2019 | 2020
ANNUAL REPORT

The trusted Authority for excellence
in medical products and cosmetics regulation.

Promoting access to safe medicines

BMRA
MEDICINES REGULATORY AUTHORITY

WE PROTECT THE PUBLIC FROM HARMFUL AND SUBSTANDARD MEDICAL PRODUCTS AND COSMETICS. WE EDUCATE THE PUBLIC BY PROVIDING INFORMATION THAT WILL HELP IT MAKE INFORMED CHOICES REGARDING HUMAN AND ANIMAL HEALTH PRODUCTS.

BMRA
MEDICINES REGULATORY AUTHORITY

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Annual Report and Audited Annual Financial Statements presented in pursuance of Section 22 of the Medicines and Related Substances Act

i. LIST OF ABBREVIATIONS AND ACRONYMS

ADR	means Adverse Drug Reaction
CME	means Continual Medical Education
CMS	means Central Medical Stores
ERM	means Enterprise-Wide Risk Management
GBT	means World Health Organisation Global Benchmarking Tool
GDP	means Good Distribution Practices
GMP	means Good Manufacturing Practices
GLP	means Good Laboratory Practices
GPP	means Good Pharmacy Practices
QMS	means Quality Management System
MRSA	means Medicines and Related Substances Act, 2013
NDQCL	means National Quality Control Laboratory
PV	means Pharmacovigilance
S & F	means Substandard and Falsified
S.M.A.R.T	means Specific, Measurable, Achievable, Realistic, and Timely
WHO	means World Health Organisation
ZAZIBONA	means Southern African Development Community (SADC) collaborative medicines registration initiative originated between the countries of Zambia, Zimbabwe, Botswana, and Namibia.

SECTION A: GENERAL INFORMATION

1. THE AUTHORITY'S GENERAL INFORMATION

The Botswana Medicines Regulatory Authority was established by the Medicines and Related Substances Act of 2013 and commenced its operations in January 2018. The Authority's primary role is to administer the Medicines and Related Substances Act, which is to regulate the supply chain of medicines, medical devices and cosmetics in Botswana to ensure their quality, safety and efficacy.

2. CHAIRPERSON'S STATEMENT

The 2019/20 financial year saw the Authority enter its second year of operation, with emphasis on the implementation of its 5-year strategic plan, which is expected to ensure attainment of the World Health Organisation's (WHO's) Maturity Level 3 rating, by the Authority. The strategy aims at, among others; continuous developing of its human capital, processes and systems to strengthen its regulatory capacity and oversight. It ensures that human and veterinary medicines, medical devices and cosmetics that are given market authorisation in Botswana are of good quality, efficacious and safe.

The Authority continued to work in pursuance of regional harmonisation through the ZAZIBONA collaborative medicines registration initiative and build partnerships with local relevant entities through memoranda of understanding (MoUs) in order to increase regulatory effectiveness, ease of doing business and execution of its mandate. In addition, several stakeholder engagements and public awareness and education campaigns were undertaken to mitigate problems often encountered throughout the supply chain.

Ongoing worldwide, regional and local concerns regarding unregistered, unsafe and counterfeit medical products that find their way into the supply chain, highlight the need for strengthening the regulatory enforcement system, market surveillance and laboratory testing capabilities. The Authority has begun operationalisation of its laboratory testing and is making plans to seek funding to construct a purpose-built quality control laboratory which will enhance its ability to test products as part of the registration process and post market surveillance in order to assess their safety, quality and efficacy.

The amendment of the Medicines and Related Substances Act, 2013, with the primary aim of aligning it to the African

Union harmonisation standards, other best practice instruments and national needs is being undertaken on an ongoing basis. The Medicines and Related Substances Regulations were successfully promulgated in December 2019. The latter provide the Authority with the necessary tools to execute part of its mandate (e.g. receive new applications for medicine registration) and thus contribute to easier access to registered new medical products.

The Board strengthened its governance processes through the establishment of the Governance and Nominations Committee (GNC), which is responsible for overseeing all governance issues and processes. The GNC also advises the Board on nominations ensuring that the right skills mix is maintained for the Board and its Committees. The Authority started implementing enterprise-wide risk management (ERM) in compliance with good governance and best practice, during the year under review.

On behalf of the Board and myself, I would like to extend our immense appreciation to the Ministry of Health and Wellness and the Ministry of Agricultural Development and Food Security for their support and guidance, all our stakeholders, including the general public, for their cooperation and support, my colleagues in the Board for providing stellar guidance to the Authority and finally the BoMRA staff who have continued to work diligently in pursuance of our strategic objectives during the year under review.

I present to you, on our behalf the Board, the BoMRA's 2019/20 Annual Report.

Duncan Thela
Chairperson of the Board of Directors

3. BOARD OF DIRECTORS

1 **Mr. Duncan Thela**
Chairperson

2 **Dr. Mbatshi Mazwiduma**
Vice -Chairperson

3 **Mr. Kagiso Balopi**
Member

4 **Mr. Meshack Baoleki**
Member

5 **Ms. Botho Bayendi**
Member

6 **Dr. Joyce Kgatlwane**
Member

7 **Dr. Tiroyaone Mampane**
Member

8 **Dr. Gontle Moleele**
Member

9 **Ms. Shameela Pholo-Winston**
Member

10 **Dr. Gaseitsewe Michael Sento**
Member

11 **Dr. Letlhogile Modisa**
Member (Ex -Officio)

12 **Dr Stephen Ghanie**
Member (Ex -Officio)

13 **Dr Malaki Tshipayagae**
Member (Ex -Officio)
Not pictured

EXECUTIVE MANAGEMENT TEAM

FROM LEFT TO RIGHT
SITTING

1. **Dr. Parthasarathi Gurumurthy**
   Director - Pharmacovigilance and Clinical Trials
2. **Dr. Stephen Ghanie**
   Chief Executive Officer
3. **Dr. Sinah Selelo**
   Chief Regulatory Officer

FROM LEFT TO RIGHT
STANDING

1. **Mr. Israel Kgosidiile**
   Public Relations Manager
2. **Mr. Nonofo Thipe**
   Corporate and Legal Secretary
3. **Ms. Lydia Maleho**
   Personal Assistant - CEO
4. **Mr. Harold Kuvenga**
   Director - Finance and Admin

NOT IN PICTURE

1. **Dr Nkaelang Modutlwa**
   Director – Registration
2. **Dr Seima Dijeng**
   Director – Licensing and Enforcement
3. **Ms. Padmine Rammidi**
   Human Resources Manager
4. **Ms. Zukiswa Raditladi**
   Quality Manager

4. STRATEGIC OVERVIEW

4.1 Legal Basis

The Authority's primary legislative framework is the Medicines and Related Substances Act (MSRA) which establishes the Authority and sets the foundations of its regulatory mandate. The MRSA's subsidiary legislation is the Medicines and Related Substances Regulations, 2019, which were prescribed by the Minister of Health and Wellness. The Regulations empower the Authority to create binding Guidelines that further set out regulatory requirements that ensure quality, safety and efficacy of medicines, medical devices and cosmetics.

4.2 Mandate

The Authority's mandate includes the following:

- Ensuring medicines and cosmetics are of the prescribed quality, safety and efficacy.
- Granting marketing authorisations for medicines for local use or export.
- Ensuring people, premises, processes, products and procedures employed to manufacture, distribute and sell medicines comply with defined standards.
- Public education in connection with the quality, safety and efficacy of medicines.
- Conducting post marketing surveillance.
- Granting approval for the use of medicine for clinical trials or medical research.

The scope of the Authority's mandate extends through the entire supply chain of medicines, medical devices and cosmetics.

4.3 Vision, Mission and Values

The Authority developed its Vision, Mission and Values to support its fundamental objectives, drive its strategy and provide value to its stakeholders. The vision, mission and values are further aimed at embracing and inculcating a culture of a high-performance and dedication.

4.3.1 Vision

The trusted Authority for excellence in medical products and cosmetics regulation.

4.3.2 Mission

We regulate medicines, medical devices and cosmetics, to promote human and animal health.

4.3.3 Values

Integrity
A transparent and impartial environment with people who are trustworthy, disciplined and maintain confidentiality.

Customer Focus
Providing quality service and upholding standards.

Efficiency
Working S.M.A.R.T and applying innovative solutions and good judgment.

Teamwork
Working together for a common goal.

4.4 Strategic Plan

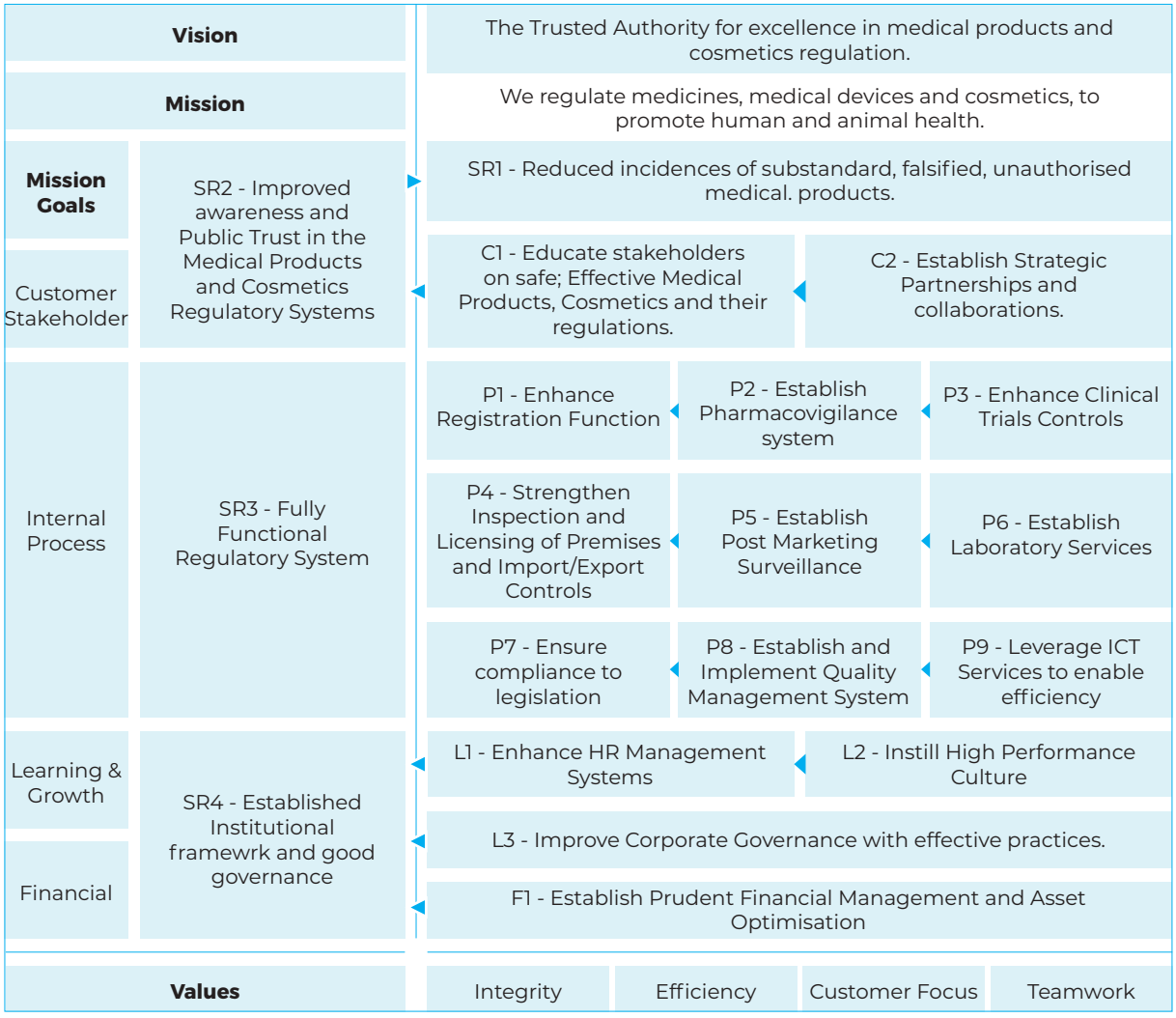
In order to guide its strategy, the Authority developed a Strategy Map and Strategic Plan for the period 2019 – 2024. The Strategy Map documents the strategic goals and objectives that the Authority pursues in order to effectively fulfil its mandate and derive value for its stakeholders.

