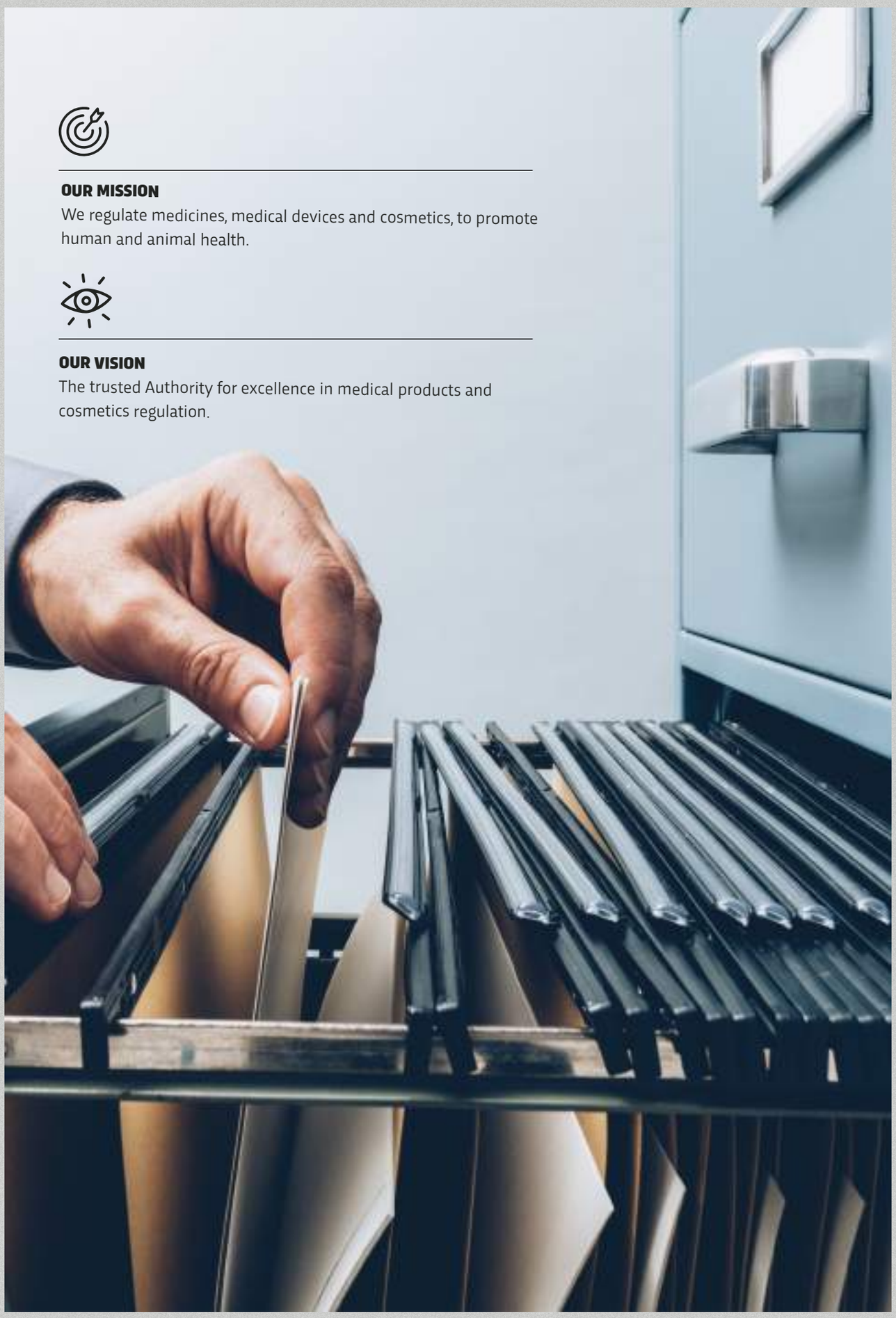
Annual Report

BMRA
MEDICINES REGULATORY AUTHORITY


Medicines Regulatory Authority

Welcome to BoMRA

2022
Annual Report



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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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

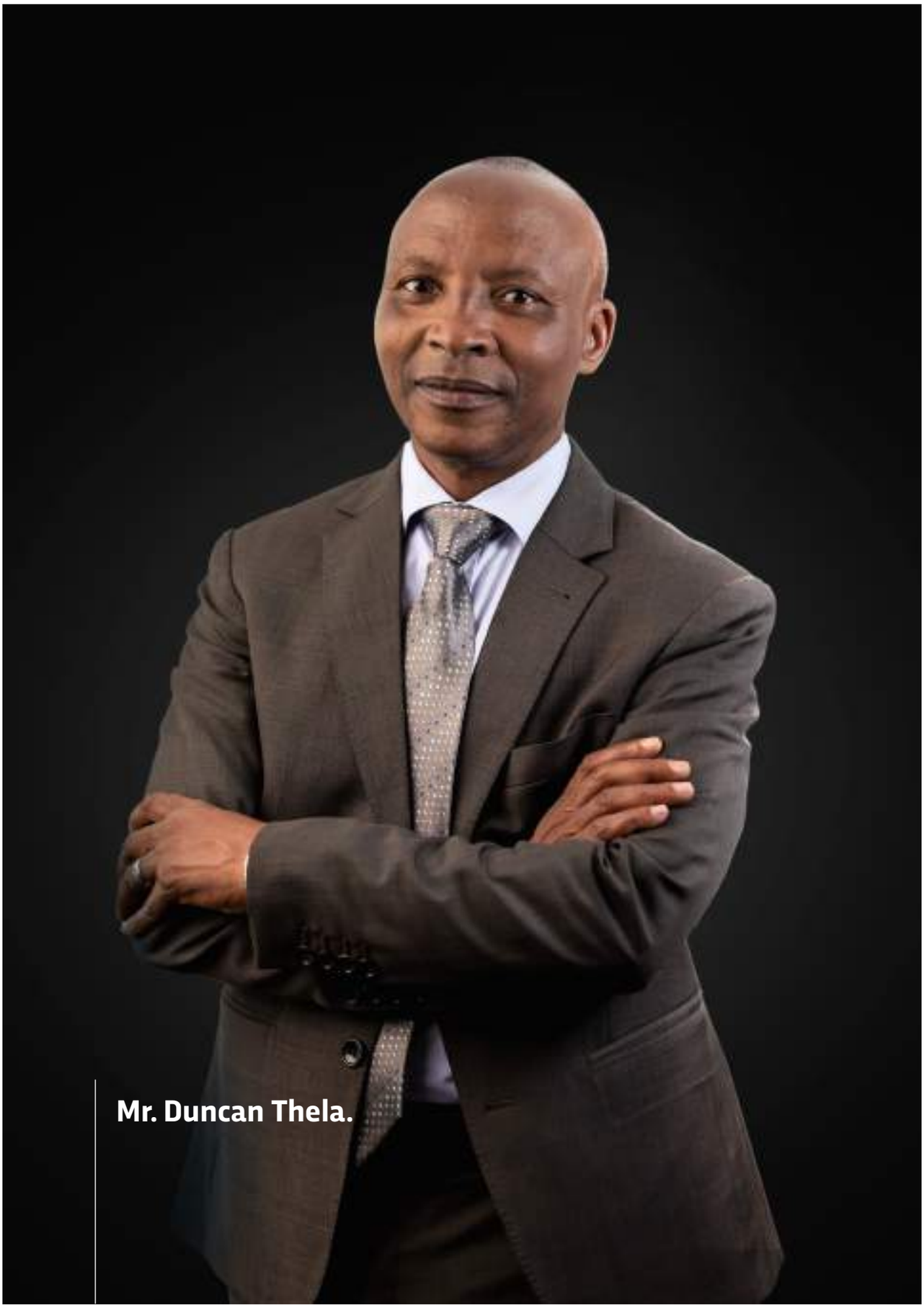
The Medicines Regulatory Authority ("Authority") is a corporate body, established under Section 3 of the Medicines and Related Substances Act ("MRSA") and commonly referred to as the Botswana Medicines Regulatory Authority or BoMRA. The Authority is responsible for ensuring the safety, efficacy and quality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

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 matters of policy 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 and 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 of 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 those 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.

2022 Annual Report


Mr. Duncan Thela.

Chairperson's Statement

I am pleased to submit the BoMRA's annual report for the financial year ending 31 March 2022. The year 2021/22 was the third year of executing the BoMRA five-year strategy, which is expected to ensure attainment of the World Health Organisation's (WHO) maturity level 3 (ML3) by 2024 for the Authority. The Authority conducted a mid-term review of the strategy, during which the key strategic objective of ensuring BoMRA reaches ML3 was reemphasized.

Attainment of ML3 will be a significant achievement since it would mean that BoMRA would be internationally recognized as a trusted, stable, and fully functional regulatory authority. ML3 status has propensity to improve pharmaceutical manufacturing investment attractiveness of Botswana (priority for government), create regulatory consistency and certainty for the pharmaceutical industry, ensure reduced incidences of substandard and falsified medicines and related substances, as well as improve public awareness and industry trust in the regulatory system and its outputs such as medical products given market authorization in Botswana.

The year under review is the second year of the ongoing COVID-19 pandemic. I would like to thank and acknowledge the BoMRA team (BoMRA staff, Technical Committees of the Board, and the Board) for a stellar job done to timely grant emergency use authorization for the Covid-19 vaccines.

BoMRA together with the Expanded Program on Immunization and District Health Management Teams and other stakeholders will continue to monitor the safety and effectiveness these vaccines, through the established vaccine safety monitoring program.

To leverage technology and improve process efficiency, the Authority is piloting an online registration system for low-risk complementary medicines. This system will enable prospective market authorization holders to register low-risk complementary medicines online 24/7, from the comfort of their offices and facilitate shorter market authorization turnaround times. In addition, the Authority is undertaking a regulatory system automation process that will automate all regulatory processes and allow for online self-service delivery to stakeholders and compliance with ICT required for ML3 and higher maturity status. This project is expected to be completed in the next financial year.

During the year under review, the Authority was able to maintain its ISO:9001 accreditation and certification and work has commenced to prepare the quality control laboratory for accreditation (ISO:17025). The Enterprise Risk Management Framework and Policy were reviewed to align these key documents to ISO:31000 - the international standard for risk management principles.

Maintenance of Quality Management System (QMS) and related ISO accreditation is a key factor for international recognition of any regulatory system and ML3 status.

During this financial year, a substantive Human Resource Director was appointed, and it is expected that this development will improve implementation of the Integrated Human Resource Management Strategy that is a key factor as BoMRA moves towards ML3.

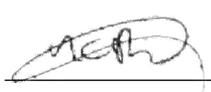
However, BoMRA bid farewell and happy retirement to its founding Chief Regulatory Officer- Dr Sinah Selelo. Dr Selelo contributed immensely to the development of the organisation especially on the legal framework and imbedding the technical processes.

Due to the ongoing Covid-19 pandemic, the Board and its Committees successfully held their meeting in a virtual environment. There was a change in the Board as the terms of the following Board members expired: Dr M. Sento, Dr J. Kgatlwane and Dr G. Moleele. Another member, Dr Modisa left his ex-officio position. I thank and appreciate these Board members for their services to BoMRA. It is through their providing advice as Board members, oversight and guidance to management, technical and support departments of the Authority that we have achieved the targets set for the 2021/22 Annual Performance Plan.

I also would like to recognize three new Board members, Dr Coyne, Dr Mangadi – Mokama and Dr Maphane who were appointed to the Board towards the end of this financial year. The Board looks forward to them continuing from where the former members left and continuing to add value to BoMRA.

On behalf of the Board I would like to appreciate the good work done by the BoMRA Team (general Staff, Executive Management and Board).

The term of office for most of the current and inaugural Board, save for the newly appointed members, comes to an end in May 2022. The Board members whose terms expire, including myself, are grateful for the opportunity afforded to us to establish and guide BoMRA to where it is today and extend our thanks to the parent ministries (Ministry of Health and Wellness and Ministry Agriculture) for their support during our tenure.



Duncan Thela (Mr)
Chairperson of the Board of Directors

Dr. Stephen Ghanie.

Chief Executive Officer's Report

We are pleased to present to you the Annual Report 2022. Despite continuing challenges in the medicines environment, Botswana Medicines Regulatory Authority continues to operate with cautious optimism.

A key focus of the Authority's strategy is to drive towards a Maturity Level 3 (ML3) rating by the World Health Organisation for Regulatory Systems based on the WHO Global benchmarking Tool.

The WHO Global Benchmarking Tool provides an objective measure for rating the development of regulatory systems and is used by the Authority to ensure that it aligns to best practice for regulators throughout the region and the world.

At its inception, BoMRA inherited a backlog of applications for Market Authorization from Drug Regulatory Unit (DRU). This entailed a total of 400 new applications (those that had not been assessed at all) and 1000 variations. This backlog was cleared to zero by 31st March 2023, which was one of the notable achievements by BoMRA through Product Evaluation and Registration (DPER).

Notable achievements during the year, the Inspections and Licensing Unit embarked on carrying out the groundwork for the attainment of ISO 17020 certification for the BoMRA inspection body.

Over the past year the department has been working on the gap analysis and addressing identified gaps to meet the requirements as set in the standards. Through the gap analysis, it has been determined that the inspectorate met 55% of the standard requirements.Our skilled, hard-working and passionate employees were fundamental to achieve the financial results and the strong progress we made in our strategic development.

Through their expertise, engagement, and relentless efforts they generate added value for BoMRA and its stakeholders.

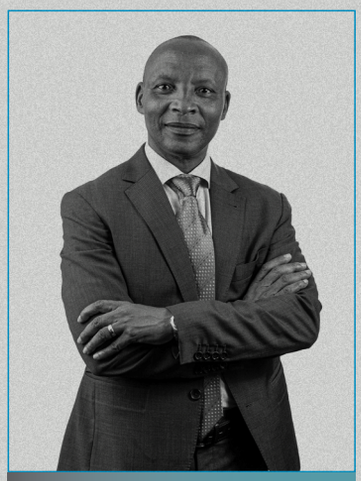
In particular, we would like to thank them for their high level of loyalty and willingness to adapt this year. Their achievements and their great collaboration motivate us to strive for ambitious goals to further develop BoMRA as a leading regulatory Authority.

The Authority largely depends on Government subvention to carry out its mandate. In addition to government subvention the Authority raises funds from the services provided to the local pharmaceutical industry and grants from donor agencies that fund some of its regulatory strengthening projects.

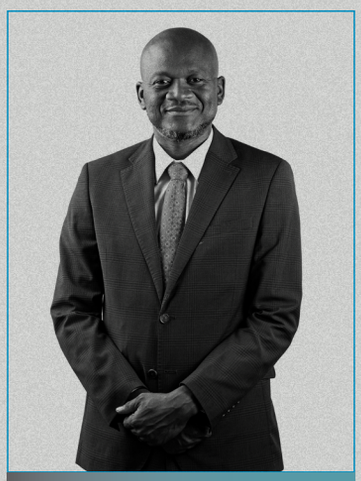
During the year ended 31st March 2022 the Authority received a subvention of P84.7 million from the Government and land values at P21 million. The regulatory fees amounted to P9.6 million and grants amounted P700 thousand. Total expenditure amounted to P79.2million, resulting in a surplus of P15.8 million.

Dr. Stephen Ghanie. (Mr)
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. Gontle Moleele
Member

Ms. Shameela Pholo-Winston
Member

Executive Management Team

Dr. Stephen Ghanie
Chief Executive Officer

Dr. Sinah Selelo
Chief Regulatory Officer

Dr. Parthasarathi Gurumurthy
Director, *Pharmacovigilance and Clinical Trials*

Mr Nonofo Thipe
Legal and Corporate Secretary

Dr. Innocent Ravengai
Acting 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

Mr. Mooketsi Maphane
Director, Human Resource & Organizational Development

Ms. Zukiswa Raditladi
Manager, Quality Management

GOVERNANCE AND THE BOARD

Governance And The Board

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

GOVERNING BODY/STRUCTURE

The Medicines Regulatory Board is the primary governance structure of the Authority and is responsible for:

- Collectively directing the business activities of the Medicines Regulatory Authority
- Collectively providing leadership and direction to Management of the Authority
- Strategic planning
- Appointments 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 must be appointed by the Minister of Health from persons with a mix of skills and expertise 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. In accordance with the MRSA Members may serve for not more than six consecutive years. Over the period, the Authority lost 7 Members, with 6 ordinary Members 'terms expiring and one ex-officio Member retiring from office.

Table 1: Board Members

Member		Date of First Appointment	End of Current Term	Term No.
1	Mr Duncan Thela (Chairperson)	01st June 2016	31st May 2022	2
2	Mr Mbatshi Mazwiduma (Vice-Chairperson)	01st June 2016	31st May 2022	2
3	Mr Kagiso Balopi	01st June 2016	31st May 2022	2
4	Ms Botho Bayendi	01st June 2016	31st May 2022	2
5	Mr Meshack Baoleki	01st June 2016	31st May 2022	2
6	Ms Shameela Pholo-Winston	01st June 2016	31st May 2022	2
7	Dr Letlhogile Modisa	01st June 2016	31st May 2022	2
8	Dr Kegomoditswe Biki Maphane	29th November 2021	30th November 2024	1
9	Dr. Lorato Mangadi-Mokama	29th November 2021	30th November 2024	1
10	Dr. Ditiro Coyne	29th November 2021	30th November 2024	1
11	Dr. Stephen Ghanie (Ex-Officio)			1

The Board has established seven Committees in terms of Section 16 of the MRSAThe committees 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, being those which 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 with their responsibilities.

Governing Body/Structure (Continued)

Table 2: Board Committees and Functions

Administrative Committees	
Committee Name	**High Level Summary of Functions and Area of Delegated Responsibility**
Finance, Audit and Risk Committee (FARC)	• Accounting practices, financial controls and reporting systems of the Authority. • Budgeting, budgetary control systems and auditing processes of the Authority. • Authority's enterprise-wide risk management, risk management and risk avoidance measures. • Economy, efficiency and effectiveness of the Authority's Information Technology.
Human Resources Committee (HRC)	• 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)	• 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.

