BOTSWANA MEDICINES REGULATORY AUTHORITY

ANNUAL REPORT 2023/24

Navigating Growth: Lessons Learned on the Path to Maturity Level 3

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BOMRA MEDICINES REGULATORY AUTHORITY
Promoting Access to Safe Medicines

BoMRA
MEDICINES REGULATORY AUTHORITY

Botswana Medicines Regulatory Authority or BoMRA 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.

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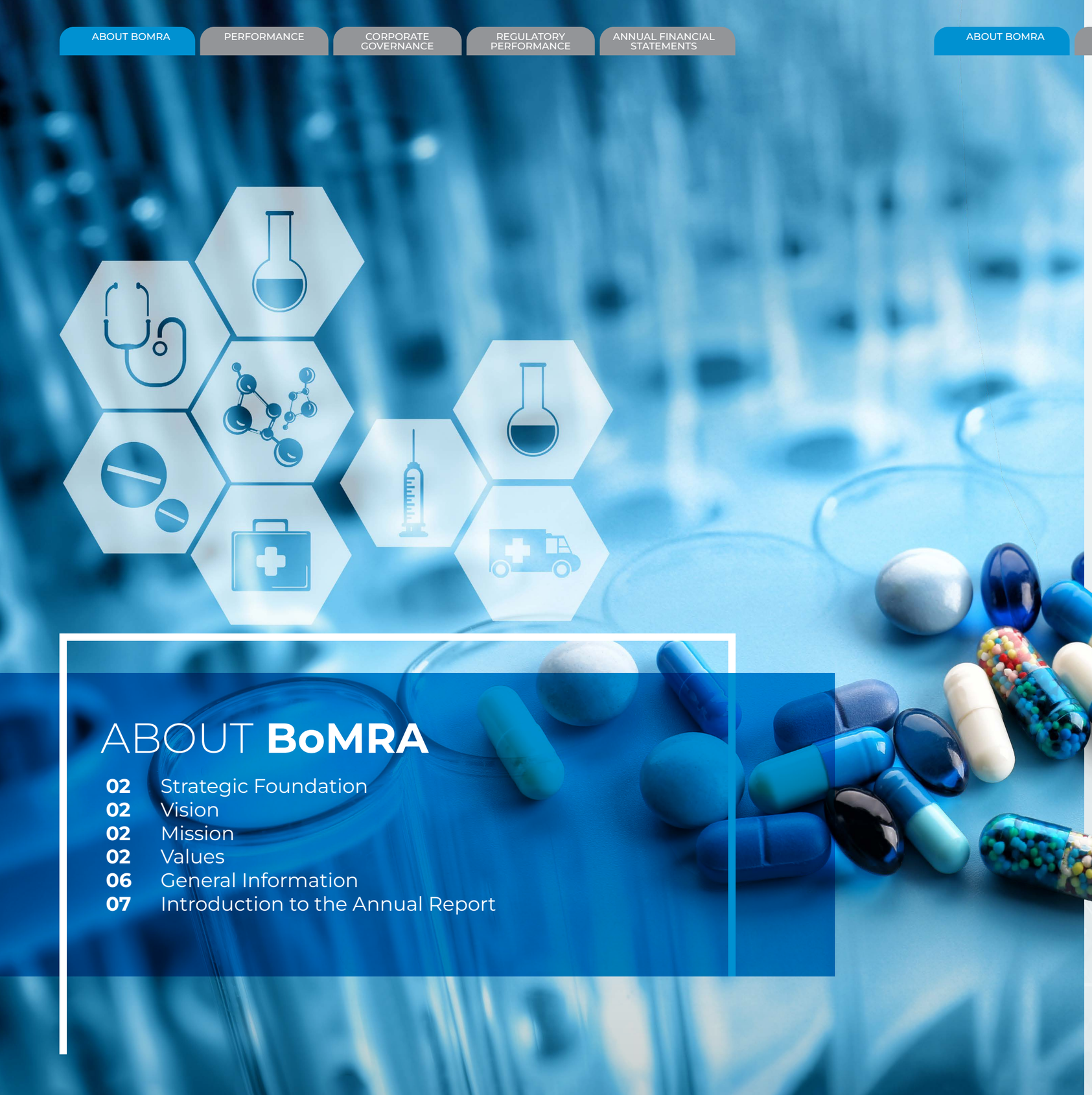

ABOUT **BoMRA**

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STRATEGIC **FOUNDATION**

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

Our Vision

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

Our Mission

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

Our Values

Integrity
Customer Focus
Efficiency
Teamwork

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STRATEGIC **FOUNDATION** [Continued]

Enhance clinical trials controls to ensure good clinical practice principles are adhered to

Establish post-marketing surveillance to monitor safety and quality of the medicines in the market

Strengthen Inspection and Licensing of pharmaceutical premises and Import/Export Controls

Establish Laboratory Services

Establish and implement a Quality Management System

Leverage ICT Services to enable efficiency

Enhance registration function

Strengthen Inspection and Licencing of Premises and Import and Export controls

Ensure Compliance to Legislation

Establish Strategic Partnerships and Collaborations

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") of 2013 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

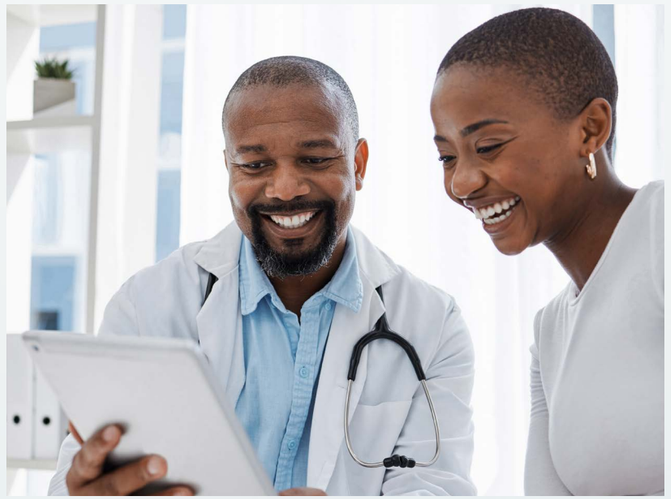
The Medicines Regulatory Board was created in terms of Section 6 of the MRSA to supervise and control the administration and financial management of the Authority; and to formulate matters of policy for the purpose of providing general or specific guidance to the Authority in respect of the performance of its functions under the MRSA of 2013.

The Chief Executive Officer ("CEO") is appointed by the Minister of Health ("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 of 2013, 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 of 2013 by the Chairperson of the Board, Dr. Kegomoditswe Biki Maphane.

INTRODUCTION TO THE **ANNUAL REPORT**

for the Year ended 2023-24



As an institution within the healthcare landscape of Botswana, BoMRA upholds a critical mandate underpinned by the Medicines and Related Substances Act (MRSA) of 2013, establishing us as a corporate entity dedicated to the regulation and oversight of medicines and related substances within the nation.

Our legislative mandate, as outlined in Section 3 of the MRSA of 2013, positions the Authority as the cornerstone of ensuring the safety, efficacy, and quality of human and veterinary medicines, medical devices, and cosmetics.

This encompasses a comprehensive remit, from product evaluation and registration to licensing, enforcement, and the critical domains of pharmacovigilance and clinical trials. The significance of our role cannot be understated, as it directly impacts the health and wellbeing of the Botswana population and extends to the regulatory oversight of products that are imported, consumed, and exported from our country.

Since BoMRA's establishment in June 2018, we have transcended the limitations of previous frameworks to embrace a more holistic and inclusive regulatory approach. Our evolution from a unit within the Ministry of Health, as per the Drugs and Related Substance Act of 1992, to a fully-fledged authority, underscores our commitment to ensuring that all medicinal products within our jurisdiction meet the highest standards of quality, safety, and efficacy.

The governance structure of BoMRA, led by the Medicines Regulatory Board, ensures diligent supervision, control, and policy formulation, guiding the Authority in fulfilling its functions. This structure is anchored by the Chief Executive Officer (CEO) and is supported by senior officers and employees committed to our Mission. The Board, with the Chairperson at its helm, represents the highest echelon of governance, embodying our commitment to accountability and excellence in the execution of our duties.

As we reflect on the past year, this report not only documents our activities, achievements, and challenges but also reinforces our strategic direction and commitment to public health. We hope that it serves as a testament to our ongoing dedication to safeguarding public health through the rigorous regulation of medicines and related substances. It is a privilege to serve the people of Botswana in this capacity, and we remain steadfast in our pursuit of excellence and innovation in the regulatory domain.

BoMRA invites all stakeholders, partners, and the public to engage with the contents of this Annual Report, which not only highlights our accomplishments, but also sets the stage for future endeavours in our continuous journey towards enhancing healthcare regulatory frameworks in Botswana.

PERFORMANCE

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CHAIRPERSON'S **REPORT**

It is a privilege to share my report as Board Chairman of BoMRA on the period under review, being the financial year 2023-4.

A common African proverb tells us, 'Little by little, the bird builds its nest,' embodying the patience and perseverance needed for steady progress. In this spirit, we continued building a robust regulatory foundation, steadily advancing toward Maturity Level 3 (ML3).

These words speak to the importance of patience, perseverance, and steady progress on the path to achieving one's goals. Such is the case for us, and certainly within this period as we marched onward in navigating growth on the path to ML3. We made transformative strides in our journey, acknowledging both achievements and challenges along our path to becoming a fully operational, world-class regulatory authority. What remains unwavering and ambitious are our goals; however, the foundation laid in this period established a solid platform for the sustained growth and governance standards required to achieve ML3. A pivotal development in the period under review was a view towards confirming a substantive Chief Executive Officer (CEO), as the CEO was in the interim engaged in an acting capacity. This represents a turning point in BoMRA's leadership, for we recognised then that having a committed CEO at the helm would bring new stability and direction, enabling more decisive governance, strategic alignment, and a clarified long-term vision.

The regulatory bill, developed in collaboration with mature regulatory bodies like the Tanzania Medicines Regulatory Authority, is foundational to achieving ML3.

As part of our path to ML3, we also welcomed a pre-assessment visit from the World Health Organization (WHO). This visit provided an invaluable opportunity for BoMRA's leadership to engage directly with WHO experts, facilitating preliminary evaluations and capacity-building sessions. Through collaborative stakeholder meetings involving the Board, management, and the Ministry of Health, we gained greater clarity about the requirements to achieve ML3. WHO's insights guided our internal evaluations and provided an objective view of our current position and the steps necessary for progress. This partnership with WHO underscores our dedication to regulatory rigour and global standards, creating a concrete framework for our ML3 aspirations.

In enhancing our governance capabilities, this year presented unique opportunities to strengthen Board oversight and alignment with best practices. We prioritised Board education by exposing members to mature ML3 regulatory authorities, offering first-hand insights into what an ML3 organisation should embody. These efforts have deepened the Board's understanding of the regulatory mandate and the intricacies of BoMRA's governance responsibilities. Such exposure enhances the Board's ability to make well-informed, strategic decisions, fostering richer dialogue and alignment with international regulatory benchmarks.

While we celebrate our achievements, we also recognise the learnings and challenges – in equal measure - that we encountered. BoMRA had set an ambitious goal to achieve ML3 by the close of this strategic cycle, which we were unable to meet. Rather than viewing this as a setback, we see it as an opportunity for reflection, learning, and recalibrating our approach. This period has allowed us to reframe our focus, with plans to accelerate our journey to ML3, emphasising the urgency and commitment needed for this milestone. We acknowledge that achieving ML3 is an ongoing process, requiring constant progress and adaptability. You will read more on this in the CEO's report.

One notable challenge has been around our legal framework. The regulatory bill, developed in collaboration with mature regulatory bodies like the Tanzania Medicines Regulatory Authority, is foundational to achieving ML3. While significant progress was made in drafting the bill, challenges in navigating governance processes and securing legislative ratification persist. Securing this legislative support is essential for our ML3 progression, as it will provide the structural backing needed for our expanded mandate. Attaining ML3 will also catalyse local pharmaceutical manufacturing, enabling Botswana to produce and potentially export high-quality medical products.

Our governance structure has also evolved with an emphasis on risk management and audit processes. While previously understaffed, the development of our risk management and internal audit functions remains a priority as we work towards building a robust governance framework. In the coming period, we plan to fully integrate risk management with internal audit capabilities, enhancing BoMRA's

CHAIRPERSON'S **REPORT**

oversight and reinforcing a culture of accountability and proactive governance.

BoMRA's next chapter centres on "ML3 and Beyond." Achieving ML3 is not the final destination; rather, it is a step towards an even higher standard. Our vision is bigger than this alone, and our commitment to ensuring the safety, efficacy, and quality of medical products on the market is the driving force behind our ambition. We aim to position BoMRA as a regional leader and centre of excellence in pharmacovigilance, offering a benchmark for other regulatory bodies on the continent, and I have every confidence we are on our way towards making this vision a reality.

We remain steadfast in our mission to protect public health through sound regulation. The 2023/24 period has highlighted the strength of our leadership, the depth of our commitment, and the importance of strategic partnerships. Ours is a journey of growth and a commitment to excellence, ensuring BoMRA remains a guardian of health, safety, and quality for Botswana and beyond, a proverbial nest to benefit all in our beautiful Botswana and indeed our beautiful Africa.

Dr. Kegomoditswe Biki Maphane
Board Chairman

ACTING CHIEF EXECUTIVE **OFFICER'S REPORT**

It is both a privilege and an honour to reflect on the period under review, a formative period of great progress for all of us at BoMRA.

Our theme, "Navigating Growth: Lessons Learned on the Path to Maturity Level 3," encapsulates a journey defined by intense learning, adaptation, agility and resilience. While we had aimed to attain Maturity Level 3 (ML3) by the culmination of our maiden strategic plan within this year, we made substantial progress in our journey and laid a strong foundation for unlocking further growth towards this goal in the early part of the new strategic plan. As I reflect on this period, I present my report as four key lessons learned during the year, for we are nothing if not an agile, growing and learning organisation.

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Lesson 1: Priorities and Nuanced Strategic Focus Are Essential

My acting CEO appointment, which began a little earlier than the commencement of the reporting period in January 2023, meant that I needed to quickly transition into a new role of elevetaed responsibility and accountability. I needed to define my leadership agenda and give assurance of stabilty to the teams during this period of transitioning. Throughout this period, my leadership approach emphasised transparency, inclusivity, and stakeholder engagement—both internally and externally. This allowed us to proactively address challenges and co-create a vibrant future for BoMRA and the broader stakeholder base. Clear priorities and a strategic focus are essential, and maintaining this focus during the year was critical to the progress we achieved.

Adapting and reframing our strategy around regulatory harmonization and capacity building became central to navigating our small market's unique challenges. Improving access to medicines by slashing registration timelines by up to 50% of the original timelines was a key strategic priority. As the pharmaceutical landscape evolves, adaptability, innovation, and public safety remain critical to our regulatory frameworks and operational success.

Lesson 2: Milestones and Achievements as a Source of Continued Learning

This year, BoMRA reached several significant milestones that reflect our commitment to capacity building, regulatory excellence, and stakeholder collaboration. Through partnerships with key international stakeholders, including the Bill and Melinda Gates Foundation and the Global Fund, we secured critical funding that strengthened both our operational capabilities and our ability to influence regional developments. These partnerships, focused on enhancing our regulatory framework, continue to play a key role in shaping our impact across multiple sectors.

"While we had aimed to attain Maturity Level 3 (ML3) by the culmination of our maiden strategic plan within this year, we made substantial progress in our journey and laid a strong foundation for unlocking further growth towards this goal in the early part of the new strategic plan."

Our appointment to the Governance structures of the SADC regulatory Harmonisation Initiative known as ZaZiBoNa was a key milestone as we are now able to influence regulatory frameworks within the region. The ZaZiBoNa initiative promotes harmonisation across the continent, improving access to essential medicines and supporting the industry's growth. As a result, we are able to register products that have been assessed through the ZaZiBoNa work-sharing pathway within 3 months. We have seen a significant expansion of our regulatory scope in the area of cosmetics, medical devices as well as veterinary medicines. Additionally, establishing strategic functions like the internal audit and strategy office has helped strengthen our governance, integrity and build long-term sustainability.

ACTING CHIEF EXECUTIVE **OFFICER'S REPORT** [Continued]

Lesson 3: Challenges and Responses Shape the Future

While we celebrate our achievements, the period under review was not without its challenges. Budget constraints, delayed legislation, and substandard and falsified (SF) medical products remained key hurdles. These challenges, particularly SF products, were exacerbated by limited human resources and a squeezed operational budget. However, BoMRA responded by implementing cost recovery strategies and strengthening donor funding to reduce reliance on government subventions and focusing on financial sustainability.

Recognising the need for effective leadership in driving organisational performance, all middle managers were enrolled for a management development program. The program equipped the team with the tools needed to navigate a complex leadership environment. This is in effect part of the broader talent management framework which will be fully rolled out in the coming financial year. By developing talent and implementing succession planning, this will foster resilience and operational integrity within the organisation.

Lesson 4: Realistic and Relevant Key Performance Indicators (KPIs) Matter

Clear KPIs were critical to our progress during the year, set as being relevant and realistic to our strategy and to the environment against which we operated. Our top three KPIs focused on product registration timelines, partnership outcomes, and public awareness initiatives. These indicators were essential for tracking our success, particularly in improving access to medicines through regulatory harmonisation efforts. Collaboration with international partners and reliance on established regulatory processes helped streamline decision-making and improved the monitoring and reporting mechanisms.

