Annual Report

2016

NATIONAL MEDICINES REGULATORY AUTHORITY

Table of Contents

List of Abbreviations

BPEC	Borderline Products Evaluation Committee
CDD Act	Cosmetic, Device and Drugs Act
CFDI	Chief Food and Drug Inspector
DO	Development Officer
FDI	Food and Drug Inspector
GDP	Good Distribution Practices
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practices
GPP	Good Pharmacy Practices
ICT	Information Communication Technology
ID Card	Identity Card
IED	Inspectorate and Enforcement Division
ISO	International Organization for Standardization
IT	Information Technology
KKS	Karyala Karya Sahayaka
MA	Management Assistant
MDEC	Medical Devices Evaluation Committee
MEC	Medicine Evaluation Committee
NDDCB	National Dangerous Drugs Control Board
NDQAL	National Drug Quality Assurance Laboratory
NMQAL	National Medicines Quality Assurance Laboratory
NMRA	National Medicine Regulatory Authority
SCOCT	Sub Committee of Clinical Trial
SDG	Sustainable Development Goals
SSFFC	Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Programme
WD	Withdrawal
WH	Withhold
WHO	World Health Organization

Message of the Chairman

I take great pleasure in presenting the Annual Report of the National Medicines Regulatory Authority (NMRA) for 2016. Functioning as an independent Authority in the Ministry of Health, Nutrition & Indigenous Medicine, our primary objective is to increase patient access to quality-assured medicines. In doing this, the NMRA is mandated to review not only the quality of medicinal products, but also their need and cost.

At present, the NMRA is striving to increase the efficiency and transparency of its activities while dealing with many legacy issues of its predecessor, the Cosmetics, Devices & Drugs Authority including a significant backlog of processing submitted applications. In charting this course, the NMRA deals with numerous challenges, especially in relation to human resource, infrastructure and finance. Above all, a major objective of the Authority, in line with public expectation and objectives of Universal Health Coverage (UHC), is to make medicines more affordable. I am extremely pleased the NMRA has been able to significantly reduce the prices of 48 essential and widely used medicines this year, which has brought much relief to patients. We will continue to work to bring more medicinal products under price regulation, thereby making them more affordable and reducing out of pocket expenses incurred by the general public on medicines.

In addition, the NMRA has ambitious plans to achieve financial independence in the near future by increasing our scope of regulatory services and increasing fees levied on the pharmaceutical industry for provision of such services. I believe increased revenues generated in this manner would support plans for complete automation of document and workflow processes in the NMRA, which will directly increase its transparency and efficiency. In addition, we hope to invest in improving the capacity of the National Medicines Quality Assurance Laboratory (NMQAL), recruit suitable officers to cadre positions in the NMRA, invest in better training opportunities for our human resource and work towards achieving 'listed' status with the World Health Organization. With the support of the Board of the Authority and the professional staff of the NMRA ably led by the Chief Executive Officer, I am optimistic 2017 will be a very successful year for our young organization. I believe the foundation to make the NMRA a top class public institution is now in place.

Professor Asita de Silva

Chairman / National Medicine Regulatory Authority

Message of the Chief Executive Officer

I being the CEO of one of the fastest growing Drug Regulatory Agencies in South - East Asia, the NMRA, feel very proud to present its Annual Report 2016. From the beginning we have recognized, understood and shared our vision, mission and goals among the members of our team which was the invaluable strength behind all these efforts. All of us together developed and agreed on a five-year corporate plan to be guided by. We are very likely to be directed and guided by our visionary leaders Hon. Dr. Rajitha Senaratne, the Minister of Health Nutrition and Indigenous Medicine, Prof Asita De Silva the Chairman, NMRA and the Board of members of the Authority.

NMRA has recorded a turnover of 114Mn through its regulatory activities. This growth has contributed very much to become independent from treasury funding which is a major qualification for a drug regulator to be recognized by WHO.

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

In 2016 Rs. 57.5 Mn of net profit recorded by the Authority with the contribution of the General Treasury of Sri Lanka and the total earnings of Rs.114.4Mn. This high return leading on recurrent grants from Treasury apart from our operational income. NMRA has recorded profit before taxation Rs.60, 547,713 during 2016 and it will lead to increase the authority performance and growth of next year.

While initiating our main tasks in 2016 we have identified our strategic goals for the future by more focusing on Effectiveness of Operations, improving financial performance and independency, developing the Human Capital Base, utilization of Modern Means of Information Technology and Systems for Improving the Productivity of Operations and strengthening the Statutory Framework of the Authority.

Dr. Kamal Jayasinghe

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

Chief Executive Officer

National Medicines Regulatory Authority

Board of Directors

1. Professor Asita de Silva - Chairman
2. Dr. Palitha Mahipala
3. Dr. Kamal Jayasinghe
4. Professor Raveendra Lal Jayakodi
5. Doctor. A. Lak Kumar Fernando
6. Mr. Deva Rodrigo
7. Ms. H. M. C. Herath
8. Dr. AnandaWijewickrema
9. Mr. R. M. P. Rathnayake
10. Dr. Gamini Perera
11. Dr Kapila Ranasinghe
12. Professor Narada Warnasuriya
13. Dr. Dilanthi Herath

Chapter 1

Corporate Profile / Executive Summary

1.1 Introduction

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

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

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

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

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

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

Committee open to the public and Advisory Committee to oversee the implementation of NMRA Act.

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

1.2 Vision, Mission, Objectives of the Organization

1.2.1 Vision

"Improve access to quality assured medicines and healthcare products"

1.2.2 Mission

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

1.3 Main Functions

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

1.4 Cadre Availability

Category of employees	Post	Approved Cadre	Actual Cadre	Vacancies / Excess
Senior level	Director General	01	01	-
	Director	04	01	03
	Director (Human Resources)	01	01 (Acting)	01
	Accountant	01	-	01
	Costing Accountant	01	-	01
	Assistant Director/Deputy Director	06	01	05
	Assistant Director/Deputy Director (ICT)	01	-	01
	Medical Officer	04	-	04
	Legal Officer	01	-	01
	Pharmaceutical Assessors	13	13	-
	Costing Officers	05	-	05
Secondary Level	Food and Drug Inspectors	20	03	17
	Pharmacists	70	51 (Acting)	70
	Administrative Officer	01	-	01
	Technical Officer	01	-	01

	Development Officers	10	15	05
	ICT assistant	01	01 (Secondment)	-
	Management Assistant	41	14 (Secondment)	27
Primary	Driver	10	05 (Secondment)	05
	Plumber	01	-	01
	Electrician	01	-	01
	Karyala Karya Sahayaka	30	02 (Secondment)	28
	Lab Assistant	08	05 (Secondment)	03
	Total	**232**	**113**	**181**