Governing Body/Structure (Continued)

Technical Committees	
Committee Name	**High Level Summary of Functions and Area of Responsibility**
Registration Committee (RC)	• 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. • 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)	• 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)*	• 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 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 Meetings Held*

	Member	30th Mar 2021	29th June 2021	12th Oct 2021	21st Oct 2021	25th Nov 2021	25th Jan 2022	02nd Mar 2021
1	Mr. Duncan Thela (Chairperson)	✓	✓	✓	✓	✓	✓	✓
2	Dr. Mbatshi Mazwiduma	A	✓	✓	✓	✓	✓	✓
3	Mr. Kagiso Balopi	✓	✓	✓	A	✓	✓	✓
4	Mr. Meshack Baoleki	✓	A	✓	✓	✓	✓	✓
5	Ms. Shameela Pholo-Winston	✓	A	✓	✓	✓	A	✓
6	Dr. Joyce Kgatlwane	✓	✓	n/a	n/a	n/a	n/a	n/a
7	Dr. Gontle Moleele	✓	✓	n/a	n/a	n/a	n/a	n/a
8	Ms. Botho Bayendi	A	✓	✓	✓	✓	✓	✓
9	Dr. Letlhogile Modisa	A	✓	✓	✓	✓	A	A
10	Dr. Malebogo Kebabonye	A	A	A	A	A	A	A
11	Dr. Gaseitsewe Michael Sento	A	A	n/a	n/a	n/a	n/a	n/a
12	Dr. Kegomoditswe Biki. Maphane	n/a	n/a	n/a	n/a	n/a	✓	A
13	Dr. Lorato Mangadi	n/a	n/a	n/a	n/a	n/a	✓	✓
14	Dr. Ditiro Coyne	n/a	n/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	05th Feb 2021	06th May 2021	25th May 2021	17th August 2021	02 Dec 2021
1	Mr. Kagiso Balopi (Chairperson)	✓	✓	✓	✓	✓
2	Mr. Mbatshi Mazwiduma	✓	✓	✓	✓	✓
3	Mr. Meshack Baoleki	✓	✓	✓	A	✓

Key: Present ✓ Apology A

PROCUREMENT AND TENDER COMMITTEE MEETINGS

Table 5: *Procurement and Tender Committee Meetings Held*

	Member	12th Mar 2021	30th Aug 2021	01st Dec 2021	21st Mar 2022
1	Mr. Meshack Baoleki (Chairperson)	✓	✓	✓	✓
2	Mr. Kagiso Balopi	✓	✓	✓	✓
3	Ms. Joyce Kgatlhwane	✓	n/a	n/a	n/a
4	Dr. Michael Sento	✓	n/a	n/a	n/a

Key: Present ✓ Apology A not applicable n/a

HUMAN RESOURCES COMMITTEE MEETINGS

Table 6: *Human Resources Committee Meetings Held*

	Member	7th May 2021	17th May 2021	8th July 2021	19th Oct 2021	9th Dec 2021	9th Mar 2022	21st Mar 202
1	Ms. Shameela Winston – Pholo (Chairperson)	✓	✓	✓	✓	✓	✓	✓
2	Dr. Mbatshi Mazwiduma	A	A	A	A	A	✓	✓
3	Dr. Letlhogile Modisa	A	A	✓	✓	✓	A	A
4	Dr. Gontle Moleele	✓	✓	n/a	n/a	n/a	n/a	n/a

Key: Present ✓ Apology A not applicable n/a

GOVERNANCE AND NOMINATIONS COMMITTEE MEETINGS

Table 7: *Governance and Nominations Committee Meetings Held*

	Member	8th Sep 2021	27th Sep 2021	5th Oct 2021	18th Jan 2021
1	Ms. Botho Bayendi	✓	✓	✓	✓
2	Mr. Kagiso Balopi	✓	✓	✓	✓
3	Mr. Meshack Baoleki	✓	✓	✓	✓
4	Ms. Shameela Winston - Pholo	A	A	✓	✓

Key: Present ✓ Apology A not applicable n/a

PHARMACOVIGILANCE ADVISORY COMMITTEE MEETINGS

Table 8: *Pharmacovigilance Advisory Committee Meetings Held*

		Dates					
	Member	29th Jul 2021	19th Aug 2021	23rd Sep 2021	25th Nov 2021	28th Jan 2022	24th Mar 2022
1	Dr. Gontle Moleele	✓	✓	✓	n/a	n/a	n/a
2	Ms. Matshidiso Matome	✓	✓	A	✓	A	✓
3	Dr. Kerapetse Sehularo	✓	A	A	✓	✓	✓
4	Dr. Lebapotswe Tlale	✓	✓	✓	✓	✓	✓
5	Dr. Veronica Moshogo	✓	A	A	✓	A	A
6	Ms. Rakgaki Ratshaa	✓	✓	✓	✓	✓	✓
7	Mr. Lesego Botsang	✓	✓	A	A	✓	✓
8	Dr. Tom Baaisi	✓	✓	✓	✓	A	A

Key: Present ✓ Apology A not applicable n/a

REGISTRATION COMMITTEE MEETINGS

Table 9: *Registration Committee Meetings Held*

	Member	18th Jun 2021	08th Aug 2021	15th Oct 2021	10th Dec 2021	11th Feb 2021
1	Dr. Goabaone Rankoane - Pono	✓	✓	✓	✓	✓
2	Dr. Bontsi Busang	✓	✓	✓	✓	✓
3	Ms. Lesego Moetedi	✓	✓	✓	✓	✓
4	Dr. Samantha Letsholo	✓	✓	✓	✓	✓

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 which aims to ensure adherence to its governance responsibilities as set out by the law, established by 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 finalised and signed off the Shareholder Compact between itself and the Ministry of Health to strengthen alignment of 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

Vision, Mission, and Values

Mission	Vision	Values
The Trusted Authority for excellence in medical products and cosmetics regulation.	We regulate medicines, medical devices and cosmetics, to promote human and animal health.	Integrity, Customer Focus, Efficiency, Teamwork,

STRATEGIC GOAL

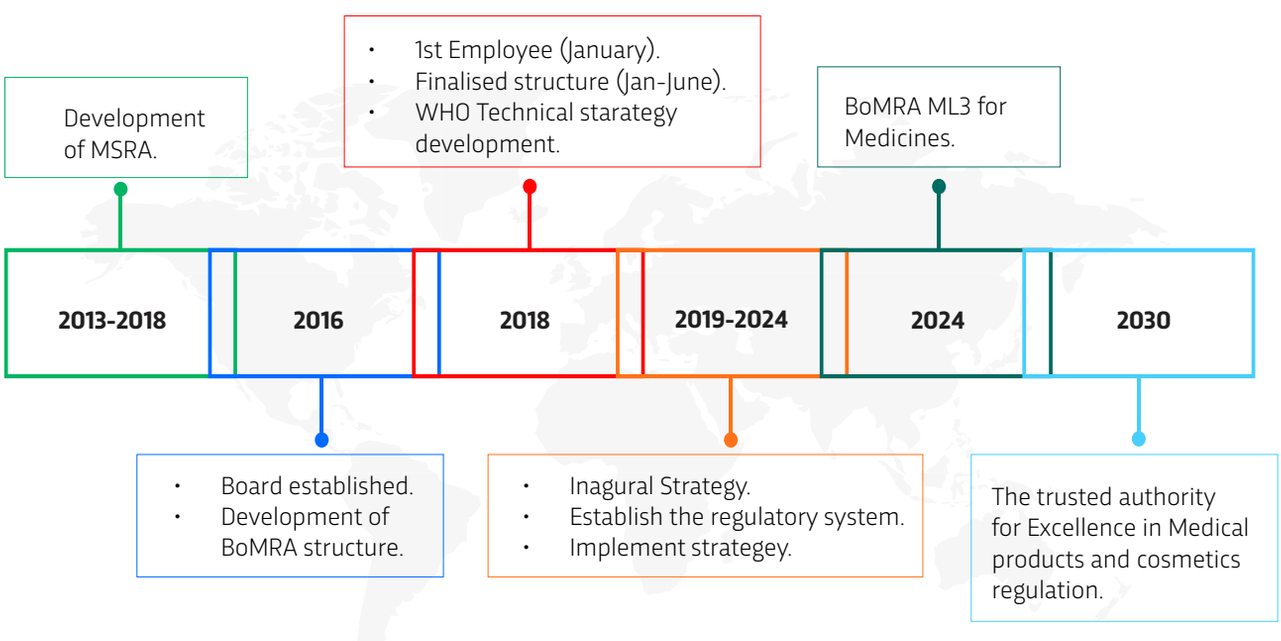
The table below shows the BoMRA strategic goals have been created to identify the intended accomplishment of BoMRA's Corporate Strategy. They are identified as the outcome of BoMRA's business efforts.

Strategic Goal	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.	High Public Confidence Level.
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 ROAD TO MATURITY LEVEL 3 – A FULLY FUNCTIONAL REGULATORY SYSTEM (SR3)

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

BoMRA TRANSFORMATION JOURNEY



STRATEGY MAP

The BoMRA Strategy Map documents the strategic goals and objectives that BoMRA pursues in order to effectively fulfill its Mandate. The strategy map below shows each strategic objective in the balanced scorecard. These objectives are grouped into perspectives to define goals and show their cause-and-effect relationships in a way that can be communicated throughout the organization.

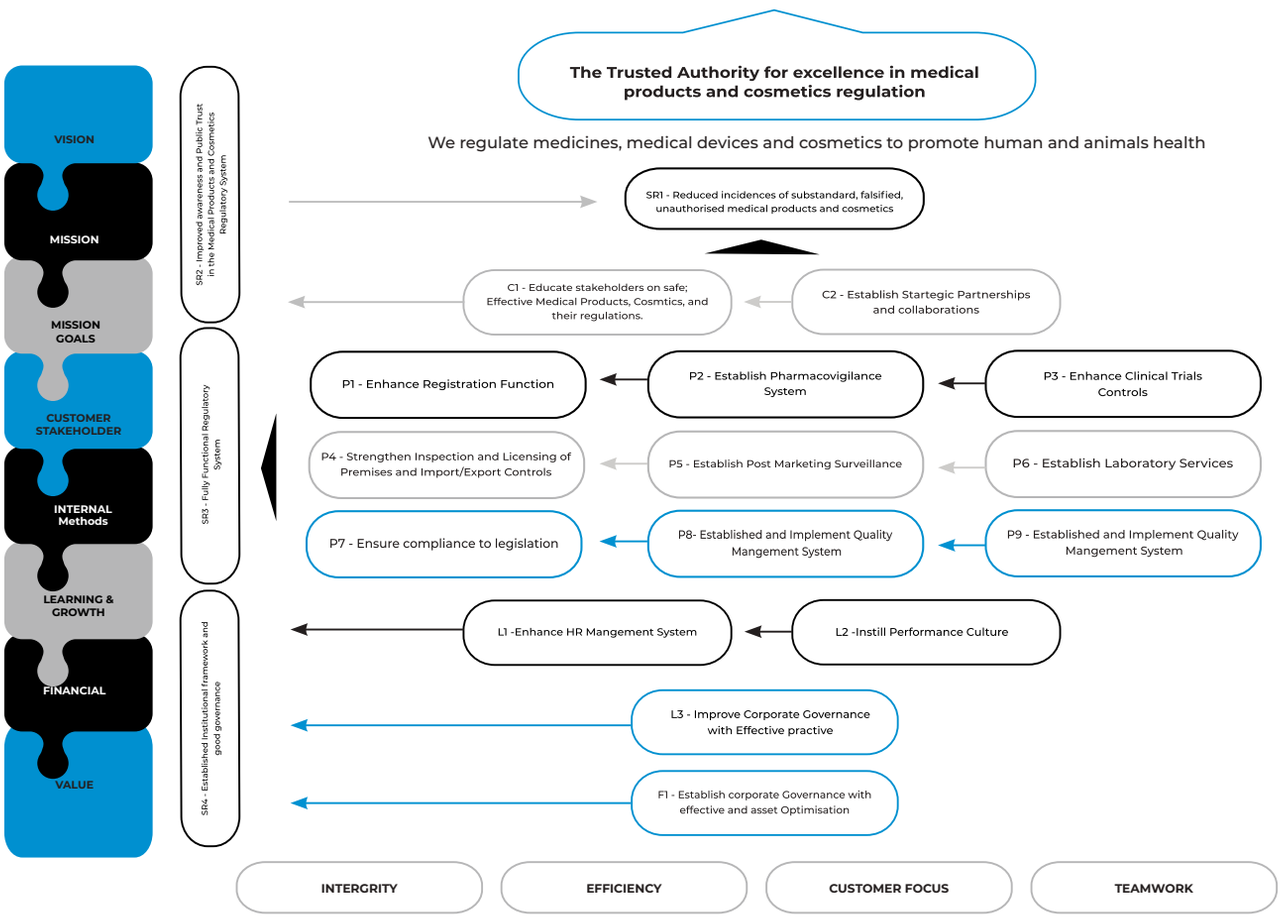
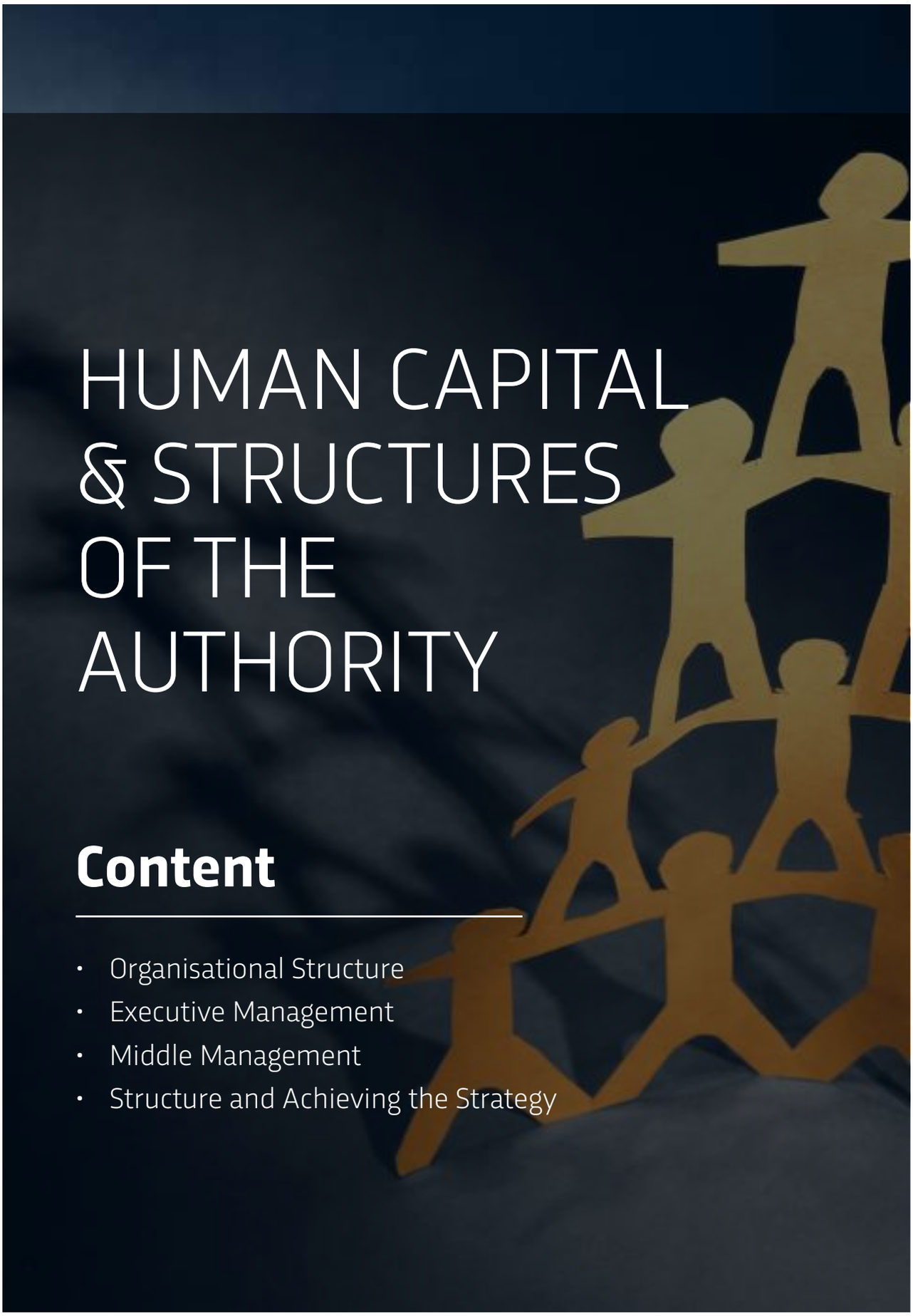


Table 12: *BoMRA Strategy Map*



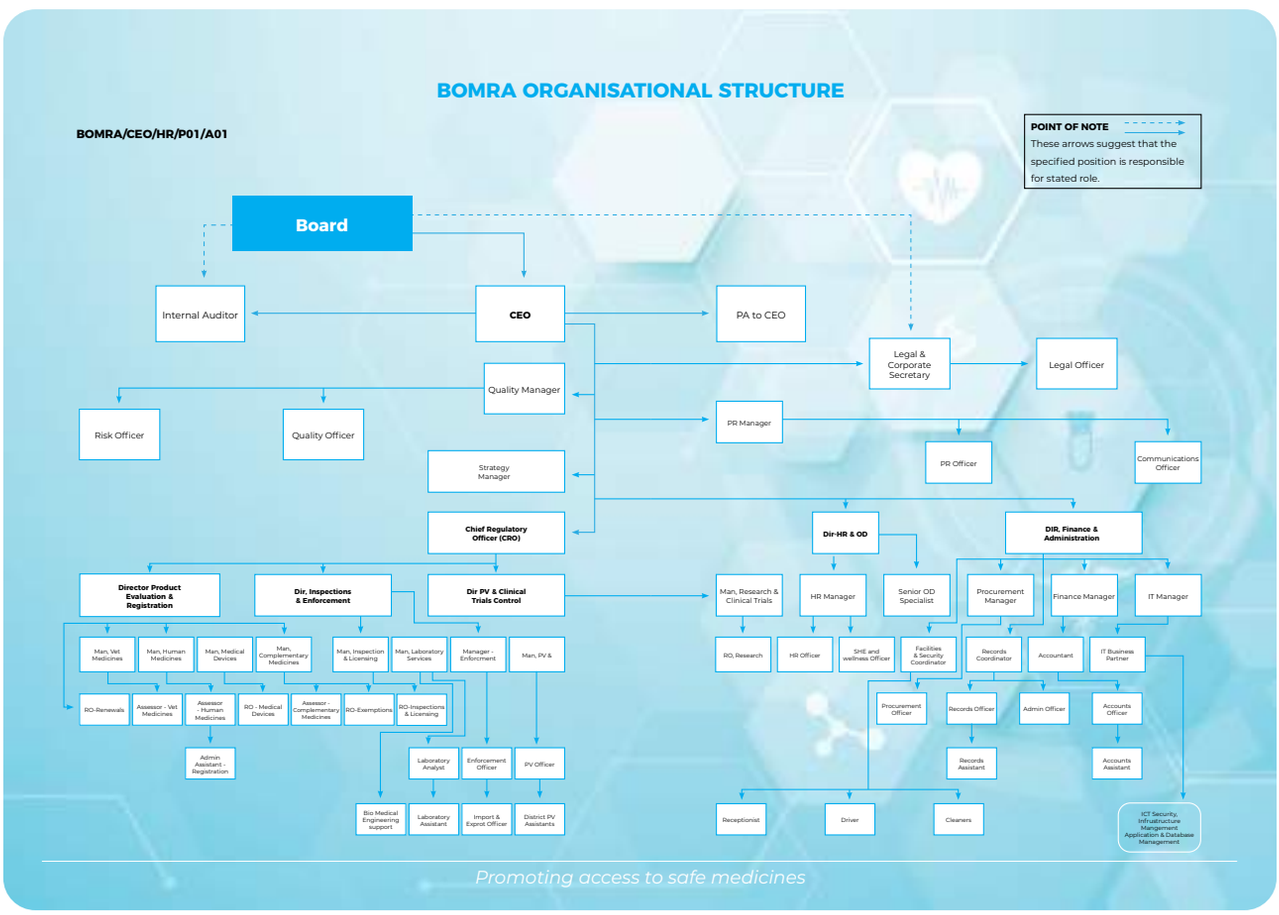
HUMAN CAPITAL & STRUCTURES OF THE AUTHORITY

Content

Departments Within The Authority

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.

