



OUR MISSION

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



OUR VISION

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



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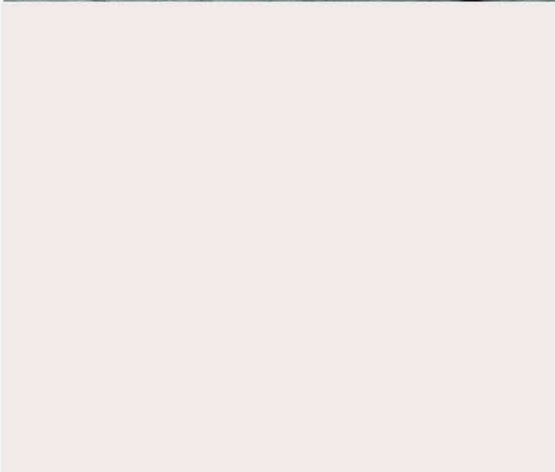
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Looking Beyond The Pandemic!





GENERAL
INFORMATION

GENERAL INFORMATION

Overview of the Authority's mandate, legal basis, key governance structures, strategy and a statement by the Chairperson of the Board.

LEGISLATIVE MANDATE

The Medicines Regulatory Authority ("Authority") is a corporate body, established under Section 3 of the Medicines and Related Substances Act ("MRSA") and referred to as the Botswana Medicines Regulatory Authority or BoMRA. The Authority is responsible for ensuring the safety, efficacy and quality of medicines and related substances, which includes both human and veterinary medicines, medical devices and cosmetics in Botswana.


The Authority's key functions are stated under Section 4 of the MRSA and include:

PRODUCT EVALUATION AND REGISTRATION
Ensuring that all medicines and related substances manufactured in, imported into, or exported from Botswana are registered and conform to established criteria of quality, safety and efficacy.
LICENSING AND ENFORCEMENT
Ensuring the personnel, premises and practices employed to import, export, manufacture, promote, procure, store, distribute and sell medicines comply with defined codes of practice and other requirements.
PHARMACOVIGILANCE AND CLINICAL TRIALS
Ensure the monitoring and reporting of adverse reactions to medicines and conducting post-marketing surveillance to ascertain the quality, efficacy and safety of medicines circulating in Botswana.

ESTABLISHMENT OF BOMRA AND ITS STRUCTURES

The Medicines Regulatory Board was created in terms of Section 6 of the MRSA to supervise and control the administration and financial management of the Authority; and to formulate policies for the purpose of providing general or specific guidance to the Authority in respect of the performance of its functions under the MRSA. The Chief Executive Officer ("CEO") is appointed by the Minister of Health and Wellness ("Minister"), on recommendation of the Board, as per Section 5 of the MRSA and is responsible for the management control, administration, and organisation of the Authority, subject to directions of the Board. The CEO is assisted by senior officers, as the Board may appoint, on recommendation from the CEO. The CEO may further appoint officers and employees to assist in carrying out the Authority's mandate.

The Board is the highest governance structure of the Authority and is led by the Board Chairperson, who is appointed from amongst the Board Members by the Minister. As per Section 22 of the MRSA, the Board must prepare a comprehensive report on its activities as well as those of the Authority and submit to the Minister. This Annual Report is hereby presented on behalf of the Board in fulfilment of Section 22 of the MRSA by the Chairperson of the Board, Mr Duncan Thela.

A professional portrait of Mr. Duncan Thela, a middle-aged Black man with a shaved head, wearing a dark grey suit, a light blue shirt, and a patterned tie. He is standing with his arms crossed, looking slightly to the right of the camera with a calm expression. The background is dark and out of focus.

Mr. Duncan Thela.

"The beginning of the 2020-21 financial year saw the Authority enter the 2nd year of its 5-year Strategy. The achievement of the Strategy is a key target of the Board as it would make the Authority a fully functional regulator, capable of adequately achieving its mandate and importantly, provide assurance that members of the public are adequately protected against any harmful medical products or cosmetics."

CHAIRPERSON'S STATEMENT

The Authority continued to engage with its shareholder, the Government of Botswana, as represented by the Authority's parent Ministry, the Ministry of Health and Wellness. The Authority intervened to play its regulatory role in the registration of vaccines to facilitate their availability in the local market. The registration Method of medicines, by nature of its importance and risks, takes time but the Authority played its part by expediting, in difficult circumstances, its assessment of the vaccines and authorisation of their use. The Authority engaged with the Ministry of Health on a variety of issues, it not only being the parent Ministry but a key partner in the pursuit of public health.

The need for partnerships is well recognised. Being centrally located in Gaborone and with a mandate spanning the entire country, partnerships provide leverage to enhance both reach and efficiency. The Authority actively pursued and solidified identified partnerships using memoranda of understanding and agreements, supported with action plans to maintain impetus and derive benefit. These included the Botswana Unified Revenue Services to enhance regulation at ports of entry and the Botswana Bureau of Standards to align standards and for capacity building. District Health Management teams across the country were a key partner in driving post marketing surveillance and reporting of adverse events whilst fellow regulatory bodies such as the Tanzania Medicines and Medical Devices Authority assisted with capacity building. These are but a few of the key partners we have and we are thankful for the continuing support of all our partners, including the Ministry of Health and Wellness.

The platform for the Authority's regulatory activities is the Medicines and Related Substances Act which was promulgated in 2013. Recognizing the passage of time since it first commenced, steps have been taken to progress its amendment to better support the Botswana environment as well as to align it to best practices in the region and throughout the world. [The Authority has worked closely with the Ministry of Health and the Attorney General's Chambers to lay the groundwork for its amendment and focus in the 2021/22 financial year shall be on engaging the relevant stakeholders, to account for their input and to complete drafting of the Bill.] The amended Act is a key requirement to achieving the Authority's Strategy as it forms the basis for the scope of activities and protections the Authority may provide to the Public.

As part of its endeavour to continually improve, the Board carried out its first Board evaluation aimed at identifying areas for enhancement in its governance activities and execution of its mandate. It is hoped that the lessons learnt will drive future success by enabling adequate support to the Authority by enhancing the way the Board works. I am thankful to the Board Members who continue to avail significant time towards the Authority's mandate and have displayed the commitment necessary to position the Authority for future success.

Notwithstanding the difficulties during the year, I am proud to report that the Authority's strategy is on course and its aim of becoming a fully functional regulator looms ever larger in the horizon. The Authority's regulatory resolve was tested in the storm, thus far, successfully weathered, I therefore take this opportunity to thank and appreciate the efforts of the CEO, the Management team and all employees of the Authority, whose efforts have not gone unnoticed. I would also like to thank all stakeholders who continue to support us, including our regulated entities and the public.

We wish to continue our current trajectory with the support of all stakeholders, and I am certain that these ends will be achieved. It is with this assuredness and hope that I proudly present to you, on behalf of the Board, BoMRA's 2020-21 Annual Report.



Duncan Thela (Mr)

Chairperson of the Board of Directors

A portrait of Dr. Stephen Ghanie, a middle-aged Black man with glasses, wearing a dark blue suit jacket, a light blue shirt, and a light blue tie. He is looking directly at the camera with a neutral expression. The background is dark and out of focus.

Dr. Stephen Ghanie.

"While many operational units ended the year operating near full functionality such as Marketing Authorisation, Licensing and Inspections, Quality Management, and Finance and Administration, the remaining units including Evaluation and Registration of Veterinary Medicines, Medical devices, and Pharmacovigilance had well crossed the half-way line in their development. When benchmarked against the WHO Global Benchmarking Tool against Maturity Level 3, Marketing Authorisation, Licensing, and Inspections scored 67%, 72% and 63% respectively."

CHIEF EXECUTIVE OFFICER'S REPORT

Following the solid completion of our first annual performance plan for the financial year ending 31st March 2020, the Authority has completed yet another impressive annual plan for this financial year. With our target focussed on our strategic foundation of reaching full functionality and World Health Organisation Maturity Level 3 after five annual cycles ending 2024, the Authority's performance against its 5-year strategy holds nothing short of successful implementation and achievement of its goals. This year-to-date performance met management expectations despite the beginning of an era marred by the Covid-19 pandemic which affected many businesses across the world, weakened many supply chains, and placed many communities and employees under unusual level of alertness and anxiety.

While many operational units ended the year operating near full functionality such as Marketing Authorisation, Licensing and Inspections, Quality Management, and Finance and Administration, the remaining units including Evaluation and Registration of Veterinary Medicines, Medical devices, and Pharmacovigilance had well crossed 50% in their development. When benchmarked against the WHO Global Benchmarking Tool against Maturity Level 3, Marketing Authorisation, Licensing, and Inspections scored 76%, 72%, and 63% respectively.

Performance of most functions exceeded 80% for the annual performance cycle under review. This demonstrates the versatility in the business continuity plan, which accorded the Authority both the ability to implement its strategic initiatives and provide uninterrupted customer service to its clients. Our predominant dependence on our specialised human resources base leveraged on well-developed remote data and voice communication services enabled successful Work-From-Home arrangements.

Notable achievements during the year were ISO 9001 certification of the Authority, development and initiation of a post market surveillance program for Botswana and exploiting 4IR to establish an online listing platform for complementary medicines.

While the Authority largely depends on Government subvention to carry out its mandate, it was able to move into the area of grants application to fund some of its regulatory strengthening projects. During the year we were successful in obtaining 2 grants from the European and Developing Countries Clinical Trials Partnership (EDCTP) to improve clinical trial regulatory processes and related tools, including the strengthening of the National Ethics Committee. These grants totaled P4 million. We were also able to raise funds from the services provided to the local pharmaceutical industry amounting to P8.2 million.

During the year ended 31st March 2021 the Authority received a subvention of P45.2 million from the Government. Total expenditure amounted to P65 million, resulting in a deficit of P11.6 million. The deficit was funded by accumulated surplus brought forward from the 2019/20 financial year.



Dr. Stephen Ghanie

Chief Executive Officer

BOARD DIRECTORS



Mr. Duncan Thela
Chairperson



Dr. Mbatshi Mazwiduma
Vice-Chairperson



Mr. Kagiso Balopi
Member



Dr. Letlhogile Modisa
Member (Ex-Officer)



Mr. Meshack Baoleki
Member



Ms. Botho Bayendi
Member



Dr. Joyce Kgatlwane
Member



Dr. Tiroyaone Mampane
Member



Dr. Gontle Moleele
Member



Ms. Shameela Pholo-Winston
Member



Dr. Gaseitsewe Michael Sento
Member



Dr. Malaki Tshipayagae
(Ex-officio)

EXECUTIVE MANAGEMENT TEAM



Dr. Stephen Ghanie
Chief Executive Officer



Dr. Sinah Selelo
Chief Regulatory Officer



Dr. Parthasarathi Gurumurthy
Director, Pharmacovigilance and Clinical Trials



Mr Nonofu Thipe
Legal and Corporate Secretary



Dr. Nkaelang Modutlwa
Director, Product Evaluation and Registration



Dr. Seima Dijeng
Director, Licensing and Inspection



Mr. Harold Kuvenga
Director, Finance and Administration



Mr. Israel Kgosidiile
Manager Public Relations



Ms. Padmine Rammidi
Acting Human Resources Director



Ms. Zukiswa Raditladi
Manager, Quality Management



GOVERNANCE & THE BOARD

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GOVERNANCE AND THE BOARD

Information on the Authority's management of governance affairs including its Board and Committees.

GOVERNING BODY/STRUCTURE

The Board's role and responsibilities include, amongst others, the following, which are part of the adopted Board Charter and derived from the MRSA:

- Collectively directing the business activities of the Medicines Regulatory Authority
- Collectively providing leadership and direction to Management of the Authority
- Strategic planning
- Appointment of Executive Management
- Audit and compliance
- Ensuring that the Authority's ethics are managed effectively

The Board is comprised of Members as per the table 1 below. The Members have a mix of skills as determined by Section 7 of the MRSA which include law, pharmaceutical industry, business management, medicine, pharmacy, veterinary medicine and two other areas as may be determined by the Minister.

Table 1: Board Members

MEMBER	DATE OF FIRST APPOINTMENT	END OF CURRENT TERM	TERM NO.
1 Mr. Duncan Thela (Chairperson)	01 June 2016	31st May 2022	2nd term
2 Dr. Mbatshi Mazwiduma	01 June 2016	31st May 2022	2nd term
3 Mr. Kagiso Balopi	01 June 2016	31st May 2022	2nd term
4 Mr. Meshack Baoleki	01 June 2016	31st May 2022	2nd term
5 Ms. Botho Bayendi	01 June 2019	31st May 2022	1st
6 Dr. Joyce Kgatlwane	01 June 2016	30th June 2021	2nd term
7 Dr. Tiroyaone Mampane	01 June 2016	31st May 2022	2nd term
8 Dr. Letlhogile Modisa (Ex-officio)	01 June 2016	n/a	n/a
9 Dr. Gontle Moleele	01 June 2016	30th June 2021	2nd term
10 Ms. Shameela Pholo-Winston	01 June 2016	31st May 2022	2nd term
11 Dr. Gaseitsewe Michael Sento	01 June 2016	30th June 2021	2nd term
12 Dr. Malaki Tshipayagae (Ex-officio)*	01 June 2019	08 October 2020	n/a
13 Dr. Malebogo Keabonye (Ex-officio)	08 October 2020	n/a	n/a
14 Dr. Stephen Ghanie	January 2018	December 2022	1st Contract

** During the year, Dr Malaki Tshipayagae was replaced by the new Director of Health Services, Dr Malebogo Keabonye.*

To assist in carrying out its mandate, the Board has established seven Committees in terms of Section 16 of the MRSA, which have been delegated specific powers, duties and functions as documented in their respective Terms of Reference. The Board Committees assist the Board to give specialised attention to various key areas, with the Board maintaining ultimate accountability. The Board Committees are in two categories, those who assist with administration of the Authority and those that provide technical support for the regulatory functions of the Authority. The committees are as per the below table 2 with their responsibilities.