Product registration, as one of our core focus areas, is central to ensuring access to medicines. Tracking decisions and outcomes based on these KPIs allowed BoMRA to assess its regulatory efficiency, aligning with the population's needs and facilitating industry growth. Additionally, public education and legislative progress remained a priority, as delays in these are necessary for industry compliance improvement.

Outlook: Future Development and Public Awareness

Several key takeaways emerged from this year. First, patience and adaptability are crucial in navigating a complex regulatory environment, particularly when legislative progress is delayed.

The need for strong regulatory frameworks and stakeholder engagement, as well as public education, was reinforced throughout the year. These efforts, combined with strategic leadership development, will continue to shape our future growth.

Looking ahead, BoMRA's focus remains on achieving ML3 while ensuring sustainable growth beyond this milestone. Our strategic direction for 2024-2029 will emphasize leverging ICT, strengthening of reliance and recognition, implementation of initiatives for manuafaturing inductry faciliation, stregnthening of patent safety, all supported by improved organisational capability and capacity.

Appreciation

As I reflect on the key takeaways from this period, I believe we are well on track towards our united ambition not only for ML3 but well beyond, as established through the BoMRA strategy 2025-2030. Closer to our hearts and our efforts and thus crucial in our next steps are the importance of public education for improved patient safety, stakeholder engagement, and regulatory reliance and recognition.

Developing strong collaborations has been vital in advancing our mission. BoMRA's commitment to

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building a resilient and impactful regulatory authority is stronger than ever. We will continue to build on the lessons learned this year.

None of this exists in a vacuum. And so, I extend my deepest gratitude to our stakeholders, partners, and staff for their unwavering support. Together, we will continue to build our organisation to Maturity level 4 and beyond This is a BoMRA not simply of and for the future, but of and for sustainable progress and deepened impact.

Dr. Seima Dijeng
Acting CEO

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CORPORATE **GOVERNANCE**

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BOARD **MEMBERS**

1. Dr. Lorato Mangadi-Mokama **2.** Dr. Ditiro Duma Coyne **3.** Ms. Tiny Ralefala
4. Dr. Seima Dijeng **5.** Dr. Kegomoditswe Biki Maphane (Chairperson)

6. Ms. Matshidiso Matome **7.** Ms. Mmama Mhlanga-Fichani **8.** Dr. Kobedi Segale
9. Dr. Kefentse Motshegwa **10.** Mr. Modisa Kebonyemodisa **11.** Ms. Elizabeth Kelentse
12. Dr. Pamela Smith-Lawrence (in absentia)

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MANAGEMENT **TEAM**

1. Ms. Ropafadzai Hove **2.** Dr. Parthasarathi Gurumurthy **3.** Mr. Harold Kuvenga **4.** Mr. Bathusi Kgosietsile

5. Dr. Seima Dijeng (Acting CEO) **6.** Ms. Zukiswa Raditladi
7. Mr. Nonofo Thipe **8.** Ms. Shirley Pine **9.** Mr. Israel Kgosidiile

LEGAL AND GOVERNANCE **REPORT**

This Governance Report for the financial year 2023-24 outlines BoMRA's commitment to maintaining the highest standards of corporate governance, ensuring transparency, accountability, and ethical leadership in all operations.

Board Responsibilities and Composition

The Board's primary responsibilities include:

- Setting strategic direction for BoMRA's affairs and operations
- Supervising and controlling the administration and financial management of BoMRA
- Formulating policies to guide BoMRA in performing its functions under the Medicines and Related Substances Act (MRSA)
- Ensuring compliance with statutory and regulatory requirements
- Overseeing risk management and internal control systems

The Board of Directors of BoMRA comprises diverse professionals with expertise in various fields as stipulated in Section 7 of the MRSA. This includes the following Members appointed by the Honourable Minister of Health:

Table 1: BoMRA Board Members

	Board Member Name	Appointed	Term Expires	**Skills** (As per section 7 of the MRSA)	Term No.
1	Dr. Kegomoditswe Biki Maphane (Chairperson)	01/10/ 2021	30/09 2024	Medicine	1st
2	Dr. Lorato Mangadi (Vice-Chairperson)	01/10/ 2021	30/09 2024	Medicine	1st
3	Dr. Ditiro Coyne	01/10/ 2021	30/09 2024	Veterinary Medicine	1st
4	Dr. Kobedi Segale	01/10/ 2021	30/09 2024	Veterinary Medicine	1st
5	Ms. Matshidiso Matome	01/11/2022	31/10/ 2025	Pharmacy	1st
6	Ms. Tiny Ralefala	01/11/2022	31/10/ 2025	Business Management	1st
7	Ms. Mmama Mlhanga-Fichani	01/11/2022	31/10/ 2025	Human Resources	1st
8	Ms. Elizabeth Kelentse	01/11/2022	31/10/ 2025	Pharmacy	1st
9	Mr. Modisa Kebonyemodisa	01/11/2022	31/10/ 2025	Law	1st
10	Dr. Pamela Smith-Lawrence (Ex Officio – Director of Health Services)	24/10/ 2022	N/A	Medicine	1st Term
11	Dr. Kefentse Motshegwa (Ex Officio – Director of Veterinary Services)	13/04/ 2023	N/A	Veterinary Medicine	1st Term
12	Dr. Seima Dijeng (Ex Officio)	01/01 2023	N/A	N/A	N/A

☑ **= Present A = Apology N/A= Not Applicable**

Note:

- Dr. Pamela Smith-Lawrence (Ex Officio–Director of Health Services) exited the Board during the year.
- Dr. Kefentse Motshegwa joined the Board as a new Ex Officio member, by virtue of his appointment as the Director of Veterinary Services.

The Board held the following sittings during the period under review:

Table 2: BoMRA Board Members Sitting Attendance

	Meeting Dates / Board Member Name	18/04/2023	20/07/2023	07/08/2023	24/10/2023	21/11/2023
1	Dr. Kegomoditswe Biki Maphane	☑	☑	☑	☑	☑
2	Dr. Lorato Mangadi	☑	A	☑	☑	☑
3	Dr. Ditiro Coyne	☑	☑	☑	☑	☑
4	Dr. Kobedi Segale	A	A	☑	A	A
5	Ms. Matshidiso Matome	☑	A	A	☑	☑
6	Ms. Tiny Ralefala	☑	A	A	☑	☑
7	Ms. Mmama Mlhanga-Fichani	A	☑	☑	☑	☑
8	Ms. Elizabeth Kelentse	☑	☑	☑	☑	☑
9	Mr. Modisa Kebonyemodisa	A	☑	A	☑	☑
10	Dr. Pamela Smith-Lawrence	☑	A	☑	N/A	N/A
11	Dr. Kefentse Motshegwa	A	A	☑	A	A
12	Dr. Seima Dijeng	☑	☑	☑	A	☑

☑ **= Present A = Apology N/A= Not Applicable**

Board Committees

To enhance effectiveness and ensure comprehensive oversight, the Board has established six (6) Committees in accordance with Section 16 of the MRSA. Each Committee operates under Board-approved Terms of Reference that clearly define its scope and functions.

All Committees are chaired by a Board member to ensure direct Board oversight and accountability and accordingly each Committee includes at least one Board member. The Board Chairperson is not a member of any Committee but may attend meetings by invitation or as required, ensuring impartial oversight of Board and Committee activities.

LEGAL AND GOVERNANCE **REPORT** [Continued]

Governance Committees

The following three (3) Committees are comprised exclusively of Board members and assist with overseeing governance aspects of the Board:

Table 3: Finance, Audit and Risk Committee Members and Attendance

Finance Audit and Risk Committee (FARC)

Oversees financial controls, budgeting, internal and external audits, risk management, and information technology systems, ensuring effective financial management, compliance with reporting standards, robust risk oversight, and the resilience and security of IT frameworks and policies.

Members	Ms. Tiny Ralefala (Chairperson)	Dr. Lorato Mangad	Dr. Pamela Lawrence-Smith
15/06/2023	☑	☑	☑
02/11/2023	☑	☑	N/A

Table 4: Human Resources Committee Members and Attendance

Human Resources Committee (HRC)

Oversees and recommends the Human Resources strategy, succession planning for key positions, executive appointments, organisational changes, Board member nominations, CEO performance objectives, and policy development, ensuring alignment with the Authority's mandate and strategic objectives

Members	Ms. Mmama Mhlanga-Fichani (Chairperson)	Dr. Ditiro Coyne	Ms. Elizabeth Kelentse
18/04/2023	☑	☑	☑
21/06/2023	☑	☑	☑
25/06/2023	☑	☑	☑
23/06/2023	☑	☑	☑
17/01/2023	☑	☑	☑
13/11/2023	☑	☑	☑
14/11/2023	☑	☑	☑

☑ **= Present A = Apology N/A= Not Applicable**

Table 5: Governance and Nominations Committee Members and Attendance

Governance and Nominations Committee (GNC)

The Governance and Nominations Committee oversees the composition and appointment of the Board and its Committees, ensuring the right balance of skills and competencies; manages Board structure, communication, and evaluation processes; ensures sound governance, ethics, and integrity practices; and supervises shareholder agreements and corporate social responsibility programmes, promoting sustainability and transparency.

Members	Mr. Modisa Kebonyemodisa (Chairperson)	Ms. Mmama Mhlanga-Fichani	Ms. Tiny Ralefala
07/09/2023	☑	A	☑

☑ **= Present A = Apology N/A= Not Applicable**

Technical Committees

The Board has established three (3) technical Committees which comprise at least one Board Member, serving as the Chairperson and various persons with expertise in specific areas as may be required for execution of BoMRA's mandate. The Committees are the Registration Committee, the Pharmacovigilance Advisory Committee and the Licensing and Enforcement Committee. These are constituted as follows:

Table 6: Registration Committee Members

Registration Committee

The Registration Committee oversees the registration of medicines and medical devices, ensuring they meet safety, quality, and efficacy standards as per the Medicines and Related Substances Act. It approves or rejects applications, considers post-registration regulatory decisions, reviews manufacturer compliance, evaluates pharmacovigilance recommendations, and recommends relevant procedures, standards, and policies to the Authority and Board.

Committee Member Name	Appointment Date	Term Expiry Date
Ms. Elizabeth Kelentse (Chairperson)	01/11/2022	02/02/2025
Dr. Samantha Letsholo	01/04/2022	02/07/2024
Ms. Lesego Moetedi	01/04/2022	02/07/2024
Dr. Goabaone Rankgoane-Pono	01/04/2022	02/07/2024
Dr. Batshanani Bontsi-Busang	01/04/2022	02/07/2024
Dr. Celda Molake-Tiroyakgosi	01/04/2022	02/07/2024
Dr. Tendani Gaolathe	01/04/2022	02/07/2024

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Table 7: Pharmacovigilance Advisory Committee Members

Pharmacovigilance Advisory Committee

The Pharmacovigilance Advisory Committee guides pharmacovigilance functions and clinical trial conduct under the MRSA. It assesses risk-benefit profiles of registered medicines, recommends safety and efficacy measures pre- and post-marketing, reviews periodic safety reports and promotional materials, advises on clinical trial applications, and proposes policies and standards related to pharmacovigilance and clinical trials. The Committee also collaborates with other committees to ensure comprehensive medicine safety and efficacy oversight throughout the product lifecycle.

Committee Member Name	Appointment Date	Term Expiry Date
Ms. Matshediso Matome (Chairperson)	01/11/2022	02/02/2025
Dr. Lebapotswe Tlale	01/05/2022	02/08/2024
Dr. Kerapetse Sehularo	01/05/2022	02/08/2024
Mrs. Bakgaki Ratshaa	01/07/2021	02/10/2023
Dr. Tom K. Baaisi	01/12/2020	02/03/2023
Dr. Edwin K. Katse	24/10/2023	25/01/2026
Dr. Botshelo T. Kgwaadira	24/10/2023	25/01/2026
Dr. Benjamin Radihephi	24/10/2023	25/01/2026
Dr. Lesego Gabaitiri	24/10/2023	25/01/2026

Table 8: Licensing Committee Members

Licensing and Enforcement Committee

The Licensing and Enforcement Committee oversees BoMRA's inspections, licensing, and enforcement activities. It recommends policies and approves guidelines for these functions, including import/export control of regulated products. The Committee monitors compliance, proposes regulatory improvements, approves enforcement criteria, reviews reports, hears appeals, and recommends licensing fees. It also supports local pharmaceutical manufacturing initiatives and advises on industry compliance improvements, ensuring comprehensive oversight of medicinal product regulation throughout the supply chain.

Committee Member Name	Appointment Date	Term Expiry Date
Dr. Kobedi Segale (Chairperson)	01/10/2021	02/01/2024
Ms. Pauline Tsiu	31/10/2023	01/02/2026
Mr. Ofitlhile Busang	31/10/2023	01/02/2026
Dr. Ellen Kahovere	31/10/2023	01/02/2026
Dr. Batatu Mazhani	31/10/2023	01/02/2026
Mr. Pilot Masunga	31/10/2023	01/02/2026
Mr. Vivek Desai	31/10/2023	01/02/2026

Strategic Overview

The year under review marked the culmination of BoMRA's inaugural five-year strategy. The primary objective was to attain World Health Organization (WHO) Maturity Level 3, as assessed by the WHO Global Benchmarking Tool for medicines regulators. While significant progress was made during BoMRA's first five (5) years, this strategic goal was not fully achieved due to challenges in revising the MRSA. The Board recognises that legal empowerment through MRSA revision is crucial for BoMRA to formally adopt good regulatory practices and achieve full functionality. Despite the delay, BoMRA remains committed to reaching Maturity Level 3. The Board, Management, and officers of BoMRA are developing a new five-year strategy that aims to surpass this initial goal, building on the foundation laid during the first strategic period.

Governance Overview

The Medicines Regulatory Board, established under Section 6 of the Medicines and Related Substances Act (MRSA), serves as BoMRA's governing body and has put in place a governance framework to ensure compliance with best practices and optimise its function in supporting the BoMRA to achieve its mandate. This governance framework is built on three key pillars:

1. The Medicines and Related Substances Act (MRSA)
2. Governance requirements for statutory bodies, including those set by the Public Enterprises Evaluation and Privatisation Agency (PEEPA) and the Botswana Accountancy Oversight Authority (BAOA)
3. Voluntary adoption of the King IV Corporate Governance Code

This robust framework ensures that BoMRA operates in compliance with legal requirements while adhering to international best practices in corporate governance.

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LEGAL AND GOVERNANCE **REPORT** [Continued]

Governance Enhancements

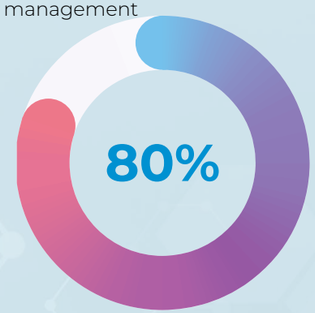
Board Charter and Shareholder Compact

To guide its operations effectively, the Board has adopted a Board Charter aligned with the Governance Framework, including King IV. Additionally, a shareholder compact has been established with the Government of Botswana, represented by the Ministry of Health & wellness defining the relationship and ensuring alignment and oversight.

King IV Compliance Review

In 2023-24, BoMRA conducted a self-assessment of its compliance with the King IV Corporate Governance Code, achieving an 80% adherence rate to applicable principles. This exercise identified areas for enhancement, including:

- Board evaluation processes
- Corporate citizenship responsibilities
- Legal compliance
- Stakeholder management



Adherence rate

Thirty-one (31) key actions across all principles have been identified for implementation in the upcoming financial year. Following implementation of the action, BoMRA plans to engage an independent third-party to assess compliance and provide impartial recommendations for further governance enhancements.

Ethical Leadership

The Board has prioritised ethical leadership by:

- Prescribing ethical standards within the Board Charter
- Enhancing the Conditions of Service to reinforce ethical standards for all employees
- Approving a specific Code of Conduct for BoMRA inspectors, recognising their unique role and powers

Future Focus

Looking ahead, the Board will prioritise:

- Developing and implementing the new 5-year strategy
- Addressing identified governance gaps, including Board evaluation processes and stakeholder management
- Engaging an independent third-party to assess our compliance with the King IV Code
- Continuing efforts to revise the MRSA to empower BoMRA in adopting good regulatory practices

The Board remains committed to upholding the highest standards of corporate governance and working to continue to drive BoMRA towards achieving its strategic objectives. We believe that our enhanced governance practices will contribute significantly to BoMRA's effectiveness as a regulatory authority and its ability to serve Batswana.

HUMAN RESOURCES **REPORT**

Shirley Amogelang Pine
Director, Human Resource & Organisational Development

Human capital is widely regarded as one of an organisation's most critical assets, driving progress and helping to achieve its mandate. This is no less true at BoMRA, where the Authority continues to ensure we have the right people in the right roles, creating value and living our Values.

The review period was pivotal, characterised by both simultaneous transition and stabilisation, with significant strides made across BoMRA's HR ecosystem. The Authority focused on stabilising and strengthening its people and culture initiatives, and this was clearly driven in the period under review.

Key considerations

Reflecting on the period, we ought to be cognisant of the fact that not only were there gaps and changes at Board and CEO levels (a newly constituted Board and an Acting CEO appointed following the departure of the previous CEO), as well as the fact that several strategic executive roles were vacant. This included the role of HR Director, with an appointment made in September 2023. Other notable executive and management vacancies filled in the period included Director Department of Product Evaluation and Registration, Manager Internal Audit and Manager Strategy & Risk.

On the one hand, this context meant that there was a veritable slowdown in activity and progress from a people perspective, and yet an unhindered level of progress in a wider strategic mandate delivery of the Authority. This can be explained in two parts, based on new recruits and appointments, and in the existing staff complement who held down the proverbial fort.