ORGANISATIONAL STRUCTURE



Departments Within The Authority (Continued)

PRODUCT EVALUATION AND REGISTRATION DEPARTMENT

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;

LICENSING AND ENFORCEMENT DEPARTMENT

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

Departments Within The Authority (Continued)

PHARMACOVIGILANCE AND CLINICAL TRIALS

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

FINANCE AND ADMINISTRATION DEPARTMENT

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.

Departments Within The Authority (Continued)

HUMAN RESOURCES DEPARTMENT

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

CEO'S OFFICE

Quality Management Unit

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

Public Relations Unit

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

Departments Within The Authority (Continued)

Legal and Corporate 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

Content

Regulatory Performance For The Year Under Review

Information on the Authority's key regulatory performance areas for the 2021/22 financial year.

PRODUCT EVALUATION AND REGISTRATION

Key Highlights for 2021/22

Strategy Update

Strategic areas of accountability (Objectives and initiatives) with final scores

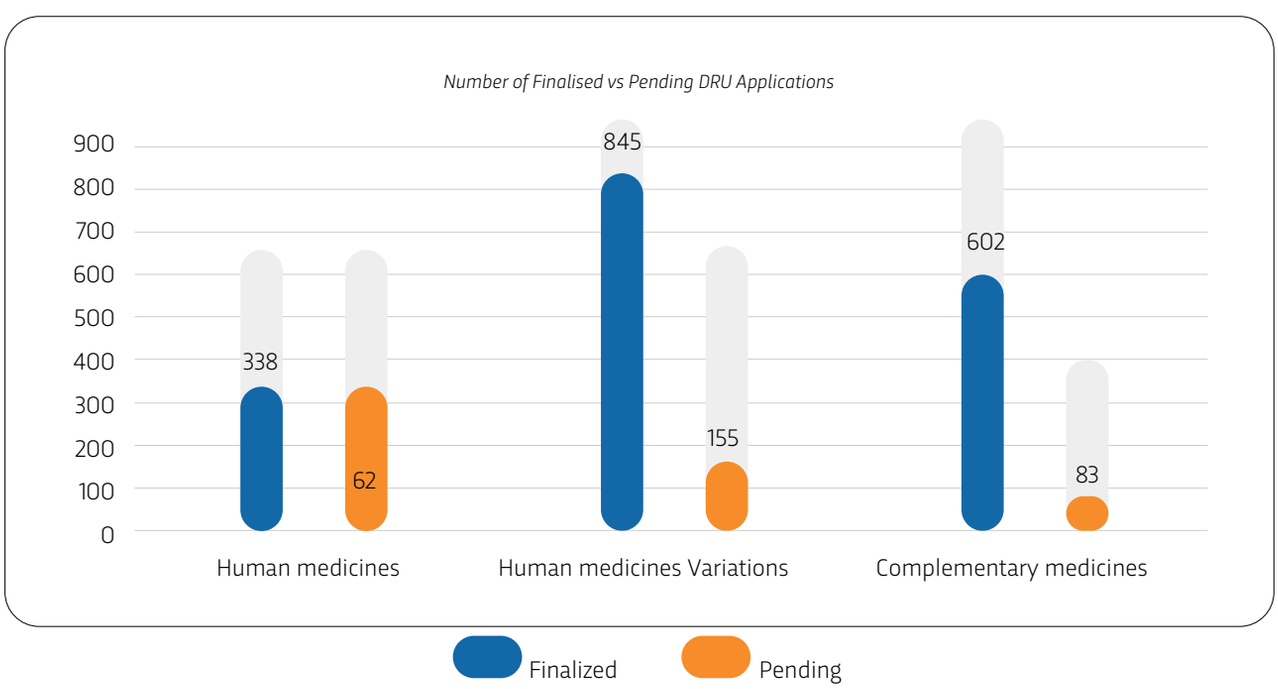
Drug Regulatory Unit (DRU) Backlog:

The backlog from the DRU was at 14% as at year end as indicated in Figure 2 below. The target to clear the backlog was not accomplished due to a number of factors that included the high rate of turnover of assessors experienced in the year as well as the vacant position of the Director and Manager for Human Medicines. It was decided to extend the project to 31 December 2022.

Figure 2: Summary of DRU Backlog

Item	Backlog Status (%)	Q4 Backlog target (%)
Human medicines	16	0
Human medicines Variations	16	0
Complementary medicines	12	0
Overall	14	0

Figure 3: Number of Finalised vs Pending DRU Applications



Regulatory Performance For The Year Under Review

NEW APPLICATIONS (SCREENING, EVALUATIONS, VARIATIONS)

There was a substantial increase in the new applications received for the financial year 2021/2022. The figure 4 below shows the applications received by 31st March 2021.

Figure 4: New applications received in 2021/2

Type of application		Received	Processed	In-process (allocated)	Pending@ (unallocated)
Human medicines					
Screening new applications	2021	470	470	0	0
	2021	500*	490	10	0
	2022	89	24	12	53
Rescreening	2021	135	135	0	0
	2021	162**	156	6	0
	2022	64	0	12	52
New applications for Registration	2021	157	157	0	0
	2021	331	116	168	47
	2022	82	0	0	0
Variation applications	2021	380	217	163	0
	2021	1265	143	1093	29
	2022	386	0	0	386
Product Renewals	2021	19	0	5	14
	2021	64	0	0	64
	2022	8	0	0	8
Complementary medicines					
Screening new applications	2021	80	80	0	0
	2021	72	67	5	0
	2022	55	9	0	46
Rescreening	2021	38	38	0	0
	2021	38	37	1	0
	2022	5	0	3	2
New applications for Registration	2021	24	16	8	0
	2021	38	22	9	7
	2022	11	0	0	11
Veterinary medicines					
Screening New applications	Since 11/2021	15	15	0	0
Rescreening		1	1	0	0
New applications for registration		2	1	1	0

Regulatory Performance For The Year Under Review

SUMMARY OF PERFORMANCE PARTICULAR EMPHASIS ON KEY STRATEGIC SUCCESSES/ CHALLENGES

The department achieved 96% of all its strategic initiative towards enhancing the Registration function
The yet to be unresolved issue of recognition of second reviews remains a constant threat to performance.

Operational and Projects Updates

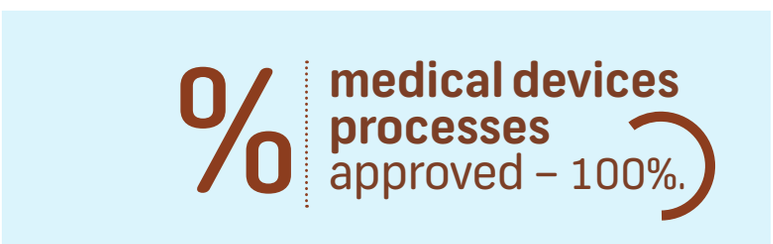
Highlights
Complementary Medicine and Cosmetics

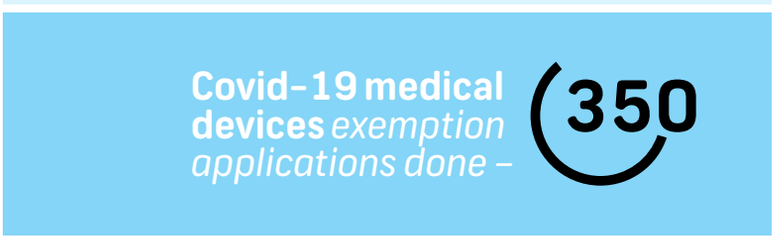
Successfully completed the cosmeceutical database covering major centers in Botswana. Database to serve as baseline study for prohibited and restricted ingredients.

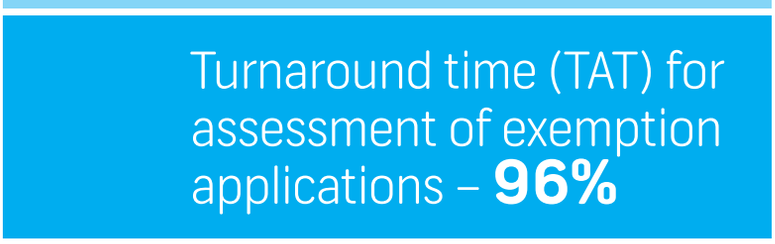
Medical Devices

Listing Project of medical devices including in vitro diagnostics at 60% on 31st March 2022.

Established medical devices registration processes, standards, and structure.







Veterinary Medicines

The Botswana Veterinary (BV) Medicinal Products Interim Register list was approved by the Registration Committee (RC) in September 2021 and by the BoMRA Board in March 2022

Responsiveness to COVID-19

High response rate to Covid 19 Pandemic by DPER in the timeous approval of Vaccine and Covid-19 related medical devices.

LICENSING AND ENFORCEMENT

Key Highlights for 2021/22
Strategy Update

The key initiatives for the Inspections and Licensing Unit were to Implement Institutional Development Plans for Inspections and Licensing & Market Control function to reach ML3; Establishing GMP inspection capacity for Human and VET; Implementation of Inspection framework and programmes and Establishment and Implementation of ISO 17020 Accreditation. Figure 2. shows the performance of the unit in the strategic objective of strengthening inspections and licensing and import/export control.

The Inspections and Licensing Unit embarked on carrying out the groundwork for the attainment of ISO 17020 certification for the BoMRA inspection body. Over the past year the department has been working on the gap analysis and addressing identified gaps to meet the requirements as set in the standards. Through the gap analysis, it has been determined that the inspectorate met 55% of the standard requirements.

During the reporting period, the department saw an increase in its scope of work with the inclusion of the inspections of medical devices manufacturers as well as public facilities. Medical devices guidelines for manufacturing and import/export control were developed, approved and their implementation commenced. Thus far two (2) Medical Devices manufacturer inspections were conducted. The outbreak of Covid-19 led to increased scope of work in terms of vaccine importation and consignment verification for all covid vaccines. This also meant a need for stakeholder engagements in facilitation of this activities.

Regulatory Performance For The Year Under Review

Licensing and Enforcement *(Continued)*

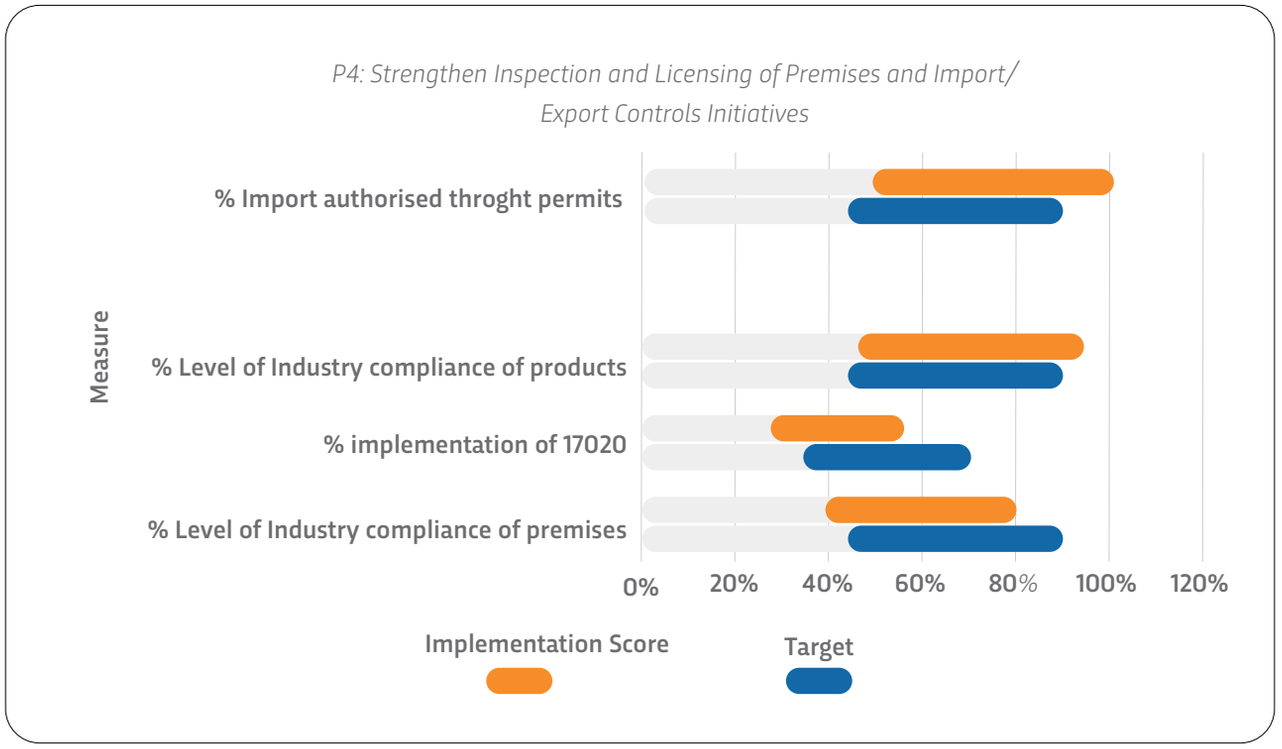
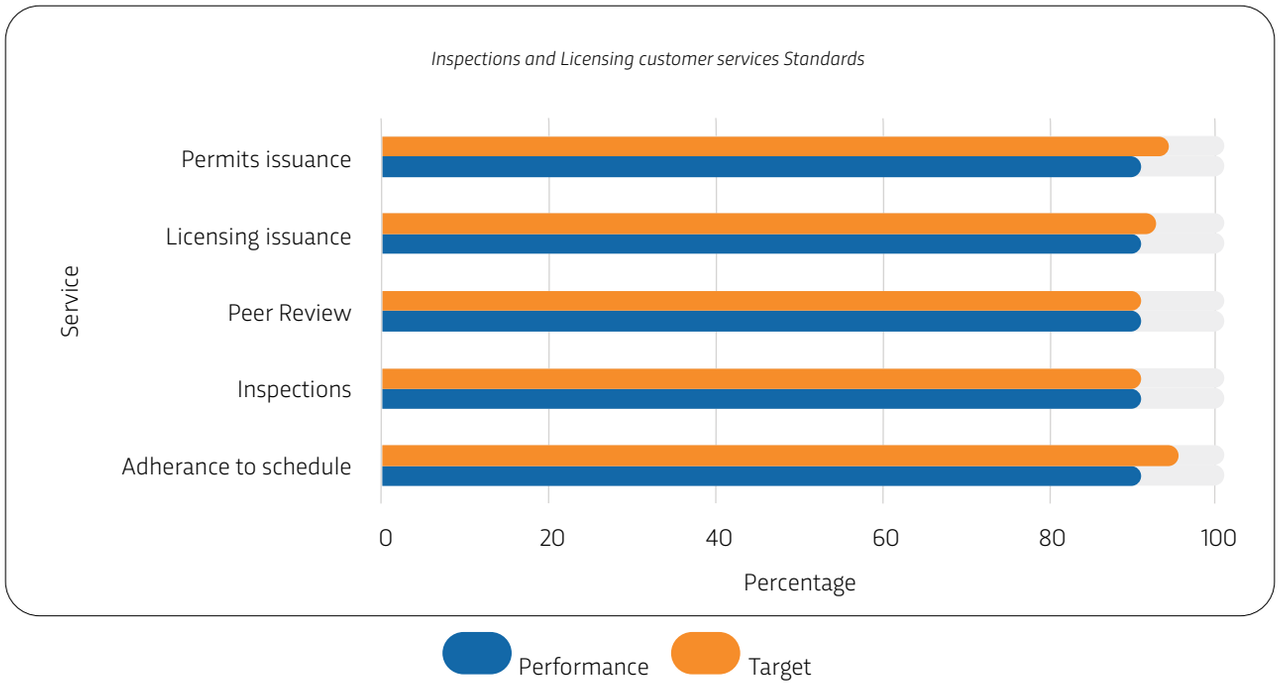


Figure 2. Implementation scores for initiatives under Strategic Objective P4

Over the past year the departmental performance on provision of services within set customer service standards is as shown in figure 3 below.