The Strategic Plan serves to guide the Authority's operations and drive it towards its vision of becoming the trusted Authority for excellence in medical and cosmetics products regulation. The Strategic plan is buttressed by the Authority's annual performance plans which ensure yearly monitoring and adjustments for continual progress towards

its strategic goals.

A key focus of the Authority's strategy is to drive towards a Maturity Level 3 (ML3) rating by the World Health Organisation for Regulatory Systems based on the WHO Global Benchmarking Tool. The GBT provides an objective measure for rating the development of regulatory systems and is used by the Authority to ensure that it aligns to best practice for regulators throughout the region and the world.

4.5 Strategic Map



4.6 Quality Policy Statement

As part of its commitment to providing quality services in response to customer needs and expectations, the Authority has undertaken to entrench a Quality Management System and does so in accordance with its Quality Policy Statement which reads:

Botswana Medicines Regulatory Authority regulates medicines, medical devices and cosmetics to promote human and animal health. We strive to provide professional and efficient services to ensure the satisfaction of our customers as well as statutory and regulatory requirements.

We are committed to continual improvement and have therefore established a Quality Management System which provides a framework for measuring and improving our performance. Our system will be monitored, measured, evaluated and enhanced regularly as the Executive Management's ultimate responsibility. There will be regular reporting and communication of the status and effectiveness at all levels.

With adequate direction and support, each employee will have a proper understanding of the importance of the QMS, their responsibility to contribute to its effectiveness and its direct relevance to the success of the Authority. Furthermore, every employee will be trained to perform the duties required by their specific role.

Although the CEO has the ultimate responsibility for quality, all employees have a responsibility within their own areas of work to help ensure that Quality Culture is practiced and nurtured at all times.

The quality statement reflects the organisation's intent and strive for excellence in the provision of service to all its stakeholders.

5. THE CHIEF EXECUTIVE OFFICER'S REPORT

I am pleased to report on the operations of BoMRA in the 2019-20 Annual Report. The emphasis of this report is to share with you the successes and challenges we had implementing our first annual plan, which was drawn from our five-year strategic plan 2019-2024.

Like most other organisations, the Covid-19 pandemic from February 2020 disrupted our business plans and caused management to rethink their priorities and explore new approaches to maintain the effectiveness of the Authority.

The Authority received its annual subvention to the amount of P34 million supplemented by funds previously earmarked for laboratory operationalisation. The **budget strategy** in its first year of strategy implementation was intended to establish functional units required to achieve full functionality while enhancing the visibility in the market of the core functions of medicines evaluation and registration, and inspections of local pharmaceutical premises. As a result of financial compliance and governance, the authority received an unqualified financial audit report for the year under review.

The development of the functional units was the focus of the strategic objectives for internal processes. **Product evaluation and registration** implemented two important initiatives. One was documentation of all functional processes and structures to meet the GBT standards, and the other was implementation of a strategy to reduce, by 35%, the medicines registration applications backlog inherited from the Ministry of Health and Wellness, when the Authority became operational from January 2018. Both initiatives were achieved. However, due to shortage of qualified personnel, the establishment of veterinary medicines, medical devices and cosmetics units could not be completed during the year under review.

Another objective of the Authority was to implement a **pharmacovigilance system**, which involves both educating Healthcare Professionals and developing processes for the reporting of adverse drug reactions. Before year-end, the WHO minimum standards for a country pharmacovigilance system had been met. However, the Authority faced challenges with the initiative to establish our country baseline for substandard and falsified medicines due to delays in operationalising the NDQCL laboratory inherited from the Ministry of Health and Wellness and further slowed down by the impact of the Covid-19 pandemic on our day-to-day operations.

The inspection and licensing of local pharmaceutical premises for human medicines was expanded to include veterinary facilities. In the case of the latter, the Authority was subjected to a routine inspection on the control of veterinary medicines from the European Commission. Further to this, we noted an urgent need to institute an organized structure to the supply chain of veterinary medicinal products, and to ensure veterinary pharmaceutical premises will be able to comply with established standards of good distribution

practices. A national track and trace system was initiated with the support of the local Global Health and Supply Chain Management office. Depending on availability of resources and level of stakeholder engagement, this project will be completed in 3-5 years. The objective of this initiative will be to ensure both integrity in our local medicines supply chain and patient protection against the effects of substandard and falsified medicines.

BoMRA established an **ISO 9001 Quality Management System** in its first year of strategy implementation. The QMS, in addition to ensuring that all functions in the Authority work together seamlessly to deliver consistent products and services impacting on client satisfaction and strategic success, is also an important deliverable of the Regulatory System required for a mature regulatory agency as espoused by the WHO. The challenge encountered from QMS was its slow uptake in the organization since a quality movement in itself is a culture code which requires large management sponsorship in order to take root.

The Authority succeeded in **reviewing the Medicines and Related Substances Act of 2013** and submitted the draft instructions to the Ministry of Health and Wellness. During the year, promulgation of the regulations of the current Act enabled the Authority to open for submission of applications for registration of medicines from February 2020. The highlight of these Medicines and Related Substances Regulations was a provision enabling the Authority to provide for paid services which should help resource special projects not funded through the subvention.

The business of the Authority is internally driven through human resources and **information technology**. The rapid growth made by the Authority during the year while working with ample information and building databases necessitated prioritization of IT infrastructure, storage and protection of data, and inhouse services. A document management system was introduced to help manage the vast number of dossiers received both at the Ministry of Health prior to 2019, and BoMRA following this date. The ERP system posed some challenges meeting its intended business objectives. In addition, our external audit also noted some important processes relating to data security that need to be documented.

The Authority's emphasis on the **development of human resources** was demonstrated by our participation in inhouse, regional and international systems strengthening trainings. A project in integrated human resource management was undertaken, resulting in organizational restructuring and enhancement of people policies aligned to best approaches of a high performing organization. The Authority piloted and adopted the WHO competency framework as a basis for job profiling and career development for its technical cadre from beginner through proficient to expert level. This project was initiated but not completed and will extend to the next operating year.

The Authority conducted a **stakeholder satisfaction survey** focusing on mandate awareness by both the public and various groups of professionals in the health sector. Awareness amongst pharmacist and veterinary groups was rated at 66% against a target of 55% for first year of the strategic plan. For the public rating was low at 28%, which calls on the Authority to review and innovate to implement a better public engagement plan.

Lastly, I would like to thank the Board, employees of BoMRA, the industry, the Ministry of Health and Wellness and all other stakeholders for all their efforts and support throughout the year.

Dr Stephen Ghanie
Chief Executive Officer

SECTION B: CORPORATE GOVERNANCE

6. CORPORATE GOVERNANCE AT BOMRA

Established by Section 6 of the MRSA, the Medicines Regulatory Board is the primary governing structure responsible for setting the direction of the affairs and operations of the Authority. In accordance with Section 7 (1) of the MRSA, the Board consists of members appointed by the Minister of Health and Wellness, after consultation with the Minister of Agricultural Development and Food Security.

The Board is comprised of persons with expertise in law, pharmaceutical industry, business management, medicine, pharmacy and veterinary medicine. The Chief Executive Officer, the Director of Health Services and the Director of Veterinary Services are ex-officio members of the Board.

7. BOARD OF DIRECTORS

The membership of the board is presented in Table 1 below:

Table 1: Board Members

Board Members				
Member		**Nature of Membership**	**Date of First Appointment**	**End of Tenure**
1	Mr. Duncan Thela	Chairperson	1st June 2016	31st May 2022
2	Dr. Mbatshi Mazwiduma	Vice -Chairperson	1st June 2016	31st May 2022
3	Mr. Kagiso Balopi	Member	1st June 2016	31st May 2022
4	Mr. Meshack Baoleki	Member	1st June 2016	31st May 2022
5	Ms. Botho Bayendi	Member	1st June 2019	31st May 2022
6	Dr. Joyce Kgatlwane	Member	1st July 2018	30th June 2021
7	Dr. Tiroyaone Mampane	Member	1st June 2016	31st May 2022
8	Dr. Letlhogile Modisa	Member (Ex -Officio)	1st June 2019	N/A
9	Dr. Gontle Moleele	Member	1st July 2018	30th June 2021
10	Ms. Shameela Pholo-Winston	Member	1st June 2016	31st May 2022
11	Dr. Gaseitsewe Michael Sento	Member	1st July 2018	30th June 2021
12	Dr. Malaki Tshipayagae	Member (Ex -Officio)	1st June 2019	N/A
13	Dr Stephen Ghanie	Member (Ex -Officio)	N/A	N/A

Over the period under review the meeting attendances for the Board are shown in Table 2 below:

Table 2: Board Meetings

Board Meetings						
		Dates				
	Member	29th August 2019	8th November 2019	12th December 2019	3rd March 2020	18th March 2020
1	Mr. Duncan Thela	✓	✓	✓	✓	✓
2	Dr. Mbatshi Mazwiduma	✓	✓	✓	✓	✓
3	Mr. Kagiso Balopi	✓	✓	✓	✓	✓
4	Mr. Meshack Baoleki	✓	✓	A	✓	✓
5	Dr. Gaseitsewe Sento	✓	✓	✓	✓	✓
6	Ms. Shameela Pholo-Winston	✓	✓	✓	✓	✓
7	Dr. Gontle Moleele	✓	✓	✓	✓	✓
8	Dr. Joyce Kgatlwane	✓	✓	A	✓	✓
9	Dr. Tiroyaone Mampane	×	×	×	×	×
10	Ms. Botho Bayendi	✓	✓	✓	✓	✓
11	Dr. Malaki Tshipayagae	✓	A	✓	✓	✓
12	Dr. Letlhogile Modisa	✓	A	A	A	✓

Key

Present	✓
Apology	A
Absent without apology	×

8. BOARD COMMITTEES

The Board has appointed seven (7) committees to assist in executing the Authority's mandate. The Committees established by the Board operate on the basis of their terms of references which set out their responsibilities. The Committees include the Technical and Non-Technical Committees.

Over the period under review the Authority established the Governance and Nominations Committee to strengthen corporate governance and its implementation within the Authority. The Authority is further in the process of establishing the Licensing Committee for oversight over the Licensing and Inspections Function.

The Committees of the Board are as set out below:

9. TECHNICAL COMMITTEES

9.1 Registration Committee

The Registration Committee is responsible for:

- Ensuring that registered medicines meet the provisions of the MRSA, Regulations, Policies, Standards, the set conditions and requirements for registration;
- Considering and advising the Authority on registration of medicines;
- Recommending rejection of applications, suspension or removal from the Register of any medicines in accordance with the Act, Regulations, Policies and Standards; and
- Reviewing of the registration fees and recommendation to the Board for endorsement and approval by the Minister.

