39**



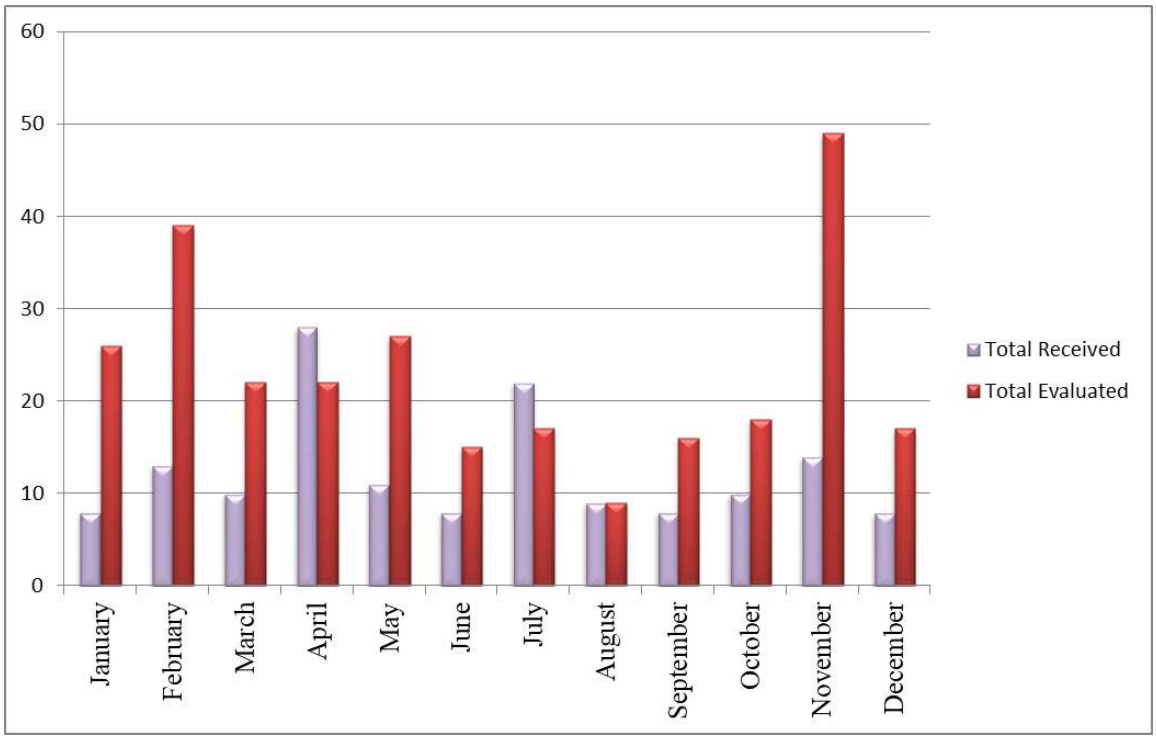
Additional Applications

Month	**Total Received**	**Total Evaluated**
January	01	03
February	02	12
March	05	02
April	07	02
May	08	-
June	02	01
July	05	08
August	05	12
September	03	11
October	03	03
November	09	06
December	-	11
Total	**51**	**71**



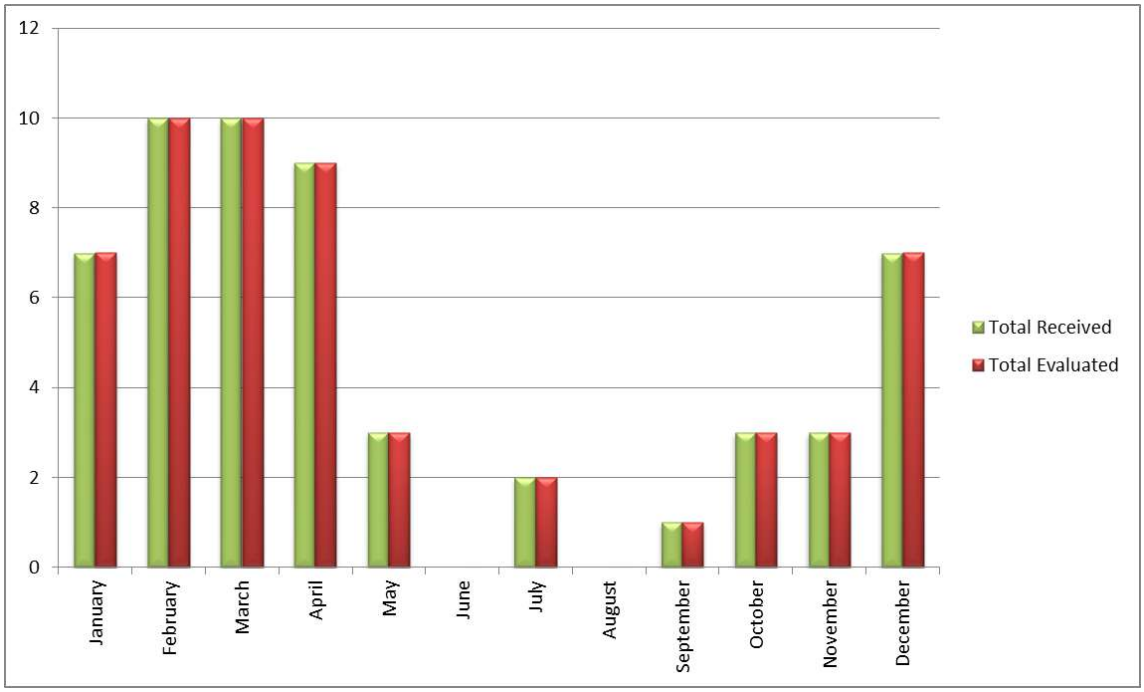
Classification Applications

Month	Total Received	Total Evaluated
January	08	26
February	13	39
March	10	22
April	28	22
May	11	27
June	08	15
July	22	17
August	09	09
September	08	16
October	10	18
November	14	49
December	08	17
Total	149	255



Sample License

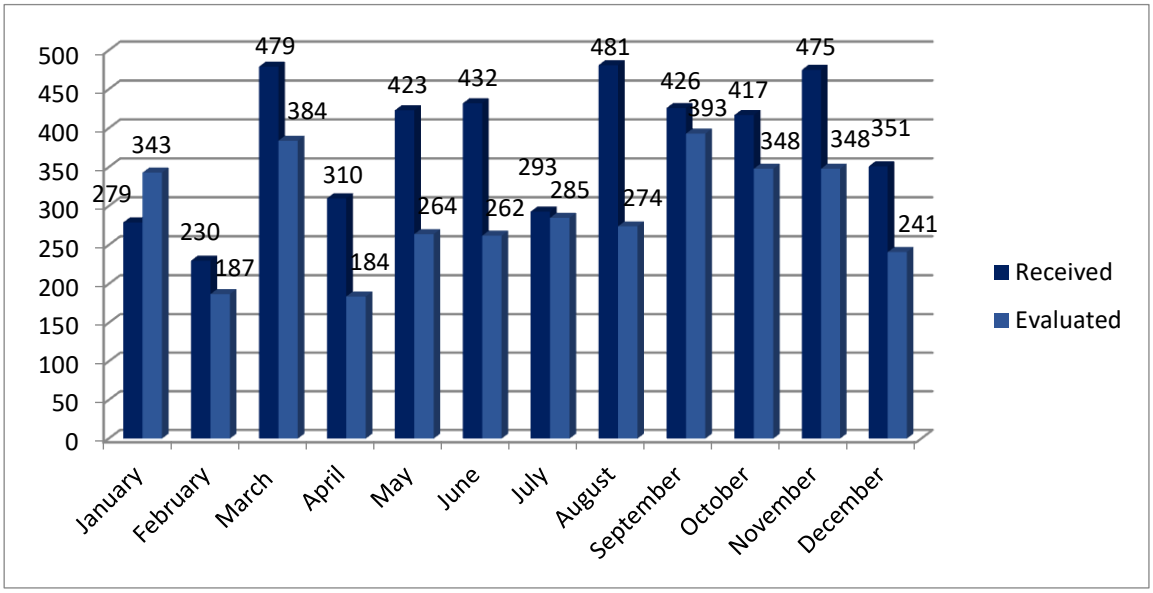
Month	**Total Received**	**Total Evaluated**
January	07	07
February	10	10
March	10	10
April	09	09
May	03	03
June	-	-
July	02	02
August	-	-
September	01	01
October	03	03
November	03	03
December	07	07
Total	**55**	**55**



Comparison between the received & evaluated sample license via bar chart

2.2.4 Cosmetic Regulatory Division

Month (2023)	New		Additional		RR		Sample Licence	
	Received	**Evaluated**	**Received**	**Evaluated**	**Received**	**Evaluated**	**Received**	**Evaluated**
January	183	206	65	78	0	1	31	58
February	95	80	105	75	8	0	22	32
March	152	129	201	86	22	14	104	0
April	64	51	226	54	8	0	12	79
May	122	105	236	83	5	12	60	64
June	140	111	177	73	8	8	107	70
July	63	143	131	60	3	3	96	79
August	192	100	200	88	6	2	83	84
September	271	102	68	134	4	5	83	152
October	220	131	105	178	3	8	89	31
November	267	147	124	147	3	1	81	53
December	187	91	90	96	5	0	69	54
Total	**1956**	**1396**	**1728**	**1152**	**75**	**54**	**837**	**756**



2.2.5 Manufacturing Regulatory Division (MFRD)

GMP audit of local manufacturing sites		
Category	**Number of Requests**	**Number of Inspections**
Medicine manufacturers	32	44
Medical devices manufacturers	21	19
Cosmetics manufacturers	38	41
Re-packing	01	01
Total	92	105

GMP audit of overseas manufacturing sites (all medicine manufacturers)			
Number of Requests	**Teams approved**	**Approval pending**	**Inspections conducted**
13 (July of 2023)	13 (July of 2023)	00 (July of 2023)	15 (January-December 2023)

Applications for Approval of Foreign Manufacturing Site		
Application type	**Received**	**Evaluated**
New	47	45

Applications for formulation approval				
Received	**Approved By MEC**	**Rejected By MEC**	**Evaluated**	**Pending**
879	648	22	553	85

	GMP certificates	**CPPs**	**Free Sales Certificates**
Requests	40	50	139
Issued	38	50	139
Pending	02	00	00

Manufacturing license for products

1. Number of applications received - 785
2. Recommended and forwarded for typing - 784

GMP Certificates Extension

1. Number of applications received - 15
2. Number of extend GMP certificates - 15

Miscellaneous Activities

Activity	**Requests**	**Letters issued**	**Pending**
Issuing of clarification letters	653	634	12-Payment pending
Recommendations for VAT/PAL exemption	752	751	00
Issuing of export approval letters	08	07	01-Payment pending

Training

1. PIC/S Seminar on Soft Skills that Make a Good GMP/GDP Inspector in 2023, which will be on 08-10 November,2023 Bangkok, Thailand organized by Thai FDA, the organizer of PIC/S
2. The Sri Lanka Pharmaceutical Manufacturers' Association (SLPMA) organized GMP training on 18-19 0f July 2023
3. Educational program on GMP inspection will be held on Monday the 15th of May 2023 NDQAL auditorium, from 9.30 a.m. onwards by MFRD