Regulatory Performance For The Year Under Review

Licensing and Enforcement *(Continued)*

Figure 3. Departmental performance on adherence to customer service standards

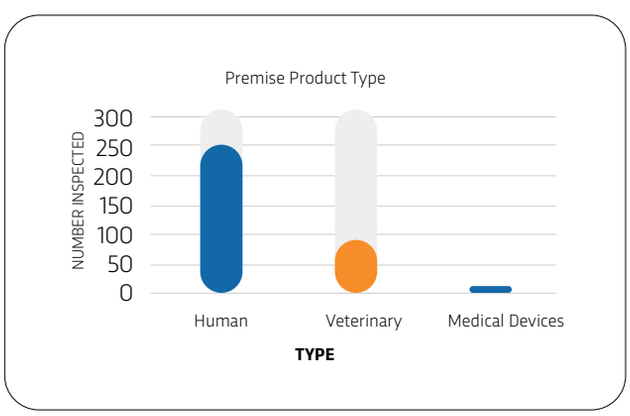
Operational and Project Updates

Over the reporting period 2021/22 the Inspections and Licensing Unit performance was as follows:

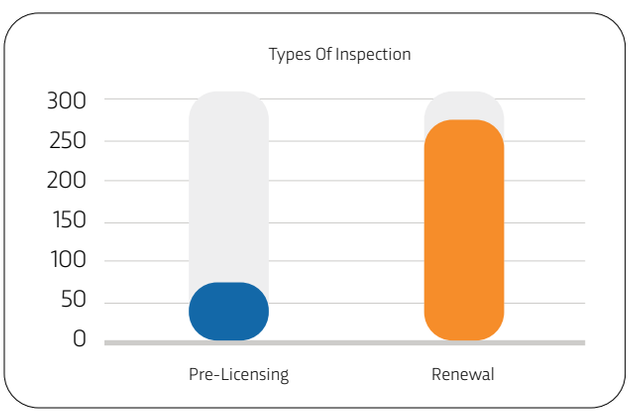
1. 345 inspections were conducted and of these 305 were illegible for licensing while 40 where ineligible for licensing as spot checks and pre-licensing. Of the inspected, 309 were retailers, 28 distributors, 3 manufacturers and 5 hospital pharmacies. Inspections conducted included 71 new facilities and 274 renewals. Among the inspected premises 251 were human medicines facilities while 92 were veterinary medicines premises and two (2) medical devices. 273 licenses were issued in 2021/22 with 63 pre-licenses and 210 renewals. Thirty-two (32) spot checks were conducted in this financial year. Overall premises compliance was recorded to be at 89.5%.

2. Two (2) local Manufacturers were inspected for Good Manufacturing Practices (GMP) compliance, two (2) local Medical Devices manufacturers were also inspected with only 1 being licenced. Three (3) collaborative virtual inspections and three (3) physical inspections were conducted with the Medicines Control Authority of Zimbabwe (MCAZ). Eight (8) GMP approvals were granted following desk assessment done through the SADC collaborative initiative ZAZIBONA. Three of these desk assessments were initiated by BoMRA.

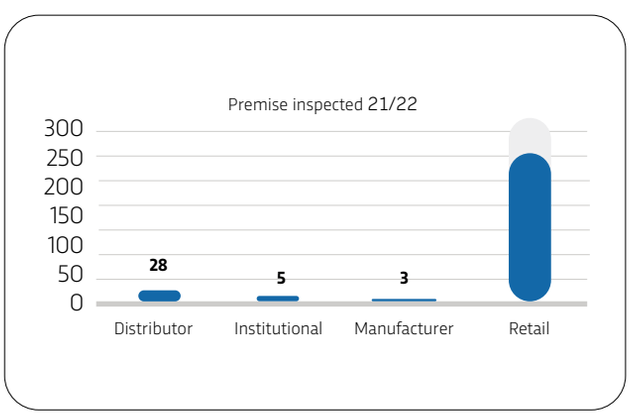
3. A total of 6981 permits were issued during the year under review. 79 export permits and 6655 import permits were issued while 59 transit permits were granted, 191 permits were issued for Narcotics and Psychotropic medicines. Of all the permit applications processed, 84% were for human medicines while 13% were for veterinary medicines. These permits covered import (94%), export (1%), transit (0.2%) and samples (0.8%) permits.



Number of Premises inspected



Type of inspection performed



Regulatory Performance For The Year Under Review

Challenges

The following are some of the notable challenges faced by the Unit,

- Prolonged failure to recruit suitable people into vacant positions.
- Loss of trained personnel
- Manual processes a challenge for services during covid 19 pandemic
- Overstretched resources due to the sudden increase in manufacturing of covid related medical devices
- Halting of International travel affecting staff training and conduct of international inspections.
- Occasional closure of borders led to increased request for permit variations due to changes in ports of entry.

ENFORCEMENT

Strategy Update

The strategic initiatives deployed for the strengthening of enforcement were as follows; Monitoring industry for compliance to MRSA, Investigation of reported or referred matters and conducting of joint operations with other law enforcement agencies

In pursuit of strengthening the enforcement of the Medicines and Related Substances Act, the Authority continued to train and participate in multi-agency joint enforcement operations during the reporting period. This was aimed at facilitating the Authority to realize Maturity Level 3 and in the long term to realize multiplier effect of strengthening enforcement.

The below table illustrates the performance attained on several objectives/initiatives pursued by the Enforcement Unit.

Objective	Initiative	Measure	Target	Achieved target
Implement enforcement of the existing framework	Investigation reported or referred matters	Percentage of closed over the total number of open investigations	90%	86%
Implement the existing enforcement framework	Monitor industry for compliance to MRSA	% Implementation of monitoring compliance annual plan	100%	106%
Establish Strategic Partnerships and Collaborations	Plan and participate in joint operations with law enforcement agencies	% Implementation of annual joint operation plan	100%	75%

The Authority trained 155 law enforcement representatives from nine (9) strategic stakeholders on understanding the control of human medicines in Botswana. Since 2021/22 a total of 209 law enforcement operatives were trained. Fig1.0 below is an overview of the considerable geographical coverage and law enforcement function by administrative district/town council, pports of entry and policing districts.

Regulatory Performance For The Year Under Review

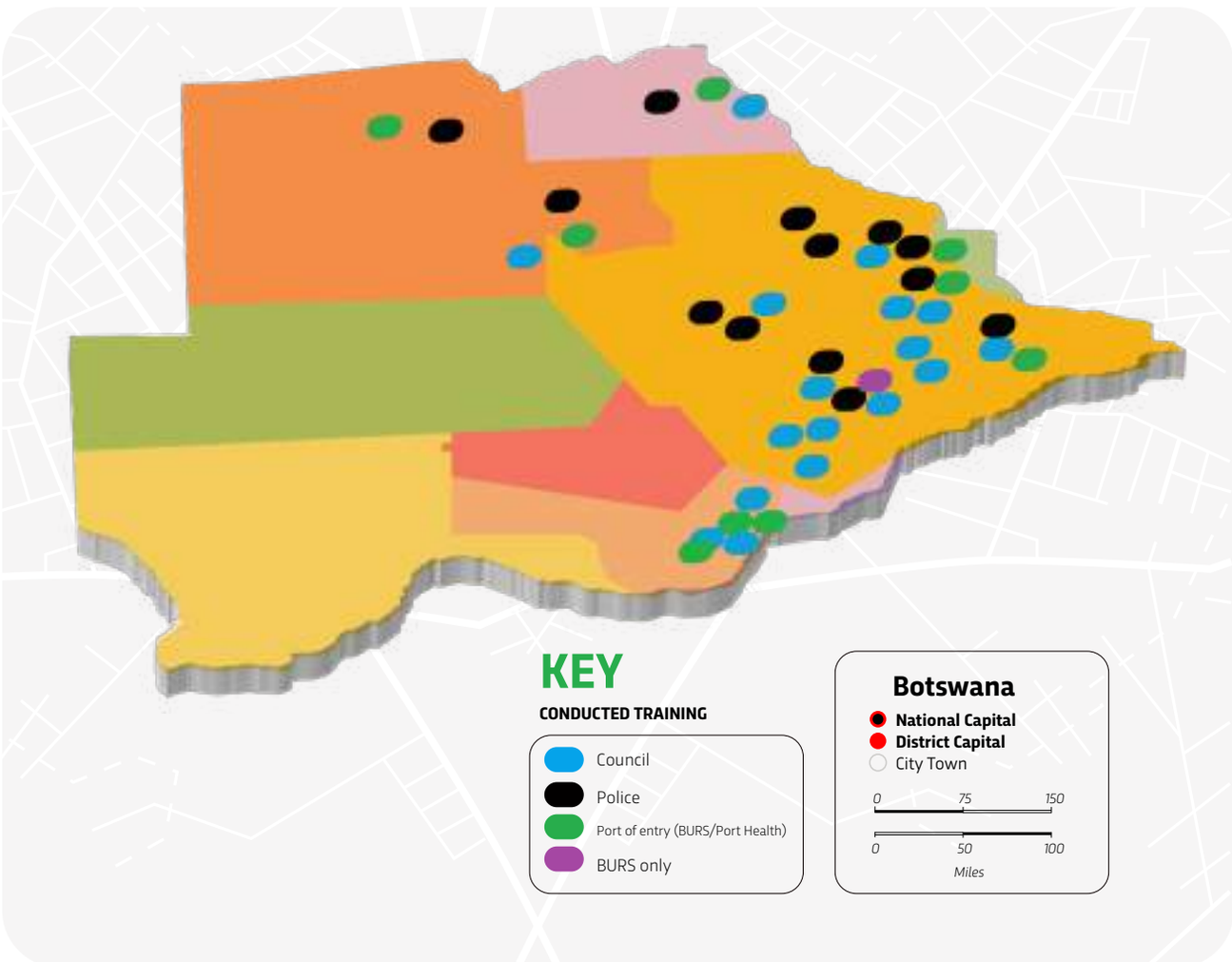


Fig 1 Geographical coverage and enforcement functions engaged from 2021/22 to-date.

The Enforcement Unit charged with driving the strategic objective 7 "Strengthening Enforcement" continued implementation of an enforcement framework which is three pillar approach comprising of proactive and reactive enforcement operational activities.

Operational updates

Common offence types

Most infringements remain product related as is translated from the number of offenders.

Common offences committed against MRSA of 2013 related to possession and selling of unregistered medicines. Informal traders remain (from 2021/22) the mostly likely to contravene sections 23 and 28. The type of active pharmaceutical ingredients found in possession of informal traders are schedule 3 medicines as per Regulations of 2019.

Unlawful dispensing of medicines has increasingly come to light in 2021/22 hence offences stated herein against section 38.

Regulatory Performance For The Year Under Review

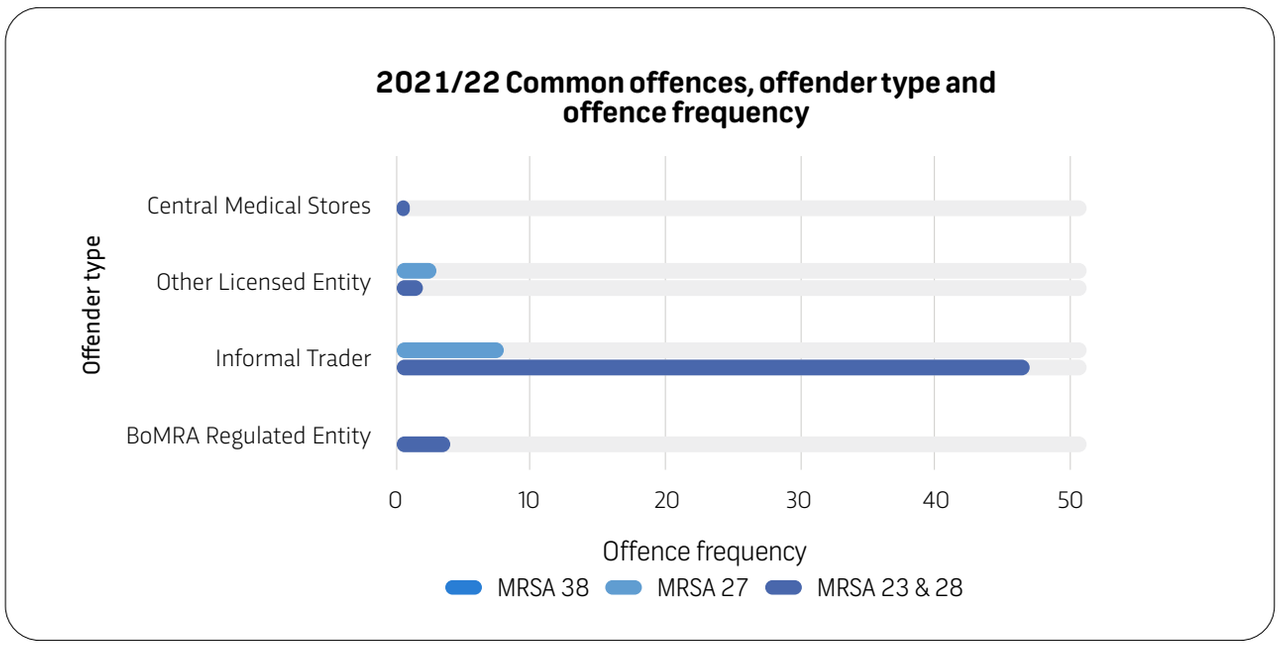
The trend of offenders

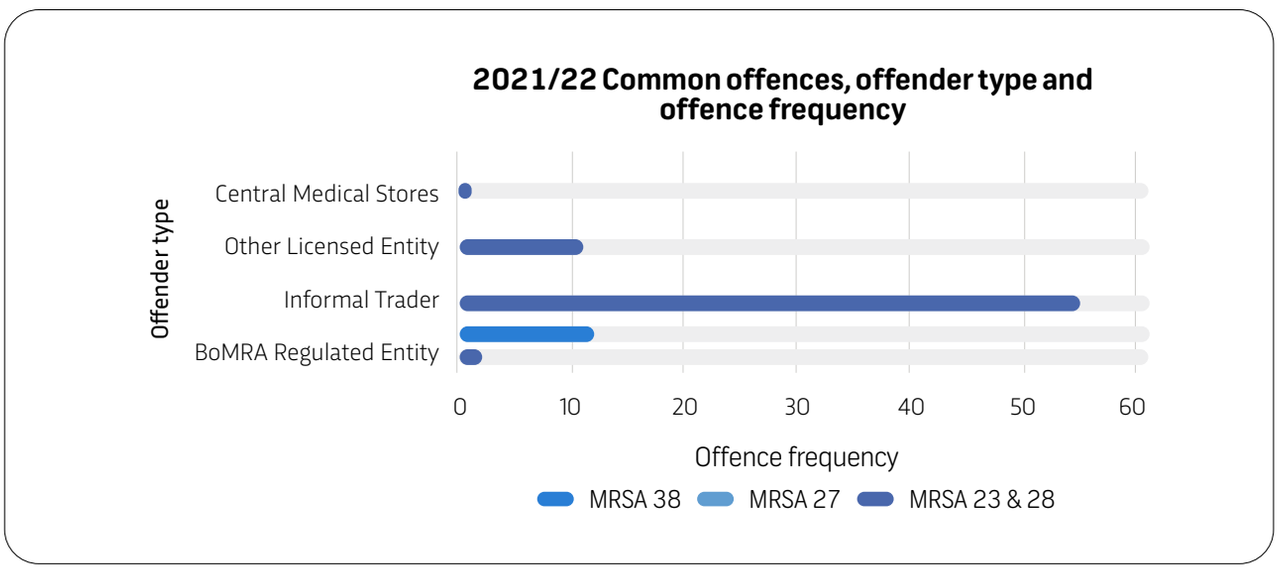
Informal traders constituted over 70% of possession/importing/selling medicines unregistered medicines which is most common offence type.

15% of entities regulated by the Authority breached the law.

The remainder of the offenders comprised entities licensed by other Authorities.

The figure 2 below summarises offender types and number of offences identified as a trend from year to year.





Regulatory Performance For The Year Under Review

Challenges

- The current MRSA does not provide enforcement power to levy administrative and collect fines, which hamstrung deterrence from committing offences. Efforts to mitigate this deficiency through involving Botswana Police Service could only go as far as disrupting the illegal trading. Informal sector offenders have changed tactics of smuggling and distributing unregistered medicines. This partly explains the continued unlawful possession and selling of unregistered medicines as evidenced by the offence trends from 2021/22 to 2021/22.
- The fines imposed averaged only 1% of the potential monetary penalties as provided in the MRSA of 2013. As per figure 3 summary the contrast between penalties stipulated by MRSA of 2013 against the actual imposed fines shall continue until the envisaged revised MRSA is enacted.
- During this formative stage, the Enforcement Unit was not optimally resourced to cover the breadth of the country, to keep abreast of offenders' changing tactics and to keep up with the frequency of offences.
- Limited capacity to keep up with social media marketing for borderline complementary medicines, for advertising of unregistered medicines and for off-label use of registered medicines.
- Ineffective border control between Botswana and her neighbours resulted in continued incidences of unregistered medicines especially in non-trained (informal sector) hands.

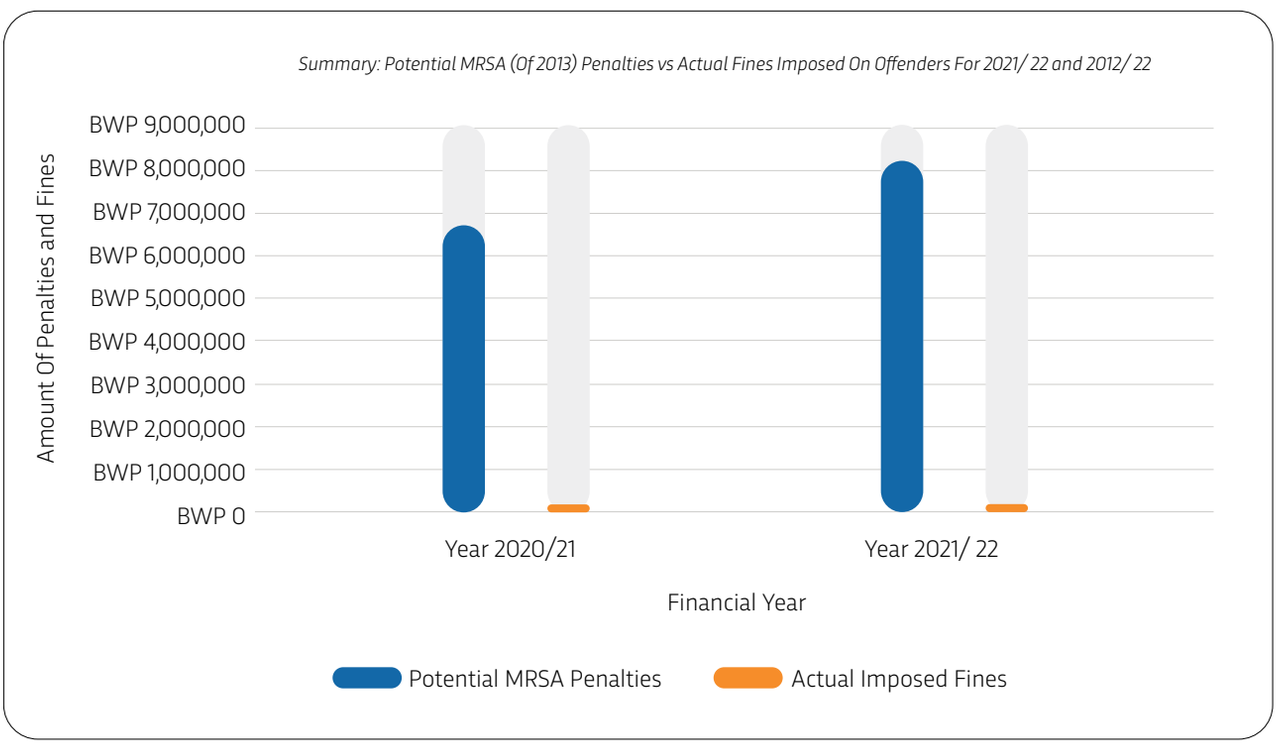


Fig 3 contrast of penalties stipulated by MRSA of 2013 against the actual imposed fines.