Table 2: Board Committees

ADMINISTRATIVE COMMITTEES	
Committee Name	High Level Summary of Functions and Area of Delegated Responsibility
Finance, Audit and Risk Committee (FARC)	<ul style="list-style-type: none"> Accounting practices, financial controls and reporting systems of the Authority. Budgeting, budgetary control systems and auditing Methods of the Authority. Authority's enterprise-wide risk management. Economy, efficiency and effectiveness of the Authority's Information Technology.
Procurement and Tender Committee (PTC)	<ul style="list-style-type: none"> 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 Methods/procedures Reviewing compliance issues submitted to the Committee by the Management Tender Committee.
Human Resources Committee (HRC)	<ul style="list-style-type: none"> 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. Recommending the CEO's performance objectives for approval by the Board.
Governance and Nominations Committee (GNC)	<ul style="list-style-type: none"> 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. Technical advisory on governance matters emanating from other Committees.
TECHNICAL COMMITTEES	
Committee Name	High Level Summary of Functions and Area of Responsibility
Registration Committee (RC)	<ul style="list-style-type: none"> 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 that meet the set standards. Considering recommendations for rejection of applications, suspension or removal from the register of any medicines in accordance with the Act, Regulations, Policies and Standards. Review of the registration fees and recommendation to the Board for endorsement and approval by the Minister.
Pharmacovigilance Advisory Committee (PVAC)	<ul style="list-style-type: none"> Guiding the Authority on pharmacovigilance functions and conduct of clinical trials. Review and approval of clinical trial applications and protocols 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. Reviewing promotional and Advertising materials for its content and presentation.
Licensing Committee (LC)	<ul style="list-style-type: none"> 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 Enforcement Department.



BOARD AND COMMITTEE MEETINGS HELD DURING THE YEAR UNDER REVIEW

The Board Member attendances for the year under review are as per the below table.

Table 3: Board and Committee meeting held

	Member	11 Jun 2020	05 Aug 2020	20 Aug 2020	10 Sept 2020	18 Nov 2020	25 Feb 2021	30 Mar 2021
1	Mr. Duncan Thela	✓	✓	✓	✓	A	✓	✓
2	Dr. Mbatshi Mazwiduma	✓	✓	A	✓	✓	✓	A
3	Mr. Kagiso Balopi	✓	✓	✓	✓	✓	✓	✓
4	Mr. Meshack Baoleki	✓	✓	✓	✓	✓	✓	✓
5	Dr. Michael Gaseitsewe Sento	✓	✓	✓	A	✓	✓	A
6	Ms. Shameela Pholo-Winston	✓	✓	✓	✓	✓	✓	✓
7	Dr. Gontle Moleele	✓	✓	✓	✓	✓	✓	✓
8	Dr. Joyce Kgatlwane	✓	✓	✓	✓	A	✓	✓
9	Dr. Tiroyaone Mampane	✓	✓	✓	A	✓	✓	A
10	Ms. Botho Bayendi	✓	✓	✓	✓	✓	✓	✓
11	Dr. Letlhogile Modisa	✓	✓	✓	✓	✓	✓	✓
12	Dr. Malebogo Kebabonye	n/a	n/a	n/a	n/a	A	✓	✓
13	Dr. Malaki Tshipayagae	A	A	✓	A	n/a	n/a	n/a

Key: Present ✓ Apology A Not Applicable n/a

The Committee Members and attendances for the year under review are as per below tables.

FINANCE, AUDIT AND RISK COMMITTEE MEETINGS

Table 4: Finance, Audit and Risk Meetings Held

	Member	2nd Jun 2020	14th Aug 2020	25th Sept 2020	05 Nov 2020	12 Feb 2021
1	Mr. Kagiso Balopi	✓	✓	✓	✓	✓
2	Dr. Mbatshi Mazwiduma	✓	✓	✓	✓	✓
3	Mr. Meshack Baoleki	✓	✓	✓	✓	✓

Key: Present ✓ Apology A

PROCUREMENT AND TENDER COMMITTEE MEETINGS

Table 5: Procurement and Tender Committee Meetings Held

	Member	12th May 2020	13th August 2020	27th August 2020	03 November 2020	14 December 2020
1	Mr. Meshack Baoleki	✓	✓	✓	✓	✓
2	Dr. Gaseitsewe Sento	✓	✓	✓	✓	✓
3	Mr. Kagiso Balopi	✓	✓	✓	✓	✓
4	Dr. Joyce Kgatlwane	✓	A	✓	✓	✓

Key: Present ✓ Apology A

HUMAN RESOURCES COMMITTEE MEETINGS

Table 6: Human Resources Committee Meetings Held

	Member	25th May 2020	10th August 2020	26th August 2020	1st February 2021	10th February 2021
1	Ms. Shameela Pholo -Winston	✓	✓	✓	✓	✓
2	Dr. Gontle Moleele	✓	✓	✓	✓	✓
3	Dr. Letlhogile Modisa	✓	✓	✓	✓	✓
4	Dr. Tiroyaone Mampane	n/a	n/a	A	A	A

Key: Present ✓ Apology A Not Applicable n/a

GOVERNANCE AND NOMINATIONS COMMITTEE MEETINGS

Table 7: Governance and Nominations Committee Meetings Held

	Member	2nd June 2020	3rd July 2020	11th August 2020	12 November 2020	19 February 2021
1	Ms. Botho Bayendi	✓	✓	✓	✓	✓
2	Mr. Kagiso Balopi	✓	✓	✓	✓	✓
3	Mr. Meshack Baoleki	✓	✓	✓	✓	✓
4	Ms. Shameela Pholo -Winston	✓	✓	✓	✓	✓

Key: Present ✓ Apology A Not Applicable n/a

PHARMACOVIGILANCE ADVISORY COMMITTEE MEETINGS

Table 8: Pharmacovigilance Advisory Committee Meetings Held

	Member	26th May 2020	30 July 2020	27 November 2020
1	Dr. Gontle Moleele	✓	✓	✓
2	Mrs. Matshidiso Matome	✓	✓	✓
3	Ms. Ratanang Balisi	✓	✓	✓
4	Dr. Kereng Masupu	A	A	A
5	Dr. Kerapetse Sehularo	✓	A	A
6	Dr. Lebapotswe Tlale	✓	✓	A
7	Dr. Tjedza Matenge	n/a	n/a	✓
8	Dr. Tom Baaisi	n/a	n/a	✓

Key: Present ✓ Apology A Not Applicable n/a

REGISTRATION COMMITTEE MEETINGS

Table 9: Registration Committee Meetings Held

	Member	18th June 2020	08 August 2020	15 October 2020	10 December 2020	11 February 2021
1	Dr. Joyce Kgatlwane	✓	✓	✓	✓	✓
2	Dr. Goabaone Rankgoane-Pono	✓	✓	✓	✓	✓
3	Dr. Samantha Letsholo	✓	✓	✓	A	✓
4	Dr. Celda Tiroyakgosi	✓	✓	✓	✓	✓
5	Dr. Batshanani Busang	✓	✓	✓	✓	✓
6	Dr. Tendani Gaolathe	✓	✓	✓	A	✓
7	Ms. Lesego Moetedi	✓	✓	✓	✓	✓

Key: Present ✓ Apology A



CORPORATE GOVERNANCE OVERVIEW

The Board has a Board Charter in place which sets out its roles and responsibilities to ensure adherence to the highest standards of Corporate Governance. The Board adopted a Governance Framework during the year under review, which aims to ensure adherence to its governance responsibilities as set out by the law, oversight bodies such as the Public Enterprises Evaluation and Privatisation Agency and the Botswana Accountancy Oversight Authority and voluntary practices as adopted from time to time. The voluntary code adopted by the Board is the King IV Code. The Board is further in the process of finalising the Shareholder Compact between itself and the Ministry of Health and Wellness, which is aimed at aligning the objectives and expectations between the Authority and the Shareholder.

The Authority met its main requirements for meetings in terms of the MRSA & Board Charter.

- **At least 6 Meetings to be held annually** – The Board held 7 meetings during the period under review.
- **Declarations of Interest at meetings of the Board** – Board Members sign declarations of interest prior to meetings of the Board, which are maintained by the Board Secretary.

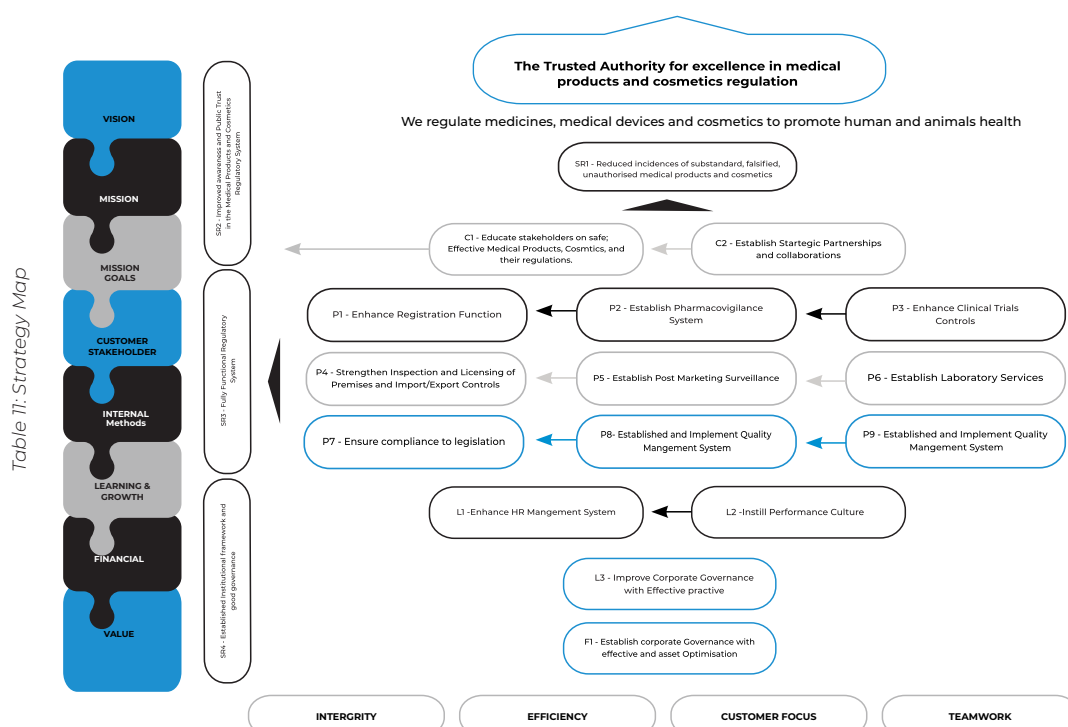
STRATEGIC OVERVIEW

One of the primary functions of the Board is to approve and monitor performance of the Authority’s strategy, to guide achievement of the Authority’s mandate in a sustainable manner. An overview of the strategy is provided below.

The Authority’s vision is to be the trusted Authority for excellence in medical and cosmetics products regulation and to this end, the Authority has put in place a five-year strategic plan, running from 2019-2024. The four key Strategic Goals, aimed at achieving the Authority’s vision, are the following:

STRATEGIC GOALS (SR)	HIGH-LEVEL TARGET
SR1: Reduced incidences of substandard, falsified, unregistered medical products and cosmetics.	Sub-standard and falsified medicines reduced by at least 25% by 2024
SR2: Improved awareness and Public Trust in the Medical Products and Cosmetics Regulatory System.	Public Confidence in the Regulatory System
SR3: Fully Functional Regulatory System	World Health Organization (WHO) Maturity level 3 – with 8 core functions rated green.
SR4: Established Institutional framework and good governance	Compliance to Quality Measures at 85% Strategy Performance Levels at 85%

The Authority has Strategic Objectives aimed at driving achievement of the Strategic Goals. Targets for the Strategic Objectives are set and amended each year through Annual Performance Plans that are approved by the Board and designed to ensure gradual progression to achieving the Strategic Goals. The Strategy Map below highlights the link between the Authority’s Strategic Goals and Objectives as well as its vision, mission and values.