1.5 Divisions under the NMRA

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

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

1.5.1 National Medicines Quality Assurance Laboratory (NMQAL)

1.5.1.1 Introduction

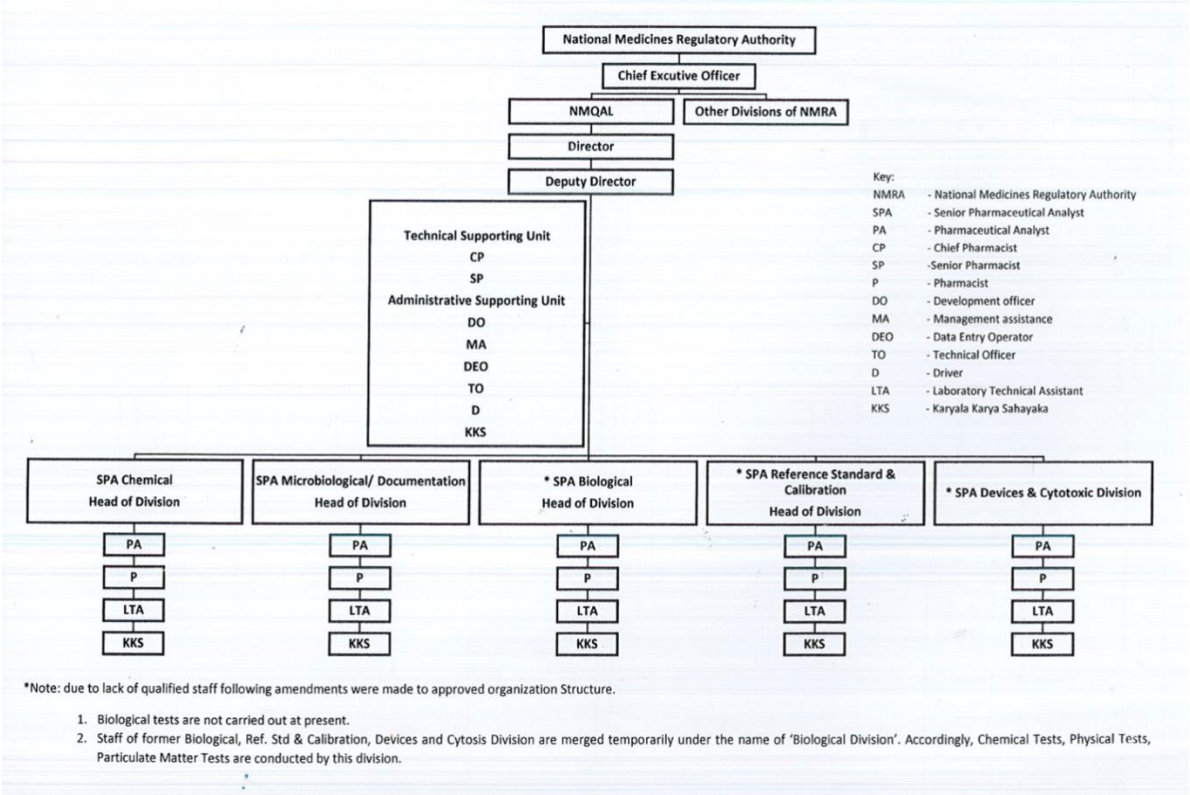
National Drug Quality Assurance Laboratory (NDQAL) was the National Laboratory established in Sri Lanka for testing Cosmetics Devices and Drugs. It was established in 1990 under Cosmetics Devices and Drug Act No.27 of 1980, with Norwegian consultancies and NORAD funds with the vision of ensuring Quality,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

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

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

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

1.5.1.2 Divisional Chart of NMQAL



1.5.1.3 Functions of NMQAL

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

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

registration samples, complaints samples, tender samples and surveillance samples collected from government and private institutions.

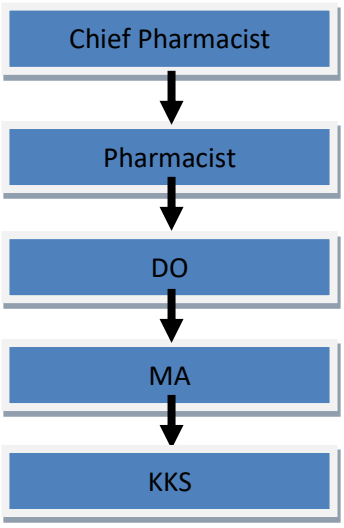
- Provide technical advices on evaluation of registration of Pharmaceuticals, Medical Devices and Borderline products as and when necessary.
- Participate in GMP inspections
- Participate in external quality assurance assessment scheme (proficiency testing)
- Conduct training programs on quality assurance system
- To coordinate with laboratories local or overseas when their services are deemed necessary as decided by the NMRA.

1.5.2 Pharmaceutical Regulatory Division

1.5.2.1 Introduction

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

1.5.2.2 Divisional Chart of the Pharmaceutical Regulatory Division



1.5.2.3 Functions of Pharmaceutical Regulatory Division

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

1.5.3 Inspectorate and Enforcement Division

1.5.3.1 Introduction

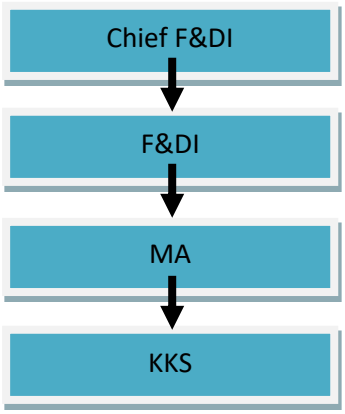
Inspectorate & Enforcement Division is a division established in the National Medicines Regulatory Authority under the NMRA Act No 05 of 2015.

The main function of the Inspectorate & Enforcement Division of the NMRA is inspecting and investigating issues pertaining to proper implementation of the provisions of the NMRA Act as may be authorized and directed by the authority. Three senior officers as Food & Drugs Inspectors have been appointed to this unit.

All three officers have been appointed as Authorized Officers under the NMRA Act by Hon. Minister to perform their duties. Currently this unit is headed by Chief Food & Drugs Inspector (CFDI).

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

1.5.3.2 Divisional Chart of the Enforcement Division



1.5.3.3 Functions of Inspection and Enforcement Division

1. Functioning as an Authorized Officer under the NMRA Act
2. Conducting Post marketing surveillance
3. Obtaining formal and informal samples when necessary

4. Inspecting & recommending drug establishments and ensure licensing
5. Inspecting & recommending drug transport vehicles & ensure licensing
6. Ensuring the implementation of product recall procedure
7. Investigating & initiate legal actions on the detentions made by the SSFFC & smuggled products
8. Investigating the availability of state-owned drugs in the private market
9. Inspecting & recommending of dangerous drugs applications
10. Organizing & conducting educational programs
11. Conducting prosecutions against the violations committed under the Act
12. Coordinating & corporation with other law enforcement agencies

1.5.4 Finance Division

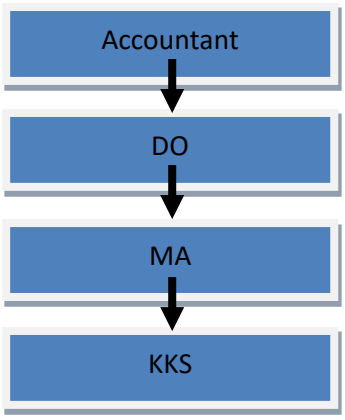
1.5.4.1 Introduction

After the establishment of NMRA under the National Medicines Regulatory Authority Act No 5 of 2015 on 2015.07.01, it has commenced its financial activities from 01.01.2016. Although the Accounts Division has been in existence since the inception of the authority, its activities were under the control of the Chief Accountant of the Ministry of Health and it was operating with minimal staff provided from the Ministry of Health.

Authority has received eighteen revenue streams under eighteen service categories. In addition to that authority has been funded from the treasury. Because of the era in which authority was being established accounts division was functioning providing essential day-to-day tasks like generating reports, notes, stationeries, etc.

It is hoped that in coming years the Finance Division will be properly maintained by recruiting an Accountant and the required staff.

1.5.4.2 Divisional Chart of the Accounts Division



1.5.4.3 Functions of Finance Division

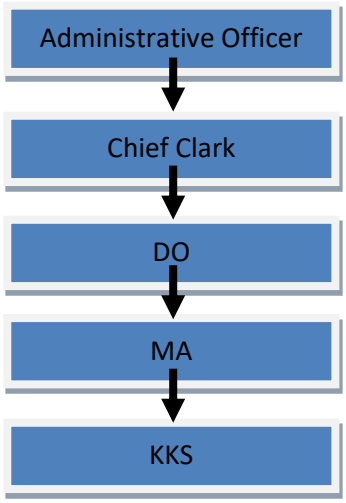
- Receiving all revenue through eighteen revenue streams.
- Bear all the expenses required to maintain the institute after independence from the Ministry of Health
- Preparing the budget for the coming year and obtaining the approval
- Maintaining all the supplies required to run the day-to-day activities of the authority
- All monetary controlling matters
- All bulk control

1.5.5 Administration Division

1.5.5.1 Introduction

Administration division maintains the performance of staff members of the NMRA to achieve the vision and mission. It helps the organization to deliver a high quality services to its clients, improve the administration and maintenance, establish the formal communication with other institutes and enhances the welfare of the staff.