Regulatory Performance For The Year Under Review

LABORATORY SERVICES

Strategy Update

The Laboratory Services Unit (LS) is mandated with BoMRA's 3rd Strategic Goal of establishing a Fully Functional Lab Services. The Unit implemented initiatives under the strategic Objective of "Establishing Laboratory Services." The LS Unit contributed to this strategic objective through working towards ISO/IEC 17025 Accreditation, developing Institutional Development Plans for attaining WHO- Maturity level 3 and Testing of Post Marketing Surveillance (PMS) samples.

The below table represents the status of all strategic initiatives under the laboratory services

Table 1 Strategic objective status

No.	Objective	Initiative	Measure	Target	Achieved target
1.	Establish Laboratory Services	Attain ISO 17025 accreditation	% Completion of accreditation milestones (Techniques for accreditation: HPLC, UV, Karl Fisher, DT, LOD, pH and TLC)	75%	87%
2.		Attain WHO Maturity Level 3	% IDP implemented	100%	58 %
3.		Testing of PMS samples	Percentage of testing samples against submitted	100%	54.4%

Operational and Project Updates

More than 400 samples were tested as part of the Post Market Surveillance. Samples received included anti-retrovirals, anti-tuberculars, antimalarials as well as antibiotics. The LS managed to test the following products.

1. Anti-tubercular drugs
2. Antibiotics
3. Some anti-retrovirals

The Laboratory serviced internal customers only, mainly the Pharmacovigilance and Clinical Trials Department on the Post market Surveillance (PMS) project. In addition to the preparations for Accreditation and WHO Maturity Level 3, the Laboratory was also involved in the development of user requirements for the BoMRA Integrated Regulatory managements system (BRIMS)

During the year under review a consultant was engaged to assist with readying the Laboratory for accreditation to ISO 17025.

Challenges

- The LS encountered long procurement processes due to sourcing of products and services from outside the country.
- Failure to test ARVs due to unavailability of reference standards and prescribed test methods
- Inadequate staffing.

Conclusion

Over the past year the Licensing and Enforcement Department had a staffing challenge caused by both resignations and recruitment delays; however, this did not deterrent from achieving good overall performance. A considerable number of new premises were included into the inspection plan over the reporting period.

The Enforcement activities of the Authority continued to grow with significant countrywide coverage and footprint realised. Strengthened Collaboration with other entities helped to support the Authority's mandate.

Regulatory Performance For The Year Under Review

On the other hand, the Laboratory Services also performed well with the initiation of efforts towards accreditation to ISO 17025. There is however a need to consider increasing staffing of the unit as the scope of work continues to expand.

PHARMACOVIGILANCE AND CLINICAL TRIALS

Key Highlights for 2021/22

Medicines, though intended for doing good, may at times cause harm. One of the important activities of BoMRA is to monitor the safety of medicines that are used amongst local population.

Systematic collection, collation, and analysis of Adverse Drug Reactions (ADRs) occurred is important to understand the burden of drug induced illness in the patient population, factors that may predispose them to develop/suffer from ADRs and provide us with an opportunity to prevent/minimize the occurrence of these sufferings.To achieve this task, BoMRA has established the Department of Pharmacovigilance and Clinical Trials.

Vaccine Safety Monitoring

Safety monitoring of medical products is one of the functions of Pharmacovigilance and Clinical Trials department of BoMRA. In April 2021 Ministry of Health and Wellness handed over the responsibility of vaccine safety monitoring completely to BoMRA. Expanded Programme of Immunisation (EPI) was covering this activity earlier. In the backdrop of this development, BoMRA is now the Secretariat of Adverse Events Following Immunisation (AEFI) Committee.

Botswana introduced Covid-19 vaccines across the country in response to the increasing number of cases of Covid-19 around the country. Hence training and capacity building amongst healthcare professionals across the country on vaccine safety surveillance was the need of the hour. In addition, retraining the members of existing National AEFI Committee, add new members of such specialties who are essential but not represented in the committee and train them is a matter of urgency.

The Authority worked tirelessly and effectively to build a vaccine safety surveillance program and established needed structures, systems, processes and procedures. Conducted awareness and training program for healthcare professionals involved in immunisation across the country on detection, reporting, investigation and management of AEFIs.

Strategic Objectives

P2 - Establishing Pharmacovigilance System
P3 - Enhance Clinical Trials Control
P5 - Establish Post Marketing Surveillance of medical products
C1- Improved awareness and public trust in medical products and cosmetic regulatory system.
C2 - Establishing Strategic partnerships and collaborations

Activities Undertaken

Establishing Pharmacovigilance System

BoMRA's endeavour to establish a robust PV system in Botswana in the last two years has progressed well. PV is an evolving discipline and therefore calls for an effective strategic approach to actively engage all stakeholders through advocacy & training. BoMRA is fostering the culture of reporting of safety issues and building strong partnerships with all stakeholders. PV team continued the outreach activities in different parts of the country. BoMRA has established Adverse Drug Reaction Monitoring Centers in different hospitals across the country to strengthen the PV activities.

1. Advocacy and Awareness

Sensitisation and awareness programs for healthcare practitioners (HCPs) was conducted on medicines and vaccines safety monitoring in several towns around the country. Public hospitals in respective towns were of prime focus. The team also engaged with private practitioners particularly pharmacies, private clinics, and hospitals. CMEs were conducted in Maun, Francistown, Gaborone and Lobatse. The team addressed the HCPs on BoMRA initiatives on medicines and vaccine safety monitoring, demonstrated & trained them on the use of ADR reporting tools launched by BoMRA.

In the year **2021-22,** one thousand six hundred and thirty-seven **(1637)** HCPs were trained and sensitised.

Regulatory Performance For The Year Under Review

Establishing Vaccine Safety Monitoring system

With the advent of Covid 19 pandemic and subsequent rollout of Covid 19 vaccines, BoMRA was handed over the responsibility of monitoring vaccine safety by the Ministry of Health.

ACTIVITY	PURPOSE	TARGET GROUP	OUTCOMES
Training of Healthcare Professionals	Information on detection, reporting and management of Vaccine safety issues	Healthcare workers	2345 AEFI Reports
Training of National AEFI Committee	Training provided on essential elements Vaccine Safety Monitoring, AEFI investigations and Causality assessment	National AEFI Committee	Capacity building in AEFI Investigation and causality assessment
National AEFI Committee meetings	Conduct Causality assessment of Vaccines and all vaccine safety issues	National AEFI Committee	64 serious AEFIs assessed for causality
Training of District AEFI Committees	Information on detection, reporting and management of Vaccine safety issues	District AEFI Committees	Capacity building in AEFI Reporting and Investigation
Producing AEFI Reporting Books	To facilitate AEFI Reporting by healthcare workers.	Healthcare workers	2000 booklets were distributed
Producing COVID-19 Vaccine Factsheets	To provide factual information about all approved COVID-19 Vaccines	Healthcare workers General Public	100 000 copies
Producing COVID-19 Vaccine Posters	To encourage reporting of AEFI amongst HCPs and Public	Healthcare workers General Public	20 000 copies printed and circulated amongst hospitals and DHMTs
Engaging Media on COVID-19 Safety Surveillance	To educate the media houses on vaccine safety surveillance and educating the public	Media	15 media houses engaged
Causality assessment of COVID-19 AEFIs	To establish association between COVID-19 Vaccine and AEFI	-----	Reported AEFIs assessed and shared with Expanded Program on Immunisation and WHO

Establishment of National Medicines Information Centre

The department established a medicines information centre to serve both HCPs and the public by providing unbiased research-based medicines information. The department answered 31 enquires received both from healthcare professionals and public.

Establishment and implementation of Veterinary Pharmacovigilance

As part of developing pharmacovigilance system for veterinary medicines, the department engaged Veterinary practitioners. A total of 65 veterinary practitioners were trained, Veterinary AE reporting booklets were printed and distributed for ease of reporting. A total of 25 Veterinary AE reports were received by the department.

Regulatory Performance For The Year Under Review

Partnerships

Active engagements and partnerships with key stakeholders are essential for a functional pharmacovigilance system. Healthcare Professionals, Academia, Public Health Programs, DHMTs, Market Authorisation Holders, Managed Care, Patients, Community practitioners, Research Institutions and Media are the stakeholders. BoMRA has established rapport with these stakeholders and are all at different levels of reaching an understanding/agreement to work together.

Public Health Programmes

PHPs are our very important partners and BoMRA has actively engaged with HIV, TB, EPI and Malaria Eradication programme in building awareness and training of healthcare professionals of respective programme on PV initiatives of BoMRA and the importance of safety monitoring in Public Health Programmes. BoMRA participated in their training program and trained their team in ADR reporting and use of reporting tools. The department was involved in safety monitoring on mass drug administration of Praziquantel. A memorandum of agreement on safety monitoring of medicines/vaccines with PHPs with the Ministry of Health is under progress.

Capacity building

BoMRA is continuing to facilitate building competency and skill amongst the team and gain necessary technical knowledge required to deliver what is expected from them. The team was trained on several aspects of pharmacovigilance including signal detection & evaluation. As part of their personal development, the team attended a workshop on Presentation Skills.

Achievements

1. During this year the department received 1420 ADRs (617 ADRs per million population) which is 3 times more than the WHO recommendation of 200 reports per million population for a functioning PV system.
2. The PV function attained implementation score of 68% on WHO Global Bench Marking self - assessment.
3. The department was successful is sourcing external funding amounting to UDS200,000 to support the PV initiatives.

Oversight and Regulation of Clinical Trials

Good Clinical Practice (GCP) inspections were conducted for 6 Clinical Trials protocols to assess the overall compliance of the conduct of the studies in selected sites with the study protocol, GCP requirements and applicable regulations. 16 amendments proposed to the approved study protocols were assessed and approved and 7 new protocols were assessed and approved for compliance with the law and ethics. Review was completed for Annual reports for 10 active Clinical trial protocols that were submitted by the applicants reflecting the status of Clinical trials in the country.

The department is currently running two projects that aim to strengthen CT regulations in Botswana. SouthErn Africa Regulatory for Clinical ResearcH (SEARCH) and Botswana Clinical Trials Regulation (BoCTRe) are the projects funded by European and Developing Countries Clinical Trials Partnership (EDCTP).

The SEARCH Project is a 3 year project which started on the 1st January 2021. The project is a consortium composed of five Southern African and European institutes. The project is implemented in Mozambique, Botswana, Eswatini and Lesotho. The aim of the project is to increase the regulatory capacities for review of clinical trials in Southern Africa by establishing European-African collaborations that facilitate the implementation of efficient processes, harmonized procedures, standardized guidelines, and effective training programs. The aim of the SEARCH project is to structurally increase the regulatory capacity for clinical trials oversight in Southern African countries.

Regulatory Performance For The Year Under Review

BoCTRe

The Botswana Clinical Trials Regulation (BoCTRe), a 2 year project is a joint initiative of BoMRA (NRA) and Health Research and Development Committee (HRDC), in the Ministry of Health and Wellness (MoHW). The goal of BoCTRe project is to strengthen the HRDC, affiliated Institutional Review Boards (hospital-based IRBs) and NRA to build effective clinical trial oversight and regulatory mechanisms. Development and implementation of electronic portal for simultaneous submission of CT protocols to BoMRA and HRDC is an important objective of this project.

Achievements

1. The CT function attained implementation score of 70% in the WHO Global Bench Marking self - assessment.
2. The department was successful is sourcing external funding amounting to 400,000 euros to support the CT regulations strengthening initiatives.
3. Active collaboration established with HRDC for better regulation of clinical trials in the country

Post Marketing Surveillance of Medical Products

Approval of Adverts and Promotional Materials

Two hundred adverts and promotional materials submitted, were evaluated and approved/feedback provided to the applicants.

Sampling

The department conducted 2 rounds of PMS sampling and submitted samples to the BoMRA laboratory for testing. The team also did PMS benchmark exercise at TMDA, the learnings to be adopted.

Achievements

1. The Market Control function attained implementation score of 85% in the WHO Global Bench Marking self – assessment and reached Maturity Level 2.
2. The department was successful in receiving a grant of USD704,000 from the Global Fund for 3 years to support the PMS activities.
3. Active participation in Member Country Mechanisms on Substandard and Falsified Medicines and member of the working group on Preventing S and F medicines distributed through informal markets.

Plan for 2022/2023

1. Continue practitioners' education programs
2. Strengthening of National Medicine Information Centre
3. Consolidating the efforts initiated in Clinical Trials Control through implementation of BoCTRE and SEARCH Projects
4. Baseline assessment for indicator products to establish prevalence of S & F products in Botswana
5. Introduce Active Safety Surveillance in Public Health Programs
6. Strengthen Pharmacovigilance Regulatory Compliance

CUSTOMER AND STAKEHOLDER FOCUS

Content

- Quality Management
- Partnerships/Harmonisation
- Public Relations

Customer And Stakeholder Focus

QUALITY MANAGEMENT

Strategic areas of accountability (Objectives and initiatives) with final scores

Strategic Goals / Objective	**P8 – Establish and Implement Quality Management System**		
Strategic Initiative	**Performance Measures**	**Target**	**Actual**
Maintain ISO 9001 Certification	% Compliance to process performance	90%	90%
	Maximum number of major NCs per function identified during an external QMS audit	1	0
Implement Enterprise Risk Management	% Priority Business Risks treated to acceptable levels	100%	41%

Strategic Goals / Objectives	**L3 – Improve Corporate Governance with Effective Practices**		
Strategic Initiative	**Performance Measures**	**Target**	**Actual**
Conduct annual World Health Organisation Global Benchmarking Tool Self Assessments to evaluate maturity level of regulatory functions.	Number of self assessments completed	8	8

Summary of performance particular emphasis on key strategic successes/ challenges

The following successes were realized during the reporting period:

a. Electronic Quality Management System (eQMS) was successfully implemented resulting in efficiencies in the QMS.
b. First annual QMS surveillance audit was successfully conducted in January 2022 resulting in no major non-conformances identified.
c. The ERM framework, policy and procedures were aligned to ISO 31000 in support of The Authority's strategic Intent.
d. d. 2 of the functions reached ML 2 through the GBT self-assessments conducted.

Operational and Projects Updates

Any other information deemed important related to operations or projects that do not feature in the strategy or has significant bearing on any stakeholder of the Authority.

The GBT self assessments that were conducted showed 2 functions to be at ML 2.

Customer And Stakeholder Focus

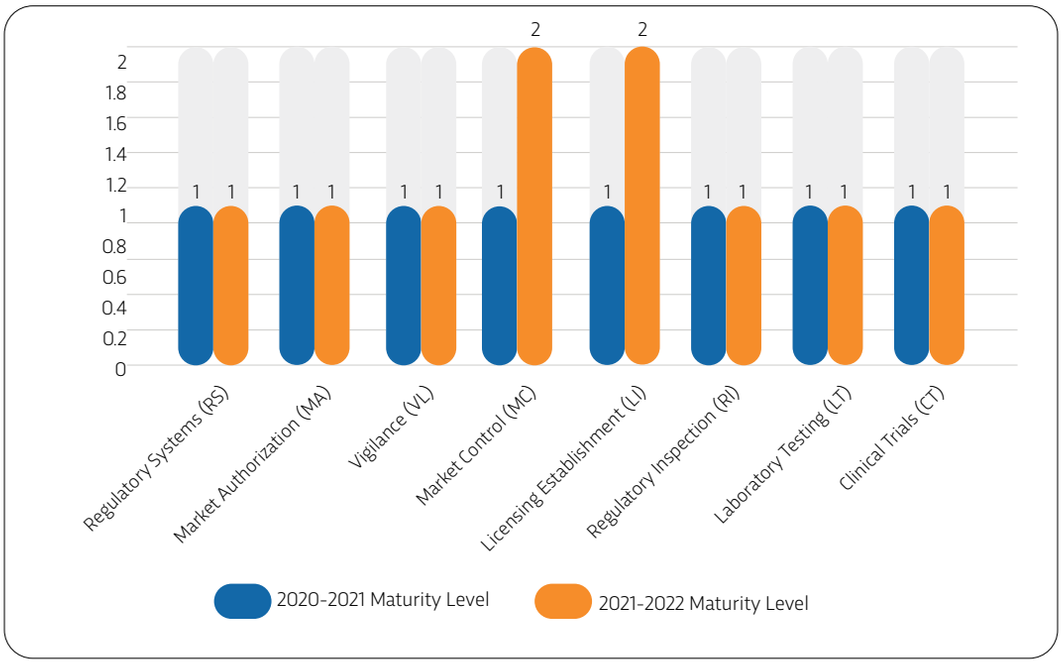


Figure 1: Maturity Level Status of the Various Functions

Market Control and Licensing Establishments reached ML 2 while the rest of the functions are still on ML 1.

The implementation score directly contributes to the maturity level score of each function. Comparing the financial years 2020-2021 and 2021-2022, there has been an increase in the implementation score across all functions.