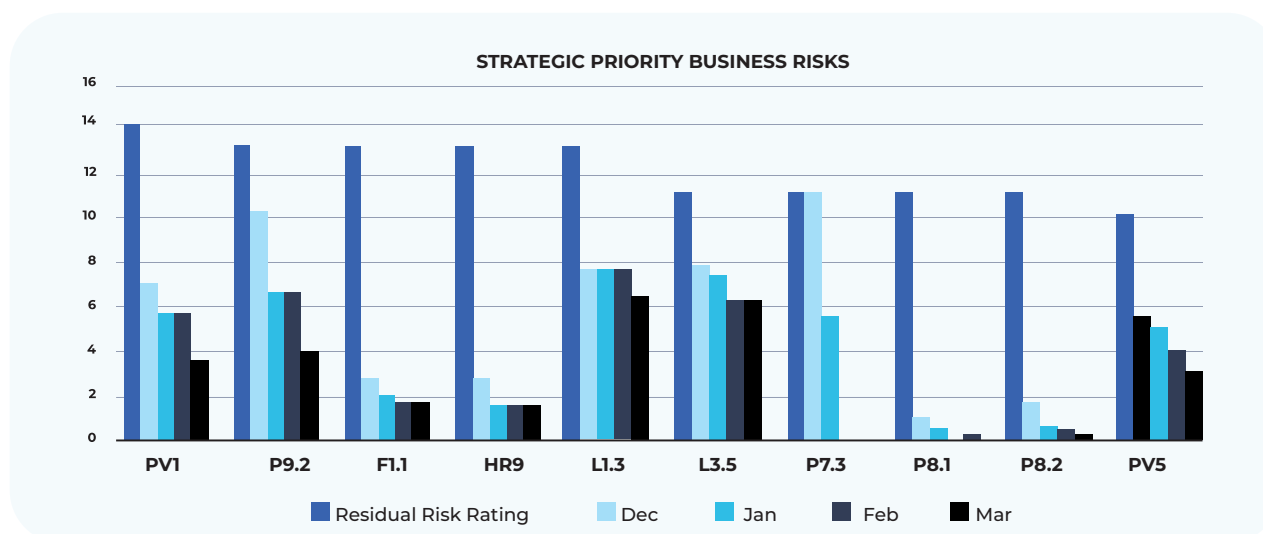
WHAT ARE THE BOMRA VALUES?

<p>INTEGRITY</p> <p>A transparent and impartial environment with people who are – trustworthy, disciplined and maintain confidentiality.</p>	<p>CUSTOMER FOCUS</p> <p>Providing quality service and upholding standards.</p>	<p>EFFICIENCY</p> <p>Working S.M.A.R.T and applying innovative solutions and good judgment</p>	<p>TEAMWORK</p> <p>Working together for a common goal.</p>
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IMPLEMENTATION OF ENTERPRISE RISK MANAGEMENT

To ensure adequate oversight, the Board monitors strategic risks as they may impede the achievement of the Authority's planned objectives. In the period under review the Board approved the Enterprise Risk Management (ERM) policy, framework and supporting documents and implementation was commenced. The figure below shows the visual representation of the Authority's risk profile showing how the risks changed from the initial residual risk exposures as they were treated to acceptable levels.

Figure 1: Strategic Priority Business Risk Profiles



As at the end of the financial year, five out of ten top strategic Priority Business Risks, representing 50%, had been treated to acceptable levels. For all the seventy-eight strategic and operational risks identified across the Authority, forty-seven risks, representing 60%, were treated to acceptable level with the remaining risks treated to cautionary level.

THE ROAD TO MATURITY LEVEL 3 – A FULLY FUNCTIONAL REGULATORY SYSTEM

One of the Strategic Goals is for the Authority to achieve a fully functional regulatory system and attainment of World Health Organization (WHO) Maturity Level 3.

The WHO Global Benchmarking Tool (GBT) is the primary means by which WHO assesses regulatory systems for the regulation of medical products. The tool and benchmarking methodology enable WHO and regulatory authorities to identify areas of strength as well as areas for improvement; facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address identified gaps; to aid in the prioritization of investments in IDP implementation; and to help monitor progress. The GBT prescribes maturity levels based on the implementation of the regulatory functions. There are 4 Maturity Levels (ML) in place as per the table below. The Authority aims to achieve Maturity Level 3 by 2024.

Figure 1: Strategic Priority Business Risk Profiles

WHO GBT MATURITY LEVELS			
1	2	3	4
No formal Approach	Reactive approach	Stable formal system approach	Continual improvement emphasized
Some elements of Regulatory System Exist	Evolving national regulatory system that partially performs essential regulatory functions	Stable, well-functioning integrated regulatory system	Regulatory system operating at advanced level of performance and continuous improvement

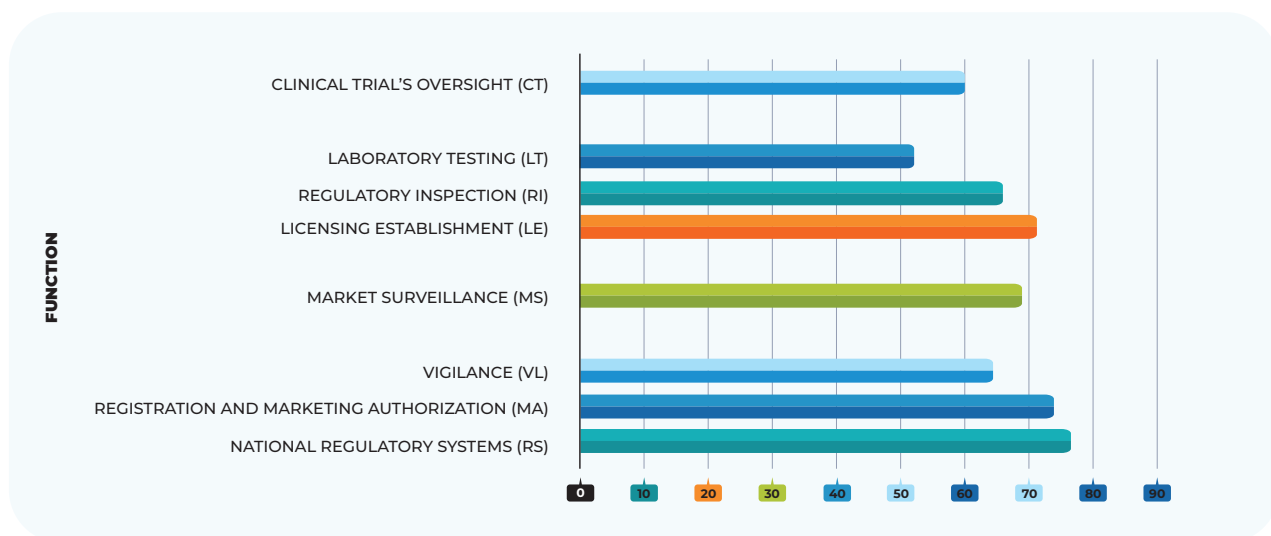
Maturity Level 3 represents the minimum target for regulators to reach a stable, well-functioning and integrated regulatory system as per the World Health Assembly resolution 67.20 . In Africa, only Tanzania Medicines and Medical Devices Authority and Ghana Food and Drugs Authority have achieved ML 3 in 2018 and 2020 respectively.

The Authority has used the GBT to self-assess the level of implementation. Below is the current ML status, based on external assessment of 4 of the Regulatory functions by a strategic partner and an internal assessment of the other 4 functions showing positive progression towards an effective medical products and regulatory system. WHO categorisation of maturity level 3 is a standard for medicines regulators which have achieved an effective medical products regulation. Many of the pending gaps include legislative gaps.

Table 10: Maturity Level Status Of The Regulatory Functions Within The Authority

	FUNCTION	IMPLEMENTATION SCORE	MATURITY LEVEL
1	National Regulatory Systems (RS)	78.0	1
2	Registration and Marketing Authorization (MA)	76.0	1
3	Vigilance (VL)	64.0	1
4	Market Surveillance and Control (MC)	69.0	1
5	Licensing Establishment (LI)	72.0	1
6	Regulatory Inspection (RI)	66.0	1
7	Laboratory Testing (LT)	53.0	1
8	Clinical Trial's Oversight (CT)	60.0	1

Figure 2: Implementation Percentage





HUMAN CAPITAL & STRUCTURES OF THE AUTHORITY

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Human Capital

Organisational Structure

Structure Explained

Structure and Achieving the Strategy

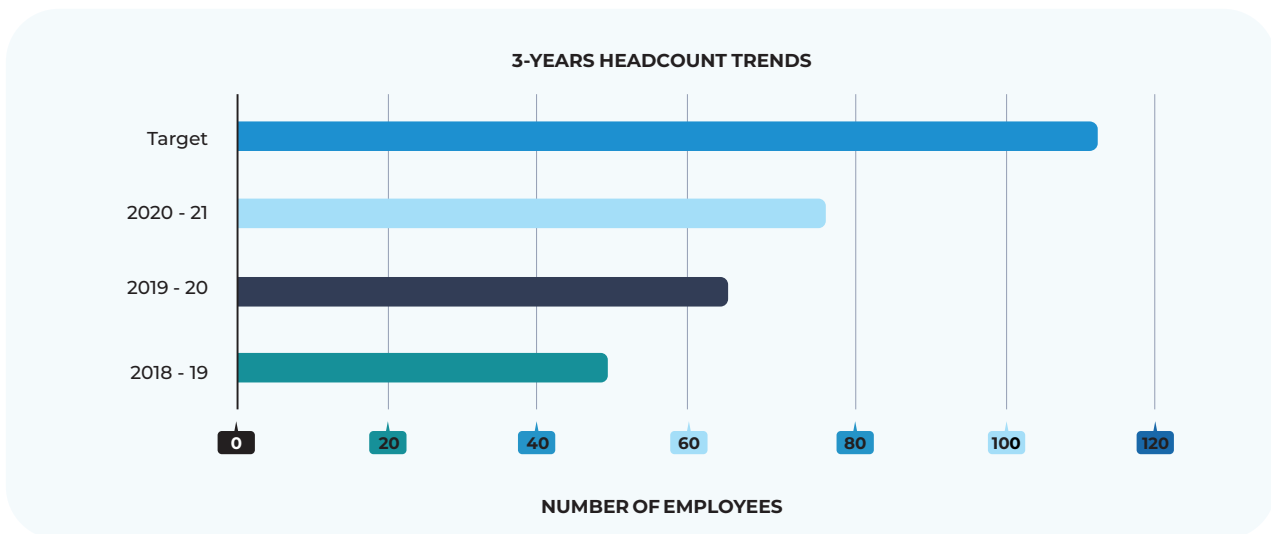
HUMAN CAPITAL AND STRUCTURES OF THE AUTHORITY

The Chief Executive Officer's Report on the Authority's business and information on the structure, human resources and the Authority's strategy.

3.1 Human Capital

The Authority's human capital is the main force behind its operations. The Authority is currently in the early stages of development and is still hiring the staff needed to carry out its purpose. The Authority's three (3) year headcount as of reporting was as shown in Figure 3 below:

Figure 3: Three (3) Year Staff Headcount



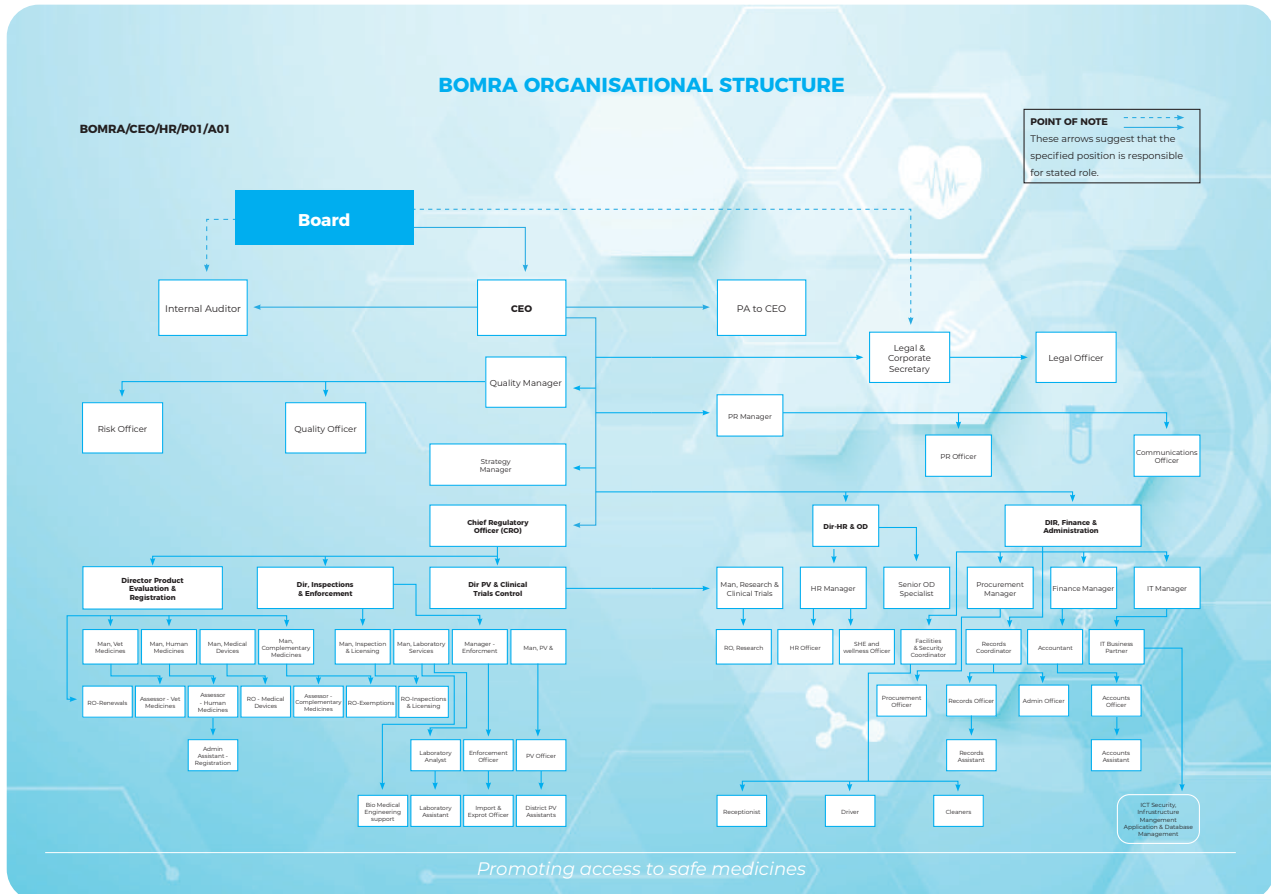
- The organisation is currently at 74.3% human capital capacity. The Authority aims to have a total headcount of 118 which will provide the necessary capacity to fulfill the mandate.
- A steady growth in headcount has been recorded over the past 3 years.
- The vacancy rate to date is recorded at 25.7% as at March 2021.