1.5.5.2 Organizational chart



1.5.5.3 Functions of Administration Division

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

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

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

Chapter - 2

Progression and Vision

As a government policy decision to have a specific pharmaceutical regulatory authority with semi-autonomy, NMRA was formed with the NMRA Act of 2015. Its responsibility is to regulate the pharmaceutical products (medicines, medical devices and the cosmetics) to achieve the interests of general public by the means of safety, efficacy, quality and price.

Being in the early years of establishment, there were many short comings to achieve its goals. Despite all of it, NMRA has managed to deliver a remarkable service to the Country.

2.1 Progress of National Medicines Quality Assurance Laboratory (NMQAL)

Approval has been granted from the Regional Procurement Committee (RPC) to purchase eleven new laboratory equipment. The total expenditure for these items was about Rs. 11.3 million. Purchasing orders to be sent to purchase following equipment. 1) Karl Fischer titrator, 2) Analytical balance, 3) pH meter, 4) Thermostatic water bath, 5) Laboratory shaker, 6) Water distiller, 7) Sterilizing oven, 8) Vacuum pressure pump (02 Nos), 9) Magnetic stirrer hot plate (02 Nos), 10) Ultrasonic bath and 11) Ageing oven.

Annual instruments maintenance and calibrations procedures were carried out as scheduled.

BPharm and BSc (pharmacy) undergraduates, from University of Ruhuna, University of Peradeniya, University of Colombo, University of Sri Jayawardanapura, Kothalawala Defense University and Open University were trained.

Plans for future:

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

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

2.2 Progress of Pharmaceutical Regulatory Division

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

Plans for future

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

2.3 Progress of Inspection and Enforcement Division

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

2.4 Progress of Finance Division

The target for 2016 was to establish an Accounts Division after the establishment of the National Medicines Regulatory Authority. The primary target for the year 2017 is to recruit an Accountant who will be the Head of the Accounts Division and to recruit the staff required to carry out its activities in a systematic and comprehensive manner.

Plans for future

1) The primary target for the year 2017 is to recruit an Accountant who will be the Head of the Accounts Division and to recruit the staff required to carry out its activities in a systematic and comprehensive manner.
2) Accounts to be handled by the NMRA and make use of the revenue effectively to achieve organizational objectives

2.5 Progress of Administrative Division

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

Plans for future

1) Human resource is planned to be improved further to improve efficiency of the organization.
2) Organizational structure to be finalized and necessary alterations to be made according to the government guidelines.
3) Separate divisions to be established for Human Resources and Legal Affairs.

Chapter - 3

Overall Financial Performance

NATIONAL MEDICINES REGULATORY AUTHORITY

STATEMENT OF FINANCIAL POSITION

As at 31 December,

	Note	2016 Rs.
Assets		
Non current assets		
Property, plant and equipment	**2**	5,528,972
Total non current assets		**5,528,972**
Current assets		
Inventory		184,542
Deposits and other receivable	**3**	21,117,000
Cash and cash equivalents	**4**	79,624,667
Total current assets		**100,926,209**
Total assets		**106,455,181**
Equity and liabilities		
Equity		
Accumulated Fund		57,557,675
Total equity		**57,557,675**
Non Current liabilities		
Capital grant	**5**	5,528,972
Deferred tax	**6**	266,519
Total non current liabilities		**5,795,491**
Current liabilities		
Advance receipts	**7**	14,360,439
Provision for Income tax		2,723,519
VAT payable		16,198,667
Stamp duty payable		7,076,700

Accrued expenses			**8**		2,742,690			
Total current liabilities					**43,102,015**			
Total equity and liabilities					**106,455,181**			

The annexed notes to the financial statement are an integral part of these financial statement.

The members of the Authority are responsible for the preparation and presentation of these financial statements.

Signed and approved for and on behalf of the Members of the Authority.

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R.A Samarajeewa

Accountant

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Prof. Asita De Silva

Chairman

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Dr. Kamal Jayasinghe

Chief Executive Officer

NATIONAL MEDICINES REGULATORY AUTHORITY		
STATEMENT OF COMPREHENSIVE INCOME		
For the year ended 31 December,	**Note**	**2016 Rs.**
Revenue	**9**	114,410,560
Government grants	**10**	49,796,981
Other Income		1,039,116
Administrative expenses	**11**	(25,497,060)
Salaries and wages	**12**	(78,394,260)
Other expenses	**13**	(1,198,671)
Amortization of capital grant		391,047
Net income before taxation		**60,547,713**
Income tax for the year	**14**	(2,990,038)
Net income after taxation		**57,557,675**

NATIONAL MEDICINES REGULATORY AUTHORITY		
STATEMENT OF CHANGES IN EQUITY		
For the year ended,		
	Accumulated Fund	**Total**
	Rs.	**Rs.**
Balance as at 1 January 2016	-	-
Profit for the year	57,557,675	57,557,675
Balance as at 31 December 2016	**57,557,675**	**57,557,675**

Cash Flow Statement

NATIONAL MEDICINES REGULATORY AUTHORITY	
STATEMENT OF CASH FLOW	
As at 31 December,	
	2016 Rs.
Net income before taxation	60,547,713
Adjustment for :	
Depreciation	391,047
Amortization of capital grant	(391,047)
Operating profit before tax	60,547,713
Changes in items of working capital	
Inventory	(184,542)
Deposits and other receivable	(21,117,000)
Advance receipts	14,360,439
VAT payable	16,198,667
Stamp duty payable	7,076,700
Accrued expenses	2,742,690
Cash generated from operations	**79,624,667**
Cash flows from investing activities	
Acquisition of Property plant and equipment	(5,920,019)
Net cash used in Investing activities	**(5,920,019)**
Cash flows from financing activities	
Contribution from Treasury for capital assets	5,920,019
Net cash used in financing activities	**5,920,019**
Net increase/ decrease in Cash & cash equivalents	79,624,667

Cash and cash equivalents at the beginning of the year				-
Cash and cash equivalents at the end of the year				**79,624,667**

General Accounting Policies

1. Accounting policies

1.1 Reporting entity

National Medicines Regulatory Authority (the "Authority") is incorporated under the National Medicines Regulatory Authority Act No.15 on 30th June 2015. It is a Government Authority under the preview of Ministry of Health and Nutrition and Indigenous of Medicine 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 (SLFRS/LKAS) issued by the institute of Chartered Accountants of Sri Lanka. These are the Authority's first financial statements prepared in accordance with SLFRS/LKAS.

2.2 Basis of measurement

The financial statements have been prepared on historical cost basis with no adjustments being made for inflationary factors affecting the financial statements.

2.3 Functional and presentation currency

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

2.4 Use of estimates and judgments

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

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

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

- Note 05 - Retirement benefit obligation

3. Summary of significant accounting policies

3.1 Significant accounting policies

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

3.1.1 Plant and equipment

3.1.1.1 Recognition and measurement

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

3.1.1.2 Owned assets

The cost of plant and equipment includes expenditure that is directly attributable to the acquisition of the asset. The cost of self-constructed assets includes the cost of materials and direct labour, any other costs directly attributable to bringing the asset to a working condition for its intended use.