2.2.6 Pricing Unit

Achievements

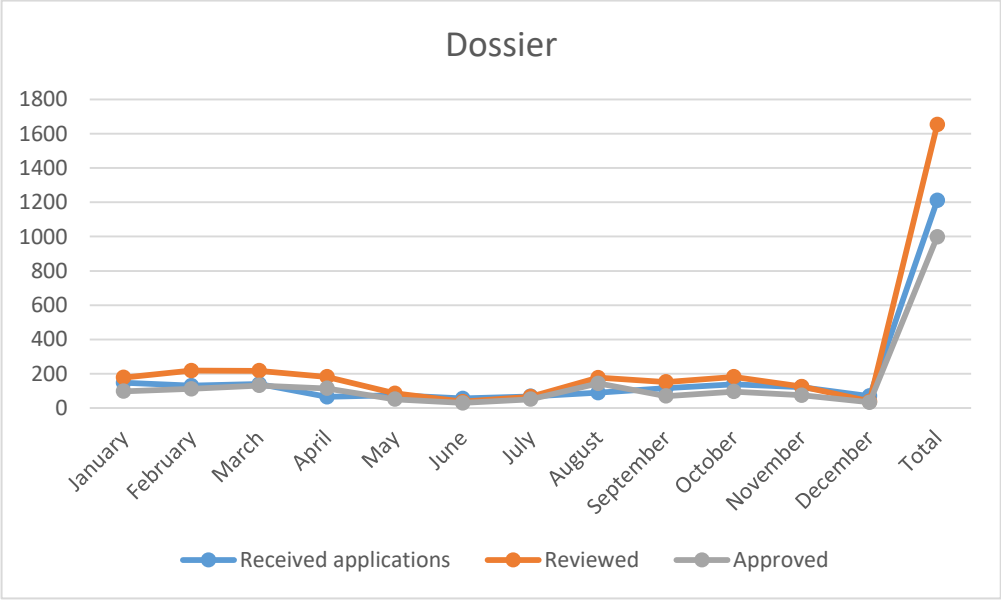
1. Enhanced transparency and accountability in pricing mechanisms achieved through the implementation of updated regulations.
2. Facilitated efficient pricing evaluations.
3. Strengthened stakeholder engagement and collaboration, fostering open dialogue and cooperation for effective pricing regulation.

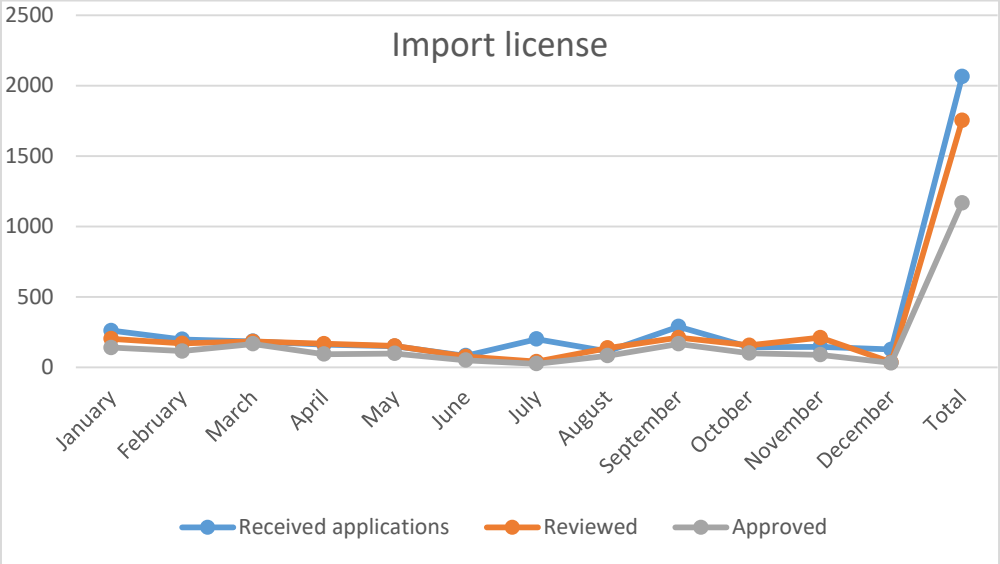
Details of committees conducted from January 2023 to December 2023

Committee name	Number of committees conducted from January –December of 2023
Pricing sub committees	36
Pricing Committees	07
Special committees with Stake holders	06

Details applications reviewed by pricing division

Dossiers													
	January	February	March	April	May	June	July	August	September	October	November	December	Total
Received applications	147	130	139	65	74	55	67	89	115	138	122	69	**1210**
Reviewed	178	218	217	181	85	37	66	177	151	181	124	38	**1653**
Approved	97	111	131	114	51	29	51	143	69	95	74	33	**998**
Negotiation Going on													**212**
Import License													
	January	February	March	April	May	June	July	August	September	October	November	December	**Total**
Received applications	262	199	185	162	150	83	201	114	290	143	147	128	**2064**
Reviewed	204	171	184	168	152	78	41	138	212	157	211	37	**1753**
Approved	141	116	167	94	99	51	26	83	167	101	90	32	**1167**
Negotiation Going on													**462**



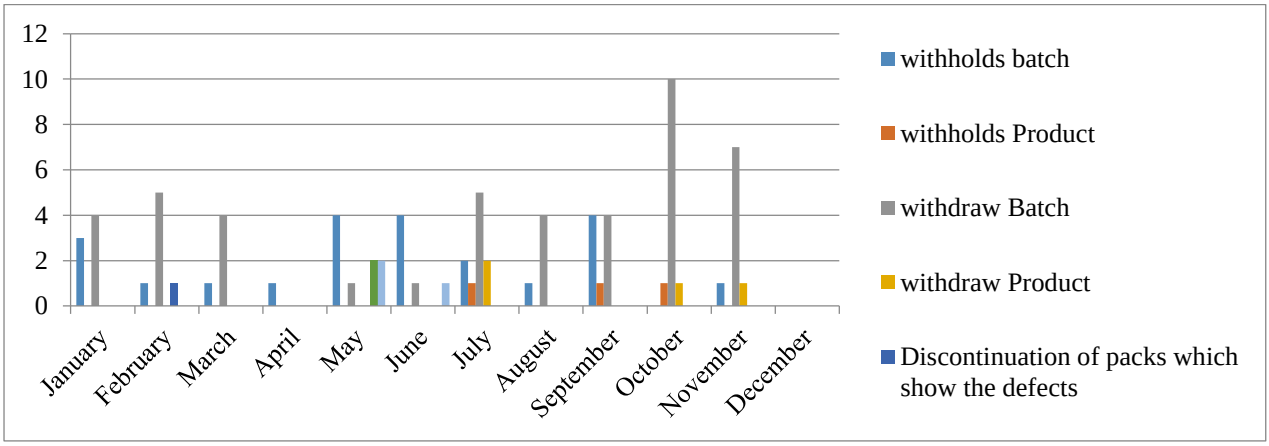


2.2.7 Pharmacovigilance division

Management of Quality Defective medicines

The Pharmacovigilance division issued notifications of Withdrawal and Withholdings of the batch/batches/product of the Pharmaceuticals based on the recommendation of D/NMQAL, SAFRESC or Recall Management Committee. The table given below is indicated number of batches, product undergone for withholding, and withdrawal in 2023. As well as voluntary recalls initiated by the manufacturers and discontinuation of use of defective packs have been conveyed to the stakeholders on time.

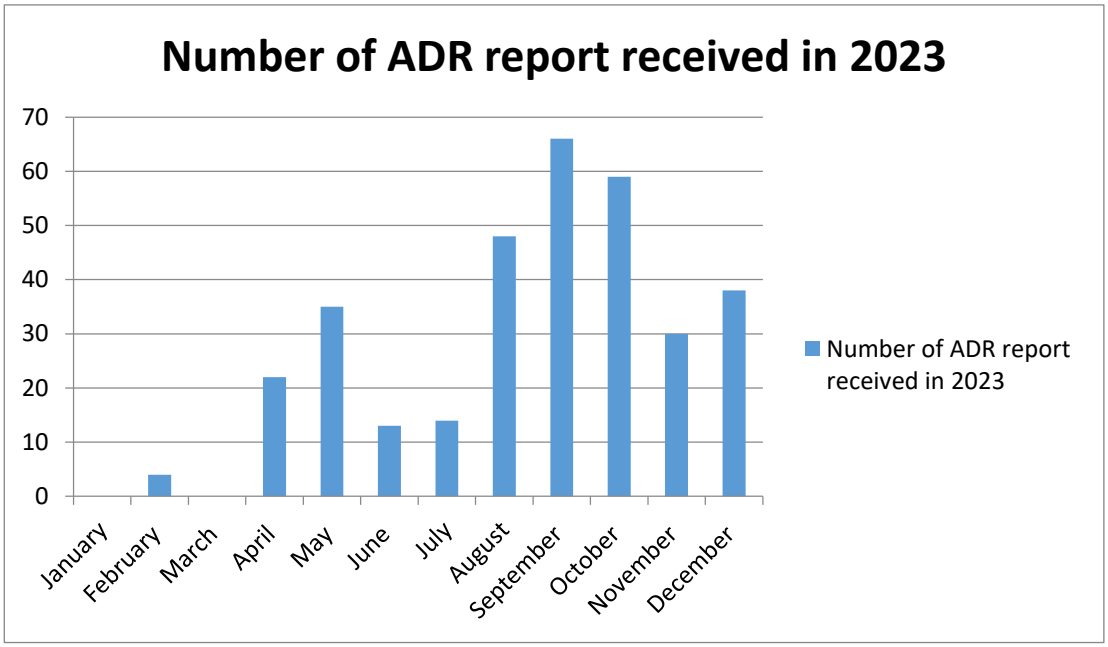
Month	withhold		withdraw		Discontinuation of packs which show the defects	Voluntary Recall		Revocation of decisions
	batch	Product	Batch	Product		batch	product	
January	3	NA	4	NA	NA	NA	NA	NA
February	1	NA	5	NA	1	NA	NA	NA
March	1	NA	4	NA	NA	NA	NA	NA
April	1	NA	NA	NA	NA	NA	NA	NA
May	4	NA	1	NA	NA	2	2	NA
June	4	NA	1	NA	NA	NA	1	NA
July	2	1	5	2	NA	NA	NA	NA
August	1	NA	4	NA	NA	NA	NA	NA
September	4	1	4	NA	NA	NA	NA	NA
October	NA	1	10	1	NA	NA	NA	NA
November	1	NA	7	1	NA	NA	NA	NA
December	NA	NA	NA	NA	NA	NA	NA	NA



Adverse reaction reporting system

1. Majority of the ADR reports were received to the Pharmacovigilance Division manually. In 2023, the online reporting system created in the NMRA website was upgraded and the government pharmacists were informed to use online system to submit ADR report efficiently.
2. What's Up group was created for Safety and Risk Evaluation Subcommittee and it was remarkably improve the communication in between committee members.
3. Falsified products in the government sector were identified though the adverse reaction reporting and immediately action was taken to withdraw the identified falsified products.
4. The officers who have being worked with the pharmacovigilance Division did not have access to the VigiFlow of Uppsala Monitoring Centre. It was taken access to the VigiFlow in 2023 for all staff involve in Pharmacovigilance Division
5. The access to the WHO Global Surveillance and Monitoring System (GSMS) were created and initiated to upload details of substandard and falsified medicines to the GSMS.
6. Progress of ADR reporting to the Pharmacovigilance Division