Driven by the Human Resources Department the Authority aims to achieve the following for their human capital:



The Authority is proud to have a diverse range of professionals with abilities in a variety of fields, including pharmacy, laboratory science, veterinary medicine, finance, law, human resources, information technology, quality, audit, business management, and marketing. These occupations are dispersed among the many Departments and Units that make up the organization, and the Authority works to maximize their integration to guarantee that the Authority's long-term goals and mandate are met. In order to maximize the attainment of the strategic goals, the organizational structure was created and is occasionally modified.

3.2 Organisational Structure



3.3 Structure Explained

Dr. Stephen Ghanie, the Authority's Chief Executive Officer, was chosen in accordance with Section 5 of the MRSA and is responsible for the organization, management, and control of the Authority. In order for the Authority to fulfill its mandate, the Chief Executive Officer must supervise how its plan is being put into action. The Chief Regulatory Officer, BoMRA Directors, Managers, and Officers provide support to the CEO. The BoMRA Departments and Units are structured to carry out activities that advance the objectives while maximizing the achievement of the plan. Directors are in charge of the Departments, and managers are in charge of the Units.

3.4 Structure and Achieving the Strategy

The organisational structure was established and is amended from time to time to ensure optimisation of the strategy and its achievement. The CEO holds ultimate accountability for implementation of the strategy as set by the Board. Whilst the BoMRA team works collectively as a team to achieve all aspects

of the Strategy, for purposes of efficiency, the various officers, departments and units are assigned responsibility for driving various aspects of the Strategy. The various responsibilities under the strategy are indicated below.

3.4.1 Chief Executive Officer's Office

The function of the CEO's Office is broad and covers strategy and APP monitoring and implementation, and like mentioned, stakeholder relationships and development plans towards full functionality and maturity level. He is assisted by his team in various areas as highlighted below.

3.4.2 Chief Regulatory Officer's Office

The Chief Regulatory Officer is responsible for overseeing and providing support to the technical departments of the Authority, implementing the Authority's strategy and annual plans/initiatives and managing the Authority's relationships with technical partners and stakeholders.

STRATEGIC OBJECTIVE	C2 - Establish Strategic Partnerships and Collaborations
Strategic Initiative	Contract terms of partnership and support with prioritized entities in the defined partnership portfolio with an emphasis on establishing and tracking action items
Strategic Objective	L3 - Improve Corporate Governance with Effective Practices
Strategic Initiatives	Conduct annual WHO Global Benchmarking Tool (GBT) Self Assessments to evaluating level of attainment and all regulatory functions.
	Develop and implement the WHO Regulatory Institutional Development Plan (IDP) to achieve ML 3
	Establish Maturity Level for Regulatory system

3.4.3 Product Evaluation and Registration Department

The Product Evaluation and Registration Department ensures that human medicines, complementary medicines, veterinary medicines, medical devices and cosmetics registered or approved for use in Botswana are safe, effective and of good quality.

Strategic Objective	P1 - Enhance Registration Function
Strategic Initiatives	Establish maturity level 3 for Human Medicines Registration processes, standards and structures;
	Establish Veterinary, Medical Devices and Cosmetics Registration processes, standards and structures;
	Initiate renewal for products registered greater than 5 years and B listed products and communicate to stakeholders;
	Implement registration backlog reduction plan;

3.5.4 Licensing and Enforcement Department

The Licensing and Enforcement Department is mandated with strengthening the Inspections and Licensing of Premises and Import/Export Controls as well as Enforcement of the MRSA and regulations thereof. The Department is also responsible for the testing and analysis of samples through the laboratory services function which became operational during the reporting period. In the current reporting year, the Enforcement function was moved from the Legal and Enforcement Unit to the Licensing and Enforcement Department following the organizational review undertaken during of the 2019/2020 financial year.

Strategic Objective	P4 - Strengthen Inspection and Licensing of Premises and Import/Export Controls
Strategic Initiatives	Establish maturity level 3 for inspections and licensing
	Establish GMP inspection capacity for Human and Veterinary manufacturing facilities
	Establish medical devices and cosmetics licensing/authorisation processes
	Implement Inspection Framework and programmes
	Develop and implement pharmaceutical track and trace system
Strategic Objective	P6 - Establish Laboratory Services
Strategic Initiatives	Attain ISO/IEC 17025 Accreditation
	Establish maturity level 3 for the laboratory
Strategic Objective	P7 - Strengthen Enforcement
Strategic Initiatives	Develop and implement an enforcement strategy

3.4.5 Pharmacovigilance and Clinical Trials

The functions of the Pharmacovigilance and Clinical Trials Department include monitoring the safety of medical products and assessment, approval and monitoring of conduct of clinical trials, approval of advertising & promotional materials used by market authorisation holders or their representatives and post marketing surveillance of medical products to identify substandard & falsified medicines circulating in the market.

Strategic Objective	P2 - Establish Vigilance System
Strategic Initiatives	Develop and Implement Pharmacovigilance strategy and plan
	Develop and Implement Practitioner Education programme on medication safety issues and Adverse Drug Reaction reporting
	Establish a National Medicines Information System
Strategic Objective	P3 - Enhance Clinical Trials Controls
Strategic Initiatives	Establish a clinical trial inspection and monitoring system
Strategic Objective	P5 - Establish Post Marketing Surveillance
Strategic Initiatives	Establish Risk Based Post Market Surveillance programme to detect and prevent falsified and substandard medicines

3.4.6 Finance and Administration Department

The Finance and Administration Department manages the Authority's financial affairs, information technology, records and facilities administration.

Strategic Objective	F1 - Establish Prudent Financial Management and Asset Optimisation
Strategic Initiatives	Drive utilisation of budget to ensure appropriate budget coverage.
	Maximise / enhance compliance to financial controls.
	Monitor the procurement plan and initiate early procurement methods. Conduct periodic reviews (quarterly) of the procurement plan.
	Source funding for the development of a laboratory on a plot in Block 10
Strategic Objective	P9 - Leverage ICT Services to enable efficiency
Strategic Initiatives	Implement the Information Technology Strategy including key projects
	Completion of Complementary Medicines system and database
	Develop and Implement Talent Management System
	Develop a Medicines Regulatory Management System
	Maximise / Enhance compliance to IT controls.



3.4.7 Human Resources Department

The Human Resources Department is mandated with ensuring that the Authority is adequately resourced, with the right talent and promotes a conducive work environment for high performance for all employees and officers of the Authority.

Strategic Objective	L1 - Enhance HR Management System
Strategic Initiatives	Implementation of Human Resources Strategy key deliverables
	Develop and implement a competency development program
	Develop and Implement Retention Strategy
Strategic Objective	L2 - Instill High Performance Culture
Strategic Initiatives	Implement Performance Management system and related policies;
	Develop transformational leadership
	Enhance engagement initiatives and implement engagement action plan

3.4.8 Quality Management Unit

The Quality Management Unit is responsible for establishment, implementation and monitoring of a Quality Management System (QMS) within the Authority. The Unit advises the CEO on the performance of the QMS by producing data and measuring against set standards. The Unit is also responsible for establishment and implementation of the Enterprise Risk Management.

Strategic Objective	P8 - Establish and Implement Quality Management System
Strategic Initiatives	Attain ISO 9001 certification
	Implement Enterprise Risk Management

3.4.9 Public Relations Unit

The Public Relations Unit is responsible for overseeing public relations and engagement of stakeholders.

Strategic Objective	C1 – Stakeholder Engagement
Strategic Initiatives	Implement Stakeholder Communications and Engagement Strategy.
	Implement Communications and Public Relations Strategy.
	Conduct Customer Service Survey
Strategic Objective	P10 - Internal Communication Effectiveness
Strategic Initiative	Implement the Internal Communications Policy

3.5 Legal and Corporate Unit

The Legal and Corporate Unit is responsible for providing BoMRA with legal services and providing Board secretarial services to the Medicines Regulatory Board. The Unit carried out enforcement of the MRSA and related legislation through the Enforcement function which has since moved to the Licensing and Enforcement Department as a stand-alone Unit.

Strategic Objective	P7 - Strengthen Enforcement
Strategic Initiative	Develop and implement an Enforcement Strategy
Strategic Objective	L3 - Improve Corporate Governance with Effective Practices
Strategic Initiatives	Implement Shareholder Compact and monitor compliance;
	MRSA reviewed and amended to adequately cover the scope;
	Implement legal Compliance Framework
	Implement Governance Framework (King IV)



REGULATORY PERFORMANCE FOR THE YEAR UNDER REVIEW

Table of Contents

Product Evaluation and Registration
Licensing and Enforcement
Pharmacovigilance and Clinical Trials

4 REGULATORY PERFORMANCE FOR THE YEAR UNDER REVIEW

Information on the Authority's key regulatory performance areas for the 2020/21 financial year.

4.1 Product Evaluation and Registration

Key Highlights

Establish WHO Maturity Level 3 for Human Medicines Registration

- The Authority conducted a self-assessment in October 2020, and engaged Tanzania Medicines and Medical Devices Authority in March 2021, to conduct an audit against the WHO GBT for the Human medicines regulatory system in preparation for the WHO ML 3 assessment.

Establishment of the Medical Devices and Veterinary Medicines Units.

- The Authority established the medical devices and veterinary Medicines Units. The medical devices unit developed and implemented the processes for exemption of Covid related medical devices and listing of all other medical devices that existed on the Botswana market. The Veterinary Medicines developed and implemented the processes for registration and listing of Veterinary medicinal products (VMPs). The Authority opened for submission of applications for registration of VMPs in November 2020.

Initiate a renewal process

- The Authority developed the process for renewal of medicines. The process was scheduled to start with submission of applications for renewal of ARVs. The notice to all stakeholders, calling for submission of these renewal applications was sent out in May 2020.

Implementation of the backlog reduction plan

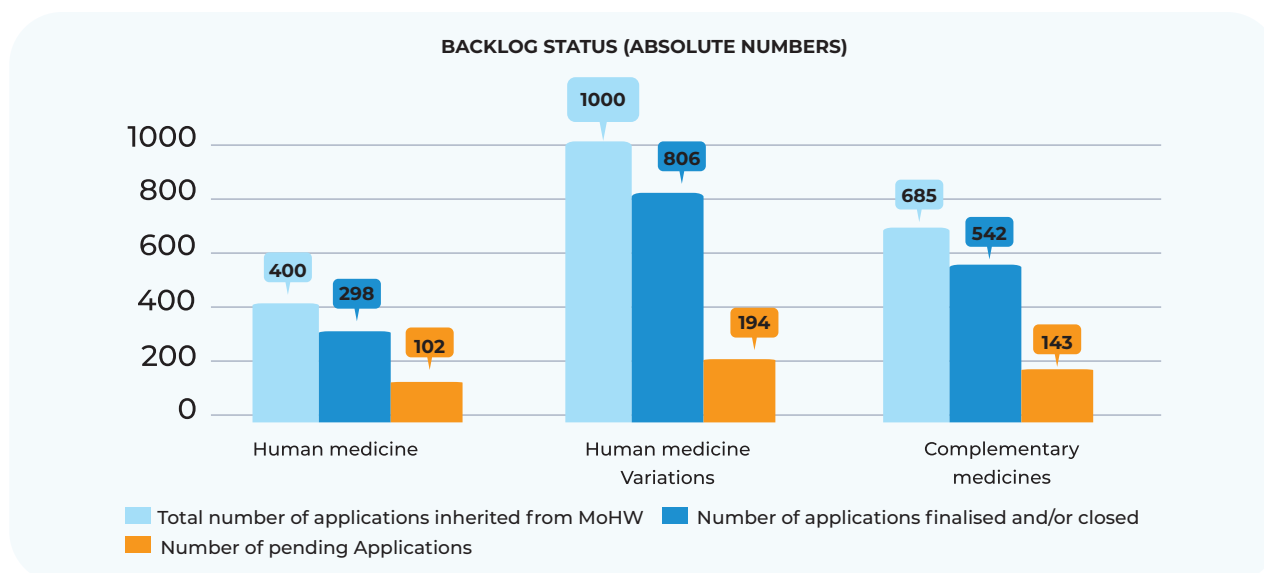
The following applications had been inherited from the Drugs Regulatory Unit, Ministry of Health and Wellness

- Human allopathic medicines applications - 400.
- Variation applications - 1000.
- Complementary medicines applications - 685.