The subsequent stabilisation phase saw the implementation of a transition plan, with the Director of Finance temporarily overseeing HR functions. This transition enabled us to re-evaluate our strategies and focus areas, ensuring continued commitment to fostering a high-performance culture and an enabling work environment.

Core objectives

Three (3) core objectives guided our efforts:

1. **Cultivating a highly engaged, motivated and productive workforce culture:**

   The Authority embarked on initiatives to build leadership capabilities and enhance training programmes, resulting in a significant increase in enrolment in Management and Executive Development Programmes. Investment was also made in support for staff in emotional wellbeing, leveraging a strategic partnership with ICAS to help ensure more psychological safety and speaking up culture across the Authority.

2. **Attracting, Retaining, and Developing Talent:**

   Domestication of the World Health Organisation competency framework initiated to ensure alignment with industry standards and facilitate talent development and retention, supporting the wider ambition to scale up institutional capacity to deliver the full spectrum of medicine regulatory services. The initiative was supported by skills-building activities, including learning visits to Ghana, Tanzania, South Africa, and Zimbabwe, which resulted in tangible outcomes by the end of the reporting period.

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HUMAN RESOURCES **REPORT** [Continued]

3. Enhancing HR Management Systems:

We focused on enhancing HR policies, with two key policies rolled out: Conditions of Services and Talent management. The Conditions of Service entailed the promotion of equal employment opportunities, a robust performance management system, and a strong focus on staff training and development. These elements encourage a high-performance culture where employees are recognised and rewarded for their contributions, it also highlights the importance of work-life balance through clear policies on working hours, leave entitlements, and flexible work arrangements. Additionally, the Conditions of Service emphasise the promotion of a safe and respectful work environment by addressing health and safety standards, employee conduct, and grievance procedures. Together, these policies foster a culture of inclusivity, continuous improvement, and mutual respect, aligning with BoMRA's strategic objectives and core values, while the Talent management encompasses continuous improvement and accountability across all management levels, with a focus on developing critical skills and creating structured talent pools.

Through performance evaluations, succession planning, and personalised development plans, BoMRA's TM framework aims at building a culture of excellence, ensuring that its workforce is equipped to meet future demands while enhancing employee engagement and retention. This comprehensive framework supports a dynamic and sustainable talent pipeline, which is essential to maintaining BoMRA's competitive edge and fulfilling its regulatory mandate.

4. Organisational development:

BoMRA has experienced significant growth in both headcount and technical capabilities, with the period under review demonstrating this expansion. Our workforce has expanded by 6.7% from the previous year, with a notable shift in gender diversity and other demographics. The Authority remains committed to fostering a diverse and inclusive environment at BoMRA. The gender ratio stands at 55% females to 45% males. This is consistent with trends in the healthcare sector, though we continue to refine our hiring strategies to achieve greater balance. Additionally, staff engagement initiatives, such as the introduction of wellness days and employee incentives to maintain wellbeing, have been positively received. Participation in annual remuneration surveys to ensure alignment with industry standards ensures our pay remains competitive relative to the market.

Additionally, the changing demographics of our workforce, with approximately 73% comprising millennials, present both challenges and opportunities.

Additionally, the changing demographics of our workforce, with approximately 73% comprising of millennials, present both challenges and opportunities. We recognise the importance of aligning our practices with the preferences of millennials and Gen Z employees, including enhancing career progression frameworks, and adjusting organisational structures to support their development and retention. Simultaneously, we are embracing and leveraging the advantages of a young workforce, such as increased diversity and agility. During the reporting period, BoMRA intensified its collaboration with the Government to build and deepen HR capacity in the broader health sector by offering internships to students from national health institutions. Our internship programme expanded significantly, fostering skills transfer and nurturing talent, as part of our effort to build a strong internal pipeline for future roles and strengthen our employer brand. We believe that nurturing and unlocking these aspects can elevate BoMRA's human capital further, supporting the delivery of our mandate.

Outlook

Looking ahead, we remain committed to fostering a culture of excellence, inclusivity, and continuous improvement. We aim to revitalise our organisational values, strengthen our teamwork culture, and reinforce integrity through enhanced recognition programmes and daily practices. Our employees remain our greatest asset, and we are dedicated to supporting them as part of our ambition to be a leading employer. The Authority will continue to develop its human capital expertise, further unlocking the depth of talent through recognition, rewards, and clear pathways for career progression.

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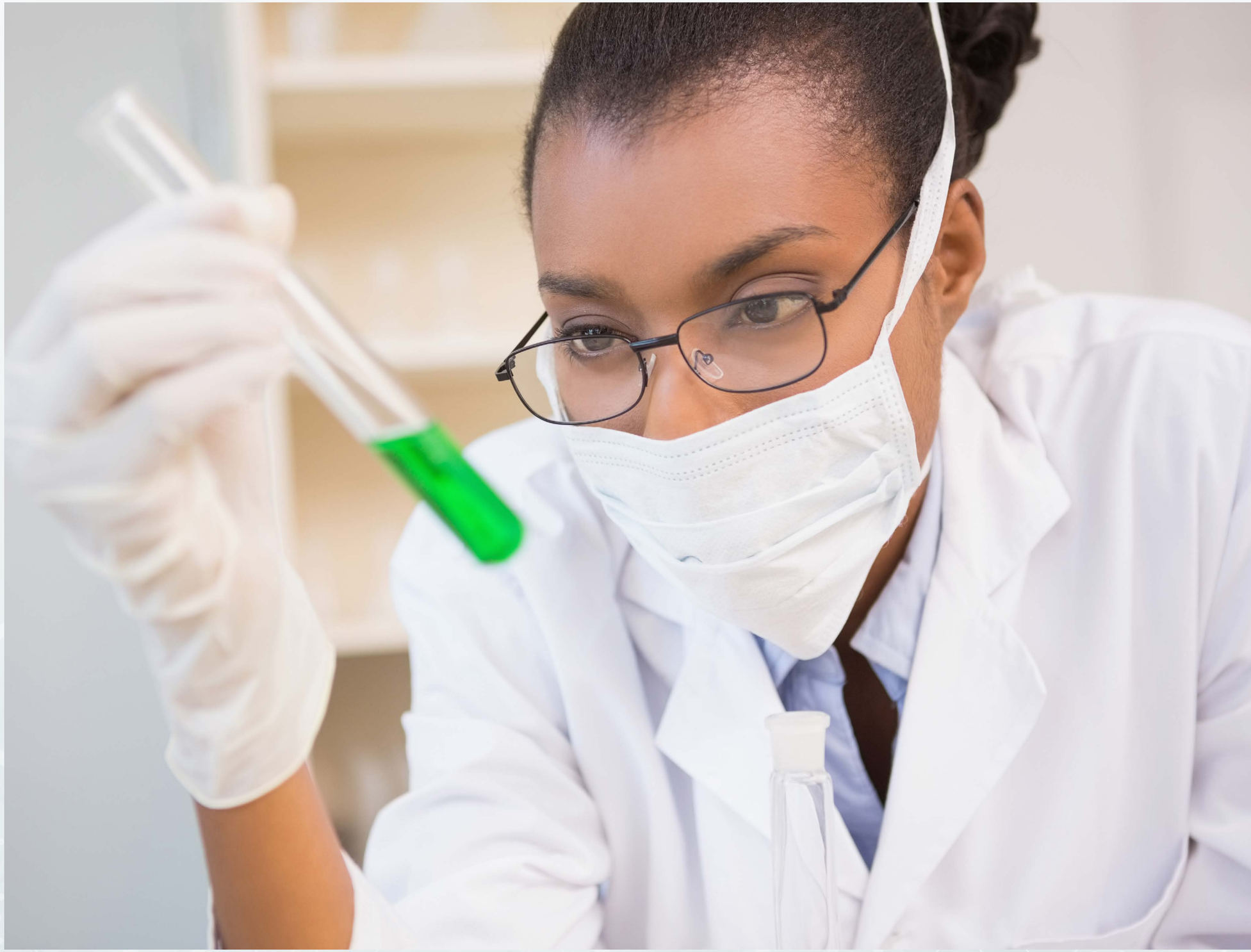
QUALITY MANAGEMENT **REPORT**

Quality Management is a unit under the CEO's Office. The unit has been established to facilitate the establishment and implementation of BoMRA's Quality Management System(s), the main strategic objective of which is to establish and implement an Integrated Management System.

During the period under review, the Quality Management Unit achieved that through the following:

- Coordinating the establishment of required documentation – policies, procedures, specifications etc.
- Promoting the culture of QMS within BoMRA through training sessions
- Conducting audits to establish conformance to the Quality Management System(s)
- Ensuring closure of non-conformities
- Facilitating resolution of customer complaints
- Assisting BoMRA in attaining ML3 and beyond

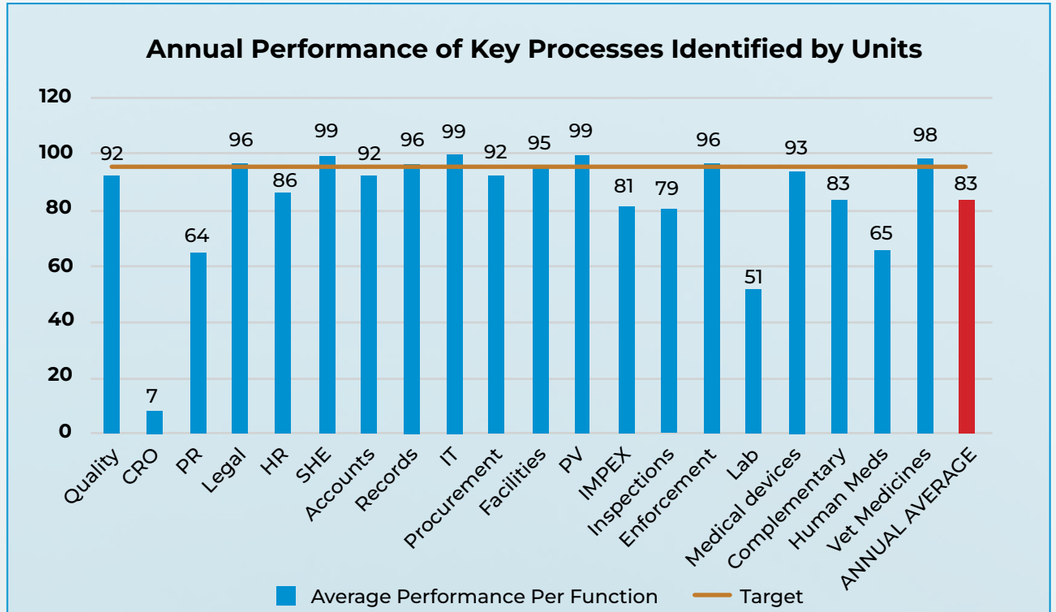


QUALITY MANAGEMENT **REPORT** [Continued]

No.	Objective	Initiative	Measure	Target	Achieved target
1.	P8 – Establish and Implement QMS	Establish and Implement an Integrated Management System	% compliance to processes	95%	83%
			# of major NCs identified during external Quality audits	0 major NCs	0 BSI surveillance audit is planned for November 2024
		Implement Enterprise Risk Management Review Enterprise Risk Strategy and Policy	% Priority Business Risks (PBRs) treated to acceptable levels	50%	66% Three PBRs were identified at the beginning of the year. 2 PBRs (PV1, PROC1) have been treated to acceptable levels while 1 PBR (QM1) remains untreated. QM1 has however moved from unacceptable rating with residual risk rating of 10 to cautionary with risk rating of 5.

Table 9: P8 Establish and implement Quality Management System

Figure 1: Shows the annual average process performance of each unit as at the end of 2023-2024 FY.



The average process performance for the 2022-2023 reporting period was 94%, as compared to 83% attained during 2023-2024 reporting period. This indicated an 11% decline, attributed to the challenges below:

Process Performance:

1. Low process performance attributed to delayed implementation of process performance metrics which ultimately led to late reporting by some functions
2. Failure to adhere to TAT/Service standards by some functions

Internal Audits:

1. Unavailability of auditors and auditees due to other competing business priorities
2. Loss of auditors to higher positions and external employment opportunities

QUALITY MANAGEMENT **REPORT** [Continued]

Key strategic successes

Key successes within this period under review as relate to the Quality Management unit include:

- BoMRA was granted re-certification for continued conformance to the ISO 9001:2015 standard by British Standards Institute (BSI) following a re-certification audit on its QMS after completion of the 3-year cycle
- Successful collaboration with strategic partners and experts on the implementation of the internal audit program
- Introduction of vigilance field visits which facilitated gap identification on our national health system
- Integration of management systems process which resulted in process efficiency. 10/11 management system processes have been integrated.

Performance Summary

The Quality Management unit did well in terms of attainment of the strategic objectives. This was evidenced by exceeding the set target in relation to implementation of Enterprise Risk Management where the unit achieved 66% against a set target of 50%. In addition, no major non-conformities were identified during the BSI re-certification audit.

B. Operational and Projects Updates

ISO IEC 17020

- Assessment of the system was done, and results indicated that out of a total of 85 requirements outlined in the ISO/IEC 17020:2012 standard, 61/85 (72%) of the requirements have been fulfilled; 24/85 (28%) have not been fulfilled. The 28% was attributed to delayed approval and implementation of documented information, inspector competency, facilities and equipment.
- In comparison to the 2022/2023 reporting period, the total number of requirements fulfilled stood at 45% (38/85) whereas the unfulfilled requirements stood at 55% (47/85). The main attributors were structural requirements, personnel requirements, requirements for facilities & equipment, as well as subcontracting.
- Vertical assessment and onsite observations were conducted in line with SADCAS requirements. Results indicated 84% compliance against the SADCAS set criteria.

ISO IEC 17025

- In terms of complying with ISO 17025 requirements, 13 out of 39 critical ISO/IEC 17025 requirements have been implemented. One of the primary challenges experienced by the lab included aging testing equipment which is critical for testing of medicinal products.

C. Enterprise Risk Management

Priority Business Risks (PBRs) Trending

- 2 PBRs (PV1, PROC1) have been treated to acceptable level while 1 PBR (QM1) remains untreated. QM1 has however moved from unacceptable rating with a residual risk rating of 10 to cautionary with a risk rating of 5 as per figure 2:

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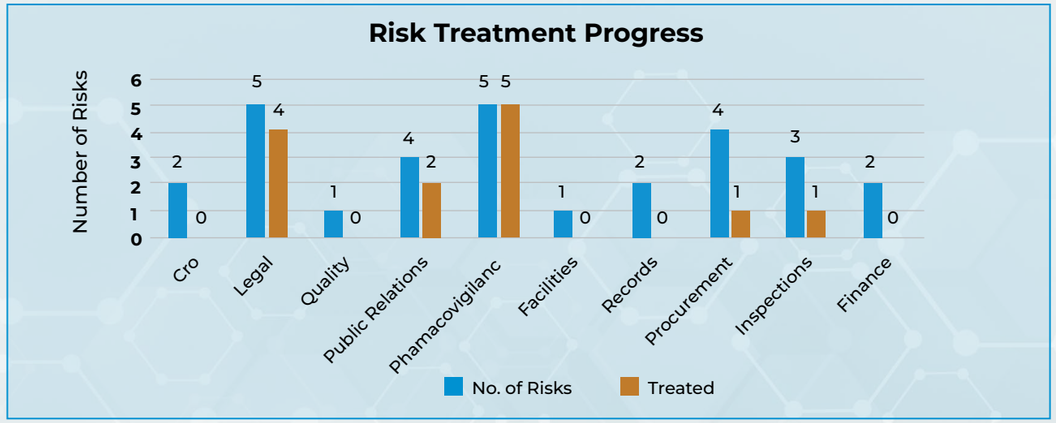
Table 10: Priority Business Risks (PBRs) Trending

Risk Description	Residual Risk Rating Before treatment	Residual Risk Rating After Treatment [March 2024]	Risk Trending
QMI-Lack of corporate Business Continuity Management (BCM)	10	5	
PVI – Inadequate Post Market Surveillance Programme	10	5	
PVI – Inadequate Post Market Surveillance Programme	10	5	

A comparison of this reporting period to the previous year reveals a decline in the number of PBRs treated to the acceptable level from 14 to 3 indicating a 78% decline. During the 2022-2023 period, 4/13 PBRs (30.8%) had been treated to the acceptable level.