Month	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**June**	**July**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
Number of ADR received	0	4	0	22	35	13	14	48	66	59	30	38



Total number of meeting coordination

1. Recall Management Committee meetings = 7
2. Safety and Risk Evaluation Subcommittee = 9

2.2.8 Clinical Trials division

1. Number of meetings for Clinical Trials Evaluation Committee(CTEC) held: 11

   Target: Minimum 10 meetings per year (target achieved)
2. Summary of clinical trial applications submitted for review

   Total number of applications received from 01.01.2023 to 31.12.2023 : 06

   Number of trial applications on Investigational New Drugs (INDs) : 03

   *Total number of applications reviewed for year 2023 : 07

   *Includes 01 application carried over from year 2022

   Total number of applications on which decisions were pending : 01

Clinical trial applications according to the type of the investigational product

Type of product	Approved	Not approved	Pending	Other	Total
Medicine	5	1	1	-	7
Medical device	-	-	-	-	-
Borderline product	-	-	-	-	-
Total	**5**	**1**	**1**	**-**	**7**

Time taken to review

NMRA reference number	Application received date	Date of letter notifying the decision	Time for final decision (with stop-clocks)	Remarks
CTM/031/2023	12.01.2023	13.06.2023	152 days	-
CTM/032/2023	09.02.2023	05.01.2024	330 days	-
CTM/033/2023	20.03.2023	10.10.2023	203 days	-
CTM/034/2023	20.07.2023	07.03.2024	229 days	-
CTM/035/2023	10.08.2023	09.01.2024	151 days	
CTM/036/2023	04.10.2021	-	-	Pending

Average time for review* : 213 days

3. Number of sample licenses issued – 148

4. Training/ workshops
   Participate to PMDA-MRCT seminar in Tokyo, Japan

2.2.9 Pharmacy Regulatory division

Retail Pharmacy 2023			
Types Of Applications	**Received Amount**	**Issued Licence**	**Under regulatory Review**
New (RPN/2023) Applications	519	125	394
Retail Pharmacy Renewal Applications (RPR)	3017	2901	116
Total	**3536**	**3026**	**510**

Wholesale Establishment 2023			
Name Of Applications	**Received Amount**	**Issued Licence**	**Under regulatory Review**
New (WEN/2023) Applications	79	34	45
Wholesale Establishment Renewal Applications (RPR)	594	519	75
Total	**673**	**553**	**120**

2.3 Progress of Inspectorate and Enforcement Division

Appearances at Magistrate Courts

Officer	No of appearances	No of cases handled		Convicted cases	Fines imposed Rs	Paper notice
		New	Pending			
Total	91	80	185	43	1,610,900.00	05

Raids conducted **- 13**

Number of places inspected -32

Number of items seized -105

Recommendation of Drug Transport Licenses

	Type of vehicle					
	Car		Van		Freezer truck	
	No. checked	No. recommend	No. checked	No. recommend	No. checked	No. recommend
Total	1025	874	92	80	106	102

Number of Pharmacies inspected (routine) - 105

Location inspection - 45
Renewals - 41
Re-location - 08

Number of complaints received - 54
No referred to relevant RDHS offices -17
Number solved - 12
Number to be solved -25
Number of various meetings attended by C-FDI -38
FDI 1 -22

Number of destructions supervised -36
Number of final checking of files by FDII (Retail/W. S/Transport) - 1563

Number of samples obtained for analysis -39
Number of consultations with Snr. State Counsels-09
Number of quality failure circulars received -26

Number of Awareness programmes represented -02
Number of participants attended -209

2.4 Progress of Finance Division

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

In addition to this, the Finance Division has been able to establish strong partnerships with relevant stakeholders such as the Ministry of Health, External Audit and other government agencies. This collaboration has allowed for better information sharing and best practices, contributing to the continuous improvement of the sector.

Progress

1. Effective utilization of income to achieve organizational objectives
2. Completion of taking over vehicles given by the Presidential Secretariat to the Authority
3. Completion of Annual Good Survey.
4. Submission of Annual Reports.
5. Purchase and installed a new Server Computer and updating the accounting system (Quick Books).

Plans for the future

1. Planning to carry out the annual goods condemning
2. Making plans to update all records

2.5 Progress of HR and Administration Division

Cadre Information as at: 2023.12.31

Designation	Salary code	Service Level	DMS Approved Cadre	Existing cadre				
			Permanent	Permanent	Contract	Secondment	Ministry of Health employees	Multi Task Force
Director Genaral/Chief Executive Officer	HM 2-1-2016	1	1	-	-	-	-	-
Director (Regulatory)	HM 1-1-2016	1	1	-	-	-	-	-
Director (NMQAL)	HM 1-1-2016	1	1	-	-	-	-	-
Director (Legal)	HM 1-1-2016	1	1	-	-	-	-	-
Director (HR and Admin)	HM 1-1-2016	1	1	-	-	-	-	-
Director (Finance)	HM 1-1-2016	1	1	-	-	-	-	-
Medical Officer	MM 1-3-2016	1	2	-	-	-	-	-
Bio Medical Engineer	MM 1-1-2016	1	2	-	-	-	-	-
Pharmaceutical Analyst	MM 1-1-2016	1	20	-	-	-	6	-
Asst. Director/Deputy Director (HR and Admin)	MM 1-1-2016	1	1	-	-	-	-	-
Asst. Director/Deputy Director (ICT)	MM 1-1-2016	1	1	-	-	-	-	-
Accountant	MM 1-1-2016	1	1	1	-	-	-	-
Cost Accountant	MM 1-1-2016	1	1	-	-	-	-	-
Internal Auditor	MM 1-1-2016	1	1	-	-	-	-	-
Pharmaceutical Assessor	MM 1-1-2016	1	25	20	-	-	-	-
Asst. Pharmaceutical Assessor	JM 1-1-2016	2	50	20	-	-	-	-
Asst. Pharmaceutical Analyst	JM 1-1-2016	2	25	-	-	-	-	-
ICT Officer	JM 1-1-2016	2	1	-	-	-	-	-
Procurement Officer	JM 1-1-2016	2	1	-	-	-	-	-
Administrative Officer	JM 1-1-2016	2	1	1	-	-	-	-
Personnel Asst.	JM 1-1-2016	2	2	-	-	-	-	-
Pharmacist	-		-	-	-	-	7	-
Asst. Drug Inspector	MA 5-1 2016	2	10	-	-	-	2	-
Development officer	MA 3- 2016	3	5	5	-	-	-	-
Data Management Officer	MA 3- 2016	3	5	-	-	-	-	-

Tech. Officer (Civil/Transport)	MA 2-2-2016	3	1	-	-	-	-	-
ICT Assistant	MA 2-1-2016	3	3	-	-	-	-	-
Management Assistant	MA 1-1-2016	3	53	38	-	-	-	-
Driver	PL 3-2016	4	10	5	-	-	1	-
Maintenance Asst.	PL 2-2016	4	2	-	-	-	-	-
Plumber	PL 2-2016	4	1	1	-	-	-	-
Electrician	PL 2-2016	4	1	1	-	-	-	-
Lab Assistant	PL 2-2016	4	8	-	-	-	-	-
K.K.S	PL 1-2016	4	30	25	-	-	-	-
Total			**269**	**117**	**-**	**-**	**16**	**-**

** Note

1. A Pharmaceutical Analyst had been appointed as acting Director General/ Chief Executive Officer
2. A Pharmaceutical Analyst had been appointed as acting Director (NMQAL)

Service Level	Approved Cadre	Existing Cadre
Senior	60	27
Tertiary	90	30
Secondary	67	43
Primary	52	33
Total	**269**	**133**

Recruitment Details for the year 2023

Position	**Number of positions filled**
Pharmaceutical Assessor	21
Driver	01
Electrician	01
Plumber	01
Karyala Karya Sahayaka	02
Total	**26**

Other activities

1. Identify the necessities of staff of the Authority to restructuring the positions of the Authority and getting approval from the Department of Management Services.
2. Established a welfare Society.
3. Bonus payment to all employees as per the PED circular
4. Issued service letters and miscellaneous letters, cadre reports as requested by employees and other institutions.
5. Payment of Annual increment of Authority staff and recommend annual increment of ministry staff.

Total License Issued for the Year 2023

No	Category		Total
1	Medicines	Sample License	849
2		Registration Certificates	1506
3		Import License	3377
4		Manufacturing License	631
5	Medical Device	Sample License	991
6		Registration Certificates	1749
7		Import License	4169
8		Manufacturing License	104
9	Cosmetic	Sample License	696
10		Registration Certificates	2658
11		Import License	4704
12		Manufacturing License	848
13	Borderline Products	Sample License	25
14		Registration Certificates	43
15		Import License	83
16		Manufacturing License	6
	TOTAL		**22439**

2.6 Progress of Legal Division

01. Total Opening Files from 21.04.2017 up to 31.12.2023	1530
02. Number of opening files in year 2023	199
03. Total Closed files 2023 (01.01.2023 Up to 31.12.2023)	221
04. Agency Transfer Closed Files (01.01.2023 up to 31.12.2023)	
Number of Free of charges files from (01.01.2023 – 31.12.2023)	5
Number of Payment Basic files from (01.01.2023 – 31.12.2023)	111
Total	116
05. Total Closed Files from 21.04.2017 up to 31.12.2023	1242
06. Total Pending Files Up to 31.12.2023	300
07. Agency Transfer Total Income (From 01.01.2023 – 31.12.2023)	Rs. 85,243,187.65/-
08. Right to Information Act	
Number of applications received (From 01.01.2023 – 31.12.2023)	27
Number of applications closed (From 01.01.2023 – 31.12.2023)	24
09. Pending Court Cases (up to 31.12.2023) – Filed by the NMRA	04
10. Pending Court Cases (up to 31.12.2023) – Filed against the NMRA	17

Regulations/ Gazettes issued under the NMRA Act from 01.01.2023 to 31.12.2023.