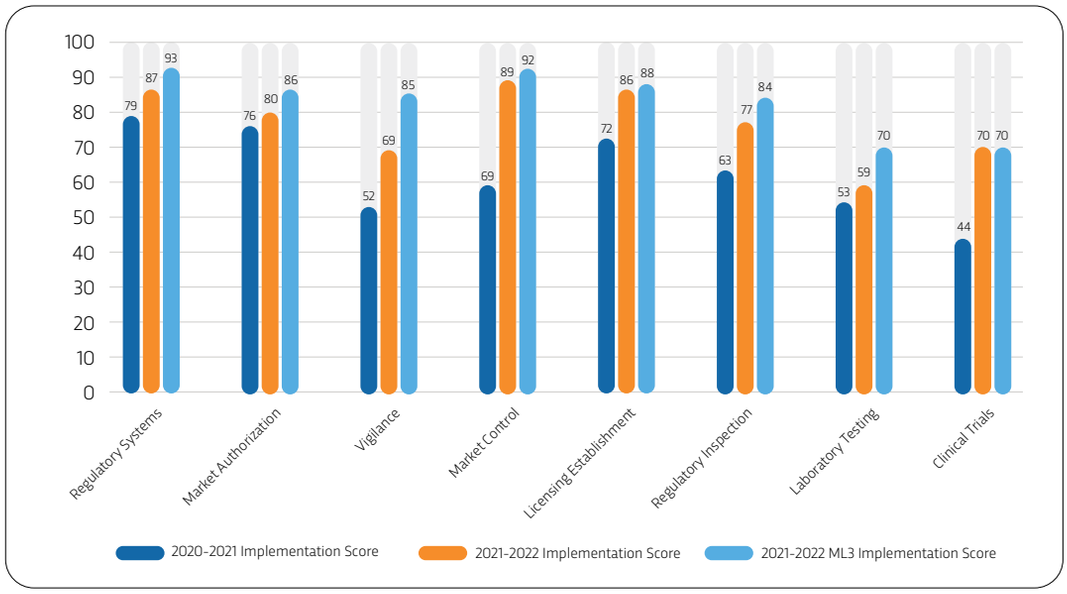


Figure 2: GBT Implementation Scores Analysis

Customer And Stakeholder Focus

Assessing functional implementation scores against ML 1, 2 and 3 requirements in line with the BoMRA strategic intent, the highest implementation score realized was 93% with the lowest being at 70%.

Any statistical data or graphical representations related to your operations that may be of value or interest to clients or interesting facts/information e.g. number of premises licensed, inspected, medicines registered/exempted etc. the idea is to buttress the report with such information and use it to generate graphs, tables and diagrams where possible. Where a graph is provided kindly provide a brief explanation of what it displays.

Statistical data has been provided above.

Definitions and Acronyms

Define any technical words and/or acronyms used

Definitions

- ML1 – a regulatory system in which some elements of regulatory systems exist.
- ML2 – a national regulatory systems that partially performs essential regulatory functions.
- ML3 – a stable, well-functioning and integrated regulatory system.

Acronyms

- GBT – Global Benchmarking Tool
- QMS – Quality Management System
- eQMS – electronic Quality Management System
- ML – Maturity Level
- WHO – World Health Organisation

PUBLIC RELATIONS

Engagement Approach

Botswana Medicines Regulatory Authority aims to forge mutual and beneficial relationships through stakeholder engagements. The engagements are also key to building a positive reputation and strengthening our brand visibility, trust, and confidence in the regulatory framework.

Our engagement initiatives are guided by the Stakeholder Engagement Policy (2019 – 2024) a communication plan and Procedures. It is, therefore, essential for the Authority to maintain mutually rewarding relationships with various stakeholder groups that we serve, ensuring that the engagements are conducted in an inclusive, consistent, and responsive manner.

These engagements are aimed at keeping stakeholders informed on the regulatory business's strategic direction, challenges, and plans vis a vis -a- vis their reasonable needs, expectations, and interests in the Authority.
Medicine safety continues to come to the attention of the wider public. Public health education plays an important role at the national, tribal, and local levels in making the public aware of the vaccines that are recommended for them.

Customer And Stakeholder Focus

Stakeholder engagement summary

Law enforcement:

1. A total of 147 Law enforcement representatives were trained on understanding the control of human medicines in "greater" Gaborone, Francistown, Northeast, Kasane, Maun, ports of entry in southern parts, in North East, Sir Seretse Khama Airport, PG Matante International airport, Ramokgweban, Botswana Post International Exchange Centre (in Gaborone) Mamuno and Mohembo.
2. A cumulative of nine (9) stakeholder organisations participated in the
3. Joint operations with Botswana Police Service, Ministry of Investment, Trade and Investment, BURS, Botswana Post, Wildlife and Parks, Environmental Health, Competition, and Consumer Protection as well as Local administrative authorities. A total of 13 joint operations varying in duration have been conducted between 2020/21 and 202½2.

General Public

Awareness raising and dissemination of information in line with the stakeholder engagement plan was successfully conducted as follows:
about the mandate and duties of the Authority as well as vaccine safety were conducted in the following

- **Kgotla meetings:** A total of 18 open kgotla meetings were conducted jointly with the ministry of health in the following areas: northeast district Ghanzi and Okavango and Northwest.

- **Full Council meetings:** A total of 8 full councils were conducted in Ghanzi, Jwaneng Kgalagadi Gaborone Kweneng, Kgatleng, Northwest, Southeast Ramotswa, Nort east

- **Online and social media campaigns-** a social media policy and a plan were developed to guide the level and direction of engagement through the social media platform. several campaigns were conducted, these include short white boar animation on VMP licensing, reporting of ADR, Import and export of medical products as well as illegal sale and advertising of media products.

- **School awareness campaign –** 4 edutainment campaigns targeting students and teachers were conducted in the following schools: school, Baitlotli Ramotswa Kelemogile, Taung JSS.

- Key messages for the students were on Adverse events following Immunisation (AEFI) - a medical occurrence that follows immunization and the role of BoMRA in the regulation of medical products and the fight against COVID-19 in Botswana.

Customer And Stakeholder Focus

Health care practitioners, Industry, and other stakeholders.

Virtual and physical Workshops, seminars and presentations were conducted throughout the period. These initiatives targeted various stakeholders in the industry sector, including distributor manufacturers, and veterinary and pharmaceutical operators. key messages include:

- Medical products safety reporting guidelines
- Inspection of retailers' guidelines & requirements
- Medical devices and complementary medical products registration

MEASURING PROGRESS

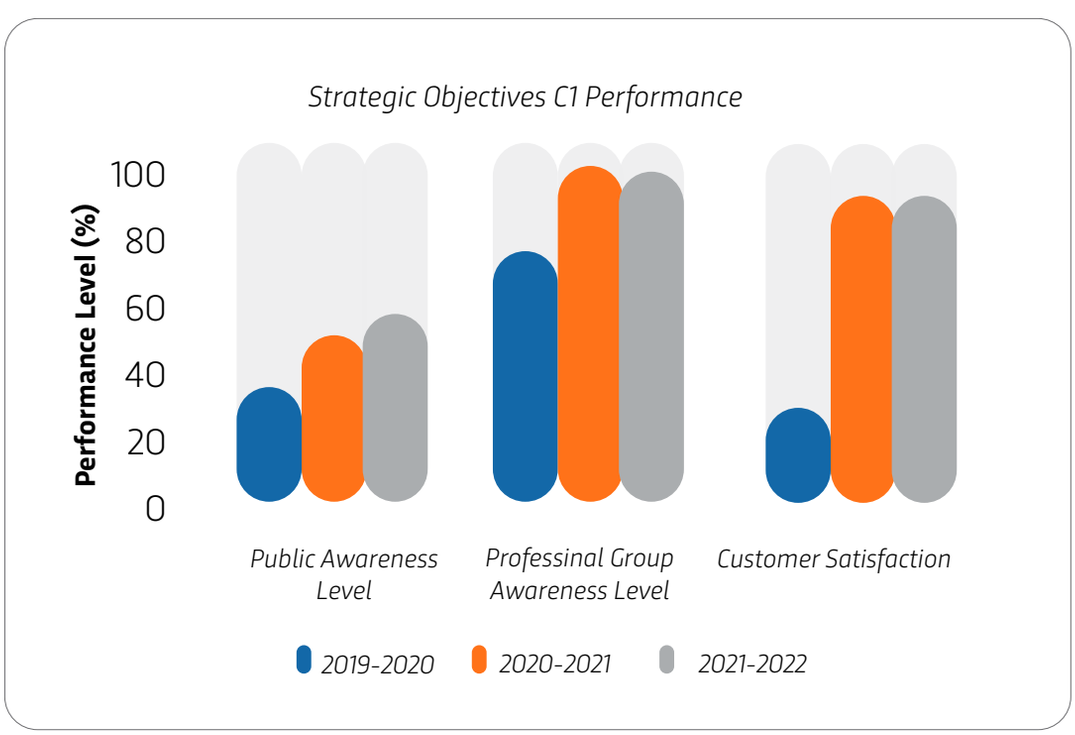
Since 2019, We have consistently measured our organisation's brand awareness, through surveys and face-to-face interviews, asking our stakeholders basic questions around

- brand recognition
- Mandate and Purpose
- Perceptions and expectations

We're pleased to note an increase in awareness, as well as a notable increase in positive awareness, in the minds of the stakeholders from **2019 to 2021.** However, there is still ample room to increase awareness of BoMRA further.

The following surveys indicated a sharp increase in Community awareness of BoMRA stood **at 49.0% for the 2020-2021 FY.**

Strategic Objective C1 Performance



Customer And Stakeholder Focus

We strive to continuously improve the Stakeholder Engagement effectiveness, focusing on the implementation of initiatives that adequately address salient issues outlined in this report.

our focus areas for the year ahead include:

- Performing regular multi-industry stakeholder perception and expectations surveys aimed at helping in the enhancement of the quality of our engagement and service.
- Increased awareness around the importance of BoMRA's function to keep citizens of Botswana safe, the MRSA Act, guidelines as well as processes and procedures.
- Increased understanding of BoMRA's mandate and responsibilities including lack of jurisdiction over traditional medicines.
- Regular engagement and awareness to prevent illegal trade and criminal activity regarding medical and cosmetic products -substandard and falsified medical products.
- Reporting of adverse drug reactions as well as increased surveillance

HUMAN RESOURCES FOCUS

Human Resources Focus

Annual Performance Plan

The HR & OD department is responsible for 2 strategic objectives which are:
- L1 (Enhance HR Management System) and
- L2 (Instilling a high-performance culture)

L1 (Enhance HR Management System) Strategic Initiatives

- Review and implement HR strategy.
- Develop and implement a competency development program including soft competencies
- Develop and implement a talent management strategy
- Review the entire organisational structure and capacity.
- Develop and implement a progressive recruitment strategy.
- Review and realign compensation and benefits structures for technical positions
- Implement Institutional Development plans for HR function to reach ML3
- Develop and Implement Retention Strategy

Review and Implement HR strategy.

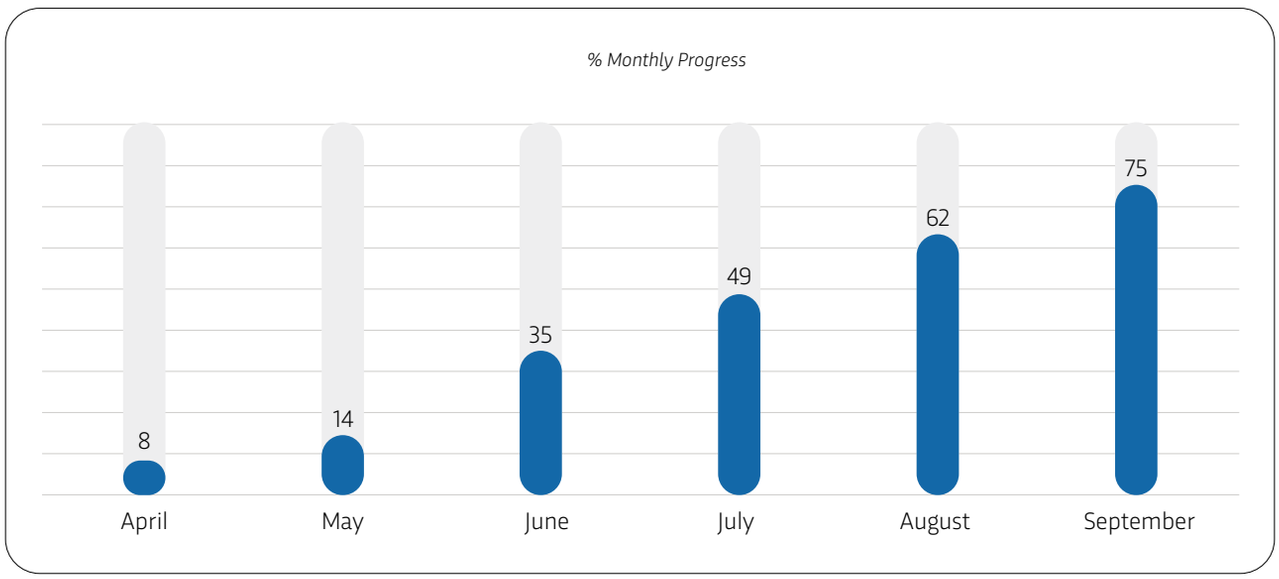
The following key milestones were identified to support the initiative, these were;
- Talent Management & Succession Planning- the framework has been drafted and presented to EXCO and CEO, however, the framework has not been presented to the HRC for approval and as a result, this remains partially fulfilled as we continue to implement some elements of the Talent management framework, some of the elements being implemented are 1. Total Rewards, 2. Talent Acquisition, 3. PMS, 4. Training & Development.

Figure 1: Elements of a Talent Management Framework

- Optimum organisational capacity entailed progressive recruitment to support the overall strategy. As of April 2022, Organisational strength was 74% from a headcount of 84 out of a complement of 113 as per the initially approved structure in 2021. The Authority conducted the Mid-term strategy review and 28 vacancies were identified as crucial to accelerate to ML3.

Human Resources Focus

% Progress against the 28 vacancies for the current cycle



Traction of the 28 vacancies stood at 75% as of September 2022 from 8% in April 2022.
The overall Headcount is 102 of the substantive positions which denotes progress of 16% from April 2022. This brings our total workforce strength to 90%.

- Leadership Development & Effectiveness- a Management Development Program has been identified with the University of Wits, this is expected to commence in November and will be targeting 16 managers. An Executive Development Program is still to be identified for Directors.

- Job Profiles Review- the exercise has been started and so far the following functions have been reviewed 1. DPER, 2. Licensing & Enforcement, 3. PV & CT, 4. Quality Management. Support functions are planned to be finalized once the technical functions are closed by the end of October.

Develop & Implement a competency development program- this entailed development of a framework for the technical cadres including the soft skills. BoMRA has managed to conduct the initial competency assessments against the framework which was provided by WHO where BoMRA was used as a pilot project in 2021. The second assessments have been a challenge as there was a delay by WHO to provide a tool for further assessments however, under the guidance of Dr Gwaza WHO has partnered with a service provider who will be instrumental in further assessments.

Review and re-align compensation and benefits structures for technical cadres- the Authority has participated in the remuneration surveys for the years 2019, 2021 and 2021 and the results have always shown that the Authority's overall remuneration structure was competitive even though pegged at the 50th percentile of the market. The rapid growth of the pharmaceutical industry presented new dynamics which rendered our remuneration structure, particularly for the technical cadres less competitive, key talents such as Dossier Assessors, and Regulatory Officers-Inspections were lost as the market continued to lure them with better wages. In February 2021, the Authority moved swiftly and made a decision to move all the technical cadres to the median of the band, this was still not enough as further loss of key talent was incurred. Subsequently, the Authority resolved to move all the employees in the technical cadres to the 75% percentile of the market. The move has ensured that we stand a good chance at retaining our key talent into the future as we accelerate toward ML3.

Implement institutional development plans for HR to reach ML3- HR has 12 identified IDPs of which only 2 have been fulfilled, and 7 are ongoing. The main impediment has been the inability to recruit an OD specialist, most of the IDPs are OD related and currently, there is inadequate capacity to mobilize at the desired speed. The plan is to ensure that 50% of the IDPs are closed by December 2022 so that we can push for a minimum of 75% by March 2023.

Human Resources Focus

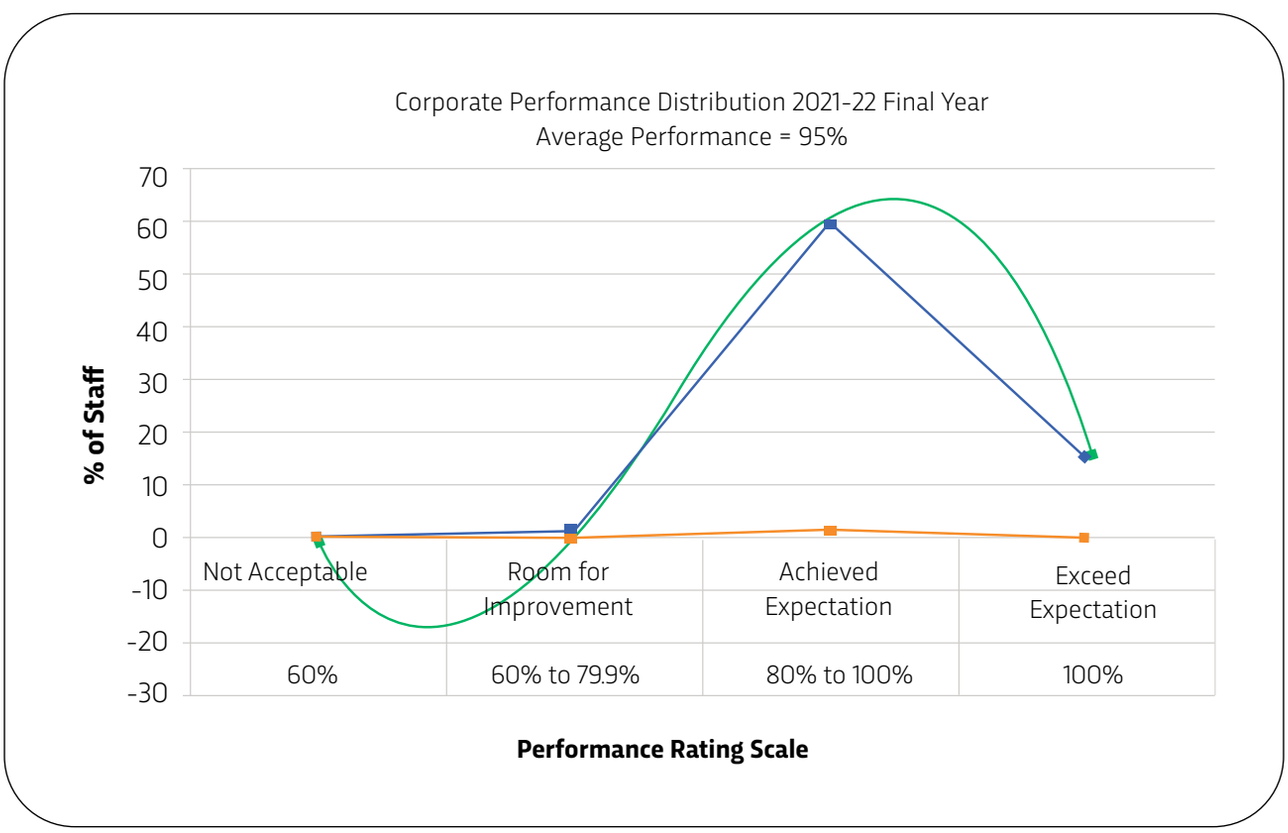
Development and implementation of the retention strategy- the measure here is the % retention of staff, the Authority has hovered between 94% - 96% on staff retention, however, the 4-6% loss was on critical positions which greatly affected the functionality of some key functions such as DPER which was the worst hit by around 30% turnover at the pick.