Figure 2: Risk Treatment Progress



- 28 risks from 10 functions formed the Corporate Risk Register (15 operational risks and 13 strategic risks)
- Only 13/28 risks have been treated to acceptable level

QUALITY MANAGEMENT **REPORT** [Continued]

Table 11: Global Benchmarking Tool (GBT)

Strategic Objective: L3 – Improve Corporate Governance with Effective Practices

No.	Objective	Initiative	Measure	Target	Achieved target
1.	Improve Corporate Governance with Effective Practices	Develop and implement the IDPs Monitoring Tool	% Technical IDPs Closed	95%	54%

a) The Global Benchmarking Tool (GBT) based self-benchmarking was conducted from 25th April to 9th June 2023 where all indicators in all regulatory functions were assessed. As part of the self-assessment, Vigilance Field Visit was conducted at 3 BoMRA Adverse Drug Monitoring Centres (AMCs) and 1 GMP Observed Audit at one of the local manufacturers in Botswana.

b) This assessment mimicked the WHO benchmarking as quantitative indicators were also considered during the exercise. Post assessment, reporting on the implementation of identified Institutional Development Plans (IDPs) was done to the Governance and Nominations Committee and monitoring also was done through the Annual Performance Plan (APP) to Management.

c) As at the end of the financial year, 54% of IDPs were addressed which shows a significant improvement of implementation compared to the 2022-2023 financial year where 18% of IDPs were implemented. The improvement is as a result of robust monitoring of IDPs by functions, accountability by management and BoMRA Board as well as inclusion of GBT in the individual performance contracts

Key strategic successes

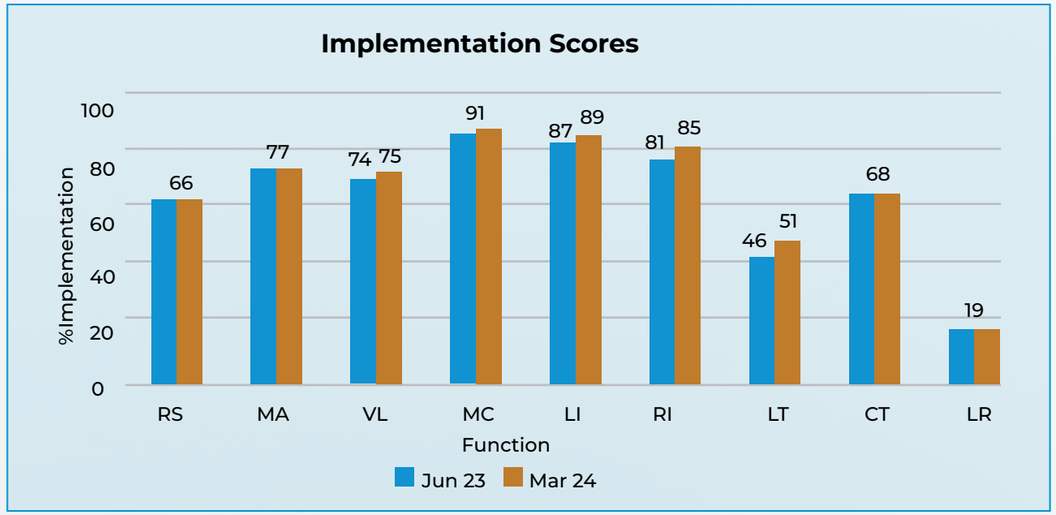
a) Regular annual self-benchmarkings
b) Medicines and Related Substances Bill, 2023 which seeks to address the legal requirements IDPs has been finalised and submitted to the Attorney General Chambers
c) Monitoring of IDPs by the BoMRA Board and Management
d) Regular GBT awareness creation to the BoMRA staff
e) Continued verification of implementation of GBT requirements through quality assurance activities and QMS Internal Audits

Key strategic challenges

a) Monitoring of stakeholders that form part of the Botswana health regulatory system.
b) Reliance and recognition requirements not being fully met
c) Tracking and adherence to regulatory timelines
d) Requirements which require prolonged implementation period
e) Communication and transparency requirements which were partially met.

Implementation Scores Analysis

Figure 3: Implementation Scores



Implementation scores show the general implementation of sub-indicators in the cGBT. As depicted by Figure 3, Market Surveillance and Control had the highest implementation scores followed by Licensing Establishment. Lot Release has the lowest implementation score of 19% as the function is relatively new.

a. Definitions and Acronyms

i. IDPs- Institutional Development Plans
ii. cGBT- Computerized Global Benchmarking Tool
iii. GBT- Global Benchmarking Tool
iv. ML- Maturity Level
v. QMS- Quality Management System

Outlook

The Quality Management unit will develop a clear roadmap for the attainment of WHO Maturity Level 3 and beyond. This will be achieved through the Global Benchmarking Tool (GBT) self-benchmarking assessments, implementation of IDPs, awareness creation activities for various stakeholders affected by WHO GBT requirements, and collaboration with strategic partners that have a great impact on the attainment of Maturity Level 3 and beyond.

The unit will also continue to focus on process automation to improve process efficiency through the development and utilisation of the quality management-related modules within the BoMRA Regulatory Information Management System (BRIMS).

Furthermore, the unit will implement a risk-based approach to the internal audit and assessment process and seeks to increase the pool of internal auditors to participate in the internal audit and assessment programme. We will not only seek to improve process performance, but also to move towards process maturity of BoMRA management systems processes.

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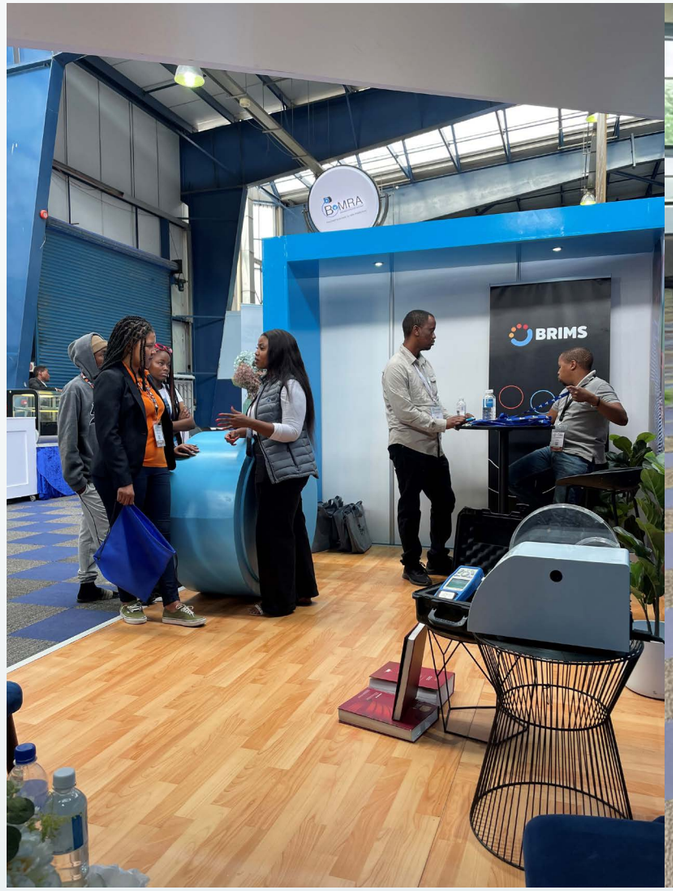
STAKEHOLDER ENGAGEMENT **REPORT**

Since the establishment of BoMRA, the public relations (PR) department has been mandated to oversee stakeholder engagement, and has centred its framework on two primary pillars, i.e. transformative stakeholder engagement and unparalleled customer service delivery.



These guiding principles have been instrumental in shaping stakeholder engagement, awareness and customer service approaches, significantly contributing to BoMRA's drive towards achieving WHO Maturity Level 3 (ML3).

During the period under review, the focus was on prioritising clear, proactive communication and developing meaningful connections with stakeholders. This was with a view towards ensuring that our stakeholders not only remain well-informed but also benefit from the highest standards of service delivery. This enabled BoMRA to consistently enhance the quality of service, aligning with our strategic vision and solidifying our Vision as a trusted authority for excellence in medical products and cosmetics regulation.

This Stakeholder Report marks the culmination of a comprehensive 5-year public relations and stakeholder engagement strategy, wherein we reflect on our public awareness performance. We present a detailed analysis of the progress made, insights gained, and lessons learned, highlighting our commitment to enhancing understanding of our mandate and fostering engagement with the communities we serve. The report also works to indicate whether these efforts have successfully achieved the intended outcomes.

A reflection on the achievements and challenges over the past year highlights steady progress in building trust and confidence through enhanced Public Awareness and Customer Service. The PR department played a crucial role in coordinating stakeholder engagement efforts, engaging with both internal and external stakeholders working together with technical departments to create regulatory awareness including working with the enforcement team in conducting enforcement activities aimed at ensuring compliance with medicines and related substances MRSA guidelines.

Guided by the Corporate Communication strategy, the unit sought to enhance stakeholder interactions and solidify its brand position, firstly to ensure that the brand is perceived positively, consistently, and relevantly in the global regulatory space, as well as embracing new digital tools and technologies to improve efficiency.

BoMRA, through PR and relevant departments, conducted physical and online workshops and digital campaigns, reaching a wide array of stakeholders.

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STAKEHOLDER ENGAGEMENT **REPORT** [Continued]

This included members of the public, healthcare practitioners, pharmaceutical distributors and other groups. The workshops were tailored to the specific needs of each stakeholder group, delivering messaging that resonated with its audiences and addressed their concerns.

The interactions provided invaluable opportunities to raise awareness about regulatory activities such as compliance, safety reporting, product quality, and regulatory standards. Specific stakeholder engagements aimed at promoting safe use of medicines were conducted, and the activities targeted healthcare professionals and patients, underscoring BoMRA's commitment to enhancing the safe use of medicines in the country. The primary goal of such dialogue was to culture of reporting ADR adverse drug reactions and adverse events following immunisation.

Several joint activities were also conducted with the enforcement team to enhance the understanding of law enforcement agents regarding the control and regulation of human medicines in Botswana. The initiative aimed to equip the officers with the essential knowledge and skills needed to effectively address the challenges posed by unauthorised and counterfeit medicines. These efforts delivered returns in the form of strengthened collaboration among enforcement agencies, leading to more coordinated and effective enforcement efforts across the country.

Engagement with Strategic Partners

BoMRA strengthened its engagement with regulatory bodies and strategic partners through formalised collaborations, including the signing of several Memoranda of Understanding (MoUs) and Service level Agreements (SLAs). These MoUs and SLAs were integral in promoting cooperation, and information sharing, particularly with the aim of harmonising regional regulatory space.

The MoUs provided a sound platform for the exchange of crucial regulatory insights and best practices, helping to strengthen BoMRA's capacity to navigate emerging challenges and align with international standards. By building these strategic alliances, BoMRA continues to support regional harmonisation and advance its mission of safeguarding public health.

Engagement activities

These MoUs and SLAs were integral in promoting cooperation, and information sharing, particularly with the aim of harmonising regional regulatory space.

STAKEHOLDER ENGAGEMENT **REPORT** [Continued]

Highlights of the 42nd ZaziBoNa

BoMRA hosted the 42nd ZaZiBoNA meeting, this being one of the region's collaborative efforts among National Medicines Regulatory Authorities (NMRAs). The meeting was attended by 16 SADC member states, including Zambia, Zimbabwe, Botswana, Namibia, South Africa, Tanzania, Malawi, DRC, Mozambique and Malawi as well as Eswatini, Angola, Seychelles, Lesotho and Madagascar. The network stands out as a unique regulatory system serving as a potential model for fostering trust mutual reliance and collaboration among regulators. The initiative promotes a collaborative model aimed at expediting the assessment of medicines while ensuring quality and safety standards.

BoMRA & BoCTRE Host SEARCH Delegates

The Pharmacovigilance and Clinical Trials Department through the Botswana Clinical Trials Regulation (BoCTRe) hosted the Southern Africa Regulatory for Clinical Research (SEARCH). The training brought together delegates from Mozambique, Eswatini, Lesotho, and representatives from the United Kingdom-based R-Evolution Worldwide. The objectives of the workshop included working to enhance regulatory capacity and oversight in clinical research among participating NRAs and to strengthen regulatory frameworks and promote excellence in clinical research standards within Botswana and across the Southern Africa region. It also sought to implement efficient processes, harmonised procedures, standardized guidelines, and effective training programmes to enhance oversight of clinical trials. Regulation and oversight of clinical trials constitute a vital regulatory function of BoMRA. In alignment with its broader regulatory functions, BoMRA has been diligently building structures, systems, processes, and procedures to effectively regulate the approval, conduct, and inspections of clinical trials.

BoMRA and SEZA Sign Service Level Agreement

The signing of a Service Level Agreement (SLA) between BoMRA and Special Economic Zones (SEZA) marked a pivotal moment in Botswana's journey towards enhancing its pharmaceutical regulatory framework within special economic zones. The SLA formalised the partnership between BoMRA and SEZA and outlined a structured framework for cooperation and coordination. Under this SLA, BoMRA commits to providing specialised regulatory services tailored to the unique needs of pharmaceutical enterprises operating within SEZA-designated zones. This includes expedited review processes for pharmaceutical product registrations, licensing, and regulatory compliance inspections.

The agreement is expected to yield tangible benefits for both the pharmaceutical industry and the broader economy by fostering a conducive regulatory environment within special economic zones. Through this, BoMRA and SEZA pave the way for sustainable growth, competitiveness, and prosperity in Botswana's pharmaceutical sector.

BoMRA Board Members and Staff Engagement

The Board paid a courtesy visit to staff at BoMRA. The visit provided an opportunity for Board members to interact with staff, fostering a sense of leadership and staff understanding of the governance roles and responsibilities of the Board.

Leveraging IT to Improve Service Delivery

The 2023/24 period marked a shift toward a more sophisticated customer service framework with technology at the heart of this transformation. This was a direct response to the fact that modern customers demand ease, speed, and empathy at every interaction. We sought to align its service delivery with these evolving expectations in particular BoMRA's customer service charter, and feedback that we continuously received.

Electronic gadgets and software were deployed during public awareness activities conducted throughout the year under review. The aim was to gather valuable feedback for continuous implementation. These activities included fairs, exhibitions, mall activations, workshops, and seminars.

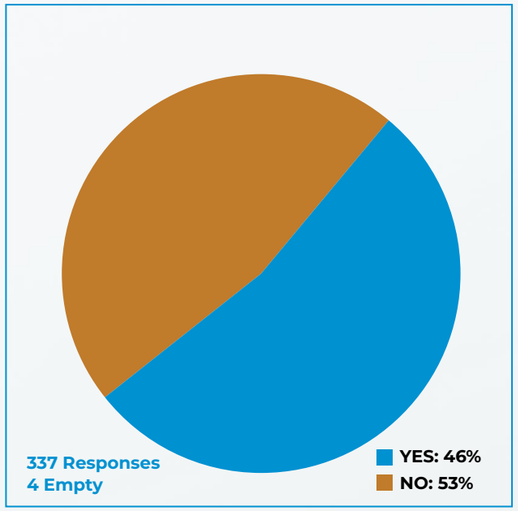
Below is a summary of the feedback collected from these events.

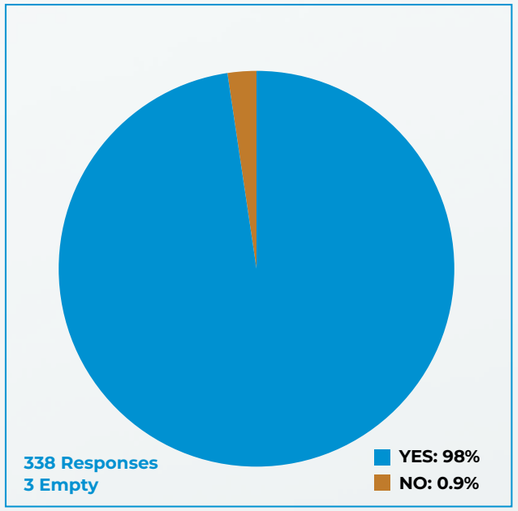
Public Awareness Feedback

Did you know about BoMRA (mandate) prior to your visit today?

337 Responses - 4 Empty

STAKEHOLDER ENGAGEMENT **REPORT** [Continued]





Most respondents 179/337 (53%) indicated they did not know about BoMRA's mandate before their visit. This suggests that there may be a significant gap in awareness about BoMRA's roles and responsibilities among the respondents. This highlights an opportunity for improved communication and education about the authority's mandate.

Analysis
An overwhelming majority (98.2%) of respondents felt informed and educated during their interaction, which indicates a positive reception of the information provided. A very small percentage (0.9%) expressed uncertainty about their level of education and information, which could be addressed in future interactions.

Do you feel informed and educated by your interaction with us today?

338 Responses - 3 Empty

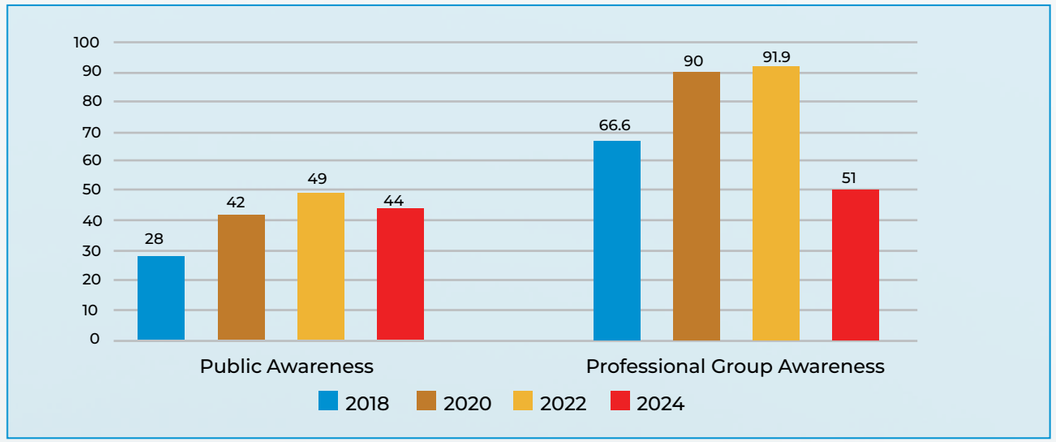
Analysis
A very small percentage (0.9%) expressed uncertainty about their level of education and information, which could be addressed in future interactions.

Awareness and satisfaction patterns
Figure 4 highlights the awareness and satisfaction pattern across primary stakeholders conducted since 2019, and provides insights into trends and areas for improvement. This includes working to build on the lessons learned to refine BoMRA's strategies, ensuring that we continue to foster informed and engaged communities.