Purchased software that is integral to the functionality of the related equipment is capitalized as a part of that equipment.

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

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

3.1.1.4 Depreciation

Depreciation is recognized in the statement of comprehensive income on a straight-line basis over the estimated useful lives of items of each part of an item of plant and equipment.
The estimated useful lives for the current and comparative periods are as follows.

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

Depreciation of an asset begins when it is available for use and ceases at the earlier of the date that the asset is classified as held for sale and the date that the asset is derecognized. Depreciation methods, useful lives and residual values are reassessed at the reporting date.

3.2 Trade & other receivables

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

3.3 Cash & cash equivalents

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

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

3.4 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.

3.4.1 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.

3.5 Employee benefits

3.5.1 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.

3.5.2 Defined benefit plan

A defined benefit plan is a post-employment benefit plan other than a defined contribution plan.

The defined benefit obligation is measured using the formula method assuming a 10% average annual salary increase, with employee turnover based on the Authority's recent experience. The present value of the defined benefit obligation is determined by discounting the estimated future payments by reference to market yields at the reporting date on high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms to maturity approximating to the terms of the related liability. The discount rate used is 10%.

However there were no employees in the Authority for the relevant period.

3.6 Trade and other payables

Trade and other payables are stated at their cost.

3.7 Revenue

3.7.1 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.

3.8 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.

Repairs and renewals are charged to statement of comprehensive income in the year in which the expenditure is incurred.

3.9 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.

3.9.1 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.

3.9.2 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.

3.10 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.

3.11 Events after the reporting date

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

NATIONAL MEDICINES REGULATORY AUTHORITY

NOTES TO THE FINANCIAL STATEMENTS

As at,

2	**Property, plant and equipment**			
		Furniture and fittings	**Office equipment**	**Computer equipment**	**Total**
	Cost	**Rs.**	**Rs.**	**Rs.**	**Rs.**
	Balance as at 1 January 2016	-	-	-	-
	Additions during the year	716,784	2,025,270	3,177,965	5,920,019
	Balance as at 31 December 2016	716,784	2,025,270	3,177,965	5,920,019
	Accumulated depreciation				
	Balance as at 1 January 2016	-	-	-	-
	Charge for the year	31,449	154,693	204,905	391,047
	Balance as at 31 December 2016	31,449	154,693	204,905	391,047
	Carrying value				
	As at 31 December 2016	**685,335**	**1,870,577**	**2,973,060**	**5,528,972**
	As at 01 January 2016	**-**	**-**	**-**	**-**

Currently the Authority is using buildings, lab equipments, vehicles and other assets which are belong to Ministry of Health Nutrition and Indigenous Medicines and the Authority is in the process of acquiring those assets.

NATIONAL MEDICINES REGULATORY AUTHORITY			
NOTES TO THE FINANCIAL STATEMENTS			
For the year ended 31 December,			**2016**
			Rs.
3	**Deposits and other receivable**		
	Deposit for fuel		50,000
	Receivable Grant		21,067,000
	Total deposits and prepayments		**21,117,000**
4	**Cash and cash equivalents**		
	Cash and cash equivalents		79,624,667
	Total cash and cash equivalents		**79,624,667**
5	**Capital grant**		
	Capital grant		5,920,019
	Amortization of capital grant		391,047
	Total Capital grant		**5,528,972**
6	**Deferred tax liability**		
	Accounting written down value of Property plant and equipment		5,528,972
	Tax base of Property plant and equipment		4,577,117
	Taxable Temporary deference		951,855
	Tax @ 28%		266,519
	Deferred Liability/ Deferred tax expense		**266,519**
7	**Advance receipts**		
	Fees received in advance		14,360,439
	Total advance receipts		**14,360,439**
8	**Accrued expenses**		
	Salaries and wages		365,456

	Other allowance		99,000
	Casual wages		40,000
	Water expense		24,507
	Electricity expense		682,875
	Telephone and Internet		10,118
	Fuel expense		3,003
	Other Repair and Maintenance		110,147
	Fuel expense		21,375
	Vehicle maintenance		260,033
	Janitorial service		338,601
	Security service		143,494
	Director General of pensions		157,113
	Maintenance of Building		486,968
	Total Accrued expenses		**2,742,690**
For the period ended 31 December,			**2016**
			Rs.
9	**Revenue**		
	Drug sample license income		2,342,000
	Device sample license income		2,154,000
	Drug import license income		11,456,000
	Device import license income		12,624,000
	Total Cont.		**28,576,000**
For the period ended 31 December,			**2016**
			Rs.
9	**Revenue (Cont.)**		**28,576,000**
	Drug manufacturing license income		280,000
	Device manufacturing license income		13,000
	Drug full registration income		34,641,000
	Drug provisional registration income		789,100
	Device full registration income		7,921,200

	Device provisional registration income		120,900
	Fees for labotary test		430,000
	Drug processing fees		4,371,000
	Device processing fees		1,636,000
	Drug advertising fees		50,000
	Company profile evaluation fees		15,500,000
	Retail pharmacy license income		12,897,360
	Wholesale pharmacy license income		3,937,900
	Transport pharmacy license income		3,247,100
	Total revenue		**114,410,560**
10	**Grants**		
	Recurrent grants		49,796,981
			49,796,981
11	**Administrative expenses**		
	Depreciation		391,047
	Water		358,474
	Eletricity		9,312,335
	Telephone		610,703
	Postage		23,750
	Stationery		180,782
	Travelling - Local		96,122
	Travelling - Foreign		198,690
	Training and development expenses		1,628,505
	Fuel expense		455,818
	Security charges		3,496,015
	Document handling charges		385,000
	Advertisements charges		618,225
	Janitorial service		4,539,462
	Vehicle maintenance		977,379

	Maintenance of Labortary equipment		314,650
	Maintenance of fire extinguisher		42,831
	Maintenance of Air-conditioning		255,258
	Maintenance of building		488,573
	Expenses for Good Manufacturing Practice visits		1,045,040
	Rates and taxes		78,401
	Total		**25,497,060**
12	**Salaries and wages**		
	Salaries and wages		73,143,068
	Other allowances		1,504,701
	Overtime payment		3,589,378
	Contribution for pension		157,113
	Total		**78,394,260**
For the period ended 31 December,			**2016**
			Rs.
13	**Other expenses**		
	Other repair and maintenance		879,648
	Refreshment and other expenses		255,402
	Unreconciled expense		63,621
	Total		**1,198,671**
14	**Income tax for the year**		
14.1	Income tax expense for the year		2,723,519
	Deferred tax expense for the year		266,519
	Tax expense for the year		**2,990,038**
14.1	Net income before taxation		60,547,713
	Add : Disallowable expense		710,070
	Less : Allowable expense		(1,342,902)
	Less : Income not subject to income tax		(50,188,028)

	Adjusted profit for the year		9,726,853
	Other profit and income liable to tax		-
	Total statutory income/ Taxable income		9,726,853
	Income tax expense for the year	at 28%	2,723,519
	Total tax payable as at 31 December 2016		**2,723,519**
15	**Related Party Transaction**		
	Key Management Compensation		
	The Authority's key management personnels include the Chairman, Chief Executive Officer and other Members of the Authority.		
	Compensation paid to key management personel during the period of 31 December 2016 are as follows .		
			Total
			Rs.
	Short term employee benefits		2,028,633
16	**Events after the reporting date**		
	There were no material events occuring after the reporting date which require adjustments to or disclosures in the financial statements.		
17	**Contingent Liabilities**		
	There is no any comiittement and contingencies as at the reporting date.		
18	**Litigation and claims**		
	There are no litigations or claims against the Authority as at the reporting date.		
19	**Board of Members responsibility**		
	Board of members are responsible for the preparation and presentation of these financial		

	statements in accordance with Sri Lanka Accounting Standards.			
20	**Approval of financial statements**			
	These Financial statements were approved by the Board of members and authorized for issue on 16 March 2018.			