L2 (Instill a high-performance culture) Strategic Initiatives

- Implement culture alignment initiatives including soft skills development
- Implement a leadership development programme

Implement culture alignment in initiatives including soft skills development- this initiative entails the measurement of employee performance. The current cycle started with Performance contracting at 92% with 8% delays emanating from the lack of key persons in some critical positions, however, we managed to push the number at end-of-year appraisals where were reached a 97.62% submission rate.

Performance Calibration was conducted and the Authority archived an overall of 95% which was an increase of 3% from the previous period. The distribution showed that our staff performance was optimised where stretch targets were set and achieved, however, the APP did not move at the same rate which pointed to some degree of misalignment in terms of performance contracts and the APP. This was noted and the calibration committee has taken measures to address the mis-alignment before the end of the year appraisals.



Human Resources Focus

Implementation of leadership development programme- in the year 2021, the Executive team enrolled in a Senior development programme and also were subjected to the 360-degree assessments which revealed some areas that needed attention, the assessments were not taken in 2022 as some areas of concern from the previous assessments remained un-addressed. A program is still to be identified for the Exco team to bridge the gaps identified. Management Development Program has been organized with Wits University, this will target 16 middle-level management and expected to start in November 2022. Communications matrix successfully completed and submitted to the PR department.

Successes

1. Managed to sustain the HR processes at above 90% as per the QMS process monitoring tool despite the challenges with a shortage of human resources in the department.
2. Successfully implemented the Performance Management cycle for the period 2021-22 at the rate despite the challenges.
3. Managed to push recruitment to bring the organisation to a manpower capacity of 90% as of October 2022 from 74% at the beginning of the period.
4. Training & Development takes place as per the training plans and to date, we sit at over 60% implementation. All the submitted training requisitions approved have met the turnaround times.
5. Successfully launched the Wellness program with ICAS and also the Team-building program with Positive performance
6. Staff retention remained at 95% despite the challenges encountered with the loss of key talent
7. Successfully implemented the review of the remuneration structure for the technical cadres where the board approval was obtained to move the technical cadres to the 75th percentile in August 2022.
8. Successfully managed to implement work-from-home procedures, WFH is now embedded in our operational plans with the support of ICT
9. In partnership with Positive performance, managed to host the first-ever team-building exercise for the Authority

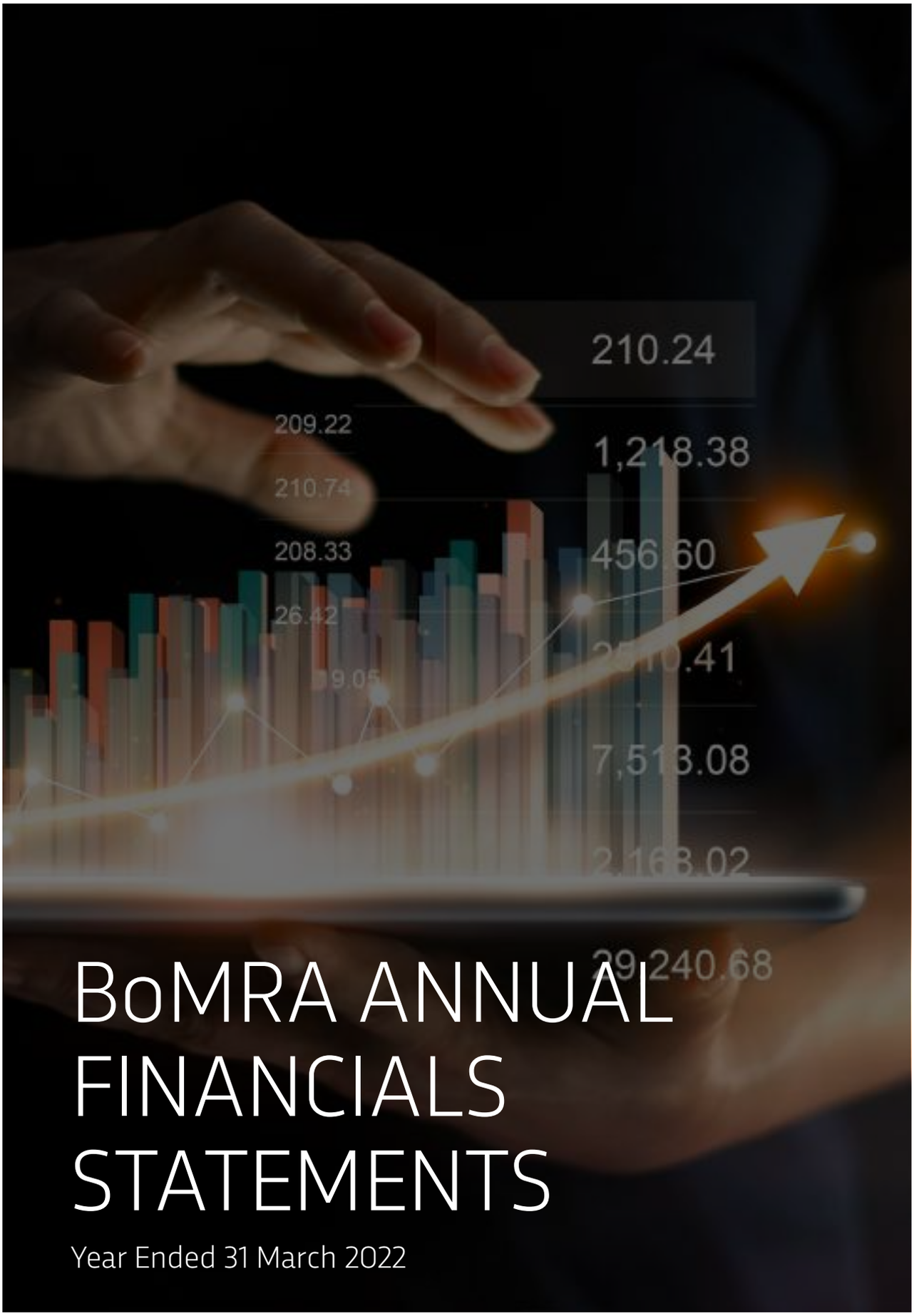
Challenges

1. Lack of human resources in key positions to drive the HR agenda, the positions of HR Manager and OD specialist remain vacant. The current HR officer is compelled to double up at the officer and Manager level which results in delays in the implementation of key HR processes. The 2 vacancies are at a strategic level and therefore, the function is operating at half the capacity

2. Lack of a prudent HR information system which results in compromised data integrity particularly in issues of leave management and employee self-service.

3. Compromised onboarding process due to the competing priorities, managers do not avail themselves when inductions are scheduled, we are compelled to rely on pre-recorded videos for inductions which do not offer insight into some process

Recruiting for key positions such as CRO, Director-DPER, Manager Inspections, Manager Enforcement, interviews have been conducted on several occasions but still positions remain vacant with people appointed to Act in such positions for pro-longed periods which creates a lot of uncertainty and limit a autonomy.



BoMRA ANNUAL FINANCIALS STATEMENTS

Year Ended 31 March 2022

General Information

BOARD MEMBERS

Mr. Duncan Thela (Chairperson)
Dr. Mbatshi Mazwiduma (Vice Chairperson)
Mr. Kagiso Balopi (Board Member)
Mr. Meshack Baoleki (Board Member)
Ms. Botho Bayendi (Board Member)
Dr. Ditiro Coyne (Board Member)
Dr. Lorato Mongadi-Mokama(Board Member)
Dr. Kegomoditswe Biki Maphane (Board Member)
Ms. Shameela Pholo-Winston (Board Member)
Dr. Kobedi Segale (Board Member)

CHIEF EXECUTIVE OFFICER

Dr. Stephen Ghanie

SECRETARY

Mr. Nonofo Thipe

PRINCIPAL ACTIVITY

Medicines Regulatory Authority regulates the supply chain of human and veterinary medicines, cosmetics and medical devices in Botswana to ensure that they conform with established criteria of quality, safety and efficacy.

BUSINESS ADDRESS

Plot 112
Gaborone International Finance Park
Botswana

POSTAL ADDRESS

Private Bag 2
Gaborone
Botswana

AUDITORS

Grant Thornton Botswana

BANKERS

First National Bank Botswana Limited
Bank Gaborone

LEGAL FORM

Medicines Regulatory Authority was established as a body corporate by the Medicines and Related Substances Act, 2013.

Statement of Financial Position as at 31 March 2022

Statement of Financial Position as at 31 March 2022

Directors' responsibility statement and approval of 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.

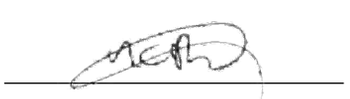
The Board acknowledges that it is ultimately responsible for the system of internal financial control established by the Authority and place considerable importance on maintaining a strong control environment. To enable it to meet these responsibilities, the Board sets standards for internal control 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.

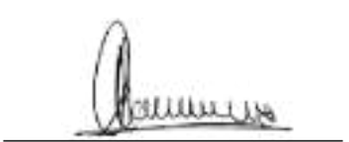
The Board has reviewed the Authority's cash flow forecast for the year to 31 March 2023 and, in light of this review and the current financial position, it is satisfied that the Authority has adequate resources to continue in operational existence for the foreseeable future.

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 4.

The annual financial statements set out on pages 5 to 22, which have been prepared on the going concern basis, were approved by the board on 18 October 2022 and were signed on their behalf by:



Chairperson



Chief Executive Officer

Independent Auditor's Report

Chartered Accountants

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Fairgrounds, Gaborone
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Gaborone, Botswana

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F +267 397 2357

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twitter.com/GrantThorntonBW

To the Members of Medicines Regulatory Authority

Opinion

We have audited the annual financial statements of Medicines Regulatory Authority ("The Authority") set out on pages 7 to 25, which comprise the statement of financial position as at 31 March 2022, statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and the notes to the annual financial statements, including a summary of significant accounting policies.

In our opinion, the annual financial statements give a true and fair view of, the financial position of the Medicines Regulatory Authority as at 31 March 2022, and its financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards and the requirements of the Medicines and Related Substances Act, 2013.

Basis for Opinion

We conducted our audit in accordance with International Standards on Auditing. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Annual Financial Statements section of our report. We are independent of the Authority in accordance with the International Ethics Standards Board for Accountants' International Code of Ethics for Professional Accountants (including International Independence Standards) (Parts 1 and 3) (IESBA Code) and other independence requirements applicable to performing audits of Auditor's Responsibilities for the Audit of the Annual Financial Statements in Botswana. We have fulfilled our other ethical responsibilities in accordance with the IESBA Code and in accordance with other ethical requirements applicable to performing audits in Botswana. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Botswana Accountancy Oversight Authority registration number: FAP 005 2022 (Audit Firm of Public Interest Entity)
Botswana Institute of Chartered Accountants membership number: MeFBW11013 (Audit and Non-Audit)

Partners
Kalyanaraman Vijay (Managing), Aswin Vaidyanathan*, Madhavan Venkatachary*, Anthony Quashie, Sunny K Mulakulam*, Aparna Vijay* (*Indian)

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Independent Auditor's Report

Other Matter

The annual financial statements of the Authority for the year ended 31 March 2021, were audited by another auditor who expressed an unmodified opinion on those statements on 06 October 2021.

Other Information

The Members of the Board are responsible for the other information. The other information comprises the information included in the document titled "Medicines Regulatory Authority Annual Financial Statements for the year ended 31 March 2022", which includes the Board's Responsibility and Approval of the Annual Financial Statements, which we obtained prior to the date of this report and the annual report which is expected to be made available to us after that date. The other information does not include the financial statements and our auditor's report thereon.

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

In connection with our audit of the annual financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the annual financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If, based on the work we have performed on the other information obtained prior to the date of this auditor's report, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Members of the Board for the Annual Financial Statements

The Members of the Board are responsible for the preparation and fair presentation of the annual financial statements in accordance with the International Financial Reporting Standards and the requirements of the Medicines and Related Substances Act, 2013, and for such internal control as the Members of the Board determine is necessary to enable the preparation of annual financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the annual financial statements, the 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 the Members of the Board either intend to liquidate the Authority or to cease operations, or have no realistic alternative but to do so.

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

Independent Auditor's Report

Auditor's Responsibilities for the Audit of the Annual Financial Statements

Our objectives are to obtain reasonable assurance about whether the annual 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 will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual financial statements.

As part of an audit in accordance with International Standards on Auditing, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual 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 company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Members of the Board.
- Conclude on the appropriateness of the Members of the Boards' 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 annual 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 annual financial statements, including the disclosures, and whether the annual financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the Members of 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.

We also provide the Members of 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.

Independent Auditor's Report

From the matters communicated with the Members of the Board, we determine those matters that were of most significance in the audit of the annual financial statements of the current year 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

In our opinion, the financial statements have been properly prepared, in all material respects, in accordance with Section 23 (a) and (b) of the Medicines and Related Substances Act, 2013.

Grant Thornton

18 October 2022

Grant Thornton
Firm of Certified Auditors
Practicing Member: Madhavan Venkatachary: CAP 0017 2022

Gaborone

Statement of Financial Position as at 31 March 2022

Independent Auditor's Report To The Minister Of Health

Report on the Financial Statements
We have audited the accompanying financial statements of Medicines Regulatory Authority, set out on pages 5 to 22, which comprise the statement of financial position as at 31 March 2022 and the statements of comprehensive income, changes in equity and cash flows for the year then ended, and a summary of significant accounting policies and other explanatory notes.

Boards' Responsibility for the Financial Statements
The members of the Medicines Regulatory Board are responsible for the preparation and fair presentation of these financial statements in accordance with International Financial Reporting Standards and the Medicines and Related Substances Act, 2013 and for such internal control as the Board Members determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility
Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control.

An audit also includes evaluating the appropriateness of the accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion
In our opinion, the financial statements give a true and fair view of the financial position of Medicines Regulatory Authority as at 31 March 2022 and of its financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards and the Medicines and Related Substances Act, 2013.

Statement Of Surplus Or Deficit And Comprehensive Income
for the year ended 31 March 2022

	Notes	2022	2021
		P	P
Revenue	3	**85,401,402**	45,160,204
Regulatory fees	4	**9,575,495**	8,190,629
Total Income		**94,976,897**	**53,350,833**
Employee costs	5	**(51,347,204)**	(44,806,155)
Governance expenses		**(1,191,466)**	(667,571)
Depreciation and amortisation expenses	5	**(6,955,257)**	(4,351,855)
Publicity and awareness expenses		**(3,949,610)**	(1,430,188)
Travel and accommodation costs		**(2,156,496)**	(773,250)
Operating expenses		**(12,865,785)**	(12,415,039)
Total Expenses		**(78,465,818)**	**(64,444,058)**
Operating surplus/(deficit)		**16,511,079**	**(11,093,225)**
Investment income	6	**30,496**	215,260
Finance costs	7	**(744,026)**	(780,139)
Total Operating surplus/(deficit) for the year		**15,797,550**	**(11,658,104)**
Other comprehensive income		-	-
Total comprehensive surplus/(deficit) for the year		15,797,550	(11,658,104)

Statement Of Financial Position
for the year ended 31 March 2022

	Notes	2022	2021
		P	P
ASSETS			
Non-current assets			
Right-of-use asset	9	**8,767,005**	10,860,809
Property and equipment	10	**36,645,968**	12,996,460
Intangible assets	11	**2,856,166**	799,750
		48,269,139	24,657,019
Current assets			
Accounts receivables	12	**1,723,789**	1,034,623
Cash and cash equivalents	13	**37,695,691**	19,130,440
		39,419,480	20,165,063
Total assets		**87,688,619**	44,822,082
RESERVES AND LIABILITIES			
Reserves			
Accumulated surplus		**23,603,892**	7,806,342
		23,603,892	7,806,342
Non-current liabilities			
Lease liabilities	9	**8,490,211**	10,654,886
Deferred income	14	**39,443,464**	13,797,768
		47,933,675	**24,452,654**
Current liabilities			
Lease liabilities	9	**2,105,724**	1,847,609
Deferred income	14	**2,795,033**	721,930
Accounts payable	15	**11,250,294**	9,993,547
		16,151,051	**12,563,086**
Total reserves and liabilities		**87,688,619**	44,822,082

Statement Of Changes In Reserves
for the year ended 31 March 2022

	Accumulated surplus	Total
Year ended 31 March 2021	**P**	**P**
Balance at 01 April 2020	19,464,446	19,464,446
Surplus for the period	(11,658,104)	(11,658,104)
Balance at 31 March 2021	**7,806,342**	**7,806,342**
Year ended 31 March 2022	**P**	**P**
Balance at 01 April 2021	7,806,342	7,806,342
Surplus for the period	15,797,550	15,797,550
Balance at 31 March 2022	**23,603,892**	**23,603,892**

Statement Of Cash Flows
for the year ended 31 March 2022

	Notes	2022 P	2021 P
Cash flows from operating activities:			
Surplus/(Deficit) for the year		**15,797,550**	(11,658,104)
Adjustments for:			
Depreciation and amortisation		**6,955,257**	4,351,855
Profit on disposal of property and equipment		**(12,256)**	(3,848)
Interest income		**(30,496)**	(215,260)
Finance costs		**744,026**	780,139
Operating income before reinvestment in working capital		**23,454,081**	**(6,745,218)**
Changes in working capital			
Increase in accounts receivables		**(689,166)**	(443,424)
Decrease in accounts payable		**1,256,747**	2,567,019
Finance costs		**(744,026)**	(780,139)
Net cash inflow / (outflow) from operating activities		**23,277,637**	(5,401,762)
Cash flows from investing activities:			
Purchase of property and equipment	9,10	**(28,186,118)**	(3,634,801)
Purchase of intangible assets	11	**(2,410,770)**	(174,796)
Proceeds on disposal of property and equipment		**41,768**	17,761
Interest income		**30,496**	215,260
Net cash outflow from investing activities		**(30,524,625)**	(3,576,576)
Cash flows from financing activities:			
Payment of lease liabilities		**(1,906,560)**	(1,434,201)
Increase in specific grants		**2,073,103**	721,929
Increase in deferred government grant		**25,645,696**	1,295,470
Net cash inflow from financing activities		**25,812,239**	583,198
Net movement in cash and cash equivalents		**18,565,252**	(8,395,140)
Cash and cash equivalents at beginning of year		**19,130,440**	27,525,580
Cash and cash equivalents at end of year	13	**37,695,692**	19,130,440

Significant Accounting Policies
for the year ended 31 March 2022

1. PRINCIPAL ACCOUNTING POLICIES

The principal accounting policies adopted in the preparation of these financial statements, which have been applied on a consistent basis with those of the previous year, are set out below.