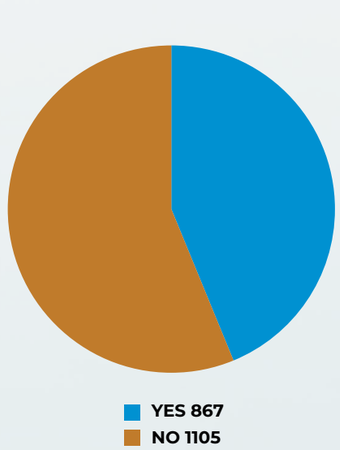
Stakeholder Satisfaction
In a rapidly evolving healthcare landscape, need to engage effectively with stakeholders to ensure that their needs are met. The insights derived from the survey responses and qualitative interviews provide a comprehensive overview of stakeholders' perceptions regarding BoMRA's initiatives and the impact on their professional practices.

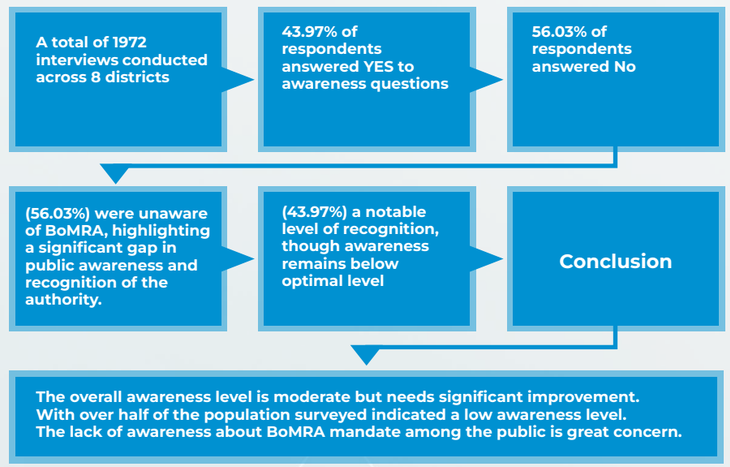
During the 2023/24 period, BoMRA conducted

Figure 4: Awareness and satisfaction patterns



2023/24 BoMRA National awareness SCORE 44%





surveys and assessments to measure satisfaction levels across various service touchpoints, identifying areas of strength and potential improvement.

Conclusion
BoMRA has made notable progress in refining regulatory and operational processes. However, there is still room for improvement in communication, system efficiency, and stakeholder engagement to fully meet the needs of Botswana's healthcare professionals.

The period under review highlights that BoMRA has, overall, made significant strides in enhancing stakeholder engagement and meeting the expectations of its customers. These efforts have not only strengthened relationships with key stakeholders but have also brought about a culture of transparency and trust within the community and BoMRA's ecosystem of stakeholders.

As we continue our journey towards achieving WHO ML 3, BoMRA remains committed to refining our strategies and practices to meet the evolving needs of our stakeholders. Our dedication to improvement will ensure that we effectively support the health and wellbeing of Batswana and become a globally trusted regulatory authority.

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REGULATORY PERFORMANCE **FOR THE YEAR UNDER REVIEW**

CHIEF REGULATORY REPORT

Ms. Ropafadzai Hove
Chief Regulatory Officer

The 2023/24 period has been marked by significant progress for BoMRA, guided by our focus on achieving Maturity Level 3 (ML3) and preparing for the next phases of the journey.

The lessons from this period have been well captured within the CEO's Report, and these proved to be incredibly clear for us as a collective. After all, as we worked to navigate growth and embrace change in the path towards ML3 and beyond, we recognise that learning and evolving are a priority and indeed the smartest way forward. Accordingly this inspired a concerted effort on internal growth, capacity building, and creating strategic partnerships essential for our regulatory aspirations.

Role and Responsibilities

Since joining the Authority, my mandate as Chief Regulatory Officer and certainly within this period under review remained consistent: providing strategic direction to the technical functions and supporting the CEO drive a strategic partnership and collaboration perspective of the strategy. During this review period, our focus was on consolidating partnerships - locally, regionally, and internationally - to accelerate our path to ML3, and indeed beyond. This has involved strategic collaboration with identified 5 key partners with the most impact on attaining Maturity Level 3.

A major evolution in our work has been an increased emphasis on not just technical partnerships, but also funding partnerships. This became necessary as budgetary constraints hampered our ability to implement key activities. By exploring avenues for funding through our partnerships, we were able to alleviate some of the financial pressures, ensuring that we could continue moving towards our goals.

Best Practice and Industry Trends

In recent years, the African landscape for medicines regulation has been shaped by a dynamic shift towards greater harmonisation, capacity building, and digital transformation. Regulatory authorities across the continent, including Botswana, have prioritised collaboration through regional initiatives such as the African Medicines Regulatory Harmonisation (AMRH) programme. This trend is fostering the alignment of regulatory standards, streamlining the approval processes for medical products, and promoting access to medicines that are safe, efficacious, and of good quality. In Botswana, we are witnessing an increased focus on leveraging digital platforms to enhance regulatory oversight, particularly through the development of robust Integrated Regulatory Information Management Systems (IRIMS). At BoMRA, the IRIMS has been named BoMRA Regulatory Information Management System (BRIMS) and it has an online self-service portal for the convenience of clients.

Additionally, there is a growing emphasis on post-market surveillance to combat substandard and falsified medicines, as well as exploring alternative and traditional medicines within a well-defined regulatory framework

These trends are positioning Botswana, alongside other African countries, to take significant strides towards regulatory maturity, ensuring public health safety and facilitating innovation in the healthcare sector.

Key Achievements

One of our primary goals this year was to bolster our partnerships and leverage them for operational success. Despite the challenges posed by being a relatively young organisation (just over five years old), we have made substantial progress. We engaged with national regulatory authorities (NRAs) with over 25 years of experience, learning from their advanced systems while sharing insights from our journey. This has positioned BoMRA not just as a recipient of knowledge, but as a contributor to regulatory discourse, particularly in the realm of quality management systems. Our involvement in regional and continental technical working groups is a testament to this growing recognition.

This area of traditional medicines is an area of increasing importance as the global population moves towards alternative medicine, and we aim to develop a clear regulatory strategy in the coming years. We established dialogue with an NRA with vast experience in establishing a robust regulatory framework for traditional medicines. While this effort began prior to the year under review, it has continued to evolve, with discussions on how best to regulate traditional medicines especially indigenous knowledge-based products., in line with our mandate.

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CHIEF REGULATORY REPORT [Continued]

Challenges and Mitigations

The external environment presented significant challenges, particularly in the form of budgetary cuts from our shareholder. These constraints impacted our ability to fully implement planned activities, forcing us to rationalise our operations. Despite these setbacks, we maintained a strong focus on our priorities, particularly in the areas of traditional medicines regulation and strategic partnership development. Once again, our lessonss here were as plentiful as they were enlightening. While we have made great strides towards ML3, the delay in passing key legislation in Parliament remains a critical barrier. Without updated legislation, Bomra risks remaining at Maturity Level 1, regardless of the progress we have made in other areas. We are, however, optimistic that with the continued support of the Ministry and our strategic partners, this hurdle will be overcome in the coming period.

Outlook and Future Focus

Our focus is now shifting towards the next proverbial goalpost indeed beyond ML3, this being attaining Maturity Level 4 (ML4) in the upcoming strategic period. With the unwavering support of our Board, Ministry, and partners, we are motivated to not only meet but exceed the expectations set out in our current strategy. This will involve further strengthening our regulatory controls, enhancing our post-marketing surveillance mechanisms, and expanding our capacity for laboratory testing.

While the year under review saw its share of challenges, the lessons learned have fortified our resolve, and of this I am certain. We are on a clear path of growth and transformation, and the steps we are taking now will lay the foundation for an even more impactful future for BoMRA.

Our commitment to ensuring the safety and efficacy of medical products in Botswana remains unwavering, and we look forward to continuing this journey with renewed focus and determination to create value, to enhance experiences of and with BoMRA and of ensuring we are not simply benchmarking with those in the region, but are a beacon of excellence for others to benchmark from – an agile, robust and nuanced body that delivers well beyond its mandate alone.

While some delays and obstacles have been met, we continue to make considerable progress in our ambitions of ML3 and beyond and the year under review contrbuted to this immensely.

Ropafadzai Hove
Chief Regulatory Officer

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PRODUCT EVALUATION AND REGISTRATION (DPER)

Mr. Bathusi Kgosietsile
Director Product, Evaluation and Registration

With a strategic objective to enhance registration, the Department of Product Evaluation and Registration (DPER) saw key initiatives geared towards implementing regulatory strategies (particularly, the medical devices and cosmetics strategies), strengthening the registration of Veterinary Medical Products (VMPs) and enhancing registration of Human Medicines.

These objectives were measured through the monitoring of service standards, ensuring that turnaround times are adhered to, with backlog not exceeding 15% across for screening, processing of new applications, variations and renewal applications for Human, Complementary and Veterinary Medicines. Furthermore, DPER was tasked with Implementation of Institutional Development Plans (IDPs) that impact the attainment of Maturity Level 3 (ML3).

Overview of performance at the end of the reporting period:

Key milestones or achievements within the year under review are as follows:

- Live transacting of most modules on the BoMRA Regulatory Information Management System (BRIMS)
- Supplementary listing of VMPs. The process was initiated but finalised in 2024
- Implementation of the Medical Devices Regulation Strategy: Call for voluntary registration of Medical Devices (MD) including In Vitro Diagnostics (IVDs) and supplementary listing of medical devices including IVDs
- Alignment of scheduling status with the Medicines and Related Substances regulations
- Implementation of Renewals and Retention processes
- Development and Implementation of notification portal for cosmetics

PRODUCT EVALUATION AND **REGISTRATION (DPER)** [Continued]

Overall registration backlog	7.75% across DPER units against a target of not more than 15%. This means that a strategic goal for this initiative was met.
Implementation of Medical Devices Regulation Strategy	64.5% (Target 60%)
Implementation of Cosmetics Regulation Strategy	55% (Target 60%)
BRIMS	At the end of the reporting period, modules for screening and exemptions were transacting in the system while development of modules for new applications, variations and renewal was at advanced stages.
Update of the medicines registers	Alignment of schedules in the registers with those in the Medicines and Related Substances Act (MRSA) was completed, while update of missing product information was near completion, over 90% updated.
Supplementary listing of VMPs and Medical Devices and IVDs	The two units completed additional listing of respective products which was necessitated by request from sectoral stakeholders.
Call for voluntary registration of Medical Devices and IVDs	As the ongoing implementation of Medical Devices Strategy, there was a call for voluntary registration targeting priority MDs
Implementation of Renewals and Retention processes	Renewal of registration for all products with more than five years Marketing Authorisation (MA) as well as implementation of retention fees for all products in the register was enforced during the reporting period.
Implementation of the Cosmetics strategy	A notification portal was developed and implemented. The prohibited list and self-service portal were fully functional.

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Trend Analysis: 2019 – 2024

Key trends captured during the period under review are presented here accordingly.

Figure 5: New applications for registration received 2020-2024

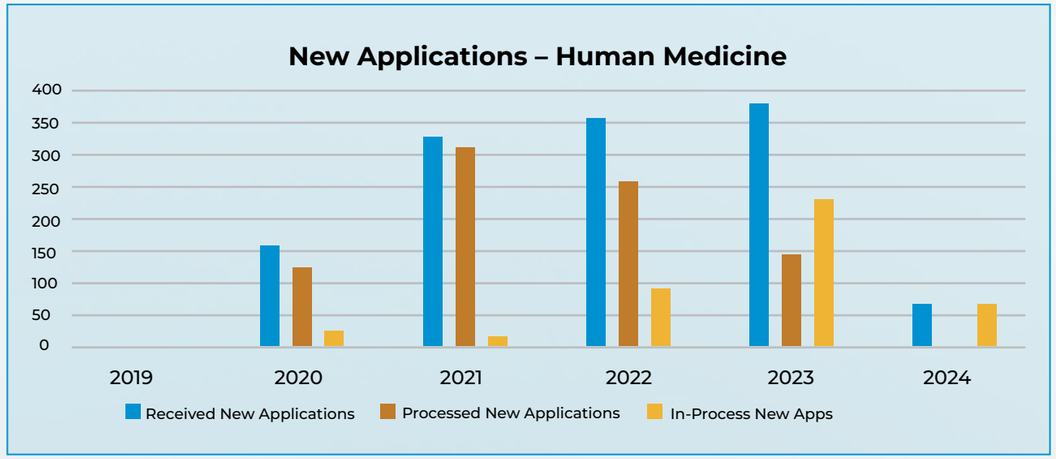
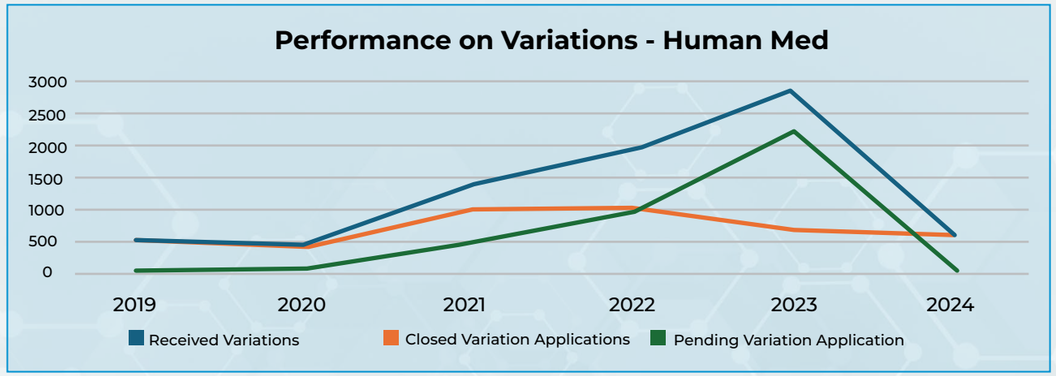


Figure 6: Variation applications received 2019-2024



PRODUCT EVALUATION AND **REGISTRATION (DPER)** [Continued]

Figure 7: Exemption from registration applications received 2020-2024

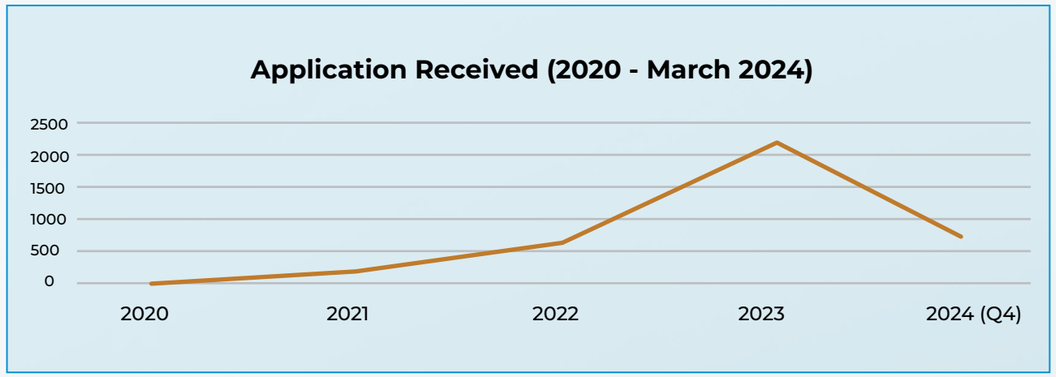


Figure 8: Showing Medical Devices Exemptions 2020-2024

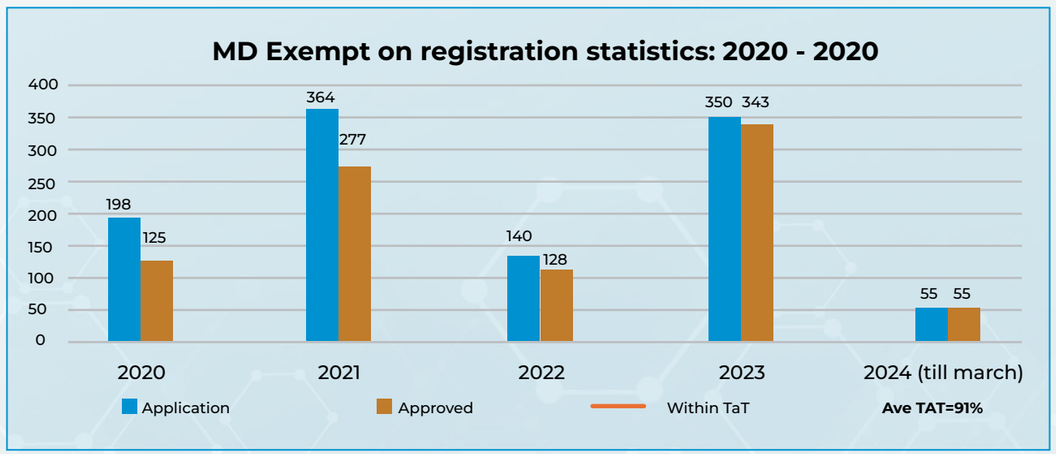


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Figure 9: Complementary medicine Screening and New applications from 2021-2024