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கணக்காய்வாளர் தலைமை அதிபதி திணைக்களம்
AUDITOR GENERAL'S DEPARTMENT

මගේ අංකය / எனது இல. / My No. HSM/A/NMRA/1/16/98
ඔබේ අංකය / உமது இல. / Your No.
දිනය / திகதி / Date 14 February 2018

The Chairman,

National Medicines Regulatory Authority.

Report of the Auditor General on the transactions of the National Medicines Regulatory Authority for the year ended 31 December 2016.

The audit of the operating activities of the National Medicines Regulatory Authority for the year ended 31 December 2016, was carried out under my direction in pursuance of provisions in Article 154(1) of the Constitution of the Democratic Socialist Republic of Sri Lanka read in conjunction with Section 13(1) of the Finance Act No.38 of 1971 and Section 5 of the National Medicines Regulatory Authority Act No.05 of 2015. The financial statements for the year 2016 that should be furnished in terms of Section 13(6) of the Finance Act had not been furnished even by the date of this report. My observations on the operation of the Authority which I consider should be furnished to the Parliament in terms of Article 154(6) of the Constitution of the Democratic Socialist Republic of Sri Lanka appear in this report.

1.2 Establishment of the Authority and its Commencement

The operations of the National Medicines Regulatory Authority, established from 01 July 2015 in terms of Section 02 of the National Medicines Regulatory Authority Act No.05 of 2015 had been commenced from 01 January 2016. The main objectives of the Authority in terms of Section 03 of that Act had been ensuring the availability of efficacious, safe and good quality medicines, medical devices and borderline products

අංක 306/72, පොල්දූව පාර, බත්තරමුල්ල, ශ්‍රී ලංකාව. . - இல. 306/72, பொல்துவ வீதி, பத்தரமுல்லை, இலங்கை. - No. 306/72, Polduwa Road, Battaramulla, Sri Lanka
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(a) to the general public at affordable prices, registration of medicines, medical devices and borderline products, issuing licenses to medicines, medical devices and borderline products;

(b) Functioning as the central regulator for all matters connected with the registration, licensing and cancellation of registration or licensing, pricing, manufacturing, importation, distribution, sale, advertising and disposal of medicines, medical devices and borderline products;

(c) Encouraging the manufacturing of good quality medicines in Sri Lanka with a view to assuring the availability of essential medicines at affordable prices;

(d) Promoting the safe and rational use of medicines, medical devices and borderline products by health care professionals and consumers;

(e) Recommending appropriate amendments to relevant laws pertaining to medicines, medical devices and borderline products;

(f) Educating the general public, health care professionals and all persons concerned on medicine, medical devices and borderline products;

(g) Regulating the promotion and marketing of medicines, medical devices and borderline products;

(h) Regulating the availability of medicines, medical devices and borderline products;

(i) Conducting post marketing surveillance on quality, safety and adverse reaction of the medicines, medical devices and borderline products; and

(j) Regulating all matters pertaining to the conduct of clinical trials in Sri Lanka.

1.3 Management's Responsibility for the Financial Statements

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

2. Financial Statements

2.1 Presentation of Financial Statements

Even though the Annual Financial Statements of the Boards of Constitution should be furnished to the Auditor General within 60 days after the close of the Year of Accounts in terms of Section 6.5.1 of the Public Enterprises Circular No.PED/12 of 02 June 2003 and the Treasury Circular No.01/2004 of 24 February 2004, financial statements for the year 2016 had not been furnished to audit even by the date of this report.

2.2 Lack of Evidence for Audit

The following Items could not be satisfactorily vouched or an opinion on those Items could not be furnished due to non- submission of evidence for audit indicated against each Item.

Item	Value	Evidence not made Available
	Rs.	
(a) Income of the Registration of Medicines, Medical Devices and Borderline Products.	167,951,285	(i) Information on the amount of applications received in the year under review for the registration of medicines, medical devices and borderline products and the amount of applications registered.
		(ii) The total income of the Authority separated into each category as stated in the Gazette Extraordinary No.1601/15 of 12 May 2009.
(b) Cheque or Cash Deposits	97,270	Receipts issued to the direct deposits amounting to Rs.97,270 including in the Bank Reconciliation

Statement as at 31 December 2016, reasons if the receipts were not issued and the details on those deposits.

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

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

Reference to Laws, Rules and Regulations		Non- compliances
(a) National Medicines Regulatory Authority Act No.05 of 2015		
(i)	Sections 62(1)(b), 86 and 105	A complete or a temporary registration could be awarded by the Authority relating to medicines, medical devices and borderline products and even though conditions should be imposed for each type of registration, conditions had not been imposed even by the date of this report.
(ii)	Sections 65(4), 86 and 105	The registration or the license of the medicine, medical device or the borderline product relating to that certificate should be considered as automatically cancelled in an instance where the application for the renewal of that certificate had not been made six months

	before the expiration of that period, by a holder of a certificate relating to medicines, medical devices and borderline products. However, it was revealed in examining a sample of 20 Files that there were 11 instances where the registration certificates had been issued in a manner contrary to those Sections.
(b) Value Added Tax (Amendment) Act No.06 of 2005	Even though the tax relating to a period which a certain tax that could be charged should be paid to the Commissioner General of Inland Revenue on a date not after the 20th of the forthcoming month after the end of the period that tax could be charged, Value Added Tax amounting to Rs.11,633,289 which had been collected in the year under review by the Authority had not been remitted to the Commissioner General of Inland Revenue even by the date of audit of 27 September 2017.
(c) Stamp Fees (Special Provisions) Act No.12 of 2006	Even though the stamp fees should be remitted to the Commissioner General of Inland Revenue within 15 days after the close of each quarter of every year, stamp fees amounting to Rs.4,608,980 which had been collected relating to the second and third quarter of the year 2016 by the Authority had not been remitted to the Commissioner General of Inland Revenue even by the date of audit of 27 September 2017.

(d)	Financial Regulations of the Democratic Socialist Republic of Sri Lanka	
(i)	Financial Regulation 395(c)	A Bank Reconciliation Statement should be prepared before the 15th of the next month relating to the position of transactions as at the end of each month, of the Bank Accounts. However, even though the Bank Reconciliation Statement relating to the month of August 2017 should be prepared by the date of audit of 27 September 2017, only the Bank Reconciliation Statement relating to April 2017 had been prepared by that date. As such, a delay of 04 months remained relating to preparing the Bank Reconciliation Statements.
(ii)	Financial Regulations 394,396	Action had not been taken in terms of the Financial Regulations relating to 03 cancelled cheques of which the total value being a sum of Rs.16,265,812 and 02 cheques which were issued but unrealized which had lapsed over 6 months, including in the Bank Reconciliation Statement as at 31 December 2016.
(e)	Public Finance Circular No.364(3) of 30 September 2002 and Guidelines 5.4.11 and 5.4.12 of the Government Procurement Guidelines	Details on the Value Added Tax amounting to Rs.11,633,289 relating to the year under review had not been informed to the Commissioner General of Inland Revenue with a copy to the Auditor General.

(f) Public Administration Circular No.09/2009 of 16 April 2009	Even though Time Notifying Machines should be used without considering the number of employees in a place of work, steps had not been taken by the Authority to repair the Fingerprint Machines which remained inoperative after the date of 31 May 2014.
(g) Treasury Circular No.842 of 19 December 1978	A Register of Fixed Assets relating to property, plant and equipment had not been maintained by the Authority even by the end of the year under review.