To date, the Authority has managed to reduce the backlog has been reduced to an overall 22% compared to the annual target of 25%. Refer to as per Figure 4 for graphical presentation of the Authority's performance for the three application lines.

Figure 4: Status of Backlog Applications Received from MoHW

	Total number of applications inherited from MoHW	Number of applications finalised and/or closed.	Number of Pending Applications	Target Reduction (%) by end of March 2020/21	Actual Reduction (%) by end of March 2020/2021
Human medicines	400	298	102	25	25
Human medicines Variations	1000	806	194	25	20
Complementary medicines	685	542	143	25	21

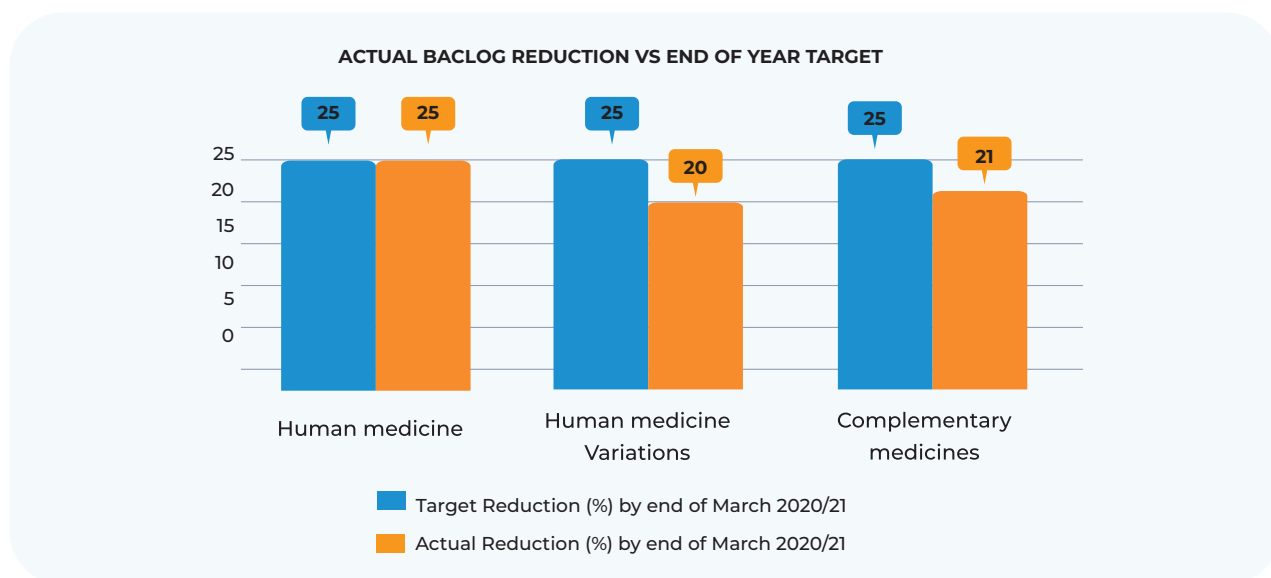


- The status of new applications received at BoMRA since February 2020 is as per figure 6 below.

Figure 6: Registration - New Applications Status Since February 2020

Type of application	Received	Processed	In-process (allocated)	Pending (unallocated)
Human medicines				
Screening new applications	566	473	28	65
Rescreening	160	131	17	12
New applications for Registration	229	26	82	121
Variation applications	854	133	480	241
Product Renewals	25	0	5	20
Complementary medicines				
Screening new applications	98	83	0	15
Rescreening	49	33	5	11
New applications for Registration	28	11	5	12
Veterinary medicines				
Screening New applications	1	1	0	0

- The number of exemptions from registration application methods is as per Figure 7.

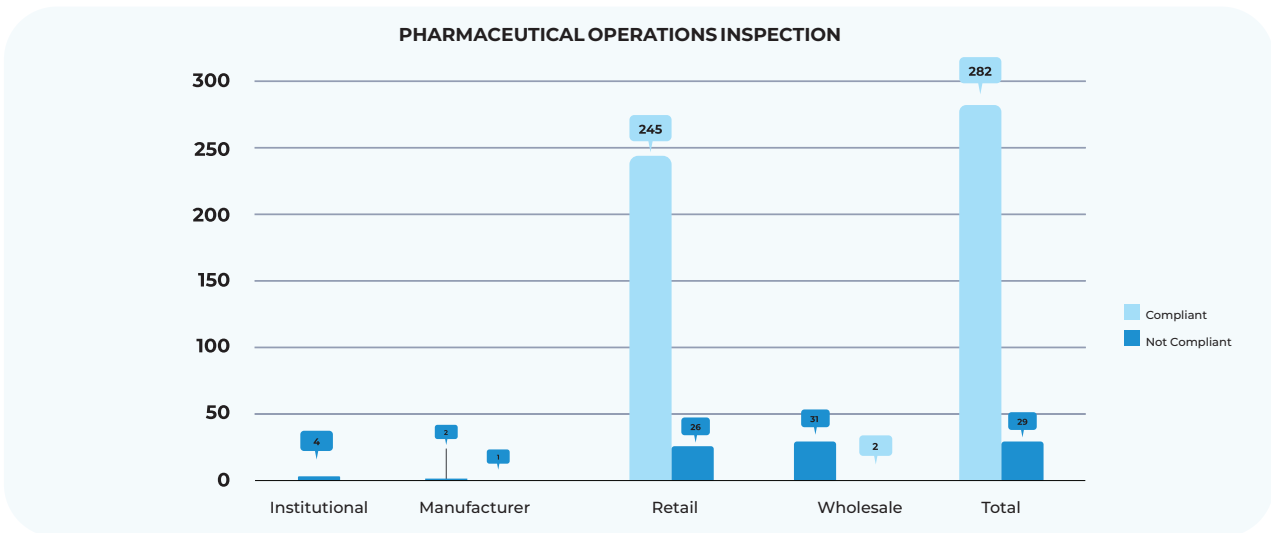


4.2 LICENSING AND ENFORCEMENT

Key Highlights for 2020/21

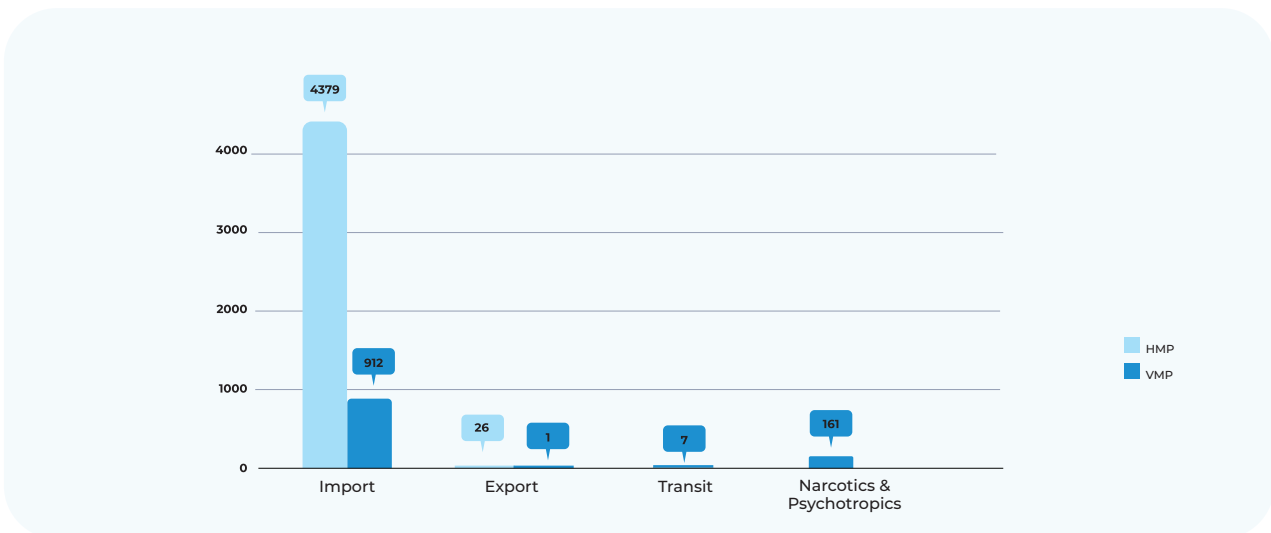
Conducted 321 inspections covering 207 human medicines and 114 veterinary medicines premises. Out of these, 271 were retailers, 33 were distributors, 14 were Institutional pharmacies while 3 were manufacturers. The premises inspected were at a 91% compliance level with set standards. Inspections are as per figure 8 below.

Figure 8: Annual Inspections - Pharmaceutical Operations



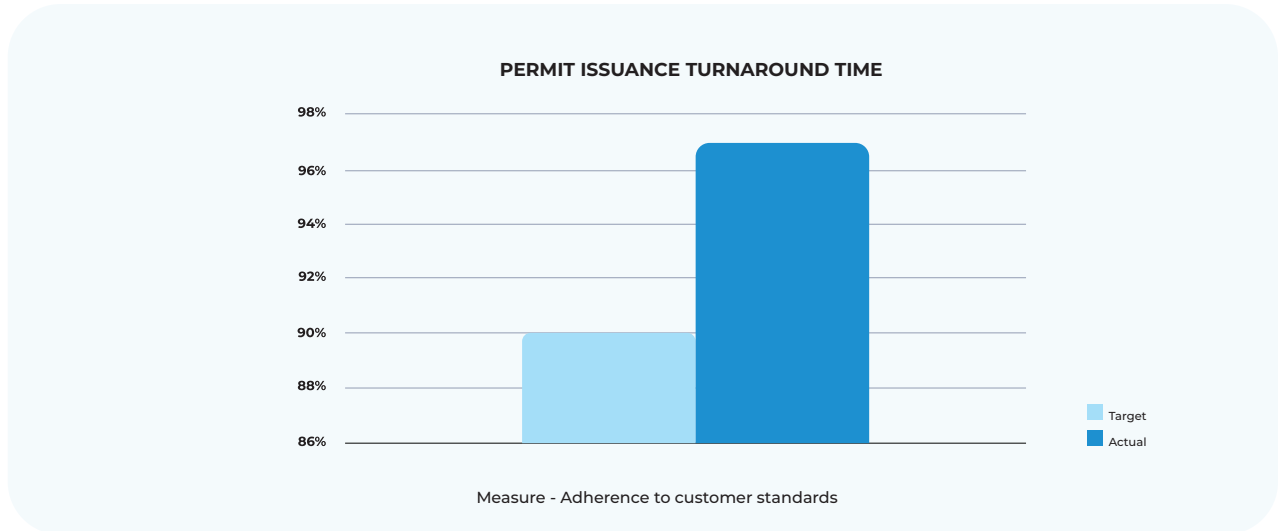
- Inspected were some of the major public institutional premises where the exercise was used in part, to carry out an assessment of premises compliance as well as to prepare the guidelines to be rolled-out in the year 2021/2022.
- 5,485 permits for import and export control of pharmaceutical products into and out of Botswana were issued to pharmaceutical operators.
- The permits issued for medicines other than Narcotics and Psychotropics included 5291 import permits, 27 export permits and 7 transit permits. 160 import and 1 export permits were issued for Narcotics and Psychotropics.

Figure 9: Permits Issued Per Category



- Overall turnaround time for permit issuance was at 97%.

Figure 10: Permits Issued - Compliance to Customer Service Standards



- 52 Law enforcement operatives were trained on understanding the control of human medicines in Botswana mainly in the southern part.
- Joint operations with Botswana Police Service; Ministry of Trade and Investment; Botswana Unified Revenue Services; Botswana Post; Wildlife and Parks; Environmental Health; Competition and Consumer Protection; as well as Local administrative authorities.
- Created working relationships with other enforcement bodies, including the Botswana Police Force throughout Botswana including Gaborone, Lobatse, Ghanzi, Maun, Francistown, Mahalapye, Palapye, Kasane, Selibe Phikwe and Nata.
- Most infringements related to the medical products being that they were unregistered and/or imported without a permit.
- Infringement of MRSA sections 23 and 28 contributed 76% of the total number of offences with Informal traders mostly likely to contravene sections 23 (registration) and 28 (Import Permits). Illegal manufacturing of hand sanitizer products was the main driver for the Infringement of MRSA section 27 which requires licensing of manufacturers by the Authority.
- 79% of offences were committed by informal traders. 11% of infringements were by entities regulated by the Authority. The remainder of the offenders comprised entities licensed by other authorities or Government.