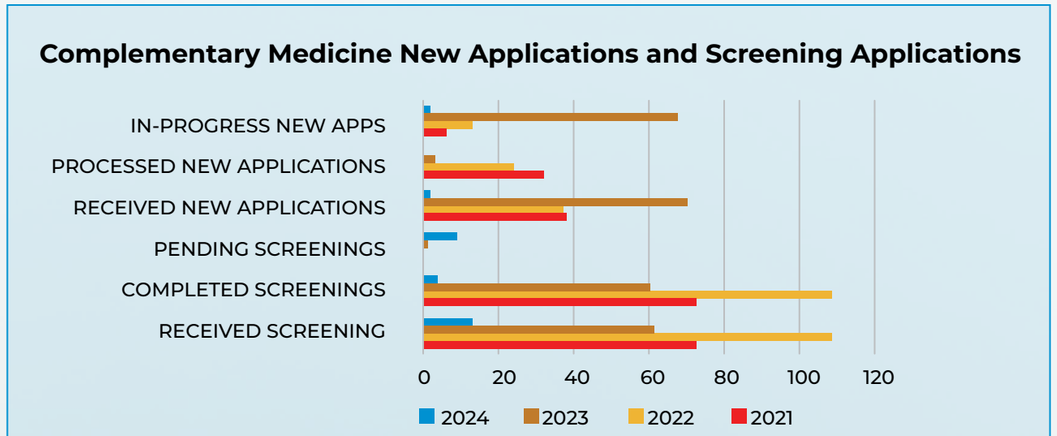
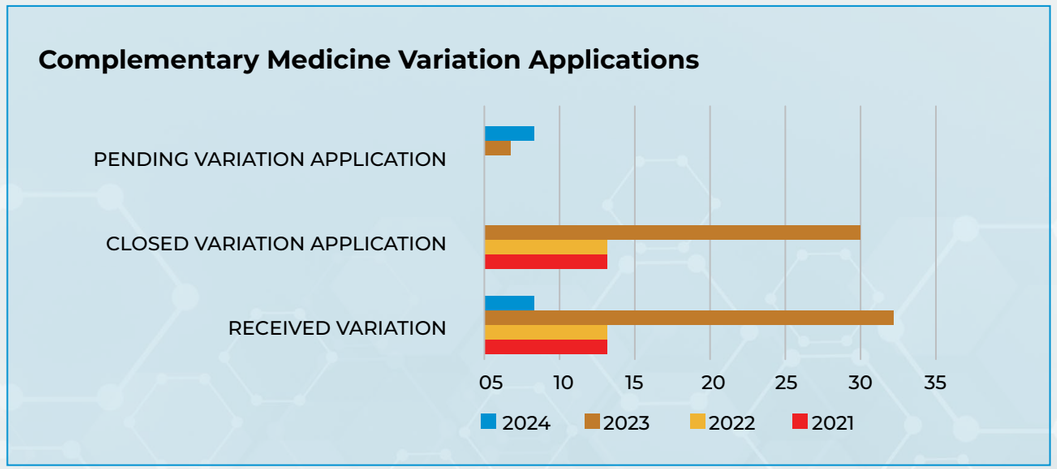


Figure 10: Complementary medicine Variation applications from 2021-2024



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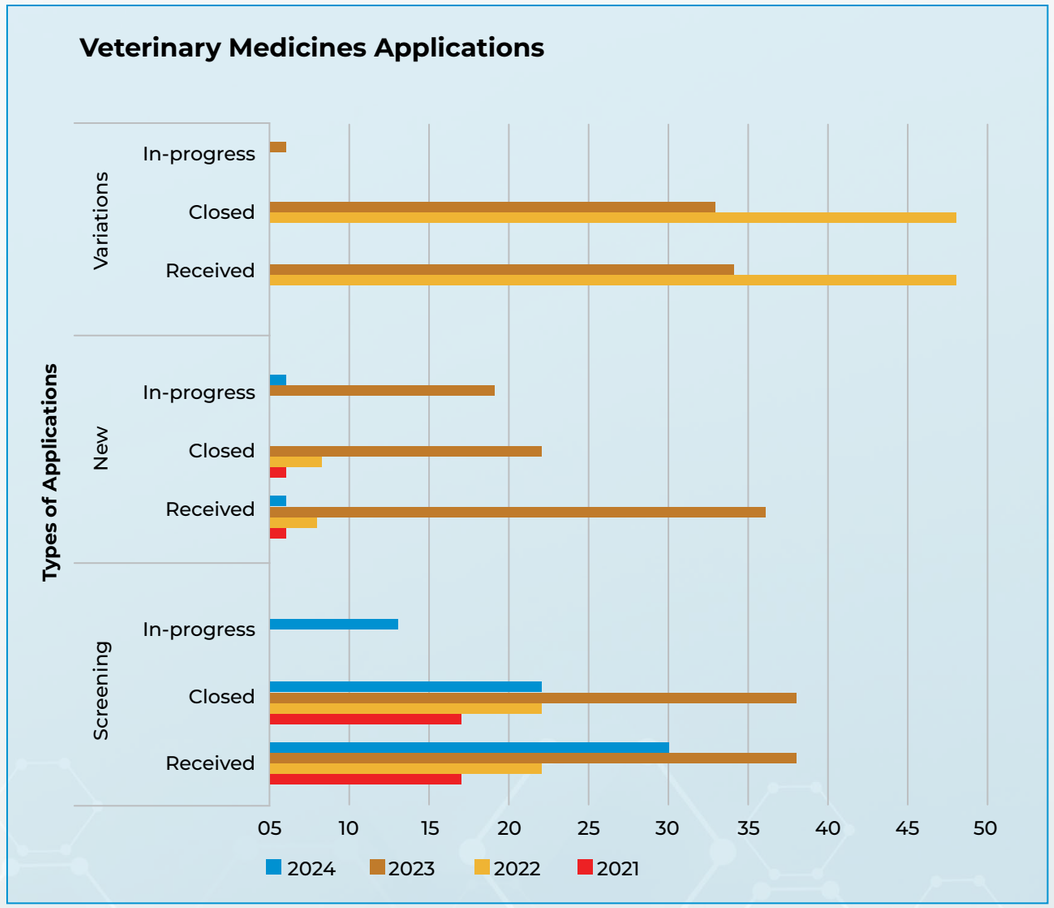
PRODUCT EVALUATION AND **REGISTRATION (DPER)** [Continued]

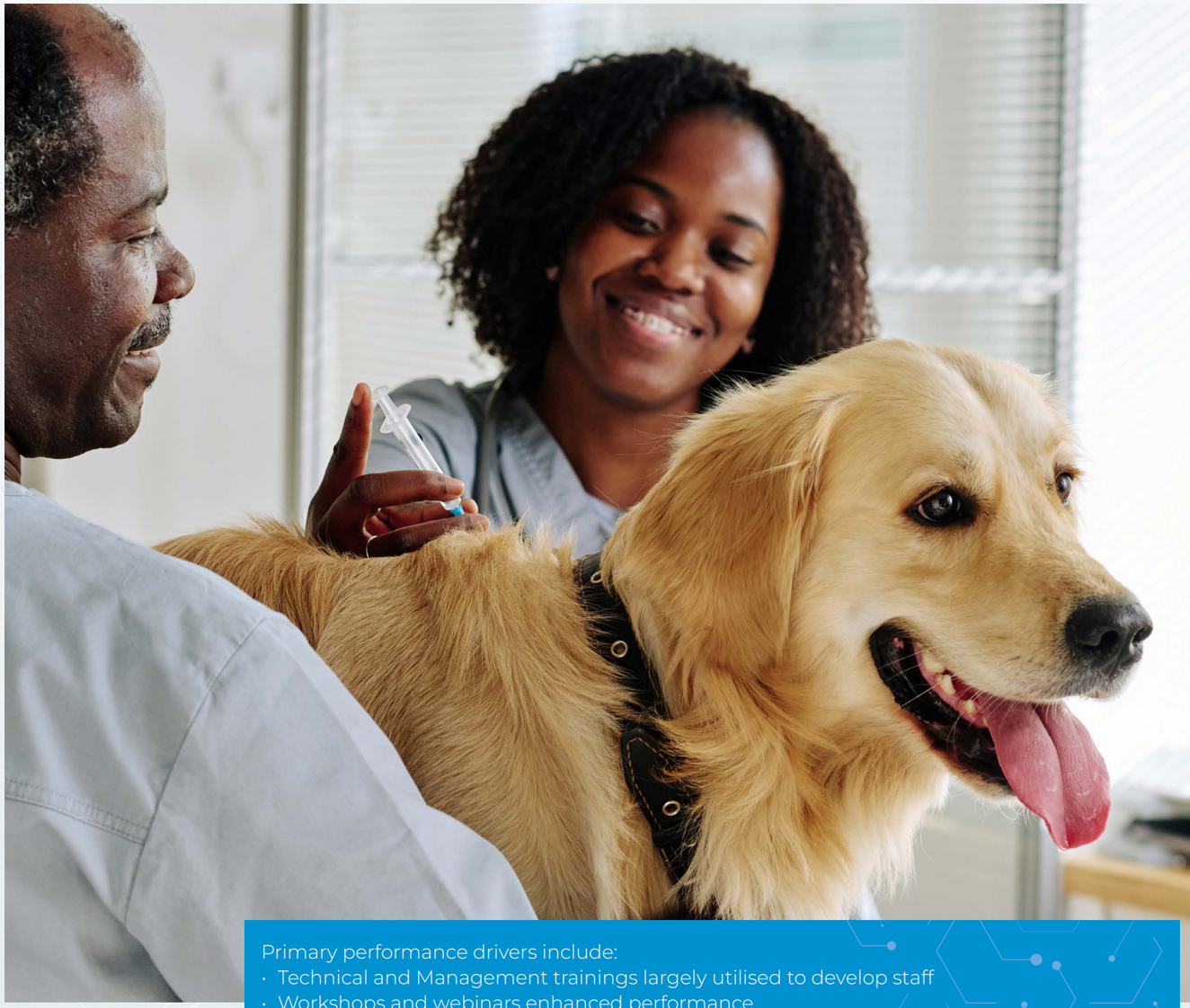
Figure 11: Veterinary Medicines Applications



MD New Applications Q1 2024

RECEIVED SCREENINGS	**6**
COMPLETED SCREENINGS	**4**
PENDING SCREENINGS	**2**
RECEIVED NEW APPLICATIONS	**4**
PROCESSED NEW APPLICATIONS	**0**
IN-PROCESS NEW APPS	**4**

No. of Listed Medical Devices	**154, 637**
No. of Listed MD Establishments	**90**



Primary performance drivers include:

- Technical and Management trainings largely utilised to develop staff
- Workshops and webinars enhanced performance
- Stakeholder engagements – information sharing and dissemination of regulatory updates
- Utilization of Memorandum of Understanding (MoU) – to address critical regulatory issues that require learnings from the MoU Partners
- Collaborative registration processes

The outlook remains positive, with an anticipated improvement in turn-around times considering digitalisation of processes, new strategies that enhance registration processes, and expansion of the regulatory scope to now include regulation of other medical devices and traditional medicines. The revision of the Act, Regulations, and Regulatory Fees are also envisioned within the next reporting period.

LICENSING AND **ENFORCEMENT**

Zukiswa Raditladi
Acting Director Licensing and Enforcement

The Department of Licensing and Enforcement is responsible for control of imports, export, transit, as well as for inspecting and licensing premises along the supply chain of all regulated products. Furthermore, the department has been mandated with testing of regulated products, for compliance with specifications to determine if products are substandard or falsified. The department is also responsible for the general enforcement of the MRSA and regulations thereof. In the reporting period, the department contributed to BoMRA's 1st strategic goal entitled **To Reduce Incidences of Substandard or Falsified and Unauthorized Medical Products** and the 3rd strategic goal of **Establishing a Fully Functional Regulatory System** through three strategic objectives namely P4 - Strengthen Inspection and Licensing of Premises and Import/Export Controls, P6 – Establish Laboratory Services and P7 – Strengthen Enforcement.

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I P4 - Strengthen Inspection and Licensing of Premises and Import/Export Controls

The Inspections and Licensing Unit conducts the inspection and licensing of both veterinary and human medicine premises as well as medical devices premises. These inspections are carried out in pharmaceutical manufacturers, wholesalers, retailers, institutions within group practices and traders of Schedule 4 and complementary medicines.

a Key Achievements

Over this past year, the department has seen an increase in pharmaceutical operations due to the onboarding of Schedule 4 and complementary medicines premises. This resulted in an additional 93 new premises inspected during the reporting year. This necessitated the development of a robust system that will allow for seamless service even when the scope of activities increases without the increase in human resources resulting in risk-based inspection scheduling. Risk-based inspection scheduling allowed for incorporation of historical compliance and other inherent risk factors in decision-making for renewal inspections.

The period under review saw the introduction of the maiden Good Manufacturing Practices (GMP) inspection plan targeting a total of 26 premises and an actual implementation of 73%. These inspections were conducted by BoMRA inspectors with the support of Tanzania Medicines and Medical Devices Authority TMDA

Table 12: Key Performance Areas

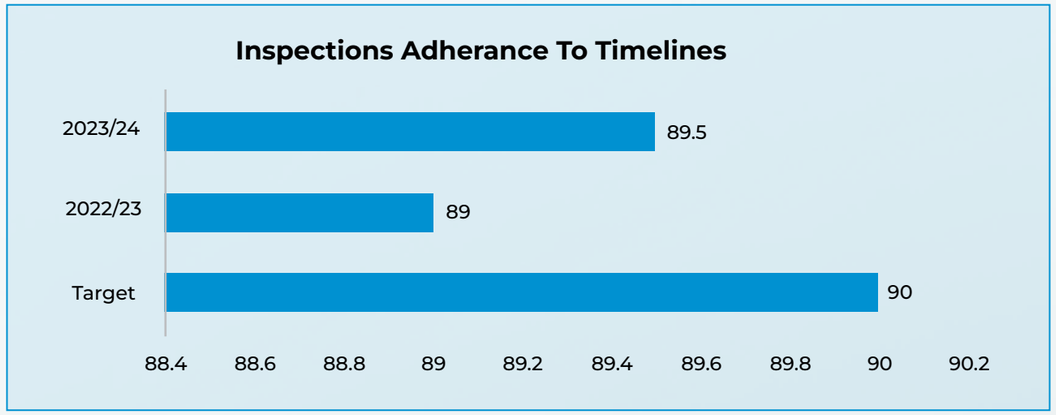
No.	Initiative	Measure	Target	Result
1	Implement GMP Inspection Plan	% Implementation of GMP Inspection Plan	95%	73%
2	Establish and implement ISO 17020 Accreditation	% implementation of 17020 standards	100%	72%
3	Implement inspection framework and programmes;	% Level of Industry compliance	95%	94%

i. Good Storage and Distribution Practices Inspections

In implementation of the inspections framework, The Authority started the year with 410 premises scheduled for inspections. By the end of the year, a total of 478 inspections had been conducted and the adherence to customer service timelines was 89.5% as shown in table 12.

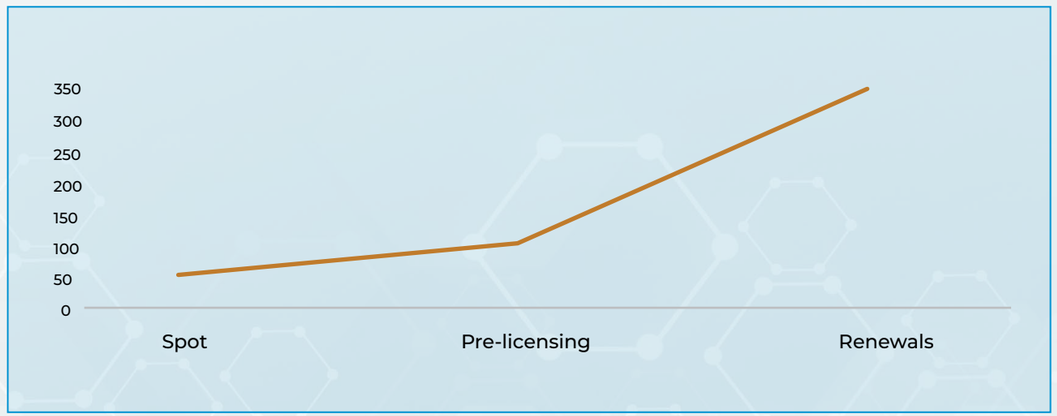
LICENSING AND **ENFORCEMENT** [Continued]

Figure 12: Adherence to Inspections Customer Service Timelines.



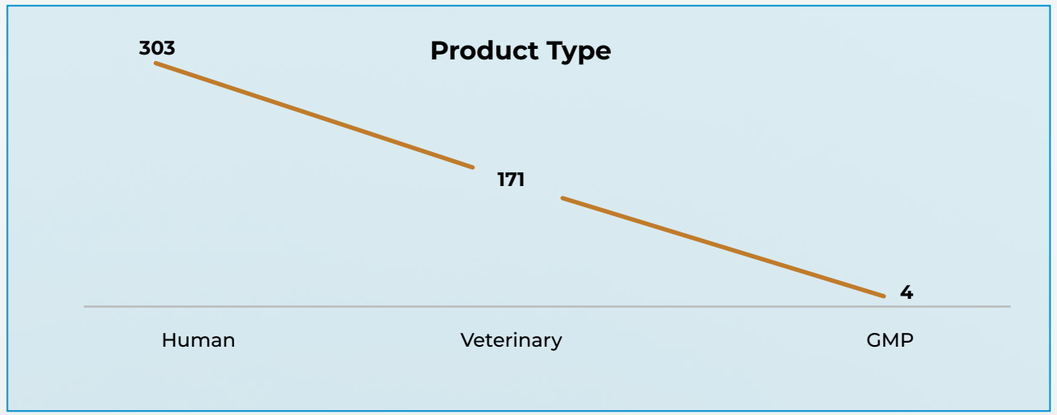
The breakdown of the type of inspections done on the 478 premises is shown on figure 12 which is made up of 59 spot inspections, 93 pre-licensing and 326 renewals.