Attendances for the Registration Committee meetings during the period under review are as per Table 3 below:

Table 3: Registration Committee Meetings

Registration Committee Meetings							
		Dates					
	Member	26th June 2019	21st August 2019	10th October 2019	10th November 2019	4th December 2019 (Special)	13th February 2020
1	Dr Joyce Kgatlwane	✓	✓	✓	✓	✓	A
2	Dr Goabaone Rankgoane-Pono	A	A	✓	A	✓	✓
3	Dr. Samantha Letsholo	A	A	✓	✓	✓	✓
4	Dr Celda Tiroyakgosi	✓	✓	✓	✓	✓	✓
5	Dr. Batshanani Busang	✓	✓	✓	✓	✓	✓
6	Dr Tendani Gaolathe	✓	✓	✓	✓	A	✓
7	Ms. Lesego Moetedi	✓	✓	✓	✓	A	A

Key

Present	✓
Apology	A

9.2 Pharmacovigilance Advisory Committee

The Pharmacovigilance Advisory Committee is responsible for:

- Guiding the Authority on pharmacovigilance functions and conduct of clinical trials;
- Making decisions on risk-benefit assessments of the medicines registered in Botswana based on the quality, safety and efficacy of the medicines;
- Making recommendations to the Registration Committee on safety and efficacy pre and post marketing authorization;
- Making recommendations on risk minimisation measures to the Marketing Authorization holders and health programmes; and
- Reviewing promotional and advertising materials for its content and presentation.

Attendances for the Pharmacovigilance Advisory Committee meetings during the period under review are as per Table 4 below:

Table 4: Pharmacovigilance Advisory Committee Meetings

Pharmacovigilance Advisory Committee Meetings			
		Dates	
Member	10th October 2019	9th December 2019	24th February 2020
1 Dr Gontle Moleele	✓	✓	A
2 Mrs Matshidiso Matome	✓	✓	✓
3 Ms Ratanang Balisi	A	A	✓
4 Dr Kereng Masupu	✓	✓	✓
5 Dr Kerapetse Sehularo	✓	✓	A
6 Dr Lebapotswe Tlale	✓	✓	✓
7 Mr Richard Leepo *	✓	*	*

Key

Present	✓
Apology	A
Resigned	*

(continued)

9.3 Licensing Committee

The Licensing Committee is responsible for:

- Reviewing and recommending policies, procedures and standards for licensing purposes.
- Approving guidelines, procedures and inspection programmes for both local and external inspections.
- Approving criteria for enforcement actions to be adopted by the Authority for matters that need not be prosecuted through the courts.
- Reviewing of the licensing fees proposed by the Authority for recommendation to the board.
- Reviewing decisions by the Licensing and Inspections Department where there are grievances and complaints by clients, where they are aggrieved by decisions made by the Authority in the execution of its licensing functions.

The Licensing Committee is yet to be fully constituted and held no meetings during the period under review.

10. NON-TECHNICAL COMMITTEES

10.1 Finance, Audit, and Risk Committee

The Finance, Audit and Risk Committee is responsible for oversight of the following:

- Accounting practices, financial controls and reporting systems of the Authority;
- Budgeting, budgetary control systems and auditing processes of the Authority;
- Authority's enterprise wide risk management, risk management and risk avoidance measures; and
- Economy, efficiency and effectiveness of the Authority's Information Technology.

Membership and Attendances for the Finance, Audit and Risk Committee meetings during the period under review are as per Table 5 below:

Table 5: Finance, Audit and Risk Committee Meetings

Finance, Audit and Risk Committee Meetings							
		Dates					
	Member	16th May 2019	7th August 2019	22nd October 2019	27th February 2020	13th March 2020	27th March 2020
1	Mr. Kagiso Balopi	✓	✓	✓	✓	✓	✓
2	Dr. Mbatshi Mazwiduma	✓	✓	✓	✓	✓	✓
3	Mr. Meshack Baoleki	✓	✓	✓	A	✓	A

Key

Present	✓
Apology	A

(continued)

10.2 Procurement and Tender Committee

The Procurement and Tender Committee is responsible for oversight of the following:

- Procurement and disposal in accordance with the Procurement Policy and the limits of the Authority as set out in the Board Charter;
- Reviewing and recommending approval of the Procurement Policy and any amendments thereto, to the Board;
- Ensuring compliance with the Procurement Policy in the execution of procurement processes/procedures; and
- Reviewing compliance issues submitted to the Committee by the Management Tender Committee.

Attendances for the Procurement and Tender Committee meetings during the period under review are as per Table 6 below:

Table 6: Procurement and Tender Committee Meetings

Procurement and Tender Committee Meetings				
		Dates		
	Member	16th May 2019	16th October 2019	1st November 2019	18th February 2020
1	Mr. Meshack Baoleki	✓	✓	✓	✓
2	Dr. Gaseitsiwe Sento	✓	✓	✓	✓
3	Mr Kagiso Balopi	✓	✓	✓	✓
4	Dr Joyce Kgatlwane	✓	✓	A	✓

Key

Present	✓
Apology	A

10.3 Human Resources Committee

The Human Resources Committee is responsible for the following:

- Reviewing and recommending the Human Resources Strategy to the Board;
- Reviewing and reporting annually to the Board, on the Authority's succession planning for critical and key positions;
- Reviewing and recommending for approval, the CEO's recommendations for appointment of Executive Management;
- Reviewing and recommending, the organizational structure changes; and
- Recommending the CEO's performance objectives for approval by the Board.

Attendances for the Human Resources Committee meetings during the period under review are as per Table 7 below:

Table 7: Human Resources Committee Meetings

Human Resources Committee Meetings						
		Dates				
	Member	15th April 2019	14th October 2019	20th November 2019	17th February 2020	11th March 2020
1	Ms. Shameela Pholo -Winston	✓	✓	✓	✓	✓
2	Dr. Gontle Moleele	✓	✓	✓	✓	✓
3	Dr. Letlhogile Modisa	A	A	✓	A	✓

Key

Present	✓
Apology	A

10.4 Governance and Nominations Committee

The Governance and Nominations Committee is responsible for

- Corporate governance practices, principles, guidelines and related policies of the Board;
- Nominations of candidates for appointment to the Board and Committees;
- Composition, development and evaluation of the Board and Committees;
- Matters relating to integrity and ethics;
- Shareholder agreement and other shareholder requirements;
- The Authority's corporate social responsibility program; and
- Technical advisory on governance matters emanating from other Committees.

Attendances for the Governance and Nominations Committee meetings during the period under review are as per Table 8 below:

Table 8: Governance and Nominations Committee Meetings

Governance and Nominations Committee Meetings			
		Dates	
	Member	6th December 2019	28th February 2020
1	Ms. Botho Bayendi	✓	✓
2	Mr Kagiso Balopi	✓	✓
3	Mr Meshack Baoleki	✓	A
4	Ms. Shameela Pholo -Winston	✓	✓

Key

Present	✓
Apology	A

SECTION C: BOMRA's MANDATE

11. ORGANISATIONAL STRUCTURE

The Authority is structured to deliver on its mandate and to ensure coverage of the entire medicines and cosmetics supply chain. The Organisation is led by the Chief Executive Officer and Executive Management team and consists of Technical Departments and Support Departments. The CEO is further supported by the Chief Technical Advisor, responsible for providing support and advice on technical matters of the Authority, driving self-assessment using the GBT and overseeing the Authority's relationships with technical partners and stakeholders.

ORGANISATIONAL STRUCTURE

ORGANISATIONAL STRUCTURE

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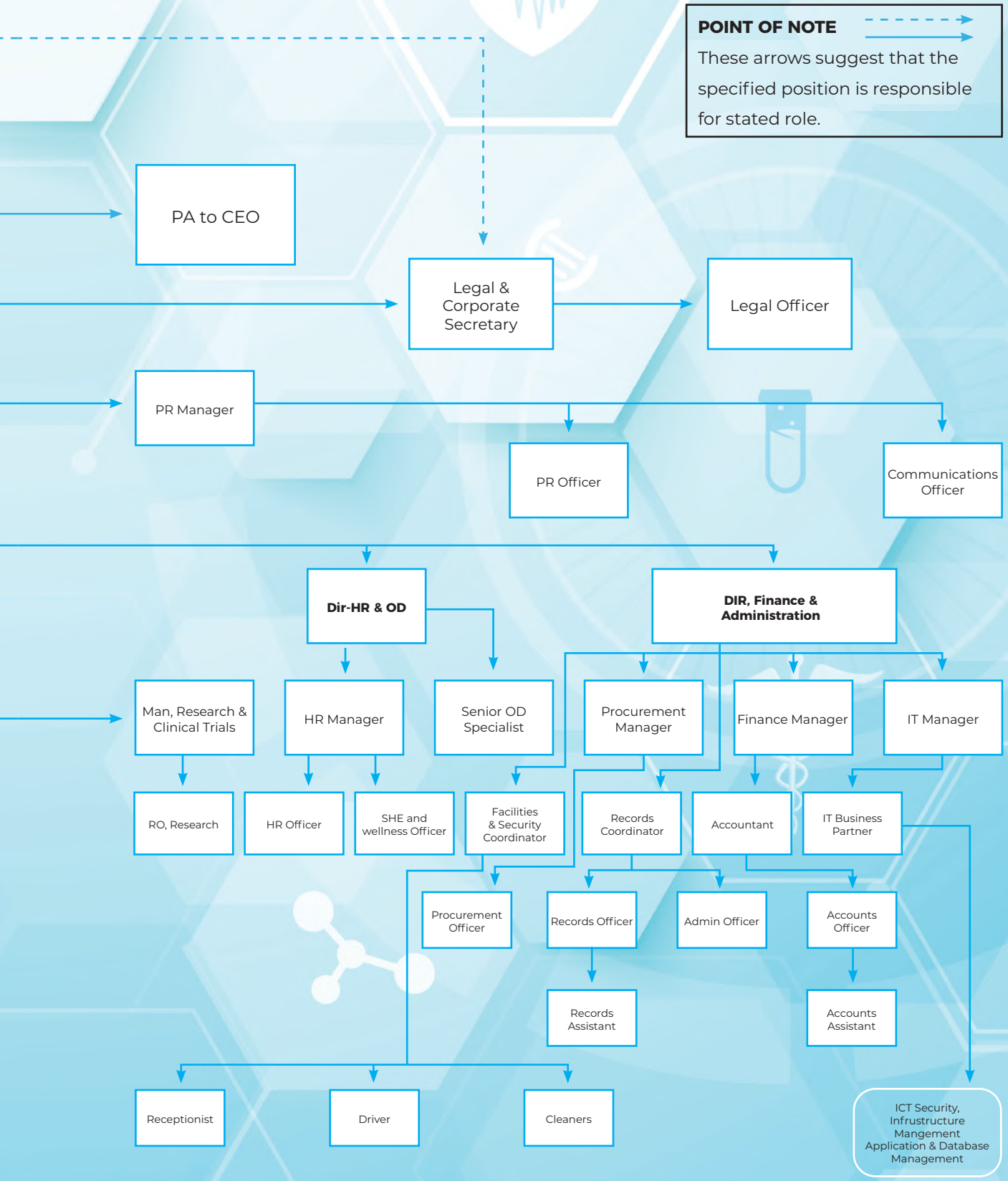