The total estimate of economic value for all offences was BWP8,878,318 (eight million eight hundred seventy-eight thousand three hundred and eighteen Pula).

4.3 PHARMACOVIGILANCE AND CLINICAL TRIALS

Key Highlights for 2020/21

- Carried out 63 training sessions where 759 Healthcare Practitioners (HCPs) were trained and sensitised on safety monitoring of medicines and vaccines.
- 8 Adverse Drug Reaction Monitoring Centres (AMCs) were launched in the last year in the hospitals listed in the table below. These AMCs will play a significant role in strengthening and expanding national pharmacovigilance (PV) program being focal points in their respective areas for collection of ADRs and promoting other PV activities of the Authority.

Table 11: Hospitals Where AMCs Launched

Identified Hospitals for AMCs	Location
Princess Marina Referral Hospital	Gaborone
Nyangabgwe Referral Hospital	Francistown
Bamalete Lutheran Hospital	Ramotswa
Sekgoma Memorial Hospital	Serowe
Letsholathebe II Memorial Hospital	Maun
Orapa Mine Hospital	Orapa
Kasane Primary Hospital	Kasane
Riverside Private Hospital	Francistown

- Engaged with Public Health Programmes (PHPs) including with HIV, TB, Expanded Program of Immunisation and Malaria Eradication programme in building awareness and training of Healthcare Professionals.
- Training for the BoMRA team on evaluation of Periodic Benefit Risk Evaluation Reports (PBRERs) and Periodic Safety Update Reports (PSURs) basic training in Good Clinical Practice (GCP) and ICH Guidelines covering conduct of clinical trials.
- 435 ADRs reported in one year against the World Health Organisation (WHO) recommendation of a good National PV system of 200 ADR reports per million population.
- Three clinical trial protocols and five protocol amendments were assessed and approved.
- Pharmacovigilance Officers were trained in the conduct of regulatory and GCP inspections and 2 clinical trials were inspected.
- Risk based post marketing surveillance (PMS) activities were initiated and completed the first round of three of sampling of medicines to establish a baseline for Substandard and Falsified Medicines.
- Secured two financial grants from European and Developing Countries Clinical Trials Partnership(EDCTP). One of the projects is for 2 years duration and focuses on developing capacity at National Ethics Committee (NEC), Institutional Ethics Committees and at BoMRA to improve the clinical trials oversight and regulation. The grant amount is € 283,250 (Approx. 3.9 million pula). The other project grant of € 90,000 (Approx. 1.2 million pula) granted to Botswana, is for 3 years and is a multi-country collaboration of four Southern African countries – Lesotho, Eswatini, Mozambique and Botswana.



210.24

209.22

1,218.38

210.74

208.33

456.60

26.42

2510.41

19.05

7,513.08

2,168.02

29,240.68



**CUSTOMER &
STAKEHOLDER FOCUS**



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Quality Management	0
Partnerships/Harmonisation	0
Public Relations	0

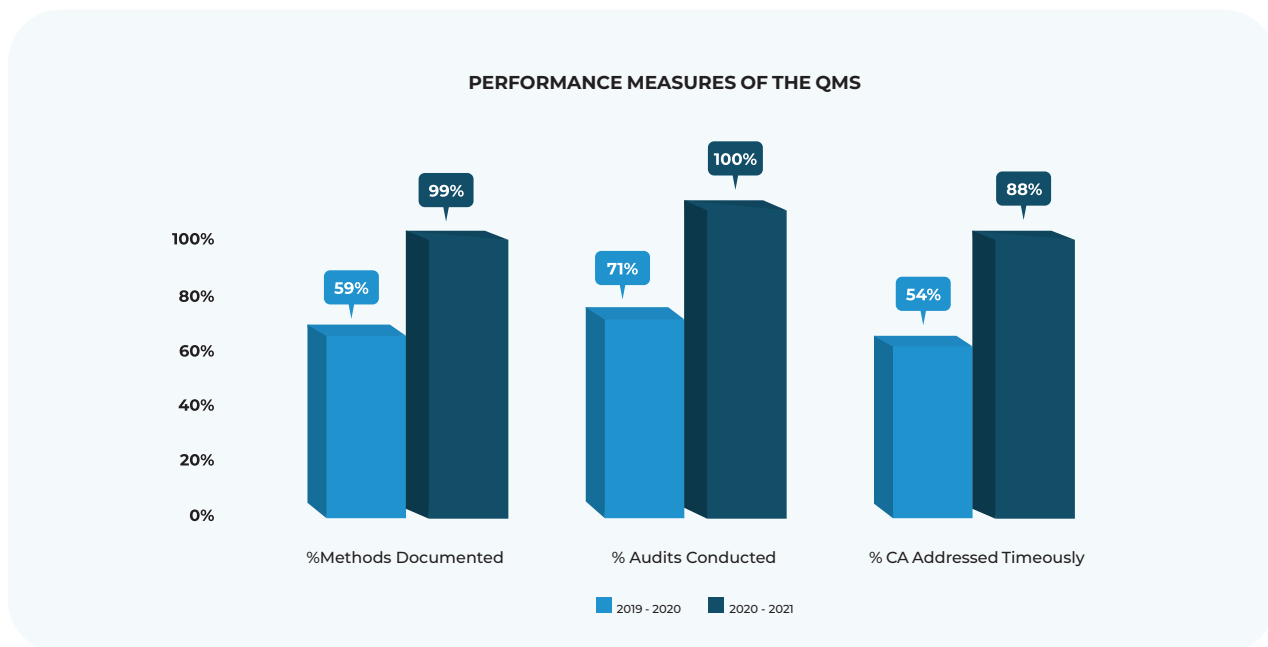
5 CUSTOMER AND STAKEHOLDER FOCUS

Depicts the Authority's interaction with its customers and stakeholders as well as how the Authority ensures the highest standards of quality service provision to its stakeholders.

5.1 QUALITY MANAGEMENT

From its inception the Authority has prioritised quality in delivery and execution of its mandate. As part of its commitment to providing quality services in response to customer needs and expectations, the Authority has established a Quality Management System (QMS). The implementation of the QMS is in line with BOMRA's 3rd Strategic Goal - Fully Functional Regulatory System and the World Health Organisation Global Benchmarking Tool. For any Medicine Regulatory Authority to be deemed fully functional by WHO, it is required that a QMS be in place and that there should be evidence of its effective implementation. In March 2021, two years after the Authority was established, it was certified by British Standards Institute to ISO 9001:2015 under certificate Number FS 739935 - a demonstration that BoMRA services can be trusted.

Figure 14: Performance of Quality Management System



5.2 PARTNERSHIPS/HARMONISATION

The Authority leverages opportunities for partnerships that may enhance efficiency in its regulatory mandate or other related mandates that are beneficial to the public. The Authority enters into Agreements and Memoranda of Understanding to form the basis for these relationships and to establish efficient and aligned cooperation between parties.

The Authority aims to not only enter into these legal relationships but sets targets to ensure such relationships are active and there are specific outputs for joint activities. As part of its 5-year strategy, the Authority aims to have in place 10 active MOU's with key partners. In the year under review, the Authority signed off 7 of the 8 planned partnership agreements/MOUs and commenced with operationalisation through putting in place action plans.

The partnerships that the Authority enters into fall under various categories, being:

- **Capacitation** – These are usually similar bodies, including regulatory bodies, where there is opportunity for capacity building, knowledge sharing and other forms of support.
- **Overlapping mandates** – These are local entities with a similar or overlapping mandate resulting in the need for alignment to ensure differentiation, and sometimes multiplicity of effect, in their roles to enhance efficiency.
- **Facilitation and Support** – these are other entities that provide opportunity for support, to enhance efficiency and support multiple mandates where functions permit.
- **Educational and Market Development** – The Authority may influence curricula as well as provide and obtain support from academia. This serves to develop the market and orient students to improve implementation once in practice.

Table 12: Partnerships Targeted for 2020/21

No.	Partner	Category
1	Medicines Control Authority of Zimbabwe	Capacitation
2	Tanzania Medicines and Medical Devices Authority	Capacitation
3	Department of Veterinary Services	Overlapping mandates
4	Radiation Protection Inspectorate	Overlapping mandates
5	Botswana Unified Revenue Services	Facilitation
6	Botswana Bureau of Standards	Facilitation
7	University of Botswana	Education and Market Development
8	Registrar of Agrochemicals (Pending)	Overlapping mandates

Implementation of the Agreements and Memoranda shall be monitored going forward.

5.3 PUBLIC RELATIONS

The Botswana Medicines Regulatory Authority engages with external stakeholders that have the potential to influence and impact our business, and with internal stakeholders to increase their engagement on delivering its mandate. The engagements are guided by a framework which directly serves the ambitions of the Authority as captured in the vision and mission statements. Our engagement practices are underpinned by our commitment to building a positive customer service experience.

Our Goal - Improved awareness and public trust in the medical products, cosmetics, and their regulation.

Our objectives -

- Educate stakeholders on safe, efficacious and quality medical products, cosmetics, and their regulations.
- Internal communication effectiveness

Our Enablers -

- **The strategy:** is the guiding document on how we achieve our objectives.
- **Policy:** sets the tone of engagements.
- **Procedures:** provide a systematic approach to our engagements, outline the rules, and methods we follow in our interactions with the stakeholders and all interested audiences
- **Plan:** outlines our annual timelines on how we are going to interact with our audiences, and stakeholders for an ongoing period.



Awareness initiatives during the 2020/21 FY

CATEGORIES:

EXTERNAL COMMUNICATION

Online awareness

A series of awareness videos were uploaded on social media platforms and aired on TV to show the preparedness and contribution in the fight against COVID-19. Stakeholders were also kept up to date with regulatory services during the lockdown and national extreme social distancing period. This was done to minimize the disruptions to the stakeholders following the outbreak.

Workshops, seminars, and training

1. Pharmacovigilance training- ADR Reporting and Program Monitoring
2. MRSA stakeholder awareness
3. Registration of medicines and medical devices
4. Regulation of veterinary medicines

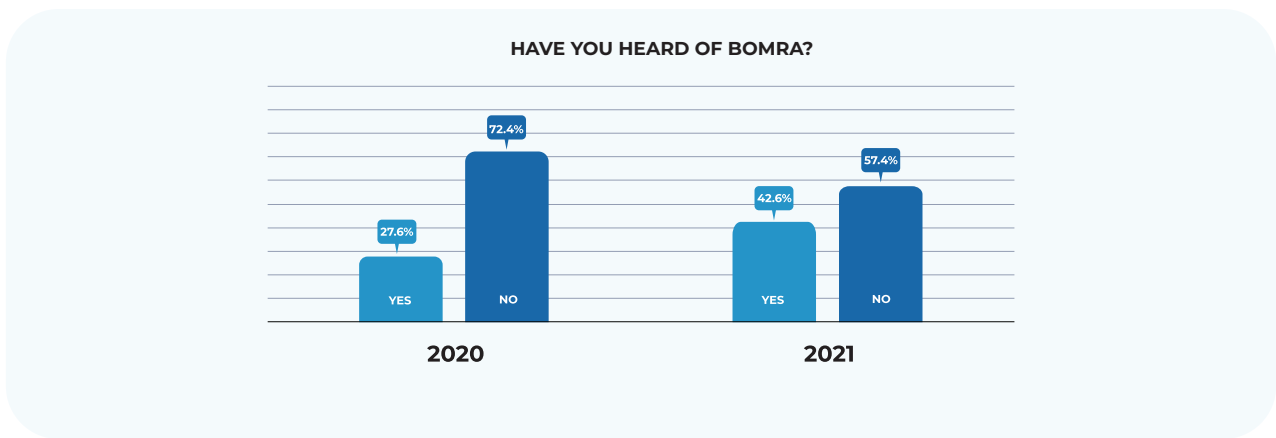
INTERNAL COMMUNICATION

1. BoMRA Policies and procedures awareness presentations
2. EQMS and ERM training

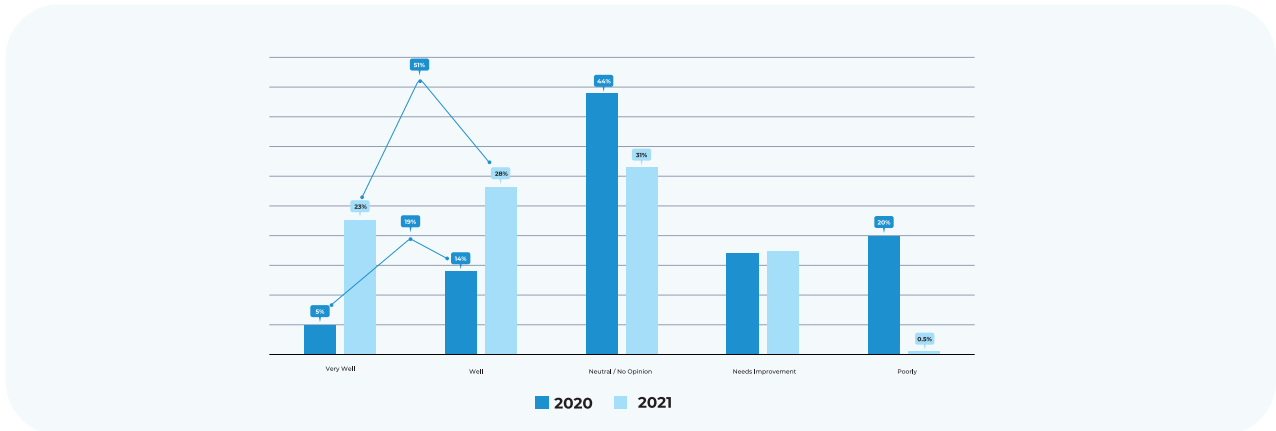
AWARENESS SURVEY

The ranking summary is from an awareness survey that was conducted in 2020 to establish the level of awareness by 2 stakeholder groups, HCPs, and the Public. The survey was conducted on the basis that information data collected from the stakeholders will be useful for the development of appropriate engagement plans. We are pleased to report an increase in awareness, as well as a notable increase in positive awareness, in the minds of the public from 2020 to 2021. However, there is still ample room to increase awareness of BoMRA and its mandate.