3. Operating Review

3.1 Performance

An opinion on the performance of the Authority could not be furnished due to details on the number of applications received in the year under review for the registration of medicines, medical devices and borderline products and the number of applications registered, details on the Divisions and Committees that should be established in the Authority in terms of the provisions stated in the National Medicines Regulatory Authority Act No.05 of 2015, not being furnished to audit.

3.2 Management Activities

The following observations are made.

(a) The 03 Divisions of Information, Education, Communication and Research Division, Manufacturing Regulatory Division and Organization Development Division out of the 11 Divisions that should be established in the Authority in terms of Section 30(2) of Chapter 2 of the National Medicines Regulatory Authority Act No.05 of 2015 had not been established even by 31 December 2016.

(b) The 02 Committees of the National Advisory Committee and the Appeals Committee out of the 6 Committees that should be established in terms of Sections 30,43,68,89,118 and 123 of the Chapters 2,3,4,5,6 and 7 of the National Medicines Regulatory Authority Act No.05 of 2015 had not been established by 31 December 2016.

(c) Even though the National Medicines Quality Assurance Laboratory that remained being implemented under the Ministry of Health, Nutrition and Indigenous Medicine should be entrusted to the Authority with effect from 01 July 2015 in terms of sections 38 (2) (a) and (b) of the act, the Laboratory had not been entrusted to the Authority even by the date of audit of 17 October 2017.

(d) It had been failed to determine and to obtain the approval for the staff for the National Medicines Quality Assurance Laboratory and to attach the 64 officers deployed in service in the current period, to the Authority even by the date of audit of 17 October 2017.

(e) Even though the equipment and samples of medicines obtained for inquiring, examination, analysis, and for clinical trials should be destroyed after their expiration, 180 such expired samples relating to the period from the year 2013 to the date of audit of 10 October 2017 had been retained in the National Medicines Quality Assurance Laboratory without being destroyed.

(f) Matters observed relating to issuing of the Letters of Non- objection are given below.

(i) Any medicines or medical devices should not either be manufactured or imported by any person without either being registered in the Authority or without obtaining a license from the Authority in terms of Section 58 of Part IV of Chapter III and in terms of Section 82 of Part IV of the National Medicines Regulatory Authority Act No.05 of 2015. The issuance of the Registration Certificates and License should be carried out by the Authority after the evaluation either of medicines or medical devices considering the necessity for ensuring that efficacious, safe and good quality medicines or medical devices are being provided in terms of Sections 59 and 83 of that Act.. Six- hundred and forty- nine Letters of Non- objection had been issued in the year 2016 for the State Pharmaceuticals Corporation, Medical Supplies Division and for other Government and Private Institutions and 557 such Letters had been issued from January to 20 October 2017 contrary to the above provisions. The Letters of Non- objection had been used for the exemption from the Sri Lanka Customs to the importers not registered under the Act and to authorized importers of medicines and medical devices.

(ii) The inflow of medical supplies without a confirmation on quality in to the country could not be prevented due to the issuance of the Letters of Non- objection and, it had been a reason to the decrease of the registration and the license fees income of the Authority on those Letters being issued without charging a fee.

(iii) Issuing of the Letters of Non-objection had been increased from about 7 per cent in the year 2017 as compared with the year 2016 in comparing the number of Letters of Non- objection issued from the period from January to 20 October 2016 and from January to October 2017.

(iv) The permission could be granted by the Authority to import and to supply medicines, medical devices or borderline products in specific amounts either in matters of occasion such as either to save a life or for the prevention of spreading of an infectious disease or an epidemic disease or for any other national need or for the national security in terms of Section 109 of Part I of Chapter VI of the National

Medicines Regulatory Authority Act No.05 of 2015. However, 183 Letters of Non-objection had been issued to the Medical Supplies Division and to the State Pharmaceuticals Corporation in the year under review on reasons such as the cancellation of registration of the relevant medicine or the medical device, the non-existence of registered suppliers, not relevant to the category of the above needs. As such, it is observed that the issuance of the Letters of Non- objection on the aforesaid reasons had caused in reducing the interest of the suppliers to obtain the registration of the medicines, medical devices and borderline products.

(v) Eight Letters of Non- objection had been issued by the Authority to the same manufacturer or supplier for the supply of medicines valued at Rs.56,068,038 in 08 instances in the year 2017, despite there were two suppliers who had obtained the full registration for the "Dextran 40 Injection sodium chloride injection IP 10% 0.9 500m*l*" medicine for a period of 05 years before the establishment of the Authority on 07 March 2013 or, and 16 March 2016.

(vi) Seven instances where Letters of Non- objection had been issued to the same supplier over again in the year under review and 10 such instances in the period up to 20 October 2017 remained.

3.3 Procurement and Contract Process

The following observations are made.

(a) It was observed in terms of the matters given below that the transparency and the economical nature had not been achieved in the procurements relating to the purchase of 13 Air-Conditioners and office equipments by spending a sum of Rs.1,643,000 and Rs.579,026 respectively by the Authority.

(i) Standard Bidding Documents had not been used in terms of the Guideline 5.3.1 (c) of the

Government Procurement Guidelines and even though the Bidding Documents should be approved by the Technical Evaluation Committee and the Procurement Committee respectively after the examination, the approval of those Committees could not be obtained for the Bidding Documents due to calling for bids 15 days and 1 month respectively before the appointment of the Technical Evaluation Committee relating to these purchases.

(ii) The responsibility of opening bids had been entrusted to the Procurement Committee in terms of the Guideline 6.3.3(a) of the Government Procurement Guidelines and it could be entrusted to the Bid Opening Committee of that Authority by the Procurement Committee. Even though this committee should consist at least of two members approved by the Procurement Committee, a Bid Opening Committee had not been appointed relating to 2 of these purchases. Moreover, even though the activities on opening bids should be reported in a prescribed Form in terms of the Guideline 6.3.6 of the Government Procurement Guidelines, , even such report had not been prepared.

(iii) Even though the power of authority for purchasing goods from Rs.1 million to Rs.5 million should be obtained from the Procurement Committee of the Department in terms of the Guideline 2.14.1 of Supplement 28 of the Government Procurement Guidelines in following the Shopping Method in the Procurement of Goods, the power of authority for the procurement of purchasing 13 Air- Conditioners costing Rs.1,643,000 had been obtained from the Divisional Procurement Committee.

(iv) The maintenance cost of those machines had not been included into the Bidding Documents prepared for the purchase of 13 Air Conditioners. Quotations had been called for the maintenance cost from that supplier after the selection of the supplier. As such, it could not be specified whether the selected supplier was the supplier who furnished the minimum quotation on not being able to carry out a comparative evaluation with the maintenance cost of the other suppliers.

(v) Bids should be accepted only at a single place either by the registered post or by obtaining a receipt by handing over bids personally to the officer who had conferred power by the Procurement Entity in the specifically scheduled place or by putting inside the sealed

Tender Box if it had mentioned in the Bidding Documents that there is a sealed Tender Box in terms of Sections i, ii, iii of the Guideline 6.3.1 (a) of the Government Procurement Guidelines. However, action had been taken by the Technical Evaluation Committee for the evaluation of the bid of a private institution sent by Fax on 26 May 2016 relating to the purchase of office equipment. As such, it was problematic to audit on the transparency of the Procurement Process due to action being taken by the Authority for purchasing the Items of high back chair and half cupboard with filing rack from the supplier who furnished bids by Fax by spending a sum of Rs.84,813.

3.4 Personnel Administration

The following observations are made.

(a) A total of 103 vacancies as 22 vacancies relating to 08 posts of the Staff Grade Level,69 vacancies relating to 05 posts of the Non- Staff Grade Level and 12 vacancies relating to 04 posts of the Minor Staff remained in the approved cadre of the National Medicines Regulatory Authority as at 31 December 2016. Even though action had been taken by the Authority to recruit two officers only for the post of the Legal Officer and for the post of Driver permanently out of those vacancies, action had not been taken to fill the remaining 101 vacancies even by 31 August 2017.