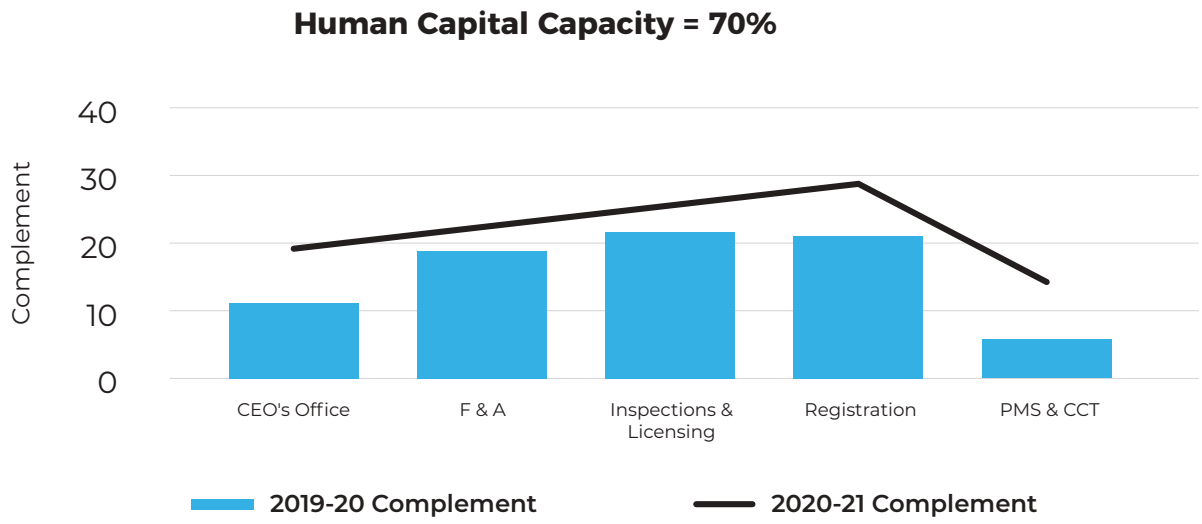
12. HUMAN CAPITAL MANAGEMENT

The BoMRA 2019-24 Corporate Strategy endeavours to ensure the Authority becomes a high-performance organisation driven by world class people management systems, the right talent and an equally conducive work environment.

The Authority has a wide spectrum of skills derived from different professions and these include, Pharmacy, Laboratory Science, Veterinary Medicine, Finance, Law, Human Resources, Information Technology, Quality Assurance, Audit, Business Management and Marketing.

The Authority is currently functioning with a complement of 70 employees spread across departments. The human capital capacity is reflected in Graph 1 below.

Graph 1 – Human Capital Capacity

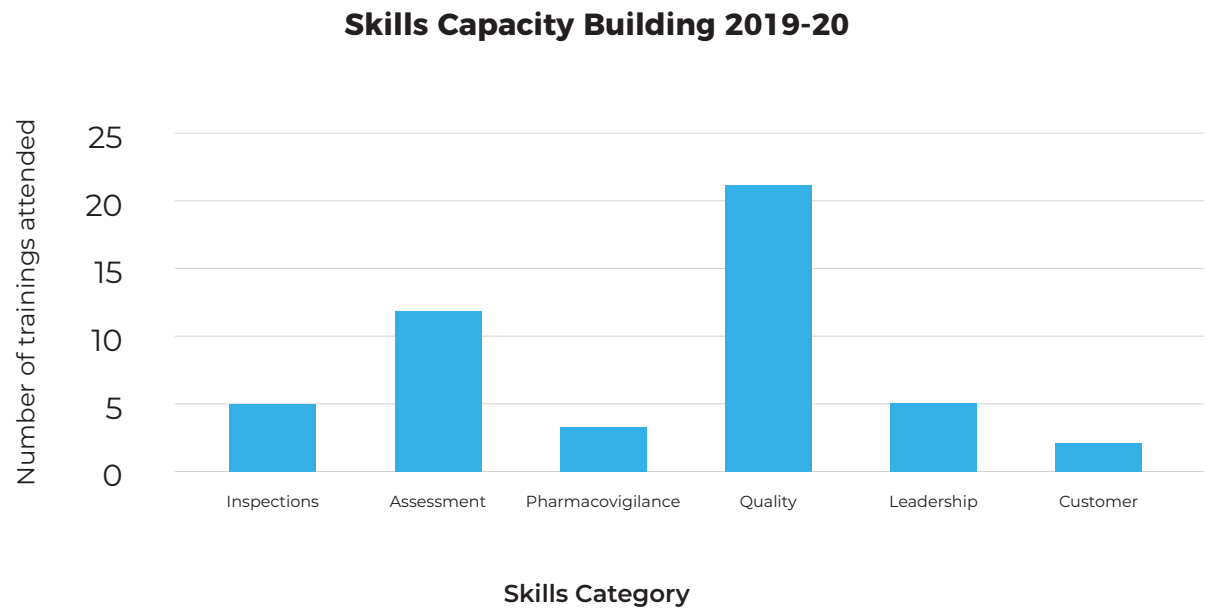


The Authority is committed to improving and continually developing the skills and competencies of its human capital. To this end, a total of 43 different training programs were undertaken. These included training to strengthen technical expertise, quality systems, leadership skills and customer service.

(continued)

The skills capacity building is reflected in Graph 2 below.

Graph 2 – Skills Capacity Building



The Authority further embarked on an organisational structural review exercise to ensure its alignment with the mandate and that it fully supports the strategic agenda.

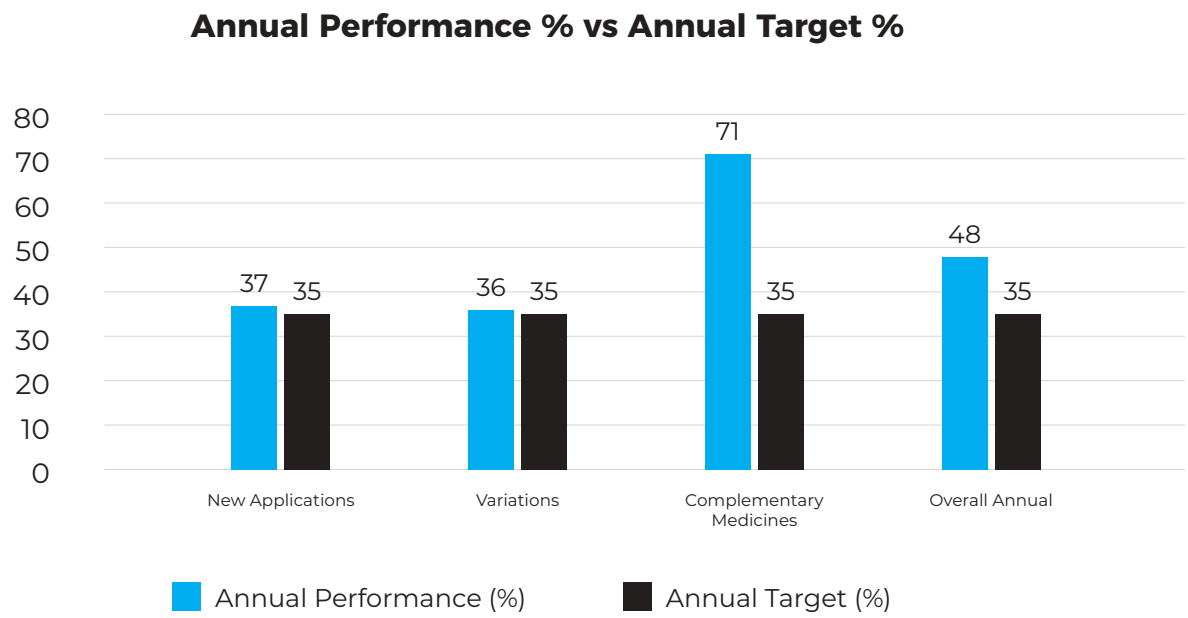
13. PRODUCT EVALUATION AND REGISTRATION

Product Evaluation and Registration ensures that medical products, medical devices and cosmetics registered or approved for use in Botswana are safe and effective for their intended use and that they meet established quality standards.

Key Highlights

- Upon commencing operations, the Authority received a backlog of applications from the Drugs Regulatory Unit, Ministry of Health and Wellness categorized as follows: Human conventional medicine applications = 400, Variation applications = 1000 and Complementary medicine applications = 685. During the course of the year the Authority had an overall backlog reduction of 48% compared to the annual target of 35%, see Table 10 and Graph 3 below.

Graph 3 - Annual Performance vs Annual Target



- Commencement of receipt of new applications from February 2020 for registration of human (conventional and complementary medicines). As of the 31st March 2020, the following applications for Screening had been received:

Table 9 – No. of Screenings

Application Type	Number Received
Screening – Conventional human medicines	106
Screening – Complementary medicines	5

14. INSPECTIONS AND LICENSING

Inspections and Licensing ensures that facilities involved in the manufacturing, distribution and sale of medical products, medical devices and cosmetics adhere to legislation and prescribed standards for the storage and handling of products to maintain their safety, quality and efficacy as well as controlling import and export of medicines.

Key Highlights

- Development of a new import and export control system for both Human and Veterinary medicines from February 2020. The new import and export control system was developed to overcome challenges identified and to improve maintenance of records.
- Completion of Inspections Framework, to be implemented from the 2020/21 financial year. The Inspection Framework provides for inspections of all the institutions, which for the first time will extend to Government public facilities. The framework identifies the key collaborating stakeholder agencies required to assist in fulfilment of the Authority's oversight of the medicines supply chain.

15. LABORATORY

The Laboratory undertakes the physicochemical analysis of medicines and related substances as well as medical devices available in the market, to determine their fitness for purpose and verify manufacturer's claims on their quality, safety and efficacy.

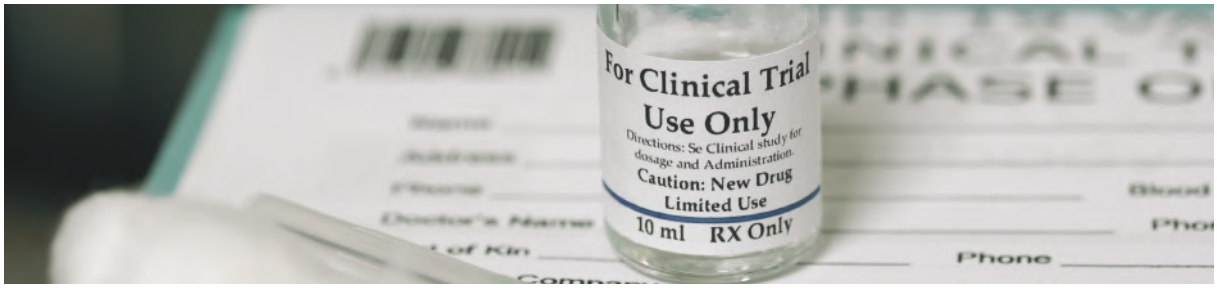
Key Highlights

The laboratory, which was handed over to BoMRA by the Ministry of Health and Wellness, was prepared for operationalisation and will support implementation of the Authority mandate.

16. POST MARKET SURVEILLANCE AND CONTROL OF CLINICAL TRIALS

This function is responsible for monitoring the safety of medical products, approval and monitoring of the conduct of clinical trials, and post marketing surveillance of medical products in order to identify substandard & falsified medicines in the market.
Key Highlights

- Achievement of the WHO minimum requirements for a functional National PV System.
- Fostering of a culture of reporting ADRs. The Authority received 221 ADR reports in the year 2019-20 against the target of 50 ADRs.
- Identification of 12 hospitals in different geographical regions of Botswana to establish Adverse drug reaction Monitoring Centres (AMC) which include both private and public institutions.
- Launch of the Med Safety App (smart phone-based ADR reporting tool) and E-Reporting (Web based reporting). The event was graced by the Honourable Minister of Health and Wellness, Dr Lemogang Kwape, WHO-HQ Representative Ms Ayako Fukushima and WHO Local office representative Ms Kefentse Moakofi. A total of 140 delegates attended the event, amongst them 125 were healthcare professionals.