The total share of survey respondents that had heard of BoMRA increased 15 points, from **27.6 % recorded in 2020 to 42.6 % in 2021**. With the Authority's plans to intensify its marketing from April 2021, awareness is expected to increase significantly.

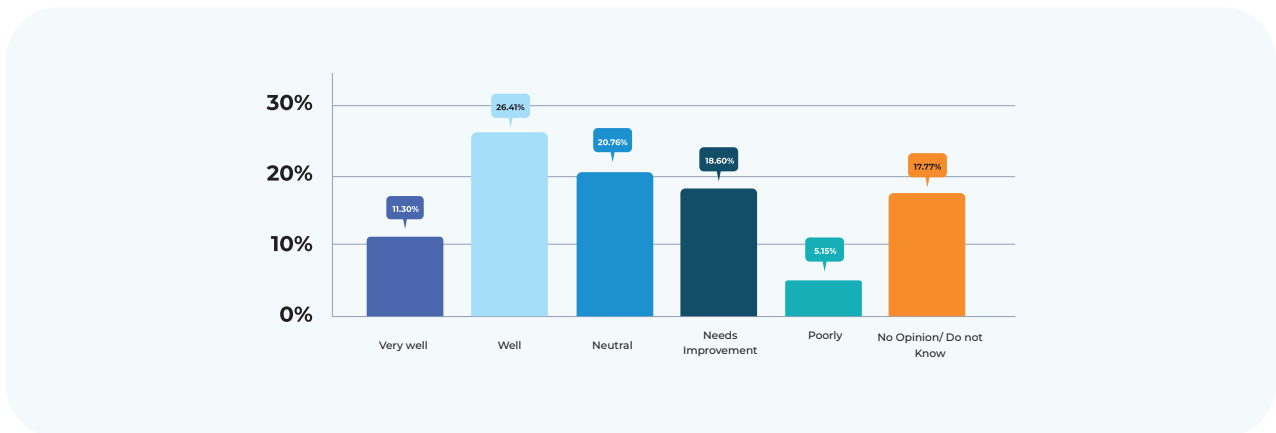


Among those survey respondents that had heard of BoMRA, the percentage who feel BoMRA is doing its job well or very well increased by 32 points, from 19% to 51%.



HEALTHCARE PRACTITIONERS

This survey targeted healthcare practitioners, majority of those surveyed believe BoMRA is doing its job “Well” or “Very Well.” (37.41% total). There is an opportunity to improve this score as well, however, with 38% of respondents being neutral or having no opinion.



VIRTUAL ENGAGEMENTS

- Targeted efforts made to enhance stakeholder engagement during the year under review were realized despite the challenges posed by Covid 19 restrictions and 2 lockdowns. We were forced to make some adjustments to our engagement plans as we shifted to virtual engagements and social media.



**BOMRA ANNUAL
FINANCIALS STATEMENTS**
For The Year Ended 31 March, 2021

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General Information

Country of incorporation and domicile	Botswana
Nature of business and principal activities	The Botswana Medicines Regulatory Authority (the Authority) was established as a body corporate by the Medicines and Related Substances Act, 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	<p>Mr. Duncan Thela (Chairperson)</p> <p>Dr. Mbatshi Mazwiduma (Vice Chairperson)</p> <p>Mr. Kagiso Balopi (Board Member)</p> <p>Mr. Meshack Baoleki (Board Member)</p> <p>Ms. Botho Bayendi (Board Member)</p> <p>Dr. Joyce Kgatlwane (Board Member)</p> <p>Dr. Malebogo Keabonye (Ex-officio Board Member) (Appointed on 08th October 2020)</p> <p>Dr. Tiroyaone Mampane (Board Member) (Resigned on 25th May 2021)</p> <p>Dr. Letlhogile Modisa (Ex-officio Board Member)</p> <p>Dr. Gontle Moleele (Board Member)</p> <p>Ms. Shameela Pholo-Winston (Board Member)</p> <p>Dr. Michael G. Sento (Board Member)</p> <p>Dr. Malaki Tshipayagae (Ex-officio Board Member) (Membership ended on 08th October 2020)</p>
Chief Executive Officer	Dr. Stephen Ghanie
Board secretary	Mr. Nonofu Thipe
Business address	Plot 112 International Finance Park Gaborone
Postal address	Private Bag 2 Gaborone Station 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 (the 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 annual financial statements and related financial information included in this report. It is the Board's responsibility to ensure that the annual 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 annual financial statements.

The annual 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 annual 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 cash flow forecast for the year to 31 March 2022 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 annual financial statements. The annual financial statements have been examined by the Authority's external auditors and their report is presented on pages 50 to 52.

The annual financial statements set out on pages 53 to 71, which have been prepared on the going concern basis, were approved by the board on 28 September 2021 and were signed on their behalf by:

Approval of financial statements



Chairperson



Chief Executive Officer



RSM Botswana

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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 45 to 63, which comprise the statement of financial position as at 31 March 2021, 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 2021, 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 accordance with 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 53 to 71. 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 (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.

Date: **06 October 2021**
Gaborone

RSM Botswana
Certified Auditors Gaborone
Practicing member: P. Muonde
Membership number: CAP00242021

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Statement of Surplus or Deficit and Other Comprehensive Income

Figures in Pula	Note	2021	2020
Revenue	3	45,160,204	57,447,662
Regulatory fees	4	8,190,629	540,273
Total income		53,350,833	57,987,935
Employee costs	5	(44,806,155)	(35,615,153)
Governance expenses		(667,571)	(823,515)
Depreciation and amortisation expenses	5	(4,351,855)	(3,324,548)
Publicity and awareness expenses		(1,430,188)	(2,643,363)
Travel and accommodation costs		(773,250)	(3,683,745)
Operating expenses		(12,415,039)	(8,933,973)
Total expenses		(64,444,058)	(55,024,297)
Operating (deficit)/surplus	5	(11,093,225)	2,963,638
Investment income	6	215,260	494,446
Finance costs	7	(780,139)	(871,500)
Total operating (deficit)/surplus for the year		(11,658,104)	2,586,584
Other comprehensive income		-	-
Total comprehensive (deficit)/surplus for the year		(11,658,104)	2,586,584

Statement of Financial Position as at 31 March 2021

Figures in Pula	Note	2021	2020
Assets			
Non-current assets			
Equipment	9	12,996,460	7,657,381
Intangible assets	10	799,750	807,037
Right-of-use asset	11	10,860,805	11,270,198
		24,657,015	19,734,616
Current assets			
Accounts receivable	12	1,034,623	591,198
Cash and cash equivalents	13	19,130,440	27,525,580
		20,165,063	28,116,778
Total assets		44,822,078	47,851,394
Reserves and liabilities			
Reserves			
Accumulated surplus		7,806,338	19,464,442
Liabilities			
Non-current liabilities			
Lease liabilities	11	10,654,886	11,077,697
Deferred income	14	13,797,768	8,465,975
		24,452,654	19,543,672
Current liabilities			
Lease liabilities	11	1,847,609	1,416,752
Deferred income	14	721,930	-
Accounts payable	15	9,993,547	7,426,528
		12,563,086	8,843,280
Total liabilities		37,015,740	28,386,952
Total reserves and liabilities		44,822,078	47,851,394

Statement of Changes in Reserves

Figures in Pula	Accumulated surplus	Total equity
Balance at 01 April 2019	16,877,858	16,877,858
Surplus for the period	2,586,584	2,586,584
Total surplus for the period	2,586,584	2,586,584
Balance at 01 April 2020	19,464,442	19,464,442
Deficit for the year	(11,658,104)	(11,658,104)
Total deficit for the year	(11,658,104)	(11,658,104)
Balance at 31 March 2021	7,806,338	7,806,338

Statement of Cash Flows

Figures in Pula	Note(s)	2021	2020
Cash flows from operating activities			
Cash (used in)/generated from operations	16	(4,621,623)	9,215,585
Interest income		215,260	494,446
Finance costs		(780,139)	(871,500)
Net cash (outflow)/ inflow from operating activities		(5,186,502)	8,838,531
Cash flows from investing activities			
Purchase of equipment	9	(3,634,801)	(3,190,991)
Purchase of intangible assets	10	(174,796)	(130,712)
Proceeds on disposal of equipment	9	17,761	25,564
Net cash outflow from investing activities		(3,791,836)	(3,296,139)
Cash flows from financing activities			
Payment of lease liabilities		(1,434,201)	(1,208,260)
Specific grant received - EDTCP		721,929	-
Increase in deferred Government grant		1,295,470	1,474,804
Decrease in Government grant for laboratory		-	(24,231,765)
Net cash inflow/(outflow) from financing activities		583,198	(23,965,221)
Net decrease in cash and cash equivalents for the year		(8,395,140)	(18,422,829)
Cash and cash equivalents at the beginning of the year		27,525,580	45,948,409
Cash and cash equivalents at the end of the year	13	19,130,440	27,525,580

Accounting Policies

1. Significant accounting policies

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

1.1 Basis of preparation

The annual 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 annual financial statements and the Medicines and Related Substances Act of 2013.

The annual 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 annual 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.

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.

Accounting Policies

1.2 Significant judgements and sources of estimation uncertainty (continued)

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 third party to purchase the asset at the end of its 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.

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.

Accounting Policies

1.3 Equipment (continued)

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 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 at amortised cost.

Financial liabilities at amortised cost.

Note 17 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.

Recognition and measurement

Accounts receivables 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.

Accounting Policies

1.5 Financial instruments (continued)

Credit risk

Details of credit risk are included in the financial instruments and risk management (note 17).

Derecognition

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

Accounts payable

Classification

Accounts payable (note 15), 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.

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 17 for details of risk exposure and management thereof.

Derecognition

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

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 reasonably certain that it will exercise.

In order to assess whether a contract is, or contains a lease, management determine whether the asset under consideration is "identified", which means that the asset is either explicitly or implicitly specified in the contract and that the supplier does not have a substantial right of substitution throughout the period of use. Once management has concluded that the contract deals with an identified asset, the right to control the use thereof is considered. To this end, control over the use of an identified asset only exists when the company has the right to substantially all of the economic benefits from the use of the asset as well as the right to direct the use of the asset.

Accounting Policies

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 lessee'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;
- there has been a change to the lease payments due to a change in an index or a rate, in which case the lease liability is remeasured by discounting the revised lease payments using the initial 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.

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 statement of surplus or deficit.

1.7 Reserves

Accumulated surplus under reserves represent excess of income over expenditure.

1.8 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.

Accounting Policies

1.6 Leases (continued)

1.9 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.

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.

1.10 Other operating income

The authority derives other income from registration of human and veterinary medicines, licensing and permits for import and export medicines and related equipment. It is recognised as income in the statement of surplus or deficit when the services are rendered and invoiced to the customer.