1.1 Basis of preparation

The annual financial statements have been prepared in accordance with International Financial Reporting Standards and International Financial Reporting Interpretations Committee ('IFRIC') interpretations issued and effective at the time of preparing these financial statements and the Medicines and Related Substance Act of 2013. The financial statements have been prepared under the historical cost convention, unless otherwise state 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.

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

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

Significant Accounting Policies *(Continued)*
for the year ended 31 March 2022

1.2 Significant judgements and sources of estimation uncertainty (continued)

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 Property and equipment

Property and 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 property and 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.

Property and 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 property and 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.

Property and 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
Land	Not depreciated		

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.

The gain or loss arising from the derecognition of an item of property and equipment is included in surplus or deficit when the item is derecognised. The gain or loss arising from the derecognition of an item of property and equipment is determined as the difference between the net disposal proceeds, if any, and the carrying amount of the item.

Significant Accounting Policies *(Continued)*
for the year ended 31 March 2022

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 (note12).

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

They are subsequently measured at amortised cost.

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

Significant Accounting Policies *(Continued)*
for the year ended 31 March 2022

1.5 Financial instruments (continued)

Accounts receivables (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 processes 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 processes related to derecognition.

Cash and cash equivalents

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

Derecognition

Financial assets

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

Financial liabilities

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

Significant Accounting Policies *(Continued)*
for the year ended 31 March 2022

1.6 LEASES

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

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.

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.

Significant Accounting Policies *(Continued)*
for the year ended 31 March 2022

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.

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 Financial Statements
for the year ended 31 March 2022

2 NEW STANDARDS AND INTERPRETATIONS

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.

	2022	2021
	P	P
3 REVENUE		
Grant received from Government of Botswana	**79,839,836**	42,646,074
Grants received from EDCPT	**691,082**	-
Amortisation of deferred income	**4,870,485**	2,514,130
	85,401,402	**45,160,204**
RECONCILIATION OF GOVERNMENT GRANT RECEIVED		
Grant received from Government of Botswana	**110,356,017**	46,455,670
Amount utilised to acquire assets	**(30,516,181)**	(3,809,596)
	79,839,836	**42,646,074**
4 REGULATORY FEES		
Regulatory fees - Registration	**7,483,688**	6,358,699
Other regulatory fees	**1,962,789**	1,831,930
Other income	**129,019**	-
	9,575,495	**8,190,629**
5 OPERATING SURPLUS		
Operating surplus/(deficit) for the year is stated after charging (crediting) the following, amongst others:		
Auditors' remuneration		
Audit fees	**75,623**	70,560
Employee costs		
Salaries, wages and other benefits	**40,573,555**	35,155,471
Recruitment and consultancy costs	**295,598**	924,058
Pension scheme contribution	**3,164,728**	2,738,705
Gratuity expense	**4,075,872**	3,868,946
Leave pay expense	**2,718,318**	1,612,518
Professional and other subscriptions	**519,133**	506,457
	51,347,204	**44,806,155**
Depreciation		
Depreciation of property and equipment	**4,507,099**	2,318,135
Depreciation of right-of-use asset	**2,093,803**	1,851,637
Amortisation of intangible assets	**354,354**	182,083
	6,955,257	**4,351,855**

Notes to the Financial Statements *(Continued)*
for the year ended 31 March 2022

		2022 P	2021 P
6	**INVESTMENT INCOME**		
	Interest income		
	Investments in financial assets:		
	Other financial assets	**30,496**	215,260
7	**FINANCE COSTS**		
	Lease liabilities	**744,026**	780,139
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	**LEASES (COMPANY AS LESSE)**		
	Net carrying amounts of right-of-use		
	The carrying amounts of right-of-use are included in the following line items:		
	Year ended 31 March 2022		
	Cost		
	Balance at beginning of the year	16,063,045	14,620,797
	Additions	-	1,442,248
	Balance at end of the year	**16,063,045**	**16,063,045**
	Depreciation		
	Balance at beginning of the year	5,202,236	3,350,599
	Charge for the year	2,093,803	1,851,637
	Balance at end of the year	**7,296,040**	**5,202,236**
	Net book value at 31 March 2022	**8,767,005**	**10,860,809**
	Depreciation recognised on right-of- use assets		
	Depreciation recognised on each class of right-of-use assets, includes depreciation which has been expensed in the total depreciation charge in surplus or deficit (note 5), as well depreciation which has been capitalised to the cost of other costs.		
	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	2,778,937	2,606,424
	Two to five years	10,004,238	11,764,937
	More than five years	-	469,066
		12,783,176	14,840,427
	Less finance charges component	(2,187,240)	(2,337,932)
		10,595,935	12,502,495
	Non-current liabilities	8,490,211	10,654,886
	Current liabilities	2,105,724	1,847,609
		10,595,935	**12,502,495**

Significant Accounting Policies *(Continued)*
for the year ended 31 March 2022

PROPERTY, PLANT AND EQUIPMENT	Land (valuation)	Motor vehicles (cost)	Computer equipment (cost)	Furniture and fixtures (cost)	Office equipment (cost)	Laboratory Equipment (cost)	Leasehold Improvements (cost)	Laboratory Work in Progress (cost)	Total (cost/valuation)
Year ended 31 March 2022	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**
Cost or valuation									
Balance at beginning of the year	-	3,309,606	5,749,841	1,344,268	1,008,162	4,393,811	1,031,691	614,472	17,451,851
Additions	21,000,000	22,330	1,419,304	688,263	347,667	4,355,276	26,763	326,515	28,186,118
Disposals	-	-	(229,678)	-	-	-	-	-	(229,678)
Balance at end of the year	**21,000,000**	**3,331,936**	**6,939,467**	**2,032,531**	**1,355,829**	**8,749,087**	**1,058,454**	**940,987**	**45,408,291**
Depreciation									
Balance at beginning of the year	-	1,005,361	2,651,964	225,109	349,509	33,124	190,324	-	4,455,391
Charge for the year	-	468,636	1,717,963	203,364	242,678	1,592,568	281,890	-	4,507,099
Disposals depreciation	-	-	(200,166)	-		-	-	-	(200,166)
Balance at end of the year	**-**	**1,473,997**	**4,169,760**	**428,473**	**592,187**	**1,625,692**	**472,214**	**-**	**8,762,324**
Net book value at 31 March 2022	**21,000,000**	**1,857,939**	**2,769,707**	**1,604,058**	**763,642**	**7,123,395**	**586,240**	**940,987**	**36,645,967**
Year ended 31 March 2021	P	P	P	P	P	P	P	P	P
Cost or valuation									
Balance at beginning of the year	-	2,782,636	4,390,405	1,143,542	879,645	93,114	362,672	240,689	9,892,703
Additions	-	526,970	1,471,416	200,726	128,517	4,300,697	669,019	373,783	7,671,128
Disposals	-	-	(111,980)	-	-	-	-	-	(111,980)
Balance at end of the year	-	3,309,606	5,749,841	1,344,268	1,008,162	4,393,811	1,031,691	614,472	17,451,851
Depreciation									
Balance at beginning of the year	-	561,492	1,356,198	98,498	166,613	1,552	50,969	-	2,235,322
Charge for the year	-	443,869	1,393,833	126,611	182,896	31,572	139,355	-	2,318,136
Disposals depreciation	-	-	(98,067)	-	-	-	-	-	(98,067)
Balance at end of the year	-	1,005,361	2,651,964	225,109	349,509	33,124	190,324	-	4,455,391
Net book value at 31 March 2021	-	2,304,245	3,097,877	1,119,159	658,653	4,360,687	841,367	614,472	12,996,460

Additions above includes assets amounting to P7,186,118 (2021: P3,634,801) acquired through grant income and the remaining assets P21,000,000 (2021: P4,036,327) were donated by the Ministry of Health.

Notes to the Financial Statements *(Continued)*
for the year ended 31 March 2022

11	INTANGIBLE ASSETS	Computer software (cost) P	Computer software work in progress (cost) P	(cost) P
	Year ended 31 March 2022			
	Cost			
	Balance at beginning of the year	1,209,139	-	1,209,139
	Additions	2,082,044	328,726	2,410,770
	Balance at end of the year	**3,291,184**	**328,726**	**3,619,909**
	Transfers			
	Depreciation			
	Balance at beginning of the year	409,389	-	409,389
	Charge for the year	354,354	-	354,354
	Balance at end of the year	**763,744**	**-**	**763,744**
	Net book value at 31 March 2022	**2,527,440**	**328,726**	**2,856,166**
	Year ended 31 March 2021			
	Cost			
	Balance at beginning of the year	1,034,344	-	1,034,344
	Additions	174,795	-	174,795
	Balance at end of the year	**1,209,139**	**-**	**1,209,139**
	Depreciation			
	Balance at beginning of the year	227,307	-	227,307
	Charge for the year	182,082	-	182,082
	Balance at end of the year	**409,389**	**-**	409,389
	Net book value at 31 March 2021	**799,750**	**-**	799,750

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

12	ACCOUNTS RECEIVABLE	2022 P	2021 P
	Accounts receivable	146,621	258,096
	Lease deposit	171,375	171,375
	Non-financial instruments		
	Prepayments	1,327,957	605,152
	Staff advances	77,836	-
	Total trade and other receivables	**1,723,789**	**1,034,623**
	Financial instrument and non-financial instrument components of receivables		
	At amortised cost	317,996	429,471
	Non-financial instruments	1,405,793	605,152
		1,723,789	1,034,623

Notes to the Financial Statements *(Continued)*
for the year ended 31 March 2022

		2022	2021
12	**ACCOUNTS RECEIVABLE (CONTINUED)**	**P**	**P**
13	**CASH AND EQUIVALENTS**		
	Cash and cash equivalents consist of:		
	Bank balances	**37,695,691**	19,120,076
	Short-term investments	**-**	10,364
		37,695,691	**19,130,440**
	Credit quality of cash at bank and short term deposits, excluding cash on hand		
	The credit quality of cash at bank and short term deposits, excluding cash on hand are placed with reputed financial institutions which are registered in Botswana. The Authority's bankers in Botswana are not rated but each of these banks are subsidiaries of major South African or United Kingdom registered institutions.		
14	**DEFERRED INCOME**		
	The Authority received a total amount of P 110,356,017 as Government grant during the reporting period. Grants related to assets are recognises using the deferred income method.		
	The grant received has been deferred as per reconciliation below:		
	Government grants- related to non current assets		
	Opening balance of deferred government grant	**13,797,768**	8,465,975
	Assets purchased during the year	**30,516,181**	7,845,923
	Amortisation of grant related to assets	**(4,840,973)**	(2,500,217)
	Adjustment on asset retirement	**(29,512)**	(13,913)
	At the end of year	**3,443,464**	13,797,768
	Grants related to specific projects		
	Opening balance	**721,930**	-
	Grants received from EDCTP for specific projects	**3,293,797**	721,930
	Grants used for specific projects operating expenditure	**(691,082)**	-
	Grants disbursed to other beneficiaries	**(529,612)**	-
	At the end of year	**2,795,033**	721,930
	Total Deferred Income	**42,238,497**	14,519,698
15	**ACCOUNTS PAYABLE**		
	Financial instruments:		
	Payable to suppliers	**3,031,343**	1,561,370
	Provision for gratuity	**4,073,001**	5,286,664
	Provision for leave pay	**4,145,950**	3,145,513
		11,250,294	9,993,547
	Categorisation of accounts payable		
	At amortised cost	**11,250,294**	9,993,547
	Exposure to liquidity risk		
	Refer to note 16 Financial instruments and financial risk management for details of liquidity risk exposure and management.		

Notes to the Financial Statements *(Continued)*
for the year ended 31 March 2022

16 **FINANCIAL INSTRUMENTS AND RISK MANAGEMENT**

Categories of financial instruments		**2022**	**2021**
		P	**P**
Categories of financial assets			
	Note (s)	**Amortised cost**	**Amortised cost**
Assets as per the statement of financial position			
Accounts receivables	12	**317,996**	429,471
Cash and cash equivalents	13	**37,695,691**	19,130,440
		38,013,687	19,559,911
Categories of financial liabilities			
Liabilities as per statement of financial position			
Accounts payable	15	**11,250,294**	9,993,547
Finance lease obligations	9	**10,595,935**	12,502,495
		21,846,230	22,496,042

CREDIT RISK MANAGEMENT

The Authority's objective when managing capital(which includes reserves, working capital and cash and cash equivalents) is to safeguard it's ability to continue as a going concern in order to perform it's mandate. The Board is of the view that these objectives are being met. During the year ended 31st March 2022, the Authority did not have any borrowings. The Authority's operations are currently being sustained by the Government of Botswana.

FINANCIAL RISK MANAGEMENT

Overview
The 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.

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

The Authority does not have any 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

Notes to the Financial Statements *(Continued)*
for the year ended 31 March 2022

16 **FINANCIAL INSTRUMENTS AND RISK MANAGEMENT (CONTINUED)**

Credit risk (Continued)

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

		2022			2021		
		Gross carrying amount	**Credit loss allowance**	**Amortised cost/fair value**	**Gross carrying amount**	**Credit loss allowance**	**Amortised cost/fair value**
Accounts receivable	12	1,723,789	-	1,723,789	1,034,623	-	1,034,623
Cash and cash equivalents	13	37,695,691	-	37,695,691	19,130,440	-	19,130,440
		39,419,480	-	39,419,480	20,165,063	-	20,165,063

Liquidity risk

The Authority 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.

2022

		Less than 1 year	**2 to 5 years**	**Over 5 year**	**Total**	**Carrying amount**
Non-current liabilities						
Lease liabilities		-	8,490,211	-	8,490,211	**8,490,211**
Current liabilities						
Accounts payable	10	11,250,294	-	-	11,250,294	**11,250,294**
Lease liabilities	9	2,105,724	-	-	2,105,724	**2,105,724**
		13,356,019	**8,490,211**	**-**	**21,846,230**	**21,846,230**

2021

		Less than 1 year	2 to 5 years	Over 5 year	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**

Notes to the Financial Statements *(Continued)*
for the year ended 31 March 2022

17 **Cash flows from operating activities:**

Certain comparative amounts were reclassified for consistency with the current year presentation of financial statements. These reclassifications had no effect on the reported results of operations. Amounts previously reported in the statement of statement of cash flows for year 31 March 2021 have been restated for these reclassification. The material reclassification processed to these financial statements are as follows:

P215,260 interest income received reclassified from cashflows from operating activities to cashflows from investing activities.

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-1).
Members of Key Management	Dr. Stephen Ghanie (Chief Executive Officer) Mr. Harold Kuvenga (Director: Finance and Administration) Dr. Sinah Selelo (Chief Regulatory Officer) Dr. Nkaelang Modutlwa (Director: Product Evaluation and Registration) Dr. Seima Dijeng (Director: Inspections and Licensing) Dr. Parthasaraty Gurumurthy (Director: Pharmacovigilance) Mr. Mooketsi Maphane (Director: Human Resources)
Main Financier	Government of the Republic of Botswana

	2022	2021
Related party transactions	**P**	**P**
Compensation to directors and other key management		
Salaries and other short term benefits	**7,360,025**	7,049,777
Gratuity	**1,898,003**	2,448,505
	9,258,028	9,498,282
Grant received		
Government of Republic of Botswana	**110,356,017**	46,455,670
Transactions with other parastatals		
Botswana Telecommunication Corporation - Telephone	**1,135,810**	599,503
Botswana Power Corporation- Electricity	**512,406**	479,358
Sitting allowance		
Medicines Regulatory Board	**636,870**	393,435
Related party balances		
Amounts included in other payables regarding related parties		
Botswana Telecommunication Corporation - Telephone	**71,531**	68,127
Botswana Power Corporation- Electricity	**45,824**	54,805
Botswana Unified Revenue Services - Paye	**705,054**	32,031

19 **Events during and after the reporting period**

The directors of the authority are not aware of any subsequent events which may require disclosure or adjustment to the financial statements.

Notes to the Financial Statements *(Continued)*
for the year ended 31 March 2022

		2022	2021
		P	P
Revenue			
Amortisation of deferred income		4,870,485	2,514,130
Grant received from the Government of Botswana		79,839,836	42,646,074
Other grants received		691,082	-
	3	**85,401,402**	**45,160,204**
Other operating income			
Other operating income	4	9,575,495	8,190,629
Operating expenses			
Amortisation and depreciation	5	(6,955,257)	(4,351,855)
Auditors remuneration - external auditors	5	(75,623)	(70,560)
Bank charges		(84,035)	(61,073)
Computer expenses		(1,714,677)	(1,999,625)
Consultancy fees		(2,630,985)	(1,773,402)
Consulting and professional fees - legal fees		(21,067)	(237,990)
Consumables		(584,411)	(189,818)
Donations		(43,246)	(129,768)
Employee costs	5	(51,347,204)	(44,806,155)
Governance costs		(1,094,776)	(667,571)
Insurance		(288,040)	(258,107)
Motor vehicle expenses		(350,077)	(80,932)
Postage		(17,333)	(9,189)
Printing and stationery		(204,678)	(406,864)
Publicity and awareness		(2,237,558)	(1,430,188)
Records management		(363,739)	(253,981)
Repairs and maintenance		(687,080)	(1,326,514)
Security		(219,166)	(213,261)
Seminars and conferences		(1,668,807)	(1,209,794)
Short term lease		(53,248)	(35,004)
Staff welfare		(926,580)	(386,615)
Technical expenses		(1,255,910)	(490,716)
Telephone and fax		(1,689,429)	(1,406,460)
Training		(1,205,722)	(1,325,454)
Travel and accomodation		(2,156,496)	(773,250)
Utilities		(590,676)	(549,912)
		(78,465,818)	**(64,444,058)**
Operating surplus/(deficit)		**16,511,079**	**(11,093,225)**
Investment income	6	30,496	215,260
Finance costs	7	(744,026)	(780,139)
Surplus / (Deficit) for the year		**15,797,550**	**(11,658,104)**

The supplementary information presented does not form part of the annual financial statements and is unaudited.

Notes

Notes