17. ENFORCEMENT

The Authority carried out enforcement activities aimed at ensuring compliance with the MRSA. The Authority engaged with various partners including the Police, Botswana Unified Revenue Services, Councils and Botswana Bureau of Standards in carrying out its enforcement operations.

Key Highlights

Commenced joint Operations with stakeholders including the Police and BURS, throughout Botswana, resulting in some cases handed over to other authorities for prosecution.

18. QUALITY MANAGEMENT

Responsible for establishing and monitoring a Quality Management System (QMS) within the Authority and advising on the performance of the QMS. For any Medicines Regulatory Authority to be deemed fully functional by WHO, it is a requirement that it should have established a Quality Management System (QMS) and that there should be evidence of effective implementation of the QMS.

Key Highlights

- Training and qualification of 4 staff members as full ISO 9001 QMS internal auditors.
- The Internal Audit Program was implemented across the Authority complemented by training of new staff, Quality Champions and other team members.

19. PUBLIC RELATIONS AND STAKEHOLDER ENGAGEMENT

The Authority engaged with internal and external stakeholders to enhance public education and stakeholder engagement.

Key Highlights

- A new corporate website for the Authority was launched (www.bomra.co.bw) on a new platform in 2019, and will deliver seamless, interactive, online services for clients and stakeholders.
- Enhanced education and awareness about the BoMRA mandate through participating in a range of activities such as Consumer Fair and Anti-Microbial Resistance Day, as well as engaging with stakeholders such as Business Botswana, and others.

20. FINANCE AND ADMINISTRATION

Finance and Administration manages the Authority's financial affairs, information technology, records and general administration. This enables the Authority to have the requisite, tools and conditions to run optimally in pursuance of its mandate.

21. COLLABORATIONS

The Authority aims to enter into strategic partnerships to enhance its functions, capabilities and operations. During the year under review two Memoranda of Understanding were signed with the Medicines Control Authority of Zimbabwe (MCAZ) and Tanzania Medicines and Medical Devices Authority (TMDA). As a strategy the Authority seeks to ensure that it leverages off the MOUs by ensuring that value added action plans are developed and initiated once MOUs are signed.

SECTION D: FINANCIAL INFORMATION

Audited Financial Statements

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The following supplementary information does not form part of the financial statements and is unaudited:

Detailed Income Statement 80

MEDICINES REGULATORY AUTHORITY FINANCIAL STATEMENTS
FOR THE YEAR ENDED MARCH 31, 2020

General Information

Country of incorporation and domicile	Botswana
Nature of business and principal activities	Medicines Regulatory Authority (the Authority) was established as a body corporate by the Medicines and Related Substances Act of 2013 to regulate the supply chain of medicines (including veterinary medicinal products), cosmetics and medical devices in Botswana to ensure that they conform with established criteria of quality, safety and efficacy.
Directors	Mr. Duncan Thela (Chairperson) Dr. Mbatshi Mazwiduma (Vice Chairperson) Dr. Gontle Moleele (Board Member) Dr. Joyce Kgatlwane (Board Member) Mr. Kagiso Balopi (Board Member) Mr. Meshack Baoleki (Board Member) Dr. Michael G. Sento (Board Member) Ms. Shameela Pholo-Winston (Board Member) Dr. Tiroyaone Mampane (Board Member) Dr. Letlhogile Modisa (Ex-officio Board Member) Ms. Botho Bayendi (Ex-officio Board Member) *(Appointed on 1st June 2019)* Dr. Malaki Tshipayagae (Ex-officio Board Member) *(Appointed on 1st June 2019)* Dr. Khumo Seipone *(Membership ended on 1st June 2019)* Mr. Thapelo Tsheole *(Membership ended on 1st June 2019)*
Chief Executive Officer	Dr. Stephen Ghanie (Ex-officio Board Member)
Board secretary	Mr. Nonofo Thipe Mrs. Latelang Chakalisa (Resigned on 31/12/2019)
Business address	Plot 112, International Finance Park Gaborone
Postal address	Private Bag 2, Gaborone Botswana
Bankers	First National Bank Botswana Limited
Auditors	RSM Botswana Certified Auditors
Legal form	A statutory body formed in terms of the Medicines and Related Substances Act, 2013. It is a body corporate.

Medicines Regulatory Board Responsibilities and Approval of the Financial Statements

The Medicines Regulatory Board (tbe Board) is required in terms of the Medicines and Related Substances Act of 2013 to maintain adequate accounting records and is responsible for the content and integrity of the financial statements and related financial information included in this report. It is the Board's responsibility to ensure that the financial statements fairly present the state of affairs of the Authority as at the end of the financial year and the results of its operations and cash flows for the period then ended, in conformity with International Financial Reporting Standards and the requirements of Medicines and Related Substances Act, 2013. The external auditors are engaged to express an independent opinion on the financial statements.

The financial statements are prepared in accordance with International Financial Reporting Standards and the requirements of Medicines and Related Substances Act, 2013 and are based upon appropriate accounting policies consistently applied and supported by reasonable and prudent judgements and estimates.

The Board acknowledges that it is ultimately responsible for the system of internal financial control established by the Authority and place considerable importance on maintaining a strong control environment. To enable it to meet these responsibilities, the Board sets standards for internal control aimed at reducing the risk of error or loss in a cost effective manner. The standards include the proper delegation of responsibilities within a clearly defined framework, effective accounting procedures and adequate segregation of duties to ensure an acceptable level of risk. These controls are monitored throughout the Authority and all employees are required to maintain the highest ethical standards in ensuring the Authority's business is conducted in a manner that in all reasonable circumstances is above reproach. The focus of risk management in the Authority is on identifying, assessing, managing and monitoring all known forms of risk across the Authority. While operating risk cannot be fully eliminated, the Authority endeavours to minimise it by ensuring that appropriate infrastructure, controls, systems and ethical behaviour are applied and managed within predetermined procedures and constraints.

The Board is of the opinion that the system of internal control provides reasonable assurance that the financial records may be relied on for the preparation of the financial statements. However, any system of internal financial control can provide only reasonable, and not absolute, assurance against material misstatement or loss.

The Board has reviewed the Authority's's cash flow forecast for the year to March 31, 2021 and, in light of this review and the current financial position, it is satisfied that the Authority has adequate resources to continue in operational existence for the foreseeable future.

The external auditors are responsible for independently auditing and reporting on the Authority's financial statements. The financial statements have been examined by the Authority's external auditors and their report is presented on pages 4 to 6.

The financial statements set out on pages 7 to 28, which have been prepared on the going concern basis, were approved by the board on 19 October 2020 and were signed on their behalf by:

Chairperson

Chief Executive Officer

RSM

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C +267 71 386 590 / 72 310 395
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www.rsm.co.bw

INDEPENDENT AUDITOR'S REPORT
To the Minister of Health and Wellness

Report on the Audit of the Financial Statements

Opinion

We have audited the financial statements of Medicines Regulatory Authority (the Authority) set out on pages 7 to 27, which comprise the statement of financial position as at 31 March 2020, and the statements of surplus or deficit and other comprehensive income, changes in reserves and cash flows for the year then ended, and notes to the financial statements, including significant accounting policies.

In our opinion, financial statements present fairly, in all material respects, the financial position of the Authority as at 31 March 2020, and its financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards and the requirements of Medicines and Related Substances Act, 2013.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the Authority in accordancewith the International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants (IESBA Code) together with the ethical requirements that are relevant to our audit of the financial statements in Botswana, and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Other Information

The Board is responsible for the other information. The other information comprises all the information in this report except for financial statements set out in pages 7 to 27.

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

In connection with our audit of the financial statements, our responsibility is to read the other information. We consider whether other information is consistent with the financial statements or our knowledge obtained in the audit. If based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report the fact. We have nothing to report in this regard.

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Responsibilities of the Board for the Financial Statements

The members of Medicines Regulatory Board(the Board) are responsible for the preparation and fair presentation of the financial statements in accordance with International Financial Reporting Standards and Medicines and Related Substances Act, 2013, and for such internal control as directors determine as 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, members of the board are responsible for assessing the Authority's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless they have no realistic alternative but to let discontinue the Authority's operations.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are 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 our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with International Standards on Auditing (ISAs) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in 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 ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess 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 our 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.

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

- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.

- Conclude on the appropriateness of the Board'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 we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the authority to cease to continue as a going concern.

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

We communicate with the Board regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

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We also provide the Board with a statement that we have complied with relevant ethical requirements regarding independence and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence and, where applicable related safeguards.

From the matters communicated with the Board we determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on other legal and regulatory requirements

Further, in accordance with Section 21 (3) of the Medicines and Related Substances Act, 2013 (the Act), in our opinion :

1. The Authority, in terms of Section 21(3) (a) of the Act provided us with the necessary information and explanations for us to perform our duties as auditors.

2. The Authority maintained accounts and related records in the manner required by under Section 21(3)(b) of the Act.

3. The Authority complied with all the financial provisions of the Act.

RSM Botswana.

RSM Botswana
A Firm Chartered Accountants
(Botswana)
P. O. Box 1816, Gaborone
Ph: 3912805 Fax: 3959636
www.rsmbotswana.co.bw

RSM Botswana
Certified Auditors
Practicing member: P. Muonde
Membership number: CAP0024

Date: 23 October 2020
Gaborone

Statement of Surplus or Deficit and Other Comprehensive Income

Figures in Pula	Note(s)	2020	2019 (15 months)
Revenue	3	57,447,662	41,836,456
Regulatory fees	4	540,273	14,875
Total income		**57,987,935**	**41,851,331**
Employee costs	5	(35,615,153)	(15,266,963)
Governance expenses		(823,515)	(629,805)
Depreciation amortisation and impairment expenses	5	(3,324,548)	(2,504,880)
Publicity and awareness expenses		(2,643,363)	(998,646)
Travel and accomodation costs		(3,683,745)	(1,541,202)
Operating expenses		(8,933,973)	(3,306,675)
Total expenses		**(55,024,297)**	**(24,244,271)**
Operating surplus	5	**2,963,638**	**17,629,051**
Investment income	6	494,446	-
Finance costs	7	(871,500)	(751,195)
Total operating surplus for the period		**2,586,584**	**16,877,856**
Other comprehensive income:			
Other comprehensive income		-	-
Total comprehensive surplus for the period		**2,586,584**	**16,877,856**

Statement of Financial Position as at March 31, 2020

Figures in Pula	Note(s)	2020	2019 (15 months)
Assets			
Non-current assets			
Equipment	9	7,657,381	6,150,180
Intangible assets	10	807,037	841,232
Right-of-use asset	11	11,270,198	12,601,566
		19,734,616	**19,592,978**
Current assets			
Accounts receivable	12	591,198	338,732
Cash and cash equivalents	13	27,525,580	45,948,409
		28,116,778	**46,287,141**
Total assets		**47,851,394**	**65,880,119**
Reserves and liabilities			
Reserves			
Accumulated surplus		19,464,442	16,877,857
Liabilities			
Non-current liabilities			
Lease liabilities	14	11,077,697	12,257,608
Deferred income	15	8,465,975	6,991,171
		19,543,672	**19,248,779**
Current liabilities			
Lease liabilities	14	1,416,752	1,269,635
Deferred income	15	-	24,231,765
Accounts payable	16	7,426,528	4,252,083
		8,843,280	**29,753,483**
Total liabilities		**28,386,952**	**49,002,262**
Total reserves and liabilities		**47,851,394**	**65,880,119**