Notes to the Annual Financial Statements

Figures in Pula	2021	2020
2. New Standards and Interpretation		
The International Accounting Standard Board (IASB) continues to issue new and revised standards. The Authority considers for adoption and disclosure standards and interpretation which are relevant to its operations. There were no new standards and interpretations which were not yet effective but relevant to the authority. There were also no new standards and interpretations which were adopted by the authority in the year under review.		
3. Revenue		
Grant received from Government of Botswana	42,646,074	55,629,948
Amortisation of deferred income	2,514,130	1,817,714
	45,160,204	57,447,662
Reconciliation of Government grant received		
Grant received from Government of Botswana	46,455,670	34,719,884
Deferred income utilised	-	24,231,765
Amount utilised to acquire assets	(-3,809,596)	(3,321,701)
	42,646,074	55,629,948
4. Regulatory fees		
Tender fees	-	30,453
Regulatory fees - Human medicine	6,358,699	344,703
Other regulatory fees	1,831,930	165,117
	8,190,629	540,273
5. Operating surplus		
Operating (deficit)/surplus for the year is stated after charging (crediting) the following, amongst others:		
Auditor's remuneration - external		
Audit fees	70,560	67,200
Employee costs		
Salaries, wages and other benefits	35,155,471	27,204,640
Recruitment costs	924,058	1,419,897
Pension scheme contribution	2,738,705	2,034,616
Gratuity expense	3,868,946	3,245,313
Leave pay expense	1,612,518	1,407,018
Professional and other subscriptions	506,457	303,669
Total employee costs	44,806,155	35,615,153
Depreciation and amortisation		
Depreciation of equipment	2,318,135	1,652,806
Depreciation of right-of-use asset	1,851,637	1,506,834
Amortisation of intangible assets	182,083	164,908
Total depreciation and amortisation	4,351,855	3,324,548

Notes to the Annual Financial Statements

Figures in Pula	2021	2020
6. Investment income		
Interest income		
Investments in financial assets:		
Other financial assets	215,260	494,446
7. Finance costs		
Lease liabilities	780,139	871,500

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

	2021			2020		
	Cost	Accumulated depreciation	Carrying value	Cost	Accumulated depreciation	Carrying value
Computer equipment	5,749,841	(2,651,964)	3,097,877	4,390,405	(1,356,198)	3,034,207
Furniture and fixtures	1,344,268	(225,109)	1,119,159	1,143,542	(98,498)	1,045,044
Motor vehicles	3,309,606	(1,005,361)	2,304,245	2,782,636	(561,492)	2,221,144
Office equipment	1,008,162	(349,509)	658,653	879,645	(166,613)	713,032
Laboratory equipment	4,393,811	(33,124)	4,360,687	93,114	(1,552)	91,562
Leasehold improvements	1,031,691	(190,324)	841,367	362,672	(50,969)	311,703
Laboratory - work in progress	614,472	-	614,472	240,689	-	240,689
Total	17,451,851	(4,455,391)	12,996,460	9,892,703	(2,235,322)	7,657,381

Reconciliation of equipment - 2021

	Opening balance	Additions	Retirement	Depreciation	Total
Computer equipment	3,034,207	1,471,416	(13,913)	(1,393,833)	3,097,877
Furniture and fixtures	1,045,044	200,726	-	(126,611)	1,119,159
Motor vehicles	2,221,144	526,970	-	(443,869)	2,304,245
Office equipment	713,032	128,517	-	(182,896)	658,653
Laboratory equipment	91,562	4,300,698	-	(31,573)	4,360,687
Leasehold improvements	311,703	669,019	-	(139,355)	841,367
Laboratory - work in progress	240,689	373,783	-	-	614,472
	7,657,381	7,671,129	(13,913)	(2,318,137)	12,996,460

Additions above includes assets amounting to 3,634,801 acquired through grant income and the remaining assets (4,036,327) were donated by Ministry of Health and Wellness.

Notes to the Annual Financial Statements

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
Plant and machinery	-	93,114	(1,552)	91,562
Leasehold improvements	-	362,672	(50,969)	311,703
Capital - Work in progress	-	240,689	-	240,689
	6,150,180	3,190,991	(1,681,990)	7,657,381

All assets were acquired through Government grants.

10. Intangible assets

	2021			2020		
	Cost	Accumulated amortisation	Carrying value	Cost	Accumulated amortisation	Carrying value
Computer software	1,209,139	(409,389)	799,750	1,034,344	(227,307)	807,037

Reconciliation of intangible assets-2021

	Opening balance	Additions	Amortisation	Total
Computer software	807,037	174,796	(182,083)	799,750

Reconciliation of intangible assets-2020

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

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

11. Leases (company as lessee)

Net carrying amounts of right-of-use assets

The carrying amounts of right-of-use assets are included in the following line items:

Buildings	10,860,805	11,270,198
Additions to right-of-use assets		
Buildings	1,442,247	-

Notes to the Annual Financial Statements

Figures in Pula	2021	2020
11. Leases (company as lessee) (continued)		
Depreciation recognised on right-of-use assets		
Depreciation recognised on each class of right-of-use assets, is presented below. It includes depreciation which has been expensed in the total depreciation charge in profit or loss (note 5), as well as depreciation which has been capitalised to the cost of other assets.		
Buildings	1,851,637	1,506,834
Lease liabilities		
Lease liabilities have been included in the lease liabilities line item on the statement of financial position. Refer to note.		
Within one year	2,606,424	2,187,654
Two to five years	11,764,937	9,900,515
More than five years	469,066	3,261,129
	14,840,427	15,349,298
Less finance charges component	(2,337,932)	(2,854,849)
	12,502,495	12,494,449
Non-current liabilities	10,654,886	11,077,697
Current liabilities	1,847,609	1,416,752
	12,502,495	12,494,449
12. Accounts receivable		
Accounts receivable	258,096	-
Lease deposit	171,375	148,820
Non-financial instruments:		
Advance to suppliers	126,377	-
Staff advances	-	77,836
Prepaid expenses	478,775	364,542
Total trade and other receivables	1,034,623	591,198
Financial instrument and non-financial instrument components of receivables		
At amortised cost	429,471	148,820
Non-financial instruments	605,152	442,378
	1,034,623	591,198
13. Cash and cash equivalents		
Cash and cash equivalents consist of:		
Bank balances	19,120,076	9,219,864
Short-term investments	10,364	18,305,716
	19,130,440	27,525,580

Notes to the Annual Financial Statements

Figures In Pula	2021	2020
Leases (company as lessee) (continued)		
14. Deferred income		
The Authority received a total amount of P 46,455,670 as a Government grant during the reporting period. Grants related to assets are recognised using the deferred income method.		
Government grants - related to non-current assets		
Opening balance of deferred government grant	8,465,975	6,991,171
Assets purchased during the year	7,845,923	3,321,703
Amortisation of grant related to assets	(2,500,217)	(1,817,715)
Adjustment on asset retirement	(13,913)	(29,184)
	13,797,768	8,465,975
Grants related to specific project		
Opening balance of specific government grant	-	24,231,765
Grants received for development of medical facilities from EDCTP association	721,930	-
Grant used for revenue expenditure	-	(23,991,076)
Grant utilised for capital work in progress	-	(240,689)
	721,930	-
15. Accounts payable		
Financial instruments:		
Payable to suppliers	1,561,370	980,194
Provision for gratuity	5,286,664	4,448,874
Provision for leave pay	3,145,513	1,997,460
	9,993,547	7,426,528
Categorisation of accounts payable		
At amortised cost	9,993,547	7,426,528
Exposure to liquidity risk		
Refer to note 17 Financial instruments and financial risk management for details of liquidity risk exposure and management.		
16. Cash generated from operations		
(Deficit)/ Surplus for the year	(11,658,104)	2,586,584
Adjustments for:		
Depreciation and amortisation	4,351,855	3,324,548
Interest income	(215,260)	(494,446)
Finance costs	780,139	871,500
(Profit)/ loss on asset retirement	(3,848)	5,420
Changes in working capital:		
Accounts receivable	(443,424)	(252,466)
Accounts payable	2,567,019	3,174,445
	(4,621,623)	9,215,585

Notes to the Annual Financial Statements

Figures in Pula		2021	2020
17. Financial instruments and risk management			
Categories of financial instruments			
Categories of financial assets			
2021			
	Note(s)	Amortised cost	Total
Accounts receivable	12	429,471	429,471
Cash and cash equivalents	13	19,130,440	19,130,440
		19,559,911	19,559,911
2020			
	Note(s)	Amortised cost	Total
Accounts receivable	12	148,820	148,820
Cash and cash equivalents	13	27,525,580	27,525,580
		27,674,400	27,674,400
Categories of financial liabilities			
2021			
	Note(s)	Amortised cost	Total
Accounts payable	15	9,993,547	9,993,547
Finance lease obligations	11	12,502,495	12,502,495
		22,496,042	22,496,042
2020			
	Note(s)	Amortised cost	Total
Accounts payable	15	7,426,528	7,426,528
Finance lease obligations	11	12,949,449	12,949,449
		20,375,977	20,375,977

Capital risk management

The Authority's objective when managing capital (which includes reserves, working capital and cash and cash equivalents) is to safeguard its ability to continue as a going concern in order to perform its mandate. The Board is of the view that these objectives are being met. During the year ended 31st March 2021, the Authority did not have any borrowings. The Authority's operations are currently being sustained by the Government of Botswana.

Notes to the Annual Financial Statements

Figures in Pula

17. Financial instruments and risk management (continued)

Financial risk management

Overview

The company 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 company if a counterparty to a financial instrument fails to meet its contractual obligations.

The company is exposed to credit risk on trade and other receivables, cash and cash equivalents.

The Authority does not have any significant account receivables since most of the services are rendered at nominal charge and are paid in advance.

Credit risk exposure arising on bank balances is managed by the Authority through dealing with well-established financial institutions with high credit ratings.

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

		2021			2020		
		Gross carrying amount	Credit loss allowance	Amortised cost / fair value	Gross carrying amount	Credit loss allowance	Amortised cost / fair value
Accounts receivable	12	1,011,247	-	1,011,247	591,198	-	591,198
Cash and cash equivalents	13	19,130,440	-	19,130,440	27,525,580	-	27,525,580
		20,141,687	-	20,141,687	28,116,778	-	28,116,778

Liquidity risk

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

The company 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 liabilities when they become due. This is achieved 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.

Notes to the Annual Financial Statements

Figures in Pula

17. Financial instruments and risk management (continued)

2021

	Less than 1 year	2 to 5 years	Over 5 years	Total	Carrying amount
Non-current liabilities					
Lease liabilities	-	10,189,604	465,282	10,654,886	10,654,886
Current liabilities					
Accounts payable	9,993,547	-	-	9,993,547	9,993,547
Lease liabilities	1,847,609	-	-	1,847,609	1,847,609
	(11,841,156)	(10,189,604)	(465,282)	(22,496,042)	(22,496,042)

2020

	Less than 1 year	2 to 5 years	Over 5 years	Total	Carrying amount
Non-current liabilities					
Lease liabilities	-	7,946,012	3,131,685	11,077,697	11,077,697
Current liabilities					
Trade and other payables	15 7,426,528	-	-	7,426,528	7,426,528
Lease liabilities	1,416,752	-	-	1,416,752	1,416,752
	(8,843,280)	(7,946,012)	(3,131,685)	(19,920,977)	(19,920,977)

Notes to the Annual Financial Statements

Figures in Pula	2021	2020
18. 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-40).	
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 Gurusurthy (Director: Pharmacovigilance)	
Main Financier	Government of the Republic of Botswana	
Compensation to directors and other key management		
Salaries and other short term benefits	7,049,777	5,663,762
Gratuity paid	2,448,505	1,624,104
	9,498,282	7,287,866
Related party balances		
Amounts included in other payables regarding related parties		
Botswana Telecommunication Corporation - Telephone	68,127	57,893
Botswana Power Corporation - Electricity	54,805	39,781
Botswana Unified Revenue Services - PAYE	32,031	-
Related party transactions		
Grant received		
Government of Republic of Botswana	46,455,670	34,719,884
Transactions with other parastatals		
Botswana Telecommunication Corporation - Telephone	599,503	546,916
Botswana Power Corporation - Electricity	479,358	251,065
Sitting allowance		
Medicines Regulatory Board	393,435	324,135

19. Events during and after the reporting period

The Authority takes cognisance of the outbreak of the corona virus (COVID-19) that declared a pandemic by the World Health Organisation (WHO). This caused large global economic shocks and the local economy was equally affected. The state of the pandemic in Botswana continues to change at fast pace with no end in sight. The Government also continues to take measures at containing the spread of the virus. These include restriction in movement of people and goods and introduction of protocols in work places and other social activities. The directors assess the status of the Authority as a going concern notwithstanding the challenging economic environment, the future remains uncertain.

Detailed Income Statement

Figures in Pula	Note	2021	2020
Revenue			
Amortisation of deferred income		2,514,130	1,817,714
Grant received from the Government of Botswana		42,646,074	55,629,947
	3	45,160,204	57,447,661
Other operating income			
Other operating income		8,190,629	540,273
Operating expenses			
Amortisation and depreciation		(4,351,855)	(3,324,548)
Auditors remuneration - external auditors	5	(70,560)	(67,200)
Bank charges		(61,073)	(67,526)
Certification costs		(490,716)	-
Computer expenses		(1,999,625)	(677,472)
Consultancy fees		(1,773,402)	(164,006)
Consulting and professional fees - legal fees		(237,990)	-
Consumables		(189,818)	(326,557)
Donations		(129,768)	-
Employee costs		(44,806,155)	(35,615,153)
Governance costs		(667,571)	(823,515)
Insurance		(258,107)	(238,931)
Motor vehicle expenses		(80,932)	(107,007)
Postage		(9,189)	(10,705)
Printing and stationery		(406,864)	(429,853)
Publicity and awareness		(1,430,188)	(2,643,363)
Records management		(253,981)	(388,913)
Repairs and maintenance		(1,326,514)	(1,006,927)
Security		(213,261)	(266,638)
Seminars and conferences		(1,209,794)	(1,918,252)
Short term lease		(35,004)	(17,983)
Staff welfare		(386,615)	(55,674)
Telephone and fax		(1,406,460)	(1,059,366)
Training		(1,325,454)	(1,801,560)
Travel and accommodation		(773,250)	(3,683,745)
Utilities		(549,912)	(329,402)
		(64,444,058)	(55,024,296)
Operating (deficit)/ surplus			
	5	(11,093,225)	2,963,638
Investment income	6	215,260	494,446
Finance costs	7	(780,139)	(871,500)
(Deficit)/ Surplus for the year		(11,658,104)	2,586,584