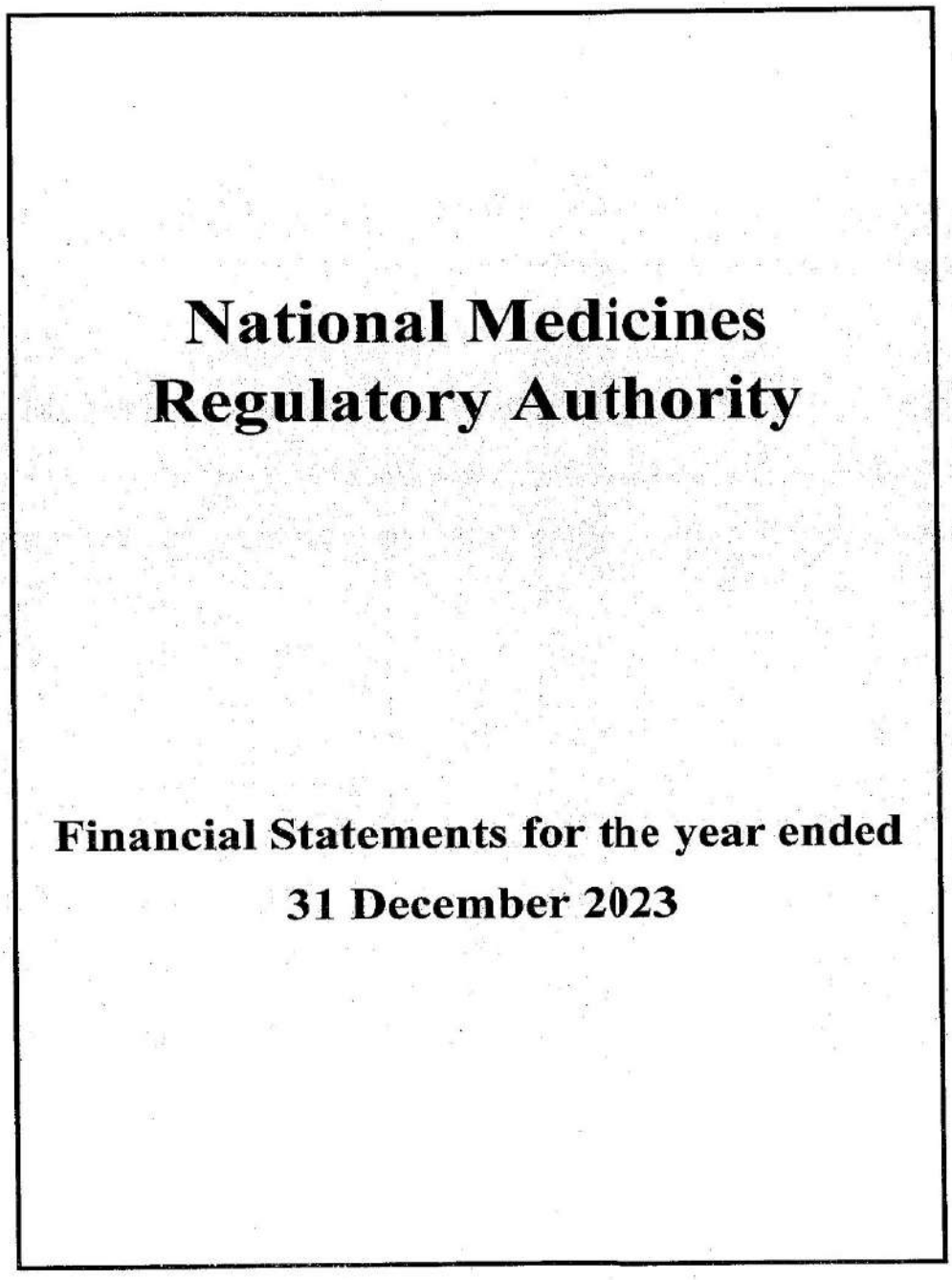
No.	Gazette No	Gazette Name & Description
01	2336/53- 2023.06.15	The Medicines (Ceiling on Prices) Regulations, 2019 published in the Gazette Extraordinary No. 2123/35 of May 15, 2019, as amended by regulations published in Gazette Extraordinary No. 2241/43 of August 19, 2021 and regulations published in Gazette Extraordinary No. 2271/23 of March 15, 2022 and regulations published in the Gazette Extraordinary No. 2277/55 of April 29,2022.

2.7 Progress of ICT Division

1. Started repairing the minor hardware issues in computers by the division.
2. Keeping the website of the NMRA up to date.
3. Started maintaining an index and proper filing system within the ICT division.
4. Took actions in changing the internet service provider in order to provide an unhindered internet connection to the NMRA Staff.
5. Adding printers to the network so the staff can share printers within the divisions.
6. Introduced a procedure for the importers and manufacturers to fill a form before coming to submit a dossier, hence making it easier for the employees in accepting dossiers.

Chapter - 3

Overall Financial Performance


National Medicines
Regulatory Authority

Financial Statements for the year ended
31 December 2023

NATIONAL MEDICINES REGULATORY AUTHORITY
STATEMENT OF FINANCIAL POSITION

As at 31 December,	Note	2023	2022 Restated Rs.
Assets			
Non current assets			
Property, plant and equipment	1	67,588,806	93,422,394
Total non current assets		**67,588,806**	**93,422,394**
Capital Working Progress	4	**3,181,869**	
Non Current Assets			
Distress Lone Balance		**9,324,030**	**8,883,610**
Staff Lone Balance		**12,066,185**	
Current assets			
Inventory	2	**14,206,534**	14,179,700
Tresury Bills and Bonds	5	**1,300,000,000**	
Deposits and other receivable	3	**126,152,777**	19,906,528
Fix Deposits			2,750,000,000
Cash and cash equivalents	6	**6,050,322,406**	2,515,746,487
Total current assets		**7,490,681,717**	**5,299,832,715**
Total assets		**7,582,842,607**	**5,402,138,719**
Equity and liabilities			
Equity			
Accumulated Fund		**5,677,570,844**	4,498,490,257
Capital Gain		**64,275,375**	64,275,375
Gov Grant		**5,920,019**	5,920,019
Total equity		**5,747,766,238**	**4,568,685,651**
Non Current liabilities			
Deferred tax	7	5,515,675	2,638,603
Provision for Gratuity	8	5,923,533	4,697,071
Total non current liabilities		**11,439,207**	**7,335,674**
Current liabilities			
Advance receipts	9	**10,887,763**	100,593,163
VAT payable	10	**21,363,694**	33,810,117
Stamp duty payable	11	**11,519,770**	11,960,316
Provision for Treasury levy	12	**880,283,892**	645,817,300
Accrued expenses and other payables	13	**26,232,641**	22,953,627
Provision for Income tax	21.2	**873,349,402**	10,982,871
Total current liabilities		**1,823,637,162**	**826,117,394**
Total equity and liabilities		**7,582,842,607**	**5,402,138,719**

* Capital Grant which was stated under Non Current Liabilities previous year was reclassified under Equity in the year under review.

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 Auth
No. 120, Norris Canal Road,
Colombo 10

We confirm that we are responsible for the fair presentation in the financial statements of financial position, results of operations, and cash flows in conformity with Sri Lanka Accounting Standards.

Dr. Ananda Wijewickrama
Chairman

Dr Saveen Semage
Chief Executive Officer

..... 2024

Chairman
National Medicines Regulatory Authority
No. 120, Norris Canal Road,
Colombo 10.

Dr. Saveen Semage
MBBS, MSc, MD
Chief Executive Officer
National Medicines Regulatory Authority

2

NATIONAL MEDICINES REGULATORY AUTHORITY
STATEMENT OF COMPREHENSIVE INCOME

For the year ended 31 December,	Note	2023	2022 Rs.
Revenue	14	2,160,659,839	2,041,175,151
Interest income	15	1,046,122,324	397,823,366
Other income	16	73,567,521	539,664
Administrative expenses	17	(179,078,653)	(145,429,428)
Salaries and wages	18	(145,391,163)	(126,232,660)
Other expenses	19	(21,600,227)	(15,151,757)
Provision for treasury levy			**(645,817,300)**
Net income before taxation		**2,934,279,641**	**1,506,907,036**
Income tax for the year	20.1	**(982,684,577)**	**(212,482,517)**
Net income after taxation		**1,951,595,064**	**1,294,424,519**

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

3

National Medicins Regulatoty Authority

Statement of Changes in net Assets/ Equity

For the Ended December 31 2023

	Gov Grant	Capital Gain	Accumulated Fund
Balance as at December 2021	5,920,019	64,275,375	2,994,730,451
Priear year adjustment			209,335,287
Tresurry Levy			
Net surplus/(deficit) for the period			1,294,424,519
Balance as at 31 December 2022	5,920,019	64,275,375	4,498,490,257
Restate Balance 01 January 2023	**5,920,019**	**64,275,375**	**4,498,490,257**
Priear year adjustment			31,759,725
Adjustment			76,009,690
Tresurry Levy			(880,283,892)
Net surplus/(deficit) for the period			1,951,595,064
Balance as at 31 December 2023	**5,920,019**	**64,275,375**	**5,677,570,844**

NATIONAL MEDICINES REGULATORY AUTHORITY
STATEMENT OF CASH FLOW

As at 31 December,	2023 Rs.	2022 Rs.
Cash Flows from Operating Activities		
Net income before taxation	2,869,057,208	2,152,724,335
Adjustment for :		
Depreciation	34,442,701	34,756,957
Interest income	(983,204,960)	(346,780,651)
Gratuity Provision	5,923,533	2,031,998
Prior year adjustment	(13,132,282)	(26,639,894)
Operating Profit before Working Capital Changes	**1,913,086,200**	**1,816,092,745**
Changes in items of working capital		
(Increase)/Decrease in Inventory	(26,834)	(12,232,616)
(Increase)/Decrease in Deposits and other receivable	(46,091,657)	(3,345,113)
(Increase)/Decrease in Advance receipts	(89,705,400)	13,407,651
(Increase)/Decrease in VAT payable	(12,446,423)	(18,653,602)
(Increase)/Decrease in Stamp duty payable	(440,546)	(18,339,572)
(Increase)/Decrease in Provision for treasury levy		-
(Increase)/Decrease in Accrued expenses and other payables	3,279,014	(78,374,880)
Cash generated from operations	**(145,431,846)**	**(117,538,132)**
Tresury levy paid	(645,817,301)	(400,000,000)
Tax Paid	(117,440,975)	(151,836,233)
Gratuity Paid	-	(169,625)
	(763,258,276)	**(552,005,858)**
Net Cash from /(Used in) Operating Activities	**1,004,396,078**	**1,146,548,755**
Cash flows from investing activities		
Acquisition of Property plant and equipment	(9,288,049)	(13,778,676)
Investment in T/bills and bonds	-	(1,599,999,928)
Investment in T/bills Mturity	1,189,685,600	1,346,823,249
Invested in FD	(3,190,000,000)	(2,750,000,000)
Interest income from T/bills and bonds	948,055,478	346,780,651
Adjustment	66,584,309	
Net Cash from Investing Activities	**(994,962,662)**	**(2,670,174,704)**
Net increase/ decrease in Cash & cash equivalents	9,433,416	(1,523,625,949)
Cash and cash equivalents at the beginning of the year	100,888,990	1,624,514,939
Cash and cash equivalents at the ending of the year	**110,322,406**	**100,888,990**

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS
For the year ended 31 December 2023

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 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 and pharmacies.

2. Basis of preparation

2.1 Statement of compliance

The financial statements have been prepared in accordance with Sri Lanka Accounting Standards (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 statement.

2.3 Basis of measurement

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

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 LKAS & SLFRS 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 following notes.

Retirement benefit obligation
Useful life time of the depreciable assets

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS
For the year ended 31 December 2023

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.

In the presentation of information in the financial statements, the information of the year 2022, 2023 and Amended 2023 has been presented.

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.

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 assets. The cost of self- constructed assets includes the cost of materials and direct labor, any other costs directly attributable to bring the assets to a working condition for its intended use. Purchased software that is integral to the functionally of the related equipment is capitalized as a part of the 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 areas follows.

Furniture & Fittings	05 years
Office Equipment	05 years
Computer Equipment	04 years
Filling 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.

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS
For the year ended 31 December 2023

3.1.4 De - recognition

The caring 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 de-recognition of an item of property, plant and equipment is included in profit or loss when item is DE- recognition.

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 instrument)
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 is 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 principle 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 short term investment.

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

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS
For the year ended 31 December 2023

3.5 Inventories

Inventories are recognized at cost and net realizable value, whichever is lower after making due allowance for absolute 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 for in preparing the 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

Provision will be made in the financial statement for retiring gratuities after the completion of one years continued services of employees.

In accordance with the Gratuity Act No. 12 of 1983, payment of retirement gratuity is made to employees after completion of five years of continuous service.