Figure 13: Types of Inspections Conducted



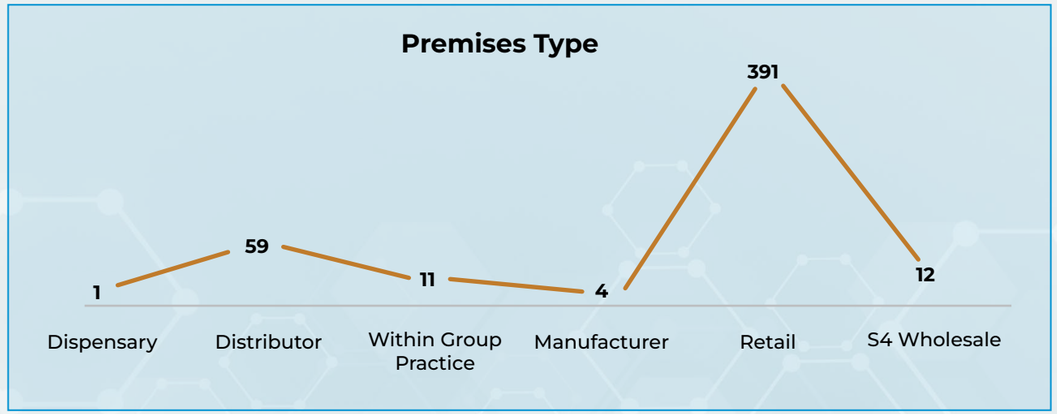
Of the 478 facilities inspected 303 of these premises were trading in human medicines, 171 veterinary medicines while 4 were manufacturers as depicted in figure 13.

Figure 14: Product Type of Inspected Premises



Furthermore, of the total 478 facilities, 1 was a human medicines dispensary, 59 were distributors, 11 were within group practice, 12 were Schedule 4 and complementary medicines wholesalers while 391 were retailers of human and veterinary medicines as shown in figure 14.

Figure 15: Types of Local Premises Inspected

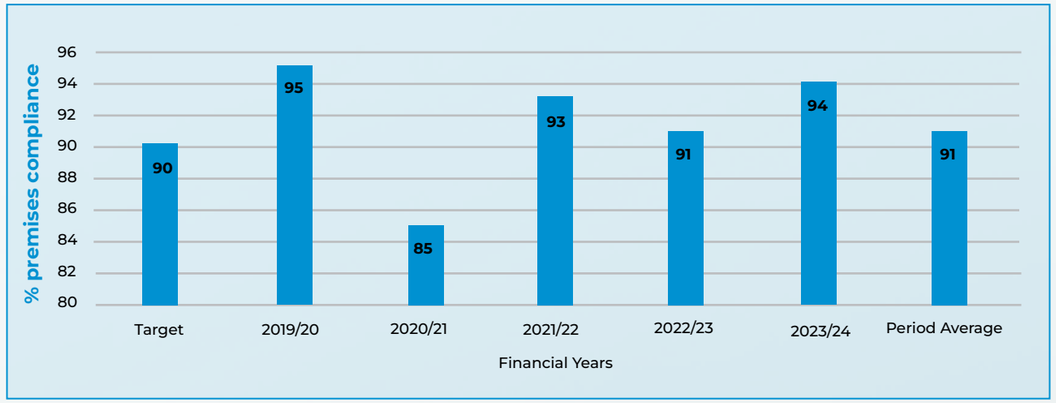


Overall, a total of 386 of the 410 renewal premises were licensed resulting in an industry compliance of 94%. Figure 15 below shows the trend of industry compliance over the past five years.

LICENSING AND **ENFORCEMENT** [Continued]

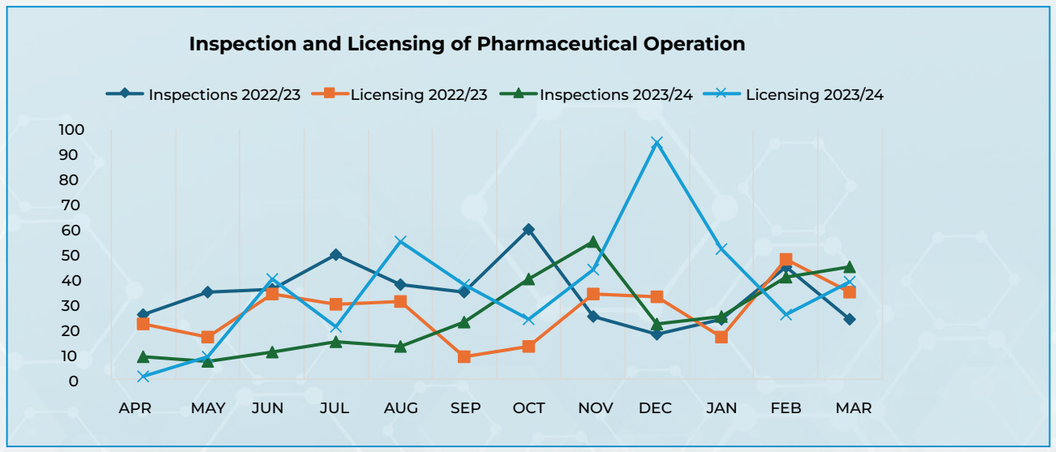
Figure 16: Industry Compliance Level Over the Past Five Years

Premises Compliance Over The Years



Over the past five years The Authority has seen an increase in inspections conducted and subsequently the licenses issued. Figure 16 depicts the inspections and licensing trends between financial year 2022/23 and 2023/24.

Figure 17: Inspections and licensing of pharmaceutical operations over the past two years.

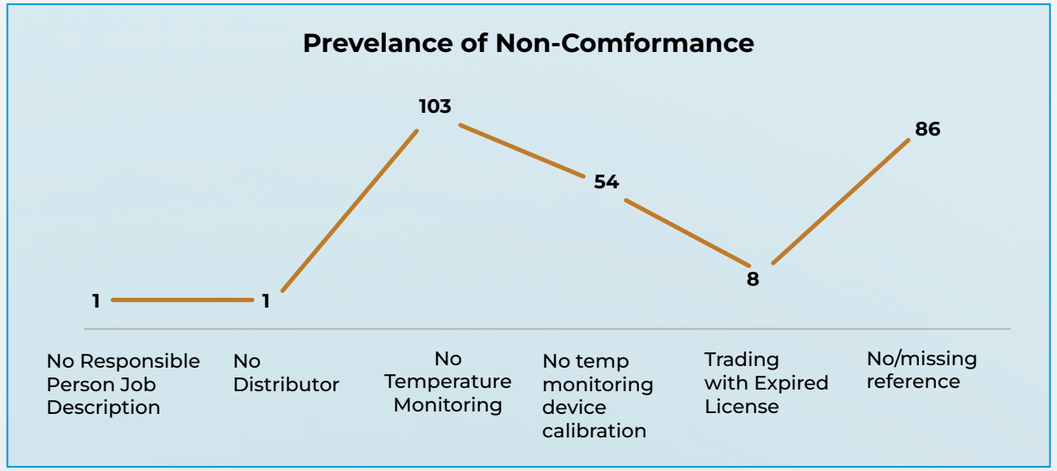


The industry compliance over the past five years shows that premises have been compliant with set minimum requirements for licensing. The 2020-2021 financial year saw a decrease in compliance level due to the introduction of licensing of veterinary medicinal products premises. The introduction of new regulatory scope always brings about challenges in understanding the new regulatory requirements by the regulated entities. Over the years, the compliance level increased as industry knowledge of regulatory requirements increased.

Continuous stakeholder engagement targeting regulated entities with a focus on training in regulatory requirements facilitated a meeting of the target for regulatory compliance level.

Figure 17 shows the prevalence of frequent non-compliances that were encountered over the reporting period. A majority of the premises were found to have major non-conformance of either no evidence of temperature monitoring or were utilising temperature monitoring devices with no evidence of their calibration.

Figure 18: Shows the prevalence of frequent non-compliances



ii. Good Manufacturing Practices (GMP)

During the reporting period, 26 GMP inspections were scheduled. Of this number, 9 were desk reviews while 17 were onsite inspections. In total 13 on-site inspections were conducted and 6 desk reviews were conducted resulting in a 73% performance. Of the 13 inspected, 6 were approved, 1 pending Corrective and Preventive Actions (CAPA), while 6 were awaiting final inspection reports. Of the six desk reviews conducted, five were approved. In implementing Recognition policy facilities were covered through the ZaZiBoNa platform 9 applications were received for desk review. 8 have been approved and 1 is under review. These covered 16 products under registration by BoMRA. 16 facilities were physically inspected and these facilities combined have more than 80 products registered in Botswana and 6 products under registration. For these ZaZiBoNa facilities, 10 from the 25 facilities (covered through both desk and onsite inspection) were licensed in 2023 while CAPA is ongoing for remaining facilities.

II P6 – Establish Laboratory Services

The Laboratory Services Unit is designated the National Quality Control Laboratory and it is responsible for testing and analysis of medicines, for the determination of their compliance with standards of quality. The laboratory, currently located at the Central Medical Stores, has a functional physicochemical laboratory, a non-functional medical devices laboratory and space for a microbiology laboratory.

LICENSING AND **ENFORCEMENT** [Continued]

a Key Achievements

The laboratory conducted analyst competence assessment for three analysts hence increasing analyst confidence for conducting analysis. Gradual equipment calibration and verification enabled functionality of key equipment, and together with analyst competence, resulted in the laboratory beginning to conduct in-house tests, which is an improvement as previously all analytical tests were outsourced. There was also the acquisition of the pharmacopeia's for methods of analysis i.e. USP 2024, BP2024, Indian pharmacopeia etc to enable ease of conducting analysis within the laboratory.

There has been a marked improvement in customer focus as the laboratory strives to reduce the analysis turnaround times with quality complaints testing completed within the 21 days service standard turnaround time, while also maintaining focus on ensuring accurate, timely and reliable results.

Table 13: Key Performance Areas

No.	Initiatives	Measure	2022/2023	2023/2024
1	Attain ISO 17025-217 Accreditation	Percentage (%) level of compliance achieved by the laboratory against the ISO17025:2017 standards.	Nil	33%

i. Sample Analysis

A total of 370 samples were received by the laboratory during the reporting period compared with 126 samples received in the last reporting period. The 370 samples were made up of 5 quality complaints samples and 365 post marketing surveillance samples. Of the 365 samples, 288 were received in December 2023 while 77 were received in March 2024.

Table 13 shows the performance of the laboratory in relation to sample testing over a period of two (2) years.

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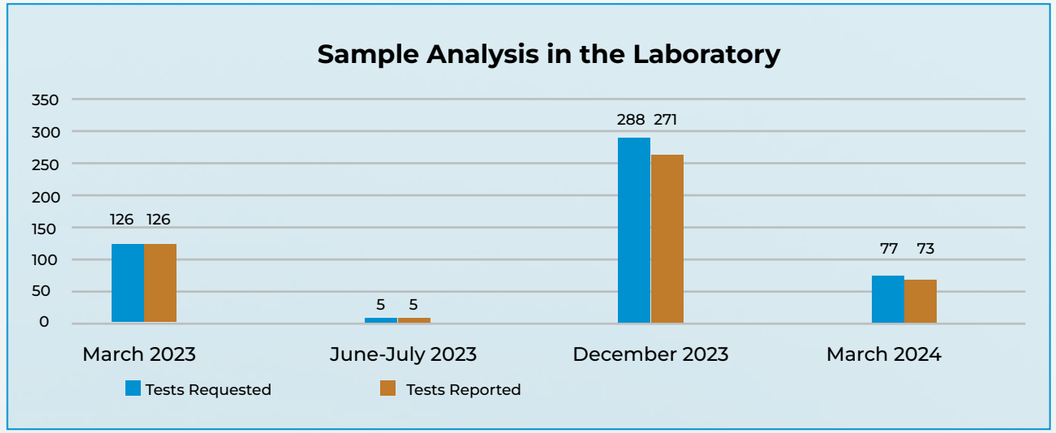
Figure 19: Actual Performance of the Laboratory Based on the Tests Reported

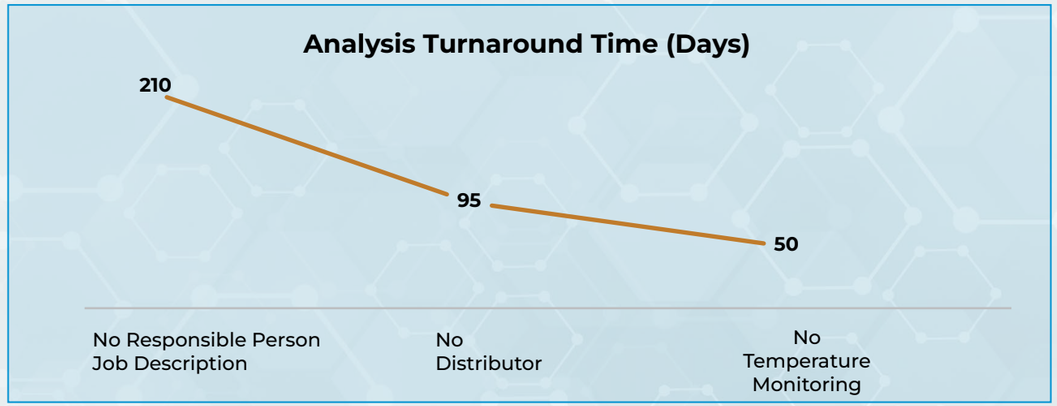


94% of the samples submitted during the reporting period were analysed and reported which is a drop from 100% attained in the previous reporting period. The drop in performance is a result of delays in receiving results from outsourced laboratories as well as frequent breakdowns of laboratory equipment which impacted turnaround times.

ii. Turnaround Times

Figure 20 shows a marked improvement in sample analysis turnaround times with the time frame decreasing from around 210 days in the previous reporting period to 50 days in the current reporting period. This, however, is still more than the set turnaround time of 21 days.

Figure 20: Performance of the Laboratory Against Turnaround Times



LICENSING AND **ENFORCEMENT** [Continued]

III P7 – Strengthen Enforcement

The Enforcement Unit is responsible for establishing and maintaining an effective and efficient import/export control system for BoMRA. The unit is further responsible for ensuring compliance with the Medicines and Related Substances Act and the regulations. This is done through collaborations with other Enforcement Agencies such as the Botswana Police Service and Botswana Unified Revenue Services.

a Key Achievements

During this reporting period, the Authority empowered 90 law enforcement agents from various law enforcement agencies these included additional two categories of stakeholders who were not covered in the previous periods. The number brings to a total of 412 officers from law enforcement agencies, representing 9 strategic stakeholders categories, who have been trained since 2020 across the country.

The quantity of unauthorised medicines confiscated in the current reporting period was thirty-five thousand and ninety-seven (35,097) units, which represented a sharp increase from eighteen thousand nine hundred and one (18,901) units confiscated over three years of 2020/21, 2021/2022 and 2022/23.

Table 14: Key Performance Areas

No.	Initiatives	Measure	2022/2023	2023/2024
1	Implementation of sixteen (16) key performance areas (KPAs)	Average % performance of the 16 KPAs	Nil	79%
2	Investigation of reported/ referred cases	% of closed cases denominated by the total number of open investigations	92%	93%
3	Monitoring of adherence to regulatory decisions	% adherence to regulatory decisions	82%	91%
4	Processing of permits with customer service standards	% of Permits issued as per the customer service standards	86%	84%

i. Increase in Country Coverage

Figure 21 below shows country coverage reached through training of law enforcement representatives as well as through collaborations with local Enforcement Agencies.

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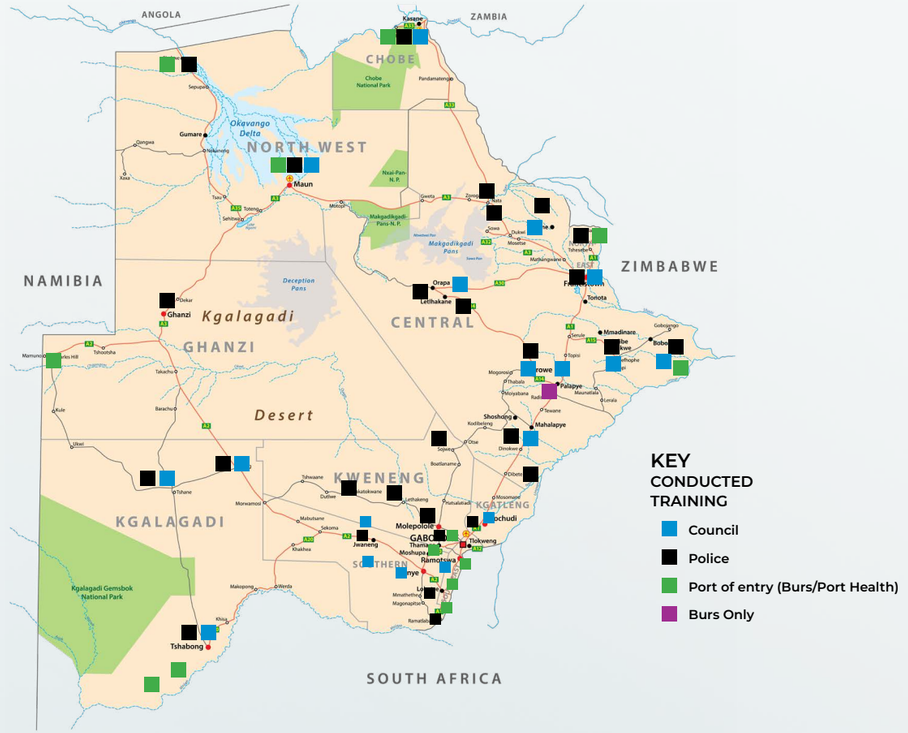
Figure 21: Geographical Coverage and Enforcement Functions Engaged Since 2020 to-date



The effectiveness of the capacity building for local law enforcement strategic partners was demonstrated by the complementary efforts that these partners implemented in the current reporting period. These include Pangea XI operation which targeted the online selling of pharmaceutical products and the World Customs Organisation STOP III operation coordinated by the Botswana Unified Revenue Service, for which the scope covered unauthorised and counterfeit medicines, amongst other products.

ii. Confiscated Products

The Number of planned annual joint operations was increased by 50%. Furthermore, the complementary efforts by strategic partners resulted in a 65% increase in confiscated unauthorized regulated products between 2023/24 translating to thirty-five thousand and ninety-seven (35,097) units compared with eighteen thousand nine hundred and one (18,901) units confiscated over three years between 2020 and 2023.