Statement of Changes in Reserves

Figures in Pula	Accumulated surplus	Total equity
Balance at April 1, 2018	**-**	**-**
	-	-
Surplus for the period	16,877,858	16,877,858
Total surplus for the period	**16,877,858**	**16,877,858**
Balance at April 1, 2019	**16,877,858**	**16,877,858**
	-	-
Surplus for the year	2,586,584	2,586,584
Total surplus for the year	**2,586,584**	**2,586,584**
Balance at March 31, 2020	**19,464,442**	**19,464,442**

Statement of Cash Flows

Figures in Pula	Note(s)	2020	2019 (15 months)
Cash flows from operating activities			
Cash generated from operations	17	9,215,585	23,519,315
Interest income		494,446	-
Finance costs		(871,500)	(751,195)
Net cash from operating activities		**8,838,531**	**22,768,121**
Cash flows from investing activities			
Purchase of equipment	9	(3,190,991)	(6,220,928)
Purchase of intangible assets	10	(130,712)	(903,632)
Proceeds from insurance claim	9	25,564	-
Net cash from investing activities		**(3,296,139)**	**(7,124,560)**
Cash flows from financing activities			
Payment on lease liabilities		(1,208,260)	(918,088)
Increase in deferred goverment grant		1,474,804	6,991,171
Decrease in government grant for laboratory		(24,231,765)	24,231,765
Net cash from financing activities		**(23,965,221)**	**30,304,848**
Net (decrease)/increase in cash and cash equivalents for the year		**(18,422,829)**	**45,948,409**
Cash and cash equivalents at the beginning of the year		45,948,409	-
Cash and cash equivalents at the end of the year	13	**27,525,580**	**45,948,409**

Accounting Policies

1. Significant accounting policies

The principal accounting policies applied in the preparation of these financial statements are set out below.

1.1 Basis of preparation

The financial statements have been prepared on the going concern basis in accordance with, and in compliance with, International Financial Reporting Standards ("IFRS") and International Financial Reporting Interpretations Committee ("IFRIC") interpretations issued and effective at the time of preparing these financial statements and the Medicines and Related Substances Act of 2013.

The financial statements have been prepared on the historic cost convention, unless otherwise stated in the accounting policies which follow and incorporate the principal accounting policies set out below. They are presented in Botswana Pula, which is the Authority's functional currency.

These accounting policies are consistent with the previous period.

1.2 Significant judgements and sources of estimation uncertainty

The preparation of financial statements in conformity with IFRS requires the use of judgements, estimates and assumptions that affect the application of policies and reported amounts of assets, liabilities, income and expenses. These estimates and associated assumptions are based on experience and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimates are revised and in any future periods affected.

Key sources of estimation uncertainty
Impairment of financial assets

The impairment provisions for financial assets are based on assumptions about risk of default and expected loss rates. The Authority uses judgement in making these assumptions and selecting the inputs to the impairment calculation, based on the Authority's past history, existing market conditions as well as forward looking estimates at the end of each reporting period. For details of the key assumptions and inputs used, refer to the individual notes addressing financial assets.

Impairment testing

The Authority reviews and tests the carrying value of assets(equipment and right of use assets) when events or changes in circumstances suggest that the carrying amount may not be recoverable. When such indicators exist, management determine the recoverable amount by performing value in use and fair value calculations. These calculations require the use of estimates and assumptions.

Accounting Policies (continued)

1.2 Significant judgements and sources of estimation uncertainty (continued)

Estimation of remaining useful lives and residual value of equipment

The Authority assess the appropriateness of the useful lives of equipment at the end of each reporting period. The useful lives of motor vehicles, furniture, fittings and computer equipment are determined based on Authority's replacement policies for the various assets. Individual assets within these classes, which have a significant carrying amount are assessed separately to consider whether replacement will be necessary outside of normal replacement parameters.

When the estimated useful life of an asset differs from previous estimates, the change is applied prospectively in the determination of the depreciation charge.

The estimate of residual values are affected by market conditions for similar used items, technological advances and pattern of use. These estimates have an impact on the level of depreciation charge to the statement of surplus or deficit and the carrying amount of these items of equipment on the statement of financial position.

Estimation of remaining useful lives and residual value of intangible assets

The Authority assesses the useful lives of an intangible assets based on similar assets, industry practices and technological advancements.These estimates are used in determining amortisation for each year.

The Authority assesses the residual value of an intangible asset shall be nil unless:

- there is a commitment by a commitment by a third party to purchase the asset at the end of it's useful life;or
- there is an active market for the assets and residual value can be determined by reference to that market, It is probable that such a market will exist at the end of asset's useful life.

Estimation of incremental borrowing rate

The Authority determines the value of right of use asset and lease liability by discounting the unpaid lease payments at the commencement date using the incremental borrowing rate.The incremental borrowing rate is the rate that authority would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment.

1.3 Equipment

Equipment are tangible assets which the Authority holds for its own use or for rental to others and which are expected to be used for more than one year.

An item of equipment is recognised as an asset when it is probable that future economic benefits associated with the item will flow to the Authority, and the cost of the item can be measured reliably.

Equipment is initially measured at cost. The cost of item of equipment shall consists of costs incurred initially to acquire an asset and any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by the management.

Accounting Policies (continued)

1.3 Equipment (continued)

Expenditure incurred subsequently for major services, additions to or replacements of parts of equipment are capitalised if it is probable that future economic benefits associated with the expenditure will flow to the Authority and the cost can be measured reliably. Day to day servicing costs are included in surplus or deficit in the year in which they are incurred.

Equipment is subsequently stated at cost less accumulated depreciation and any accumulated impairment losses.

Depreciation of an asset commences when the asset is available for use as intended by management. Depreciation is charged to write off the asset's carrying amount over its estimated useful life to its estimated residual value, using a method that best reflects the pattern in which the asset's economic benefits are consumed by the Authority. Leased assets are depreciated in a consistent manner over the shorter of their expected useful lives and the lease term. Depreciation is not charged to an asset if its estimated residual value exceeds or is equal to its carrying amount. Depreciation of an asset ceases at the earlier of the date that the asset is classified as held for sale or derecognised.

The useful lives of items of equipment have been assessed as follows:

Item	Depreciation method	Average useful life
Furniture and fixtures	Straight line	10 years
Motor vehicles	Straight line	5 years
Office equipment	Straight line	5-10 years
Computer equipment	Straight line	3-5 years
Leasehold improvements	Straight line	3-4 years
Laboratory equipment	Straight line	5 years

The residual value, useful life and depreciation method of each asset are reviewed at the end of each reporting year. If the expectations differ from previous estimates, the change is accounted for prospectively as a change in accounting estimate.

Each part of an item of equipment with a cost that is significant in relation to the total cost of the item is depreciated separately.

The depreciation charge for each year is recognised in surplus or deficit unless it is included in the carrying amount of another asset.

Impairment tests are performed on equipment when there is an indicator that they may be impaired. When the carrying amount of an item of equipment is assessed to be higher than the estimated recoverable amount, an impairment loss is recognised immediately in surplus or deficit to bring the carrying amount in line with the recoverable amount.

An item of equipment is derecognised upon disposal or when no future economic benefits are expected from its continued use or disposal. Any gain or loss arising from the derecognition of an item of equipment, determined as the difference between the net disposal proceeds, if any, and the carrying amount of the item, is included in surplus or

Accounting Policies (continued)

1.3 Equipment (continued)

deficit when the item is derecognised.

1.4 Intangible assets

An intangible asset is recognised when:

- it is probable that the expected future economic benefits that are attributable to the asset will flow to the Authority; and
- the cost of the asset can be measured reliably.

Intangible assets are initially recognised at cost.

Intangible assets are carried at cost less any accumulated amortisation and any impairment losses.

The amortisation period and the amortisation method for intangible assets are reviewed every period-end. Amortisation is provided to write down the intangible assets, on a straight line basis, to their residual values as follows:

Item	Depreciation method	Average useful life
Computer software	Straight line	6 years

1.5 Financial instruments

Financial instruments held by the Authority are classified in accordance with the provisions of IFRS 9 Financial Instruments. Broadly, the classification possibilities, which are adopted by the Authority ,as applicable, are as follows:

Financial assets which are debt instruments:

- Amortised cost.

Financial liabilities:

- Amortised cost;

Note 18 Financial instruments and risk management presents the financial instruments held by the Authority based on their specific classifications.

The specific accounting policies for the classification, recognition and measurement of each type of financial instrument held by the Authority are presented below:

Accounts receivable
Classification

Accounts receivable, excluding prepayments, are classified as financial assets subsequently measured at amortised cost (note 12).

They have been classified in this manner because their contractual terms give rise, on specified dates to cash flows that are solely payments of principal and interest on the principal outstanding, and the Authority's business model is to collect the contractual cash flows on Accounts receivable.

Accounting Policies (continued)

1.5 Financial instruments (continued)

Recognition and measurement

Accounts receivable are recognised when the Authority becomes a party to the contractual provisions of the receivables. They are measured, at initial recognition, at fair value plus transaction costs, if any.

They are subsequently measured at amortised cost.

The amortised cost is the amount recognised on the receivable initially, minus principal repayments, plus cumulative amortisation (interest) using the effective interest method of any difference between the initial amount and the maturity amount, adjusted for any loss allowance.

Credit risk

Details of credit risk are included in the Accounts receivable note (note 12) and the financial instruments and risk management note (note 18).

Derecognition

Refer to the derecognition section of the accounting policy for the policies and processes related to derecognition.

Accounts payable
Classification

Accounts payable (note 16), excluding amounts received in advance, are classified as financial liabilities subsequently measured at amortised cost.

Recognition and measurement

They are recognised when the Authority becomes a party to the contractual provisions, and are measured, at initial recognition, at fair value plus transaction costs, if any.

They are subsequently measured at amortised cost using the effective interest method.

The effective interest method is a method of calculating the amortised cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the financial liability, or (where appropriate) a shorter period, to the amortised cost of a financial liability.

If Accounts payable contain a significant financing component, and the effective interest method results in the recognition of interest expense, then it is included in surplus or deficit in finance costs (note 7).

Accounts payable expose the Authority to liquidity risk and possibly to interest rate risk. Refer to note 18 for details of risk exposure and management thereof.

Accounting Policies (continued)

1.5 Financial instruments (continued)

Derecognition

Refer to the "derecognition" section of the accounting policy for the policies and processes related to derecognition.

Cash and cash equivalents

Cash and cash equivalents comprise cash on hand and demand deposits, and other short term highly liquid investments that are readily convertible to a known amount of cash and are subject to insignificant risk of change in value. Cash and cash equivalents are measured at amortised cost, which generally approximates fair value.

Derecognition
Financial assets

The Authority derecognises a financial asset only when the contractual rights to the cash flows from the asset expire, or when it transfers the financial asset and substantially all the risks and rewards of ownership of the asset to another party. If the Authority neither transfers nor retains substantially all the risks and rewards of ownership and continues to control the transferred asset, the Authority recognises its retained interest in the asset and an associated liability for amounts it may have to pay. If the Authority retains substantially all the risks and rewards of ownership of a transferred financial asset, the Authority continues to recognise the financial asset and also recognises a collateralised borrowing for the proceeds received.