3.8 Trade and other payables

Trade and other payables are stated at their cost.

3.9 Revenue

3.9.1 Services

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

3.9.2 Interest Income

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

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS
For the year ended 31 December 2023

3.10 Government Grant

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 assets.

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

Transactions 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.

Monitory 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 operating cash flows for the purpose of presenting the cash flow statement.

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS
For the year ended 31 December 2023

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 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,31/12/2023

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.	Vehicle Rs.	Total Rs.
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
Balance as at 01 January 2023	15,257,976	114,953,047	13,084,081	20,366,336	20,826,653	7,051,280		191,539,373
Additions during the year	-	-		5,731,180	375,000			6,106,180
Balance as at 31 December 2023	15,257,976	114,953,047	13,084,081	26,097,516	21,201,653	7,051,280	-	197,645,554
Accumulated depreciation								
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
Balance as at 01 January 2023	15,257,976	51,437,138	6,249,287	10,432,317	12,078,336	2,661,925		98,116,979
Charge for the year	-	21,428,551	2,295,525	3,508,296	3,198,541	1,706,720		32,137,632
Adjustment				(197,864)				(197,864)
Balance as at 31 December 2023	15,257,976	72,865,690	8,544,811	13,742,748	15,276,877	4,368,645	-	130,056,747
Carrying value								
As at 31 December 2023	**(0)**	**42,087,357**	**4,539,270**	**12,354,768**	**5,924,776**	**2,682,635**	-	**67,588,806**

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

For the year ended 31 December,		2023 Rs.	2022 Rs.
2	**Inventory**		
	Opening Inventory	14,179,700	1,947,084
	Purchased for year	5,764,015	16,421,587
		19,943,715	18,368,671
	Consumption	5,737,182	4,188,970
	Closing Inventory	14,206,533	14,179,700
3	**Deposits and other Receivable**		
	Deposit for Fuel	300,000	100,000
	Other Receivables	50,000	50,000
	Prepayments	797,033	2,288,578
	Festival Advance	8,750	
	Advance Receivables	13,500	100,000
	Building Rent	1,560,094	14,512,500
	Distress Loan Receivable	3,173,370	2,752,200
	Deposit for Drinking water	327,250	103,250
	NMRA Staff Loan Receivable	3,460,293	
	Investment Interest Receivable	116,462,487	
	Total deposits and prepayments	**126,152,777**	**19,906,528**
4	**Capital Working Progress**		
	Corporate Line	3,181,869	
		3,181,869	
5	**Investments - Bonds**		
	Opening Balance	**1,318,820,656**	
	Adjustment on Audit Quary	(18,820,656)	
		1,300,000,000	
	Treasury Bills		
	Opening Balance	1,096,036,841	2,141,652,055
	Invest for the Year	-	1,599,999,928
	Receivable Interest for the year	92,491,542	366,809,414
	Maturity Investment	(1,189,985,600)	(1,693,603,900)
	Adjustment on Audit Quary	76,009,690	
	Adjustment on Audit Quary	(74,552,473)	
		(0)	2,414,857,497
6	**Cash and cash equivalents**		
	BOC Current and Savings Account(ZIBA)	110,322,406	100,888,990
	Short term Investment	5,940,000,000	
	Total cash and cash equivalents	**6,050,322,406**	**100,888,990**

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2023 Rs.	2022 Rs.
7	**Deferred tax liability**		
	Accounting written down value of Property plant	67,588,805	93,422,394
	Tax base of Property plant and equipment	(49,203,222)	(74,575,231)
	Taxable Temporary deference	18,385,583	18,847,163
	Tax	5,515,675	2,638,603
	Deferred Liability at the end of the year	5,515,675	2,638,603
	Deferred Liability as at beginning of the year	(2,638,603)	(13,488,345)
	Adjustment for after applied currect rates		10,416,052
	Charge as deferred tax during the year	**2,877,072**	(433,690)

		2023 Rs.	2022 Rs.
8	**Provision for Gratuity**		
	Opening Balance	4,697,072	2,834,700
	Expence for the year	1,226,460	2,031,997
	Paid Amount		(169,625)
	Provision for the year	**5,923,533**	**4,697,072**

		2023 Rs.	2022 Rs.
9	**Advance receipts**		
	Fees received in advance		72,972,666
	Deposit to be Classified	7,583,570	25,420,629
	Over Payment	3,304,193	2,199,867
	Total advance receipts	**10,887,763**	**100,593,163**

		2023 Rs.	2022 Rs.
10	**VAT payable**		
	Opening Balance	33,810,117	52,463,719
	VAT for the year	324,415,133	248,225,346
	Input VAT for the year	(7,248,277)	(4,144,228)
	Other Adjustment		
	Paid for the year	(329,613,279)	(262,734,720)
	VAT Payable	**21,363,694**	33,810,117

11	**Stamp duty payable**		
	Opening Balance	11,960,316	30,299,888
	Stamp Duty for the year	40,727,136	36,373,220
	Paid for the year	(41,167,681)	(54,712,792)
	Stamp duty payable	**11,519,770**	11,960,316

12	**Provision for Treasury levy**		
	Net income before taxation	2,934,279,641	2,152,724,336
	Provision 30% for year	880,283,892	645,817,301
	Opening Balance	645,817,300	400,000,000
	Paid for the year	(645,817,300)	(400,000,000)
	Tresury Levy Payable	**880,283,892**	**645,817,300**

14

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2023 Rs.	2022 Rs.
13	**Accrued expenses and other payables**		
	Accounts Payables	8,823,034	7,108,861
	Accrued expenses	7,909,366	5,088,990
	Other Payables	3,787,896	2,185,893
	Retention Deposit	215,219	142,304
	EPF Payable	13,803	10,080
	ETF Payable	2,070	1,512
	Bank TFR - Sal. Payable	500	
	Bank TFR - Sal. Payable	102,136	74,343
	Audit Fees Payable	1,260,000	1,248,000
	Committees & Evaluation Payable	47,475	47,475
	Contribution for MOH Staff Salary	4,071,142	7,046,169
	Total Accrued expenses	**26,232,641**	**22,953,627**

		2023 Rs.	2022 Rs.
14	**Revenue**		
	Drug Sample import License Income	29,236,592	20,259,036
	Device Sample import License Income	33,886,539	28,837,583
	Cosmetic Sample import License Income	264,200	330,900
	Borderline Sample import License Income	1,034,281	1,260,123
	Drug Import License Income	115,959,436	107,404,406
	Device Import License Income	143,563,915	103,521,803
	Cosmetic Import License Income	9,103,000	8,157,000
	Borderline Import License Income	3,079,622	2,553,747
	Drug Manufacturing License Income A	23,847,646	20,746,583
	Drug Manufacturing License Income B	63,335	109,426
	Device Manufacturing License Income A	2,446,599	1,794,620
	Device Manufacturing License Income B	694,273	709,296
	Cosmetic Manufacturing License Income	871,000	1,019,000
	BorderlineManufacturing License Income	204,784	57,012
	Drug Registration Income FR Local A	4,161,250	8,505,735
	Drug Registration Income FR Local B		218,306
	Drug Registration Income FR Foreign	113,477,722	201,813,637
	Drug Registration Income PR Local A	8,964,105	12,121,241
	Drug Registration Income PR Local B		
	Drug Registration Income PR Foreign	11,261,960	10,204,979
	Device Registration Income FR Local A	737,987	703,388
	Device Registration Income FR Local B	317,359	278,304
	Device Registration Income FR Foreign	108,098,249	127,916,234
	Device Registration Income PR Local A	592,954	610,705
	Device Registration Income PR Local B	141,078	501,992
	Device Registration Income PR Foreign	46,698,578	62,646,422
	Cosmetic Registration Income FR Foreign	2,700,000	2,016,500
	Cosmetic Registration Income FR Local	174,000	133,000
	Cosmetic Registration Income PR Foreign	5,574,000	7,232,000
	Cosmetic Registration Income PR Local	262,500	437,500
	Cosmetic Registration Income Renewal	67,500	35,000
	Borderline Registration Income FR Foreign	3,676,631	525,533
	Borderline Registration Income PR Foreign	1,163,076	2,767,179

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

Borderline Registration Income PR Local	130,485	57,012
Laboratory Test	22,660,321	15,353,144
Drug Processing Fees Local A	76,610,602	48,844,931
Drug Processing Fees Local B	288,249	-
Drug Processing MP Foreing	25,659,008	24,713,084
Drug Processing Combined	10,153,026	5,575,371
Drug Processing New Dosage	3,866,291	738,811
Drug Processing Foreing	197,572,351	209,814,180
Drug Processing Fees Renewal Local A	1,650,030	4,007,969
Drug Processing Fees Renewal Foreign	42,550,848	138,499,630
Drug Processing Fees Therapeutic	26,679,323	22,415,812
Drug Processing Fees NCE	3,043,866	8,016,605
Drug Processing Fees NCE int	11,355,941	3,212,559
Device Processing Fees Local A	4,663,162	2,676,033
Device Processing Fees Local B	1,521,143	753,151
Device Processing Fees MP Foreign	99,663,392	99,945,393
Device Processing Fees Foreign	230,813,613	171,313,920
Device Processing Fees Renewal Local A	546,126	369,811
Device Processing Fees Renewal Local B		40,600

		2023 Rs.	2022 Rs.
14	**Revenue Cont.....**		
	Device Processing Fees Renewal Foreign	17,249,412	53,232,412
	Cosmetic Processing Fees	1,032,500	995,000
	Borderline Processing Fees Foreing	9,503,099	9,073,016
	Borderline Processing Fees Local	865,022	550,621
	Borderline Processing Fees Ini for Foreign	13,032,581	16,387,056
	Borderline Processing Fees Renewal	246,564	
	Clinical Trial Processing Fees	1,561,300	1,161,905
	Drug Advertising Fees		359,999
	Retail Pharmacy License Income	72,868,854	46,058,454
	Wholesale Pharmacy License Income	14,876,547	12,439,863
	Transport Pharmacy License Income	38,622,597	29,266,658
	Drug WOR	15,091,431	13,445,367
	Device WOR	24,462,741	18,290,251
	Borderline WOR		-
	GMP Device Local Repac		
	Device GMP - Local A	321,459	726,901
	Device GMP - Local B	445,589	278,020
	Medicine GMP Repack	33,601	
	Medicine GMP Foreign	13,077,584	
	Drug GMP -Foreing SAARC	84,973,577	27,655,599
	Drug GMP - Local A	1,219,505	1,909,696
	Drug GMP - Local B	70,293	140,819
	Drug WHO Inspection	510,478	748,768
	Device WHO Inspection	693,317	245,188
	Drug COPP Certificate	824,405	148,433
	Additional Drug Foreing	88,112,569	68,220,321
	Additional Drug Local A	16,724,379	10,818,351
	Additional Drug Local B	36,692	350,040
	Additional Drug Variation	39,784,281	23,139,961
	Additional Drug MP	6,543,010	4,611,473