(b) Fourteen officers had been occupied to service for 12 posts of the Office Assistant and 02 posts of Typist exceeding the approved cadre as at 31 December 2016.

(c) The authority had failed to recruit staff in terms of Section 17 of the National Medicines Regulatory Authority Act No.5 of 2015 and 30 officers of the Combined Service and 107 officers of the Ministry of Health and Indigenous Medicine had been occupied in service as at 31 December 2016 without properly releasing from service. As such, even though an approximate period of 02 years had lapsed since the establishment of the Authority by 31 August 2017, the Authority had failed to permanently fill those posts.

(d) A Scheme of Recruitment had not been prepared for the 06 posts of the Assistant Director/ Deputy Director, Drug Analyst, Cost Officer, Drug Inspector, Pharmacist and Laboratory Assistant including in the approved cadre of the National Medicines Regulatory Authority even by 31 August 2017.

(e) Newspaper advertisements had been published on 12 June 2016 and on 22 November 2016 respectively for the recruitment of one officer for the post of the Administrative Officer and 41 officers for the post of Management Assistant and action had not been taken to make those recruitments even by the date of audit of 31 August 2017 in terms of Section 5.4 of the Scheme of Recruitment relating to those posts.

(f) Necessary action had not been taken by the Authority from 24 November 2016 to the date of audit of 31 August 2017 to recruit a new officer on the officer selected by a newspaper advertisement dated 12 June 2016 for the post of the Director (Human Resources) refusing to assume duties of that post on 24 November 2016.

(g) Employment Particulars had not been properly provided for 124 officers occupied to service in the National Medicines Regulatory Authority as at 31 December 2016.

(h) Twenty- one posts in the Staff- Grade level, 9 posts in the Non- Staff Grade level and 6 posts of Minor Employees including in the cadre approved for the National Medicines Quality Assurance Laboratory as at 31 December 2016 remained vacant and the Laboratory had been maintained up to the date of audit of 25 October 2017 with those vacancies and, 9 minor employees had been occupied in service exceeding the approved cadre for 2 posts of other minor employees.

4. Accountability and Good Governance

4.1 Corporate Plan

The Corporate Plan of the Authority had not been furnished to audit.

4.2 Action Plan

The Action Plan for the year 2016 had not been furnished to audit.

4.3 Procurement Plan

A Main Procurement Plan including the procurement activities intended for a period of at least three (03) years had not been prepared in terms of the Guideline 4.2.1(b) of the Government Procurement Guidelines 2006 and a Procurement Plan and Procurement Time Table for the year under review had not been prepared.

5. Systems and Controls

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

Areas of Systems and Controls	Observations
(a) Accounting of Income	Non- classification and accounting of the income.
(b) Issuing Letters of Non- objection	Not taking action to maintain at a minimum level.
(c) Recruitment of Staff	Not occupying the staff in terms of the Act.

(d) Control of Fixed Assets	Non transfer of fixed assets from the Ministry.
(e) Maintenance of the Registers relating to the registration certificates of medicines and medical devices	Non- inclusion of the members in some registration certificates in the registers maintained according to the numerical order of the registration certificates.
(f) Financial Control	Not properly preparing the Bank Reconciliation Statements and delays in preparing it.

Sgd./ H.M. GAMINI WIJESINGHE
Auditor General

H.M Gamini Wijesinghe

Auditor General

ජාතික විගණන කාර්යාලය
தேசிய கணக்காய்வு அலுவலகம்
NATIONAL AUDIT OFFICE

මගේ අංකය எனது இல. My No.	HSM/A/NMRA/1/16/98	මෙය අංකය உமது இல. Your No.		දිනය திகதி Date	26 August 2018

The Chairman,

National Medicines Regulatory Authority

Report of the Auditor General on the Financial Statements of the National Medicines Regulatory Authority for the year ended 31 December 2016 in terms of Section 14(2)(c) of the Finance Act, No.38 of 1971.

The audit of financial statements of the National Medicines Regulatory Authority for the year ended 31 December 2016 comprising the statement of financial position as at 31 December 2016 and the statement of comprehensive income, statement of changes in equity and cash flow statement for the year ended and a summary of significant accounting policies and other explanatory 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 Section 13(1) of the Finance Act, No.38 of 1971 and Section 20 of the National Medicines Regulatory Authority Act, No.15 of 2015. The Report of the Auditor General on the transactions of the Authority was issued to the Chairman of the Authority on 14 February 2018 on the delay in furnishing the financial statements for the year ended 31 December 2016. My comments and observations which I consider should be published with the Annual Report of the Authority in terms of Section 14(2)(c) of the Finance Act appear in this report.

අංක 306/72, පොල්දූව පාර, බත්තරමුල්ල, ශ්‍රී ලංකාව இல. 306/72, பொல்துவ வீதி, பத்தரமுல்லை, இலங்கை. No. 306/72, Polduwa Road, Battaramulla, Sri Lanka.
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1.2 Management's Responsibility for the Financial Statements

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

1.3 Auditor's Responsibility

My responsibility is to express an opinion on these financial statements based on my audit. I conducted my audit in accordance with Sri Lanka Auditing Standards consistent with International Standards of Supreme Audit Institutions (ISSAI 1000- 1810). Those Standards require that I comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatements.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Authority's preparation and fair presentation of financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Authority's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of financial statements. Sub- sections (3) and (4) of the Finance Act, No.38 of 1971 give discretionary powers to the Auditor General to determine the scope and extent of the audit.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my audit opinion.

1.4 Basis for Qualified Opinion

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

2. Financial Statements

2.1 Qualified Opinion

In my opinion, except for the effects of the matters described in paragraph 2.2 of this report, the financial statements give a true and fair view of the financial position of the National Medicines Regulatory Authority as at 31 December 2016 and its financial performance and cash flows for the year then ended in accordance with Sri Lanka Accounting Standards.

2.2 Comments on Financial Statements

2.2.1 Sri Lanka Auditing Standards

Even though the Accounting Policies used, relevant to understand the financial statements should be disclosed in terms of the Paragraph 117 of the Sri Lanka Accounting Standard 1, Accounting Policies on the remaining stocks and Government Grants had not been disclosed by the Authority.

2.2.2 Accounting Policies

Even though the Historical Cost Method being the measuring method commonly used in preparing the financial statements by the Institutions in terms of the Paragraph 456 of the Conceptual Framework for Financial Reporting, it remains being consolidated with other measuring methods. It had been stated that only the Historical Cost Method will be based

under the Accounting Policy 2.2 in the financial statements without identifying measuring methods separately for the Assets and Liabilities of the Authority.

2.2.3 Accounting Deficiencies

The following observations are made.

(a) The Medicines Trade and Medicines Import License Fees Income amounting to Rs.30,,000 received in the year under review for the year 2017 had been brought to account as an income in the year under review.

(b) The income relating to the year under review had not been identified and had not been brought to account in the sum of Rs.14,360,439 stated as the income received forward under Non- current Liabilities as at 31 December of the year under review.

(c) A sum of Rs.12,000 relating to 04 Medicines Manufacturing Licenses issued in the year under review had been credited to the Payable Advance Account instead of crediting to the Income Account.

(d) The Property, Plant and Equipment Depreciation relating to the year under review had been brought to account less than a sum of Rs.11,477.

2.2.4 Lack of Evidence for Audit

The Schedules, Detailed Information and Time Analysis relating to the Advance Receipts relating to the Device Import License Income amounting to Rs.12,624,000, Un- reconciled Expenses amounting to Rs.63,621 included in Other Expenses in the Statement of Income and Advance Receipts amounting to Rs.14,360,439 included in the Non- current Liabilities as at 31 December 2016 had not been furnished to audit.