Financial liabilities

The Authority derecognises financial liabilities when, and only when, the Authority obligations are discharged, cancelled or they expire. The difference between the carrying amount of the financial liability derecognised and the consideration paid and payable, including any non-cash assets transferred or liabilities assumed, is recognised in surplus or deficit.

Reclassification
Financial assets

The Authority only reclassifies affected financial assets if there is a change in the business model for managing financial assets. If a reclassification is necessary, it is applied prospectively from the reclassification date. Any previously stated gains, losses or interest are not restated.

The reclassification date is the beginning of the first reporting period following the change in business model which necessitates a reclassification.

Accounting Policies (continued)

1.6 Leases

The Board assessed the contract to use the premises from which it operates as a lease.The contract is a lease as it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The lease term is determined as the non cancellable period of the lease together with the period covered by the option to extend the lease that the Board is reasonable certain that it will exercise.

Authority as lessee

A lease liability and corresponding right-of-use asset are recognised at the lease commencement date, for all lease agreements for which the Authority is a lessee, except for short-term leases of 12 months or less, or leases of low value assets.

Lease liability

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, The lease payments are discounted using the lesse's incremental borrowing rate.

The lease payments are apportioned between the finance charge and the reduction of outstanding liability.The finance charge is allocated to each period during the lease term so as to produce a constant periodic return on the remaining balance of the liability.

The lease liability is presented as a separate line item on the Statement of Financial Position.

The lease liability is subsequently measured by increasing the carrying amount to reflect interest on the lease liability (using the effective interest method) and by reducing the carrying amount to reflect lease payments made. Interest charged on the lease liability is included in finance costs (note 7).

The Authority remeasures the lease liability (and makes a corresponding adjustment to the related right-of-use asset) when:

- there has been a change to the lease term, in which case the lease liability is remeasured by discounting the revised lease payments using a revised discount rate;

When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right-of- use asset, or is recognised in surplus or deficit if the carrying amount of the right-of-use asset has been reduced to zero.

Right-of-use assets

Right-of-use assets are presented as a separate line item on the Statement of Financial Position.

Right-of-use asset is subsequently measured at cost less accumulated depreciation and impairment losses. The right-of-use asset is depreciated over the shorter period of lease term and useful life of the underlying asset.

The depreciation charge for each year is recognised in surplus or deficit .

Accounting Policies (continued)

1.7 Impairment of assets

The Authority assesses at each end of the reporting period whether there is any indication that an asset may be impaired. If any such indication exists, the Authority estimates the recoverable amount of the asset.

If there is any indication that an asset may be impaired, the recoverable amount is estimated for the individual asset. If it is not possible to estimate the recoverable amount of the individual asset, the recoverable amount of the cash-generating unit to which the asset belongs is determined.

The recoverable amount of an asset or a cash-generating unit is the higher of its fair value less costs to sell and its value in use.

If the recoverable amount of an asset is less than its carrying amount, the carrying amount of the asset is reduced to its recoverable amount. That reduction is an impairment loss.

An impairment loss of assets carried at cost less any accumulated depreciation or amortisation is recognised immediately in surplus or deficit.

1.8 Reserves

Accumulated surplus under reserves represent excess of income over expenditure.

1.9 Employee benefits

Short-term employee benefits

The cost of short-term employee benefits, (those payable within 12 months after the service is rendered, such as paid vacation leave and sick leave, bonuses, and non-monetary benefits such as medical care), are recognised in the period in which the service is rendered and are not discounted.

The expected cost of compensated absences is recognised as an expense as the employees render services that increase their entitlement or, in the case of non-accumulating absences, when the absence occurs.

Defined contribution plans

Payments to defined contribution retirement benefit plans are charged as an expense as they fall due.The Authority's liability for retirement benefits is limited to amounts not yet remitted to the plan at the reporting date.

1.10 Government grants

Government grants are recognised when there is reasonable assurance that the Authority will comply with the conditions attaching to them.

Government grants are recognised as income over the periods necessary to match them with the related costs that they are intended to compensate.

Accounting Policies (continued)

1.10 Government grants (continued)

A government grant that becomes receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Authority with no future related costs is recognised as income of the period in which it becomes receivable.

Government grants related to assets, including non-monetary grants at fair value, are presented in the statement of financial position by setting up the grant as deferred income. The deferred income is amortised on annual basis using a method that is reflective of the pattern of use of the assets financed by the capital grant.

Grants related to income are presented as income under surplus or deficit separately.

1.11 Other operating income

The Authority derives other income from licensing and registration fees.These are recognised in the statement of surplus ordeficit based on the consideration received.

2. New Standards and Interpretations

Only standards and interpretations that are relavant to the financial statements of the Authority are disclosed in this note.

Standards and interpretations issued and effective

The Authority did not adopt new standards and interpretations effective from the current year..

Standards and interpretations issued not yet effective

The Authority has not early applied amendments to the following standards.

Amendments to IAS 1 and IAS 8 definition of material:

The amendments are intended to make the definition of material in IAS 1 easier to understand and are not intended to alter the underlying concept of materiality in IFRS Standards.The definition of material in IAS 8 has been replaced by a reference to the definition of material in IAS 1.In addition, the IASB amendment other standards and the conceptual framework that contain a definition of material or refer to the term 'material' to ensure consistency.

These amendments are effective for reporting periods beginning on or after January 01, 2020.

The Authority does not anticipate that the application of the amendments to the standards in the future will have an impact on the Authority's financial statements.

3. Revenue

Figures in Pula	2020	2019
Grant received from Government of Botswana	55,629,948	41,175,100
Amortisation of deferred income	1,817,714	661,356
	57,447,662	**41,836,456**
Recociliation of Government grant received		
Grant received from Government of Botswana	34,719,884	48,299,659
Deferred income utilised	24,231,765	-
Amount utilised to acquire assets	(3,321,701)	(7,124,559)
	55,629,948	**41,175,100**

4. Regulatory fees

Figures in Pula	2020	2019
Tender fees	30,453	7,375
Regulatory fees	509,820	7,500
	540,273	**14,875**

5. Operating surplus

Operating surplus for the year is stated after charging (crediting) the following, amongst others:

Auditor's remuneration - external		
Audit fees	67,200	-
Employee costs		
Salaries, wages and other benefits	27,204,640	10,761,789
Recruitment costs	1,419,897	1,249,530
Pension scheme contribution	2,034,616	541,330
Gratuity expense	3,245,313	1,878,388
Leave pay expense	1,407,018	557,046
Professional and other subscriptions	303,669	278,880
Total employee costs	**35,615,153**	**15,266,963**

Depreciation and amortisation		
Depreciation of equipment	1,652,806	598,716
Depreciation of right-of-use asset	1,506,834	1,843,765
Amortisation of intangible assets	164,908	62,399
Total depreciation and amortisation	**3,324,548**	**2,504,880**

6. Investment income

Interest income		
Investments in financial assets:		
Other financial assets	494,446	-

7. Finance costs

Figures in Pula	2020	2019
Lease liabilities	871,500	751,195

8. Taxation

No provision has been made for taxation is required as the Authority is exempt from taxation in terms of Second Schedule of the Income Tax Act (Chapter 52:01).

9. Equipment

	2020			2019		
	Cost	Accumulated depreciation	Carrying value	Cost	Accumulated depreciation	Carrying value
Computer equipment	4,390,405	(1,356,198)	3,034,207	3,439,041	(366,677)	3,072,364
Furniture and fixtures	1,143,542	(98,498)	1,045,044	616,658	(21,371)	595,287
Motor vehicles	2,782,636	(561,492)	2,221,144	2,396,033	(178,577)	2,217,456
Office equipment	879,645	(166,613)	713,032	297,164	(32,091)	265,073
Laboratory equipment	93,114	(1,552)	91,562	-	-	-
Leasehold improvements	362,672	(50,969)	311,703	-	-	-
Laboratory - work in progress	240,689	-	240,689	-	-	-
Total	**9,892,703**	**(2,235,322)**	**7,657,381**	**6,748,896**	**(598,716)**	**6,150,180**

9. Equipment (continued)

Reconciliation of equipment - 2020

	Opening balance	Additions	Depreciation	Total
Computer equipment	3,072,364	994,564	(1,030,921)	3,034,207
Furniture and fixtures	595,287	532,065	(82,308)	1,045,044
Motor vehicles	2,217,456	386,603	(382,915)	2,221,144
Office equipment	265,073	581,284	(133,325)	713,032
Laboratory equipment	-	93,114	(1,552)	91,562
Leasehold improvements	-	362,672	(50,969)	311,703
Laboratory - work in progress	-	240,689	-	240,689
	6,150,180	**3,190,991**	**(1,681,990)**	**7,657,381**

Reconciliation of equipment - 2019

Computer equipment	-	3,439,041	(366,677)	3,072,364
Furniture and fixtures	-	616,658	(21,371)	595,287
Motor vehicles	-	2,396,033	(178,577)	2,217,456
Office equipment	-	297,164	(32,091)	265,073
	-	**6,748,896**	**(598,716)**	**6,150,180**

All assets were acquired through government grants.

10. Intangible assets

	2020			2019		
	Cost	Accumulated amortisation	Carrying value	Cost	Accumulated amortisation	Carrying value
Computer software	1,034,344	(227,307)	807,037	903,632	(62,399)	841,233

Reconciliation of intangible assets - 2020

	Opening balance	Additions	Amortisation	Total
Computer software	841,233	130,712	(164,908)	807,037

10. Intangible assets (continued)

Reconciliation of intangible assets - 2019

	Opening balance	Additions	Amortisation	Total
Computer software	-	903,632	(62,399)	841,233

Carrying amount of intangible assets acquired by means of government grant

Figures in Pula	2020	2019
Software acquired	807,037	841,233

Intangible assets consists of server software, accounting and payroll system software. The software was obtained by means of a government grant and initially recognised at cost.

11. Right-of-use assets

Carrying amount of right-of-use assets		
Cost of right of use assets	14,618,297	14,442,831
Initial direct costs incurred	2,500	2,500
Accumulated depreciation on right of use assets	(3,350,599)	(1,843,765)
	11,270,198	**12,601,566**

12. Accounts receivable

Lease deposit	148,820	148,820
Other receivables	-	82,375
Non-financial instruments:		
Staff advances	77,836	-
Prepaid expenses	364,542	107,537
Total trade and other receivables	**591,198**	**338,732**

12. Accounts receivable (continued)

Split between non-current and current portions

Figures in Pula	2020	2019
Current assets	591,198	338,732

Categorisation of Accounts receivable
Other receivables are categorised as follows in accordance with IFRS 9:

Financial Instruments: At amorised cost	148,820	231,195
Non financial instruments	442,378	107,537
	591,198	**338,732**

Exposure to credit risk
The Authority does not offer services on credit.Therefore it is not exposed to credit risk.

13. Cash and cash equivalents

Cash and cash equivalents consist of:

Bank balances	9,219,864	45,948,409
Short-term investments	18,305,716	-
	27,525,580	**45,948,409**

14. Lease liabilities

Figures in Pula	2020	2019
Minimum lease payments due		
- within one year	2,187,654	2,100,148
- in second to fifth year inclusive	9,900,515	9,504,495
- later than five years	3,261,129	5,365,487
	15,349,298	16,970,130
Less: Future finance charges	(2,854,849)	(3,442,887)
Present value of minimum lease payments	**12,494,449**	**13,527,243**
Present value of minimum lease payments due		
- within one year	1,416,752	1,269,635
- in second to fifth year inclusive	10,612,415	7,208,455
- later than five years	465,282	5,049,153
	12,494,449	**13,527,243**
Non-current liabilities	11,077,697	-
Current liabilities	1,416,752	13,527,242
	12,494,449	**13,527,242**

15. Deferred income

The Authority received a total amount of P 34,719,884 as a government grant during the reporting period.Specific grant which remained unutilised (P 23,991,076) due to delay in proposed laboratory construction was used to meet the operational expenses.Grants related to assets are recognised using the deferred income method.