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

	2023 Rs.	2022 Rs.
Additional Device Foreing	115,989,406	114,702,756
Additional Device Local A	5,027,258	696,921
Additional Device Local B	1,298,669	626,880
Additional Device MP	2,666,499	1,767,775
Additional Device Variation	11,722,761	5,015,173
Additional Borderline Foreign	9,551,735	6,058,558
Additional Borderline Local	316,073	-
Additional Borderline Variation	197,340	201,899
Agency Transfer	73,738,321	51,454,105
Device Free sale Certificates	139,194	196,839
Borderline Clarification	33,171	3,712
Device Clarification	801,867	605,757
Drug Clarification	15,441,915	11,910,570
Device Amendment	821,730	259,310
Drug Amendment		-
Cosmetic Amendment	84,000	26,000
Borderline Amendment	36,692	114,433
Cosmetic Amendment Certificates	129,000	55,000
Device Amendment Certificates	9,872,359	2,838,236
Drugs Amendment Certificates	7,115,010	5,863,495
Phar. & Trans.Amended License	216,447	478,723
Packing / Repacking Medicine	32,792	
Packing / Repacking Device	16,347	

	2023 Rs.	2022 Rs.
Drug Formulation Approval	7,329,333	3,856,063
Borderline Formulation Approval	140,072	530,125
Borderline Advertisement		202,999
Device Advertisement	1,701,863	1,679,446
Medicines Advertisement	1035443.1	
Device Duplicate Certificate	83,364	-
Drug Free Sale		-
Automation Income		-
Medicine Duplicate	333,288	
Borderline Duplicate	251,553	
Cosmatic Duplicate	1,000	
Total Income	**2,160,659,839**	**2,041,175,151**

17

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2023 Rs.	2022 Rs.
15	**Interest Income**		
	Tresury Bills and Bond Int.	326,872,791	366,809,414
	Distress Loan Interest	512,324	363,032
	Staff Loan Interest	325,222	
	Savings A/C Interest	34,311,936	30,650,920
	Fix Deposit interest	684,100,051	
		1,046,122,324	**397,823,366**
16	**Other Income**		
	Tender Application Fees	223,000	242,000
	Other Income	72,999,521	33,583
	Supplier Registration	345,000	216,000
	Accomandation fee		48,081
		73,567,521	**539,664**

		2023 Rs.	2022 Rs.
17	**Administrative expenses**		
	Depreciation	32,137,633	34,756,957
	Water	767,853	503,462
	Electricity	11,950,623	7,065,813
	Telephone	2,258,927	1,580,700
	Postage	783,240	300,155
	Stationery	5,737,182	4,188,970
	Travelling - Local	292,860	5,777,333
	Travelling - Foreign	32,088,177	26,015,991
	Training and development expenses	3,741,418	1,828,308
	Fuel expense	3,391,591	2,229,611
	Security charges	6,684,824	6,681,014
	Document handling charges	3,132,051	2,206,598
	Publication, Translation and advertisement charge	5,316,137	1,249,123
	Cleaning service	5,875,887	6,399,870
	Maintenance of Vehicle	4,237,848	4,255,527
	Maintenance of Filling Stores		1,184,500
	Maintenance of Laboratory equipment	10,195,595	4,034,973
	Maintenance of fire extinguisher		-
	Maintenance of Air-conditioning	655,850	321,650
	Maintenance of building	4,915,920	2,679,177
	Maintenance of computer items and other	799,422	224,250
	Maintenance of website	113,708	18,150
	Maintenance of Office Equipment	1,168,366	1,230,438
	Maintenance of Software & Packages	6,713,590	3,955,504
	Reservation of Conference Hall	130,000	
	Rates and taxes	475,999	475,999
	Audit fee	1,272,000	1,236,000
	Lab expenses	9,550,019	
	Sample Testing Expenses	16,088	20,923
	Books, Journals & Information	5,579,937	6,883,347
	Consultation Fee	109,752	81,109
	Sanitary Items Expense	95,200	177,469
	Building Rent	17,632,688	16,402,500
	Consumable Expenses	629,800	361,675

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2023 Rs.	2022 Rs.
	Admini Ex . Cont……		
	Mask Expenses		501,770
	Interview Fees	29,625	20,625
	Vehicle Insurance	568,346	561,111
	Vehicles Parking Fee	30,500	18,825
	Total	179,078,653	145,429,428

		2023 Rs.	2022 Rs.
18	**Salaries and wages**		
	Salaries and wages	87,190,901	77,739,135
	Other allowances	7,952,433	2,885,577
	MOH Staff Salary	33,318,906	28,768,736
	Overtime & 1/20 payment	4,287,262	4,918,202
	Secondment allowance	76,468	136,025
	Contribution for Pension		
	Contribution for Employee Provident Fund	6,552,674	6,316,020
	Contribution for Employee Trust Fund	1,638,168	1,579,005
	Gratuity Expense	1,226,461	2,031,998
	Staff Bonus	3,147,890	1,857,963
	Total	145,391,163	126,232,660

		2023 Rs.	2022 Rs.
19	**Other expenses**		
	Refreshment and other expenses	3,613,286	6,112,973
	Bank Charges	2,112,664	192,497
	Staff Tea	6,184,915	4,503,103
	Legal Expenses	1,010,700	653,975
	Payment for Committees	2,234,000	2,562,000
	Miscellaneous Expenses	4,925,635	527,209
	Expert for Reviewing of Dossiers	974,900	600,000
	Surcharges	1,563	-
	Corporate Plan Expenses	542,564	-
	Expences for Basic requarment on poposed Narahenpita Buil.		-
	Total	21,600,227	15,151,757

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

		2023 Rs.	2022 Rs.
20	**Income tax for the year**		
20.1	Income tax expense for the year	979,807,505	303,330,629
	Deferred tax expense for the year	2,877,072	(433,690)
	Tax expense for the year	**982,684,577**	**302,896,939**
20.2	Net income before taxation	2,934,279,641	1,506,907,036
	Add : Disallowable expense	44,648,993	45,373,033
	Less : Allowable expense	(31,478,189)	(31,450,020)
	Adjusted profit for the year	2,947,450,445	1,520,830,049
	Other profit and income liable to tax		
	Total statutory income/ Taxable income	2,947,450,445	1,520,830,049
	Income tax for the year	884,235,134	212,916,207
	Adjustment Income tax 2022	90,833,350	
	Income tax adjustment for FD int of 2022	15,203,418	
	Adjustment Int Income on Tresury Bond	(2,634,892)	
	Adjustment Int Income on Tresury Bills	(10,437,346)	
	Adjustment Int Income on Bond Bills 2022	2,607,842	
	Administrative Review 2019/2020		
	Surcharge on Administrative Review 2019/2020		
	Pre payment		(201,933,336)
	Income tax expense for the year	979,807,506	212,916,207
	Opening Balance	10,982,871	151,836,233
	Paid for the year	(117,440,975)	(151,836,233)
	Total tax payable as at the year end	**873,349,402**	**10,982,871**

		2023 Rs.	2022 Rs.
21	**Prior year adjustment**		
	Salary Deposit	46,335	
	Rembursement Salary	(181,909)	
	Accrued	(1,409,898)	
	Arr. Special Allowance	(114,274)	
	committee	(120,500)	
	OT and 1/20	(136,761)	
	Depriciation	197,864	
	Refund Amount	(1,168,142)	
	Reject Refund	796,858	
	Tresury Bond	(18,820,656)	
	Tresury Bills	(74,552,473)	
	Fixed Deposit Int	108,595,839	
	Tresury Bond	18,627,442	
		31,759,725	**209,335,287**

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

22 Revenue and Expenditure for the year 2023 have been analyzed and presented indetail as compared to the year 2022

23 **Calculation of Income tax**

Income tax adjusted acording to the Audit Quary of Fixed Deposit, Tresury Bond ,Tresury Bills

Income tax calculated as per the Income Tax Act

As per paragraph 6 of the Tax Notification No. dated 15 December 2022, the new tax rate will be 30% from 01 October 2022.

24 **Contingent Liabilities & Cotingent Assets**

According to the letter dated 18.10.2023 of the Inland Revenue Department, the arrears of income tax for the assessment year 2019/2020 is Rs.298,893,905 and the penalty and interest amount is Rs.59,778,7811 and Rs 59,778,781
In this regard, a discussion has been requested with the Commissioner General of Inland Revenue and further work will be done after that.

As per the Cabinet observations vide letter No. PED/PMD/CM/2023/HEA/3700 dated 23.08.2023 and No. AMP/23/1547/610/05 dated 05.09.2023 It has been decided to purchase a suitable building from the existing fund of the National Medicines Regulatory Authority and Following the approved procurement procedures.

By letters No. PED/A/Rev/-L/1/15(ii) and PED/A/Rev-/1/15(iii) of the Deputy Secretary to the Treasury, dated 26 October 2023, 12 December 2023 and 06 February 2024, reviewed It has been informed that Rs.5,000,000,000 should be paid as Treasury Levy for the year.

As per the observation of ministry of finance , Economic, Stabilization and National Policies NMRA should the Rs.4,000,000,000 from the fund of Rs.5,000,000,000 owned by the National Medicines Regulatory Authority will be used for the construction work of the building under construction near the women's hospital premises in Borella Castle.

Rs.1,000,000,000 will be used to modernize the Suvasiripaya building and improve the facilities of the authority's laboratory.

25 **Litigation and claims**

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

In the year 2023 – 83 cases have been filed by remaining 02 Food & Drugs Inspectors of the IED alone, for the various violations identified under the act.

Rs 824,000.00 has been collected for 44 cases out of 83 filed as fines imposed by respective Magistrate Court in Maligawatta, Nugegoda, Hulftsdrorp 5, Fort, Mt Lavinia & Moratuwa.

Number of pending cases are 39 at the moment by February 2024.

21

NATIONAL MEDICINES REGULATORY AUTHORITY
NOTES TO THE FINANCIAL STATEMENTS

26 Approval of financial statements

These Financial statements were approved by the Board of members and authorized for issue on 28 February 2024 and Amended and Re approved on 07/08/2024

27 Nature of the Prior year adjustment

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

28 The total interest given under Note No. 15 for the year 2021 includes Treasury bills and bonds interest , Loan interest and saving A/C Interest and FD interrest.

Income Tax computation
Year of Assement 2023

	2023	2022
	Rs.	
Net income before taxation	2,934,279,641	1,506,907,035
Add : Disallowable expense		
Depreciation	32,137,633	34,756,957
Refreshment expenses	9,798,201	10,616,076
Rates and Tax	475,999	
Leagal Fee	1,010,700	
Gratuity Pro.	1,226,460	
	2,978,928,634	1,552,280,068
Less : Allowable expenses		
Capital allowance	(31,478,189)	(31,450,020)
Less : income not subject to income tax		
Amortization of capital grant		
Adjusted net profit for the year	2,947,450,446	1,520,830,048
Taxable profit trade and	**2,947,450,446**	**1,520,830,048**
Tax Loss:		
Total statutory income	2,947,450,446	1,520,830,048
Tax expense for the period, @ 30%	884,235,134	212,916,207
Opening Balance	**10,982,871**	
Tax expense for the period	884,235,134	212,916,207
Adjustment for Income tax	90,833,350	
Adjustment Int Income for FD 2022	15,203,418	
Adjustment Int Income on Tresury Bond	(2,634,892)	
Adjustment Int Income on Tresury Bills	(10,437,346)	
Adjustment Int Income for Bond 2022	2,607,842	
	990,790,376	212,916,207
payment	**(10,982,871)**	**(201,933,336)**
Self Assesment payment for 2023	(106,458,104)	
Income Tax payable	**873,349,402**	**10,982,871**

23

MSU/B/NMRA/1/23/32 08 October 2024

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 2023 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 Policies

MSU/B/NMRA/1/23/32 08 October 2024

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 2023 in terms of Section 12 of the National Audit Act, No. 19 of 2018.