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

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

Reference to Laws, Rules, Regulations and Management Decisions	Observations
Gazette Extraordinary Paper No.1601/15 of 12 May 2009.	Even though fees amounting to Rs.10,000 each should be charged for the renewal of a Registration Certificate for the issuance of a Temporary Certification of Registration of Medicine and in a manner that the Certificate could be valid for five years in terms of the Gazette Notification, a sum of Rs.3,000 each had been charged for those certificates issued as per the Gazette Notification Paper, contrary to the provisions in the Gazette Notification Paper. Even though the fee for the initial registration of a medical device that would be valid for five years had been a sum of Rs.7,500 and a total sum of Rs.21,000 as a sum of Rs.5,000 for 04 of those certificates and a sum of Rs.1,000 for a certificate and the fee for the issuance of a temporary certificate for the registration of a medical device had been a sum of Rs.2,000 as per the Gazette Notification Paper, a total sum of Rs.2,000 had been charged as a sum of Rs.1,000 each for 02 of those certificates.

Sgd./ H.M. GAMINI WIJESINGHE
Auditor General

H.M Gamini Wijesinghe
Auditor General

Chapter - 4

Performance Index

Process	Total for year	Completed	Percentage completed (%)
National Medicines Quality Assurance Laboratory (NMQAL)			
Quality tests	455	388	85.27%
Pharmaceutical Regulatory Division			
Medicines	358	323	90.22%
Devices	574	447	77.87%
Inspectorate and Enforcement Division			
Cases	96	83	86.45%

Above are the main functions of the NMRA. To finish one dossier number of other functions were performed (manufacturing site registration, market authorization registration, issuing of sample import license etc.). To support the above main functions all other divisions performed their supportive functions effectively.

Chapter - 5

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 - 6

Human Resource Profile

6.1 Cadre Management

	Approved Cadre	Existing Cadre	Vacancy
Senior Level	38	17	22
Secondary Level	144	84	121
Primary Level	50	12	38
Total	**232**	**113**	**181**

Chapter - 7

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	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
1.2	Advance accounts on public officers	Applicable – Not done	Lack of human resources	Planed to recruit relevant staff in near future
1.3	Business and product advance accounts (commercial advance account	-		
1.4	Store advance accounts	-		
1.5	Special advance accounts	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
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	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future

2.2	Updating and maintaining personal payroll documents / personal payroll cards	Applicable		
2.3	Updating and maintaining the list of audit queries	Applicable		
2.4	Updating and maintaining the internal audit record	Applicable		
2.5	Preparing all monthly account summaries and submitting them to the treasury on time	Not Applicable		
2.6	Updating and maintaining the cheque and cash order register	Applicable		
2.7	Updating and maintaining inventory	Applicable		
2.8	Updating and maintaining the stock inventory	Applicable		
2.9	Updating and maintaining the register on loss and damage	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
2.10	Updating and maintaining the list of liabilities	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
2.11	Updating and maintaining the sub paper book register (GA-N20)	Applicable		
3	**Representation of function for financial control**			
3.1	Delegating financial powers within the organization	Applicable		
3.2	Should have made the institution aware about the delegating financial powers	Applicable		
3.3	Delegating authority where two or more officers could approve each transaction	Applicable		
3.4	Acting under the control of the Accountant in using the Government	Applicable		

	payroll software package as per government accounts circular No.171/204 dated 11.05.2014			
4	**Preparation of Annual Action Plan**			
4.1	Preparation of Annual Action Plan	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
4.2	Preparation of Annual Action Plan	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
4.3	Preparation of Annual Internal Audit Plan	Not Applicable	Lack of human resources	Planned to recruit relevant staff in near future
4.4	Preparing the annual estimate and submitting it to the Public Enterprise Department on the due date	Not Applicable	Lack of human resources	Planned to recruit relevant staff in near future
4.5	Submitting the annual cash flow statement to the treasury operations department on time	Not applicable		
5	**Audit Quarries**			
5.1	Having answered for all the audit queries mentioned by the auditor general on the due date which has been fixed by him	Applicable		
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		
6.2	Having responded to each internal audit within a month of time	Applicable		
6.3	Submitting copies of all the internal	Applicable –	Lack of human	Planned to

	audit reports to the Department of Audit Management ,in terms of sub-sections -40 (4) of the National Audit Act No.19 of 2018	Not done	resources	recruit relevant staff in near future
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	Lack of human resources	Planned to recruit relevant staff in near future
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	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
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	Not Applicable	Lack of human resources	Planned to recruit relevant staff in near future
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	Not Applicable	Lack of human resources	Planned to recruit relevant staff in near future
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		
8.4	Should have made excesses, deficiencies and other recommendations revealed in the annual board of survey during the period mentioned in the circular	Not Applicable	Lack of human resources	Planed to recruit relevant staff in near future
8.5	Disposal of the unserviceable items in	Not Applicable	Lack of human	Planed to

	terms of FR 772		resources	recruit relevant staff in near future
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	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
9.2	Should have been disposed unserviceable vehicles not less than the period of 06 months, upon becoming unnerved.	Applicable		
9.3	Maintaining and updating the log entry of vehicles	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
9.4	Taking actions according to the FR 103,104,109 and 110 with regard to the every vehicle accident	Applicable		
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	Applicable		
9.6	Having taken over full ownership of the leased vehicles log books after the leasing period	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
10	**Bank Account Management**			
10.1	Should have prepared and certified the bank reconciliation statements on the due date and submitted them for audit	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
10.2	Should have settled inactive bank accounts brought forward during or before the year under view	Not applicable		

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.	Applicable		
11	**Utilization of funds**			
11.1	Incurring expenditure not exceeding the provision which had been made	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
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	Applicable – Not done	Lack of human resources	Planned to recruit relevant staff in near future
12	**Advance Accounts of Public Officers**			
12.1	Compliance with the limits	Not applicable		
12.2	Having done an age analysis of the outstanding loan balances	Not applicable		
12.3	should have settled the outstanding debt balance being for more than one year	Not applicable		
13	**General Deposit Account**			
13.1	Should have acted in accordance with FR 571 with regard to the expired deposits	Not applicable		
13.2	Updating and maintaining the control account for the general deposit accounts	Not applicable		
14	**Imprest Account**			
14.1	Should have forwarded the cash book balance to the treasury operations department, at the end of the year under review	Not applicable		
14.2	Interim imprest issued under FR 371,having been settled within one	Not Applicable		

	month after the completion of particular work			
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	Applicable		
15.2	Having credited the collected revenue directly to the revenue income without depositing to the deposit account	Applicable		
15.3	Having submitted the outstanding revenue reports to the auditor general, as per FR 176	Applicable		
16	**Human Resource Management**			
16.1	Maintaining Staff within the approved cadre limit	Applicable		
16.2	Should have provided duty lists in writing to all staff members	Applicable		
16.3	submitting all reports to the department of Management Services in terms of MSD circular no. 04/2017 dated 20.09.2017	Applicable		
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	Applicable		
17.2	Providing information about the organization through its website and having made facilities for the public to	Applicable		

	put their comments/allegations about the organization, through the website or alternative channels			
17.3	Should have submitted reports twice or once a year as per section 8 and 10 of right to information act	Applicable		
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	Applicable		
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	Applicable		
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	Lack of human resources	Planned to recruit relevant staff in near future
19.2	Should have ensured at least 12 hours of training per year for each member of the staff , in the above HR plan	Applicable - Not done	Lack of human resources	Planned to recruit relevant staff in near future
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	Lack of human resources	Planned to recruit relevant staff in near future
19.4	Should have appointed senior officer	Applicable -	Lack of human	Planned to

	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	Not done	resources	recruit relevant staff in near future
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	Not applicable		