15. Deferred income (continued)

The Grant received has been deferred as per reconciliation below:

Figures in Pula	2020	2019
Government grants - related to non current assets		
Opening balance of deferred government grant	6,991,171	-
Assets purchased during the year	3,321,703	7,124,560
Assets received from the Government of Botswana	-	527,967
Amortisation of grant related to assets	(1,817,715)	(661,356)
Adjustment on asset retirement	(29,184)	-
	8,465,975	**6,991,171**
Government grants - related to specific projects		
Opening balance of specific government grant	24,231,765	-
Grants received for development of a laboratory	-	24,231,765
Grant used for revenue expenditure	(23,991,076)	-
Grant utilised for capital work in progress	(240,689)	-
	-	**24,231,765**

16. Accounts payable

Financial instruments:		
Payable to suppliers	980,194	801,949
Provision for gratuity	4,448,874	1,878,388
Provision for leave pay	1,997,460	849,972
Pension payable	-	721,774
	7,426,528	**4,252,083**

Categorisation of accounts payable

At amortised cost	7,426,528	4,252,083

Exposure to liquidity risk
Refer to note 18 Financial instruments and financial risk management for details of liquidity risk exposure and management.

17. Cash generated from operations

Figures in Pula	2020	2019
Surplus for the year	2,586,584	16,877,856
Adjustments for:		
Depreciation and amortisation	3,324,548	2,504,881
Interest income	(494,446)	-
Finance costs	871,500	751,195
Amount received on asset retirement	(25,563)	-
Non cash movement on asset retirement	30,983	-
Changes in working capital:		
Accounts receivable	(252,466)	(338,732)
Accounts payable	3,174,445	4,252,083
Deferred income - non cash grant related to asset	-	(527,968)
	9,215,585	**23,519,315**

18. Financial instruments and risk management

Categories of financial instruments
Categories of financial assets

2020

	Note(s)	Amortised cost	Total	Fair value
Accounts receivable	12	148,820	148,820	
Cash and cash equivalents	13	27,525,580	27,525,580	27,525,580
		27,674,400	**27,674,400**	**27,525,580**

2019

Accounts receivable	12	231,195	148,820	-
Cash and cash equivalents	13	45,948,409	45,948,409	45,948,409
		46,179,604	**46,179,604**	**45,948,409**

18. Financial instruments and risk management (continued)

Categories of financial liabilities

2020

	Note(s)	Amortised cost	Total	Fair value
Accounts payable	16	7,426,528	7,426,528	-
Finance lease obligations	14	12,494,449	12,494,449	-
		19,920,977	**19,920,977**	**-**

2019

Accounts payable	16	4,252,083	4,252,083	-
Finance lease obligations	14	13,050,728	13,050,728	-
		17,302,811	**17,302,811**	**-**

Capital risk management

The Authority's objective when managing capital(which includes reserves, working capital and cash and cash equivalents) is to safeguard it's ability to continue as a going concern in order to perform it's mandate.The Board is of the view that these objectives are being met. During the year ended 31st March 2020, the Authority did not have any borrowings.The Authority's operations are currently being sustained by the Government of Botswana.

Financial risk management

Overview

The Authority is exposed to the following risks from its use of financial instruments:
- Credit risk;
- Liquidity risk; and
- Market risk (currency risk and interest rate risk).

Credit risk

Credit risk is the risk of financial loss to the Authority if a counterparty to a financial instrument fails to meet its contractual obligations.

The Authority is exposed to credit risk on accounts receivable, cash and cash equivalents.

Credit risk exposure arising on cash and cash equivalents is managed by the Authority through dealing with well-established financial institutions with high credit ratings.All cash and cash equivalents are placed with financial institutions registered in Botswana.

The Authority does not have any trade receivables.All it's operations are on cash basis.

18. Financial instruments and risk management (continued)

Credit risk exposure arising on investments is managed by the Authority through dealing with well-established financial institutions with high credit ratings.All investments are placed with financial institutions registered in Botswana.The investment was made in funds that were ranked as low risk.

The maximum exposure to credit risk is presented in the table below:

		2020			2019		
		Gross carrying amount	Credit loss allowance	Amortised cost / fair value	Gross carrying amount	Credit loss allowance	Amortised cost / fair value
Accounts receivable	12	591,198	-	591,198	338,732	-	338,732
Cash and cash equivalents	13	27,525,580	-	27,525,580	45,948,409	-	45,948,409
		28,116,778	**-**	**28,116,778**	**46,287,141**	**-**	**46,287,141**

Liquidity risk

The Authority is exposed to liquidity risk, which is the risk that the Authority will encounter difficulties in meeting its obligations as they become due.

The Authority manages its liquidity risk by effectively managing its working capital, capital expenditure and cash flows, ensuring it maintains adequate cash and cash equivalents to settle liabilties when they become due.This is acheived by continuously monitoring forecasts and actual cash flows, and by matching the Government subvention to maturity profiles of financial liabilities.

The maturity profile of contractual cash flows of non-derivative financial liabilities, and financial assets held to mitigate the risk, are presented in the following table. The cash flows are undiscounted contractual amounts.

18. Financial instruments and risk management (continued)

2020

		Less than 1 year	2 to 5 years	Over 5 years	Total	Carrying amount
Non-current liabilities						
Lease liabilities	14	-	7,946,012	3,131,685	11,077,697	11,077,697
Current liabilities						
Accounts payable	14	7,426,528	-	-	7,426,528	7,426,528
Lease liabilities	14	1,416,752	-	-	1,416,752	1,416,752
		(8,843,280)	**(7,946,012)**	**(3,131,685)**	**(19,920,977)**	**(19,920,977)**

2019

		Less than 1 year	2 to 5 years both inclusive	Over 5 years	Total	Carrying amount
Non-current liabilities						
Lease liabilities	14	-	7,208,923	5,049,153	12,258,076	12,258,076
Current liabilities						
Accounts payable	16	4,252,083	-	-	4,252,083	4,252,083
Lease liabilities	14	1,269,635	-	-	1,269,635	1,269,635
Deferred income - specific project		24,231,765	-	-	24,231,765	24,231,765
		(29,753,483)	**(7,208,923)**	**(5,049,153)**	**(42,011,559)**	**(42,011,559)**

18. Financial instruments and risk management (continued)

Interest rate risk

Cashflow interest rate risk is the risk that future cash flows of a financial intrument will fluctuate because of changes in market interest rates.The Authority invests all it's surplus funds and gratuity fund in money market instruments.These instruments earns interest at floating rates.The average interest earned ranges between 3.1% p.a to 3.75% p.a.

A 50 basis point increase in the interest rate would have resulted in a surplus of P 45,000 for the year.Similarly a 50 basis point decrease would have resulted in an equal and opposite effect on the surplus.The 0.5% is applied to the carrying amount of interest earning assets over a six months investing period

Figures in Pula	2020	2019
Cash and cash equivalents	27,475,841	45,948,409
Net increase or decrease in surplus	45,000	-

19. Related parties

The Authority was established by the Medicines and Related Substances Act of 2013 and is therefore related to the Government of Republic of Botswana.Transactions with related parties are in the normal course of business.

Relationships

Medicines Regulatory Board	Refer to general information for a list of Medicines Regulatory Board (Page-1).
Members of Key Management	Dr. Stephen Ghanie (Chief Executive Officer) Mr. Harold Kuvenga (Director: Finance and Administration) Dr. Sinah Selelo (Chief Technical Officer) Dr. Nkaelang Modutlwa (Director: Product Evaluation and Registration) Dr. Seima Dijeng (Director: Inspections and Licensing) Dr. Parthasaraty Gurumurthy (Director: Pharmacovigilance) Ms. Latelang Chakalisa (resigned on 31st December 2019)
Main Financier	Government of the Republic of Botswana

Compensation to directors and other key management		
Salaries, bonus and other benefits	5,391,655	3,438,259
Leave pay contribution	272,107	370,531
Gratuity contribution	1,624,104	1,234,544
	7,287,866	**5,043,334**

19. Related parties (continued)

Related party balances

Figures in Pula	2020	2019
Amounts included in Other payables regarding related parties		
Botswana Telecommunications Corporation - Telephone	57,893	19,869
Botswana Power Corporation	-	22,665
Related party transactions		
Grant received		
Government of the Republic of Botswana - Cash	34,719,884	72,531,424
Government of the Republic of Botswana - Asset	-	527,968
Transactions with other parastatals		
Botswana Telecommunications Corporation - Telephone	546,916	312,999
Botswana Power Corporation - Electricity	251,065	292,273
Sitting allowance		
Medicine Regulatory Board	324,135	158,737

20. Comparitive figures

The Authority commenced operations from January 2018, initial reporting period was for a period of 15 months.Therefore comparative figures are for a period of 15 months.

21. Events after the reporting period

On 11 March 2020, the World Health Organisation declared the Corona virus disease (COVID-19) a pandemic.As a result, the Government of Botswana declared a state of emergency and a lockdown from the 2nd of April 2020 for a continuous period of 28 days.The Government made a commitment to assist organisations that would be negatively affected by COVID-19. The Authority therefore expects to continue to receive its funding from Government and continue as going concern. We assessed the significant judgements and estimates used by the Authority to determine the amounts recognised in the financial statements at year end and concluded that there were no significant changes to the amounts recognised.

Detailed Income Statement

Figures in Pula	Note(s)	2020	2019
Revenue			
Grant received from the Government of Botswana		55,629,947	41,175,100
Amortisation of deferred income		1,817,714	661,356
	3	**57,447,661**	**41,836,456**
Other operating income			
Other operating income		540,273	14,875
Operating expenses			
Amortisation and depreciation		(3,324,548)	(2,504,880)
Advertising		(1,128,278)	(456,146)
Auditors remuneration - external auditors	5	(67,200)	-
Bank charges		(67,526)	(16,381)
Certification costs		-	(8,248)
Computer - related expenses		(677,472)	(530,905)
Consultancy fees		(153,736)	-
Consumables		(326,557)	(130,729)
Employee costs		(35,615,153)	(15,266,963)
Governance costs		(823,515)	(629,805)
Insurance		(238,931)	(77,599)
Motor vehicle expenses		(107,007)	(45,182)
Printing and stationery		(429,853)	(262,764)
Professional fees		(10,270)	(8,000)
Publicity and awareness		(3,396,199)	(542,500)
Records management		(388,913)	-
Repairs and maintenance		(1,025,574)	(174,664)
Security		(266,638)	(150,376)
Staff welfare		(55,010)	-
Subscriptions		(37,139)	(291,789)
Telephone and fax		(1,070,071)	(459,615)
Training		(1,801,560)	(785,463)
Travel and accomodation		(3,683,745)	(1,541,202)
Utilities		(329,401)	(339,068)
		(55,024,296)	**(24,222,279)**
Operating surplus	5	**2,963,638**	**17,629,052**
Investment income	6	494,446	-
Finance costs	7	(871,500)	(751,195)
Surplus for the year		**2,586,584**	**16,877,857**

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