1. Financial Statements

1.1 Qualified Opinion

The audit of the financial statements of the National Medicines Regulatory Authority for the year ended 31 December 2023 comprising the statement of financial position as at 31 December 2023 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 material accounting policy information was carried out under my direction in pursuance of provisions in Article 154 (1) of the Constitution of the Democratic Socialist Republic of Sri Lanka read in conjunction with provisions of the National Audit Act No. 19 of 2018 and Finance Act No. 38 of 1971 . My report to Parliament in pursuance of provisions in Article 154 (6) of the Constitution will be tabled in due course.

In my opinion, except for the effects of the matters described in Paragraph 1.5 of this report, the accompanying financial statements give a true and fair view of the financial position of the Authority as at 31 December 2023 and, of its financial performance and its cash flows for the year then ended in accordance with Sri Lanka Accounting Standards.

1.2 Basis for Qualified Opinion

(a) Although the previous years' errors of Rs. 13,961,263 and Rs. 828,980 which should be corrected in accordance with Paragraphs 42(a) and 42(b) of Sri Lanka Accounting Standards No. 08 respectively had been directly adjusted to the accumulated fund of the year under review, actions had not been taken to correct by restating comparative figures and restating opening balances respectively.

(b) Any adjustment recognized in the year under review for income tax of previous periods should be included in the income tax expense of the year under review in terms of Paragraph 80 (b) of Sri Lanka Accounting Standards No. 12. Nevertheless, even though the income tax rate has been revised to 30 per cent with effect from 01 October 2022 in terms of Paragraph 6 of Notice to Tax Payers No. PN/IT/2022-03 dated 15 December 2022, the Authority had applied the tax rate of 14 per cent for the entire year and as a result, an under-adjustment of tax had not been made during the year under review for the underestimation of the prior year tax expenditure.

(c) If the future economic benefits related to an item of property, plant and equipment are likely to flow to the entity, it should be recognized as an asset in terms of Paragraph 7 (a) of Sri Lanka Accounting Standard 16. Nevertheless, Authority had not taken actions to assess and account for the four-storied office building in Colombo 10 owned by the Ministry of Health, which has been in use for over 8 years, the three-storied building where the National Medicines Quality Assurance Laboratory is established, the land where those buildings are located and 06 vehicles, and another 03 vehicles taken over from the Presidential Secretariat and therefore, it was not possible to calculate and account for the depreciation. As a result, the non-current assets and capital grant balances had been understated in a quantitative value and annual profit and accumulated fund balance had also been overstated.

(d) Actions had not been taken to annually review the useful lives of property, plant and equipment in terms of Paragraph 61 of Sri Lanka Accounting Standards No. 16 and if

the expected conditions differ from the estimates, such differences should be accounted for in accordance with Sri Lanka Accounting Standards No. 8. Nevertheless, due to the actions have not taken by the Authority, a number of 339 asset items with a cost of Rs. 40,425,110 with a zero book value were still being used as at 31 December 2023 and actions had not been taken to disclose it in accordance with Paragraph 76 of this Standard.

(e) Due to erroneous deduction of Rs. 10,464,396 from income tax expense in relation to adjustment of Treasury Bills and Treasury Bond Interest Income in correction of previous year's accounting errors, income tax expense and income tax liability payable for the year under review had been understated by this value.

(f) Although the amount of Rs 7,583,570 received directly to the bank by 31 December 2023 had been identified as deposits to be classified under current liabilities, thus the nature of liabilities included in unclassified deposits was not clear to the audit, the accuracy of the relevant balance was not confirmed during the audit.

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

1.3 Other Information Included in the Annual Report 2023 of the Authority

The other information comprises the information included in the Annual Report 2023 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 2023 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 According to the requirements of Section 12(a) of the National Audit Act No. 19 of 2018, I have obtained all information and clarifications required for the audit subject to

the observations set out in Paragraph 1.2 of this report and, proper financial records had been maintained by the Authority as per my investigation.

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)	**National Audit Act No. 19 of 2018**	
(i)	Section 40 of the Act and Paragraph 4.4 of the Guidelines for State - owned	Actions had not been taken to appoint an Internal Auditor and establish an Internal Audit Division .

	Enterprises published by Public Enterprises Circular No. 01/2021 dated 16 November 2021	
(ii)	Section 38 (1) (e) of the Act	Answers had not been given for 05 Audit Queries.
(b)	**Establishments Code of Democratic Socialist Republic of Sri Lanka**	
(i)	Paragraph 8.1 of Chapter II	Appointment letters had not been issued for 07 officers who had been absorbed for the post of Drug Evaluation Officer.
(ii)	Paragraphs 10.1, 10.2 and 10.3 of Chapter II	The Administrative Officer and 10 Drug Evaluation Officers had not given medical reports as per General Format 169.
(iii)	Paragraph 10.7 of Chapter II	Although every officer is required to sign an agreement in General Format 160 when accepting a post, actions had not been taken accordingly.
(iv)	Paragraph 2.10 of Chapter VI	Full details of matters to be reported by the Head of Department in respect of each appointment had not been submitted to the Auditor General.
(v)	Paragraphs 5.2 and 5.3 of Chapter VI	Although no letter whatsoever relating to a disciplinary matter should be filed in the personal file unless there is a conviction for a charge, actions had not been taken

		accordingly.
(vi)	Paragraph 4.1 of Chapter VIII	Although staff officers are not entitled to overtime pay, a sum of Rs. 646,694 had been paid as overtime allowances to 36 officers.
(vii)	Paragraph 23 of Chapter XII	Four officers had gone abroad for a conference without having approved foreign leave.
(viii)	Paragraph 3.1 of Chapter XV	Two probationary officers were invited to participate in a South East Asia regional workshop
(ix)	Paragraph 10.4 of Chapter XXIV	The conditions in respect of distress loan guarantee of officers with less than 10 years of service were not fulfilled and distress and staff loans had not been secured by guarantee.
(c)	**Public Enterprises Circulars**	
(i)	Paragraph 6.7 of the Operational Manual for State-Owned Enterprises published by Circular No. 01/2021 dated 16 November 2021	Since the establishment of the Authority in 2015, an annual Board of Survey had not been conducted until 2021 and although the Annual Board of Survey had been started for the year 2022, it had not been completed. An Annual Board of Survey had also not been conducted for the year under review.
(ii)	Paragraph 2.2.2 (a) (v) of the Guidelines for State Owned	False approvals not applicable to the officers as well as false assurances that the

	Enterprises published by Circular No. 01/2021 dated 16 November 2021	Memorandum of Board of Directors have been prepared considering all the provisions, regulations, circulars, procurement procedures etc. related to the Authority had been included in the Memorandum of Board of Directors.
(iii)	Paragraph 2.3 of the Guideline	The Strategic Plan had not been prepared for the year under review.
(iv)	Paragraph 2 (a) of Annexure 01 of the Guideline	Although the Action Plan of the organization should be prepared clearly indicating the activities, the Action Plan prepared for the year under review had not been prepared accordingly.
(v)	Paragraph 3 (a) of Annexure 01 of the Guideline	Budgeted Income Statement, Budgeted Statement of Financial Position and Budgeted Cash Flow Statement had not been prepared for the year under review and the Annual Budget had not been used as an effective instrument of control.
(vi)	Paragraph 2.6 of the Guidelines	The Chief Executive Officer had acted as the Board Secretary without amending the Act.
(vii)	Circular No. PED-08/2022 dated 21 December 2022	Although it had not entitled for leave encashment allowance, a sum of

		Rs.8,129,017 had been paid as leave encashment allowance or the year 2022 and the year under review.
(d)	**Public Finance Circulars**	
	Paragraph 9 of Circular No. 01/2020 dated 28 August 2020	Actions had not been taken to obtain the relevant securities from the officers who should keep securities.
(e)	**Budget Circulars**	
(i)	Paragraph 02 of Circular No. 03/2022 dated 26 April 2022	A total of Rs.24,532,653 had been paid as special allowances and as attendance allowances without obtaining approval of Cabinet of Ministers.
(ii)	Paragraphs 03 (viii) and 03 (x).	A sum of Rs.1,750,000 and Rs.14,010,000 respectively had been paid as distress and staff loans without obtaining approval of Cabinet of Ministers.
(iii)	Paragraph 6 (a) of Circular No. 01/2023 dated 27 January 2023	Although officers should not be participated foreign conferences using domestic funds, a sum of Rs.1,983,315 had been paid for 4 officers apart from that.
(f)	**Public Administration Circulars**	

(i)	Circular No. 05/2008 dated 06 February 2008 and No. 05/2008 (I) dated 24 January 2018	Even though 09 years had elapsed since the establishment of the Authority, an appropriate Citizen/Beneficiary Charter had not been approved and implemented.
(ii)	Paragraph 3.1 of Circular No. 30/2016 dated 29 December 2016	Fuel checks had not been done in respect of the vehicles.
(iii)	Paragraph 4 of Circular No. 02/2018 dated 24 January 2018	A Human Development Plan had not been prepared.
(g)	Asset Management Circulars	
(i)	Circular No. 01/2017 dated 28 June 2017	Information about 13 items of computer equipment and office equipment valued at Rs.6,106,180 purchased during the year under review had not been submitted to the Comptroller General.
(ii)	Paragraph 02 of Circular No. 02/2017 dated 21 December 2017	Actions had not been taken to take over 06 vehicles belonging to the Ministry of Health so far.

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,

Powers, Functions and Duties		Observations
National Drug Regulatory Authority Act No. 05 of 2015		
(i)	Sub - section 14 (a)	The Authority had not collected data on the quantity of drugs, medical devices, borderline products or investigational medicinal products imported under licenses and even a system so that data can be collected had not been prepared.
(ii)	Sub - section 14 (k)	The Authority had not collected data on the use of medicines, medical devices, borderline products or investigational medicinal products in Sri Lanka, including data on industry and trade expenditure related to promotional activities and even a system so that data can be collected had not been prepared.
(iii)	Sub - section 30 (1) and 31(1)	The National Consultative Committee consisting of 24 members whose main task is to advise the Minister and the Authority on relevant matters for the proper implementation of the National Drug Policy of Sri Lanka had not yet been established.
(iv)	Sub - section 45 (1), 70 (1) and 91(1)	Although the Authority shall appoint expert panels consisting of expert professionals having expertise in the respective fields for drugs, medical devices and borderline products respectively, actions had not been taken

		accordingly.
(v)	Sub - section 84 (2) and Section 85	Although registered medical devices and in cases where registration is refused, an order regarding such refusal shall be published in the Gazette and notified to the public, since the establishment of the Authority till now, that regulatory requirement had not been fulfilled.
(vi)	Sub - section 69 (1) (b) (v)	Neither the Director General of the Sri Lanka Atomic Energy Regulatory Council nor his nominee had been appointed to the Medical Device Evaluation Committee. The need to represent the Medical Equipment 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, was not fulfilled.
(vii)	Sub - section 72 (1) and 93 (1)	Although the Authority shall issue general guidelines to such evaluation committees for evaluation of medical devices and borderline products, such guidelines had not been prepared. Further, orders had also not been prepared for the enforcement of guidelines on good manufacturing practices and other relevant guidelines, specifying the procedures to be followed, including specific time frames, for conducting medical device and limited product evaluations in terms of Sub-sections 72 (4) and 93 (4) .
(viii)	Sub - sections 74 (1) and	Authorized medical devices and registered

	95 (1)	borderline products had not been listed by the Minister from time to time in terms of Sub - sections 74 (1) and 95 (1) .
(ix)	Sub - sections 83 (4) (b) හා 102 (4) (b)	The medical devices and borderline products submitted for registration had not been submitted to the National Drug Quality Assurance Laboratory for checking the quality.
(x)	Sub - sections 83 (6) and 102 (6)	The Minister had not formulated the orders 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.
(xi)	Sub - sections 103(2) and 104	Although an order shall be published in the Gazette and notified to the public in respect of borderline products registered and in cases where registration is refused, that regulatory requirement has not been fulfilled from the date of the establishment of the Authority up to now.
(xii)	Section 123	The Minister should appoint an Appeal Committee to hear and decide the appeals submitted to the Authority and the Committee should consist of one member appointed from among the retired Judges of the Supreme Court of Sri Lanka or the Court of Appeal, the Secretary of Health and one member appointed from among

the retired medical specialists who have shown great merit in the field of medicine. Nevertheless, this Appellate Committee had not yet been appointed and instead, an Appeal Panel had been established as per the Decision of the Board of Directors to include the Chairman, Chief Executive Officer and one Board Member of the Authority as per Decisions of Board of Directors. Accordingly, the Appeal Committee which was established had been in contrary to the Act and its independence was problematic in the audit.

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 the date of this report.

2.3 Other Matters

(a) With the enactment of the National Medicines Regulatory Authority Act, the Cosmetics, Devices and Drugs Act No. 27 of 1980, which was in force until then in Sri Lanka regarding the regulation of drugs, devices and cosmetics, was repealed. The approval of the Cabinet of ministers had been received for Memorandum of Cabinet of Ministers No. 17/2221/718/120 presented by the then Minister of Health in accordance with handing over to the National Medicines Regulatory Authority to carry out the regulation of cosmetics using the provisions of the Cosmetics, Devices and Medicines Act that existed until the new Cosmetics Act will passed and implemented. Nevertheless, although it has been 09 years since the Cosmetics, Devices and Drugs Act No. 27 of 1980 was repealed, it had failed to prepare and pass a new act on the regulation of cosmetics or to amend the Authority Act as required and actions had not been taken to revise the fees between Rs.500 and Rs.5,000 charged under the previous arrangements for services such as evaluation for cosmetics registration, issuance of registration certificates, issuance of import licenses, etc.

(b) An applicant who did not fulfilled the required qualifications had been appointed as an Administrative Officer . During the period of employment of the Authority, approval had not been obtained for lectures in any other institution or to engage in any other profession as per the Paragraph 04 of the Letter of Appointment of this officer and even though he had worked as a guest lecturer, he had not paid the royalty due to the government.

(c) There had not been approved written criteria, guidelines or independent selection committee established within the Authority regarding selection or recommendation of officers to training workshops, programmes held in foreign countries and the Chief Executive Officer had made relevant recommendations. A Junior Management Level Administrative Officer belonging to the Tertiary Level had been sent for this workshop instead of sending a Senior Level Policy Officer in the relevant subject area which was the nomination criteria for the Southeast Asia

Regional Workshop on "Accelerating Technology Transfer for Local Production and Improving Access to Medical Products" held in Thailand.

(d) Although the Board of Directors of the Authority shall consist of 13 members representing various sectors as specified, due to vacancies of the posts of Obstetrician and Gynecologist, Professor of Pharmacology in a University, Professor/Lecturer in Pharmacology during the year under review, this composition remained incomplete in several cases. The risk of adverse effect on the decisions taken could not be excluded in the audit due to incomplete composition of Board of Directors. Similarly, expediting mechanism (Special Pathway) for waiver of registration of medicines has also been approved during the tenure of vacant posts of Professor/Lecturer in Pharmacology.

(e) The approved number of posts in the Authority was 257 at the beginning of the year under review and the actual staff was 158 and the number of vacancies was 98. It had been 38 per cent of the number of approved posts. There were 143 vacancies in respect of 28 posts at the Senior, Tertiary, Secondary and Primary Levels of the Authority as 33, 69, 22 and 19 respectively as at 31 December 2023, and it had been 53 per cent of the new staff out of 269 posts approved by the Department of Management Services during the year under review .

(f) Out of the 33 vacancies at the Senior Level, there were vacancies for the main posts related to the administrative, financial and operational activities of the Authority namely Chief Executive Officer, Director (Regulatory), (NMQAL), (Legal), (Human Resource and Administration) and (Finance) and out of the 130 posts of Drug Analyst, Assistant Drug Analyst, Drug Evaluation Officer, Assistant Drug Evaluation Officer and Assistant Drug Inspector who had been assigned directly in the performing of the tasks assigned to the Authority by the National Medicines Regulatory Authority Act, 82 equivalent to 63 per cent had been vacant.

(g) The post of Pharmacist is not an approved post of the Authority and an approval obtained for the employment of pharmacists in the Authority had not been submitted to the audit. Nevertheless, 07 pharmacists had been employed and salaries and allowances had been paid.

(h) Although the post of Assistant Drug Inspector in the approved staff has been assigned the duties of carrying out special investigations on complaints, conducting emergency raids and taking necessary legal action, it was problematic in the audit whether this designation included the authorized officers under Sub-section 124(1) of the National Medicines Regulatory Authority Act and actions had not been taken to resolve this situation quickly.

(i) Scheme of Recruitment and Promotion had not been prepared for the 4 posts out of the 33 approved posts, belonging to the higher management level and one post belonging to the secondary level namely, the posts of Director (Regulatory), (NMQAL), (HR and Administration), (Finance) and Technical Officer (Civil/ Transport) .

(j) The posts of Director (NMQAL), Assistant Director (IT), Legal Officer, and Administrative Officer had remained covering up duty or acting basis appointments for a long time without recruitment of employees and the posts of Medical Officer and Internal Auditor had remained in vacant from the date of approved. The risk of adversely affecting of existence of more than half of the approved positions in vacant and the main positions related to the administrative, financial and operational activities of the Authority thus, as well as the positions that directly contribute to the performance of the tasks assigned to the Authority by the Act remained in vacant for an efficient and effective medicines regulatory process could not be ruled out in the audit.

(k) 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 for that. Nevertheless, due to the negligence or deliberateness of the respective private company, some information that had been included in this data system had been deleted and this service had been disabled until the investigations of the Criminal Investigation Department were completed. According to the report submitted by the expert committee appointed in this regard, it had been informed that the data that had been deleted from the system could not be restored and actions had not been taken for the recovery of loss incurred up to the date of this report or further action to be taken against the respective company

(l) In addition to the points mentioned in this report, the matters observed during the audit of the year under review in respect of the intervention of the National Medicines Regulatory Authority regarding the urgent purchase of medicines, failure of considering the government medicines requirements in the registration of drugs, issuing letters of medicines registration and waiver of registration by the Authority, regulating the price of medicines, checking the condition of medicines and regulating medicines storage and transportation of medicines have been included in Paragraphs 7.5 to 7.11 of the Special Audit Report tabled in Parliament No. SPR/2024/03 dated 10 May 2024.

W.P.C. Wickramarathne

Auditor General.

Chapter - 4

Performance Achieving Sustainable Development Goals (SDG)

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

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

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

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

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

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

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

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

Chapter - 5

Compliance Report

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

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

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

8.3	Should have conduct board of survey in accordance with Public Finance Circular No.05/2016 and submitted the relevant reports to the Auditor general on the due date	Applicable - not done		Planned to implement
8.4	Should have made excesses, deficiencies and other recommendations revealed in the annual board of survey during the period mentioned in the circular	Applicable - not done		Planned to implement
8.5	Disposal of the unserviceable items in terms of FR 772	Applicable - not done		Planned to implement
9	**Vehicle Management**			
9.1	Preparing daily running charts and monthly summery reports for the pool vehicles and submitting them to the Auditor General on the due date	Compliant		
9.2	Should have been disposed unserviceable vehicles not less than the period of 06 months, upon becoming unnerved.	Compliant		
9.3	Maintaining and updating the log entry of vehicles	Compliant		
9.4	Taking actions according to the FR 103,104,109 and 110 with regard to the every vehicle accident	Compliant		
9.5	Re-inspecting the fuel combustion of vehicles in accordance with the provisions of paragraph 3.1 of public Administration circular No.2016/30 dated 29.12.2016	Compliant		
9.6	Having taken over full ownership of the leased vehicles log books after the leasing period	Not Applicable		
10	**Bank Account Management**			

10.1	Should have prepared and certified the bank reconciliation statements on the due date and submitted them for audit	Compliant		
10.2	Should have settled inactive bank accounts brought forward during or before the reviewing year	Compliant		
10.3	Should have acted in accordance with the financial regulations regarding the balances revealed and adjusted in the bank reconciliation statements and settled those balances within a period of one month.	Compliant		
11	**Utilization of funds**			
11.1	Incurring expenditure not exceeding the provision which had been made	Compliant		
11.2	Reaching liabilities at the end of the year after utilization of the provision provided in accordance with section 94 (1),not exceeding the limit	Compliant		
12	**Advance Accounts of Public Officers**			
12.1	Compliance with the limits	Not applicable		
12.2	Having done an age analysis of the outstanding loan balances	Not applicable		
12.3	should have settled the outstanding debt balance being for more than one year	Not applicable		
13	**General Deposit Account**			
13.1	Should have acted in accordance with FR 571 with regard to the expired deposits	Not applicable		
13.2	Updating and maintaining the control account for the general deposit accounts	Not applicable		
14	**Imprest Account**			
14.1	Should have forwarded the cash book balance to the treasury operations department, at the end of the year under	Not applicable		

	review			
14.2	Interim imprest issued under FR 371,having been settled within one month after the completion of particular work	Not Applicable		
14.3	Having issued the interim imprest at present not exceeding the approved limit in terms of FR 371	Not applicable		
14.4	Doing reconciliation of imprest account's balance with treasury book, monthly	Not applicable		
15	**Revenue Account**			
15.1	Should have made repayments from the income collected in accordance with the relevant regulations	Compliant		
15.2	Having credited the collected revenue directly to the revenue income without depositing to the deposit account	Compliant		
15.3	Having submitted the outstanding revenue reports to the auditor general, as per FR 176	Compliant		
16	**Human Resource Management**			
16.1	Maintaining Staff within the approved cadre limit	Compliant		
16.2	Should have provided duty lists in writing to all staff members	Compliant		
16.3	submitting all reports to the department of Management Services in terms of MSD circular no. 04/2017 dated 20.09.2017	Compliant		
17	**Providing information to the public**			
17.1	Appointing an information officer in accordance with the right to information act and regulations and updating and maintaining an document consist of such information provided	Compliant		

17.2	Providing information about the organization through its website and having made facilities for the public to put their comments/allegations about the organization, through the website or alternative channels	Compliant		
17.3	Should have submitted reports twice or once a year as per section 8 and 10 of right to information act	Compliant		
18	**Implementation of the citizens charter**			
18.1	Should have formulated and implemented a citizen's / clients' charter in accordance with the provisions of the circular No.05/2018 and 05.2018 (1) of the Ministry of Public Administration and Management	Compliant		
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	Applicable - Not done		Planned to implement
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		