The table below summarises the types of commonly found active pharmaceutical ingredients (API) in unauthorised medical products since 2022/21. These are high-risk regulated products, which were confiscated from un-trained and non-professional settings and people during joint operations.

LICENSING AND **ENFORCEMENT** [Continued]

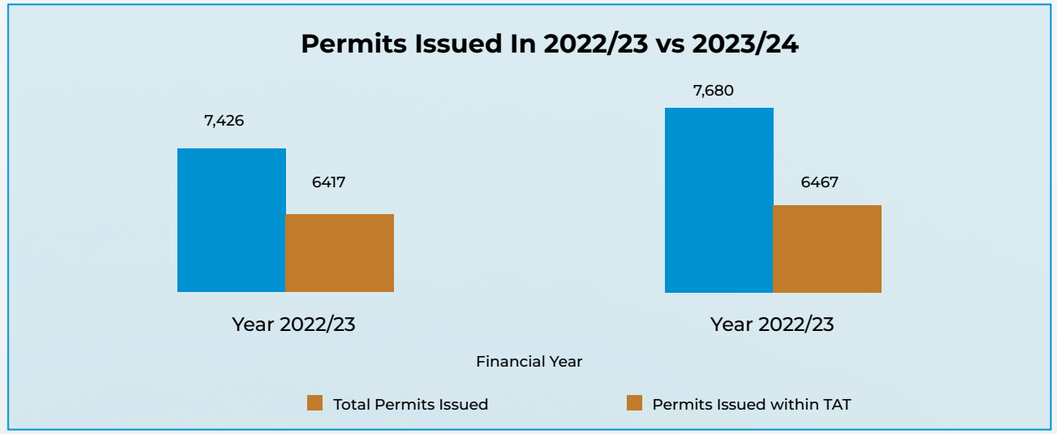
Year	Active ingredients	Formulation types and Remarks
2020/21 to 2022/23	Sildenafil 50mg, Sildenafil 100mg, Misoprostol, Cyproheptadine Diclofenac, Levonorgestrel 150µg, Levonorgestrel (75µg) and Ethylestradiol (30µg)	• Tablets • All these are high risk products in Schedules 2 and 3.
	Betamethasone, Clobetasol, Hydroquinone, Combination of Betamethasone, Gentamycin and Tolnaftate	• Cream, Oil and Lotion • All these are high risk products in Schedules 2 and 3.
2023/24	Sildenafil 100mg, Sildenafil 200mg, Misoprostol, Cyproheptadine, Diclofenac, Levonorgestrel, Tetracycline Levonorgestrel (75µg) and Ethylestradiol (30µg)	• Tablets and capsules • Oral Tetracycline emerged as an API which was not identified in previous periods. • Sildenafil 200mg emerged a new strength which was not identified
	Betamethasone, Clobetasol, Hydroquinone, Combination of Betamethasone, Gentamycin and Tolnaftate	• Cream, Oil and Lotion • No new emerging API were identified in the reporting period.

Table 15: Confiscated Products

iii. Permit Issuance

The total number of applications for permits increased by 3.4% compared with the previous period resulting in a total of 7680 applications received.

Figure 22: Adherence of the Permitting Process to Turn Around Times



There has been a decrease of 2% from 86% to 84% for adherence to the set turnaround times for permits issuance. This decrease was due to the increase in the number of applications received while the human resources remained the same.

iv. Offences Against the Medicines and Related Substances Act

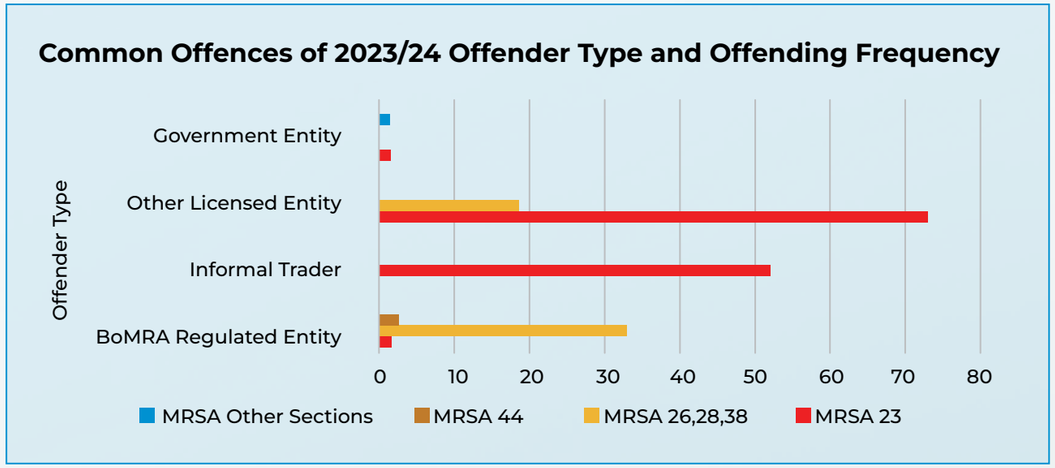
Product-related offences are amongst the top three recorded in the reporting period. Street vendors (informal traders) continued to commit the highest number of offenses against section 23. The active pharmaceutical ingredients found in possession of informal traders are Schedule 2 – which are pharmacy and prescription-only medicines; as well as Schedule 3 – which are pharmacy-only medicines. Contravention of sections 26 and 28 were amongst the top three (3) offences and these were committed by entities regulated by the Authority.

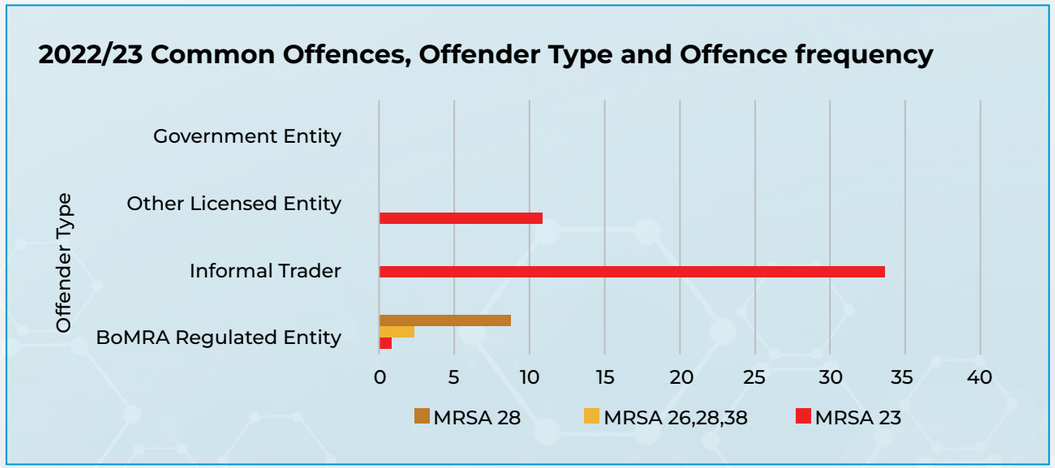
Informal traders constituted 60% of possession/importing/selling unregistered medicines and this figure represented a 1% increase from 2022/2023.

ABOUT BOMRA | PERFORMANCE | CORPORATE GOVERNANCE | REGULATORY PERFORMANCE | ANNUAL FINANCIAL STATEMENTS

LICENSING AND **ENFORCEMENT** [Continued]

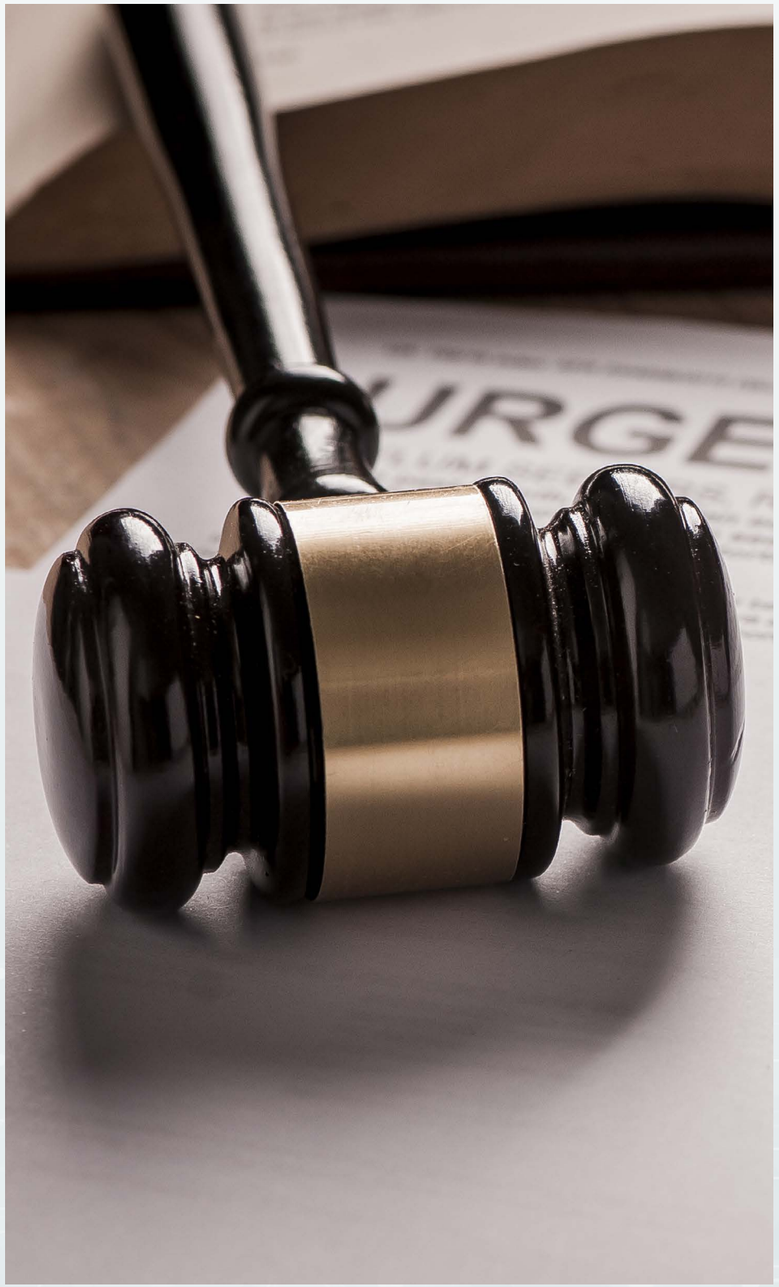
Figure 23: Contraventions Against the Medicines and Related Substances Act





Overall 22% of the offences were committed by the entities regulated or licensed by The Authority. This year's figure is a 4% increase from the previous reporting period of 2022/2023. Entities licensed by other authorities were also found to sell or distribute unauthorised (unregistered) regulated products.

These offences resulted in a 2% increase in the fines collected by strategic partners such as the Botswana Unified Revenue Service (BURS) and the Botswana Police Service (BPS).



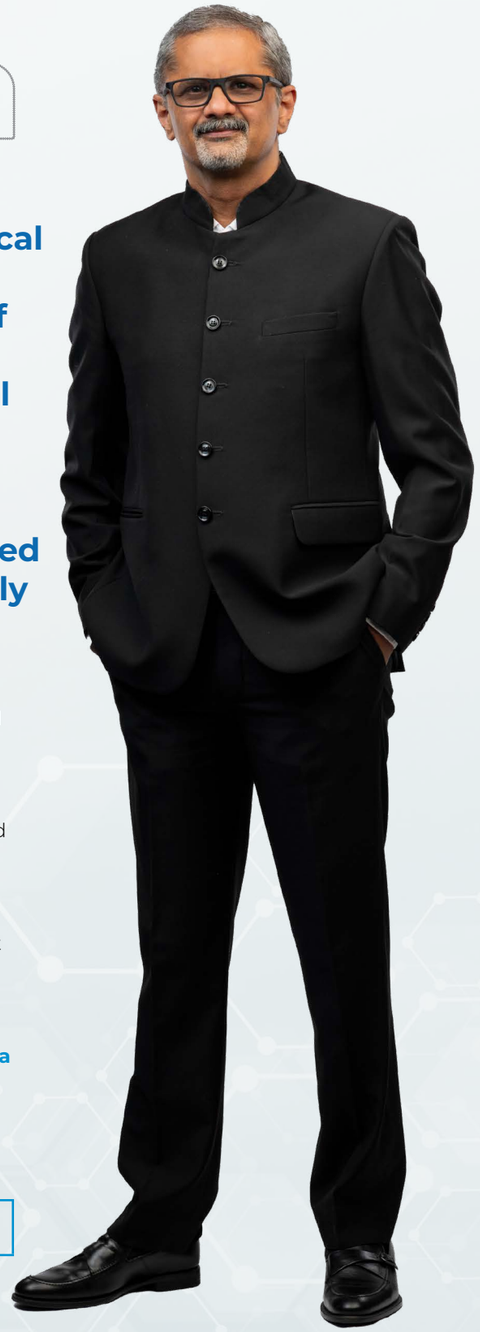
IV Outlook for the Department

The Licensing and Enforcement Department will focus on the development and utilization of the relevant modules within the BoMRA Regulatory Information Management System (BRIMS). This will result in increased efficiencies positively impacting the adherence to customer service standards.

The Department will continue working towards having internal recognition on the competence of the laboratory and the inspectorate through accreditation of the laboratory and the inspectorate. This will also contribute to the attainment of ML 3 where competence is a key requirement. To enable informative regulatory decisions, the laboratory will increase inhouse scope of testing to 5 test methods which the laboratory will report per tested sample. Furthermore, the laboratory will build the Raman spectroscopy library for BoMRA. This involves creating a comprehensive database of Raman spectra for different pharmaceutical compounds found in the Botswana market. This library will serve as a reference tool for identifying unknown substances, verifying the authenticity of raw materials, and ensuring compliance with regulatory standards on a device that can be used on site resulting in a reduction in cost as not all samples will be taken to the laboratory for analyses.

The Department will also introduce Pre-shipment Inspection for high-risk products and facilities. This will minimize the number of substandard, falsified and counterfeit products that end up in the Botswana market.

PHARMACOVIGILANCE AND **CLINICAL TRIALS (PVCT)**



Dr . Parthasarathi Gurumurthy
Director Pharmacovigilance and Clinical Trials

The Department of Pharmacovigilance and Clinical Trials (PVCT) is mandated with monitoring the safety of medical products registered for use in Botswana; approval & oversight of clinical trials; conduct Post Marketing Surveillance for quality and prevent substandard & falsified medicines entering the supply chain in Botswana.

The Department of Pharmacovigilance and Clinical Trials (PVCT) is mandated with monitoring the safety of medical products registered for use in Botswana; approval & oversight of clinical trials; conduct Post Marketing Surveillance for quality and prevent substandard & falsified medicines entering the supply chain in Botswana. In its endeavour to help ensure the successful implementation of BoMRA's Corporate strategy, the PVCT department contributes directly to several goals and objectives as indicated below:

PVCT alignment to strategy and National Agenda

Strategic Goal SR1 - Reduce the incidence of Substandard, Falsified and unregistered medicines through the strategic objective

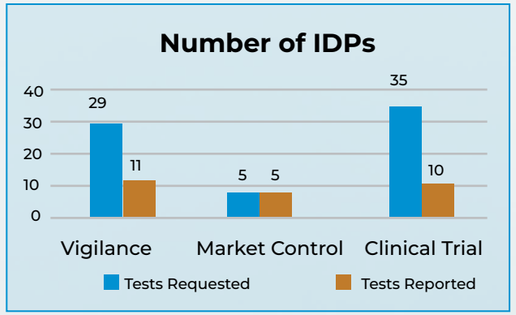
P5 - Establish Post Marketing Surveillance

Strategic Goal SR3 - Fully Functional Regulatory System through the strategic objectives

P2 - Establish a Vigilance system
P3 - Enhance Clinical Trials Control

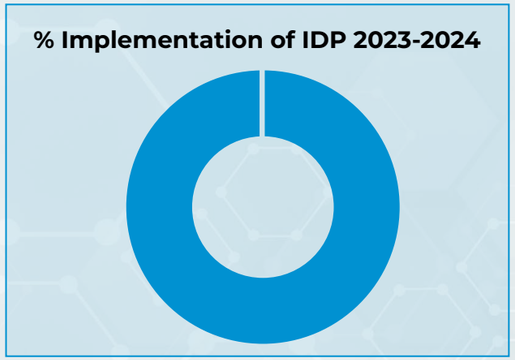
Pharmacovigilance and Clinical Trial Department's contribution towards the attainment of Maturity Level 3 (ML3) Status.

Figure 24: identified IDPs for Vigilance, Market Control and Clinical Trial functions



Institutional Development Plans (IDPs) identified were 11, 7 and 10 in 2023-2024 for vigilance, market control and clinical trials respectively.

Figure 25: 100% Implementation of all technical IDPs



By the end of the financial year ALL IDPs were fully implemented.

PHARMACOVIGILANCE AND **CLINICAL TRIALS (PVCT)** [Continued]

Key Activities 2023 - 2024

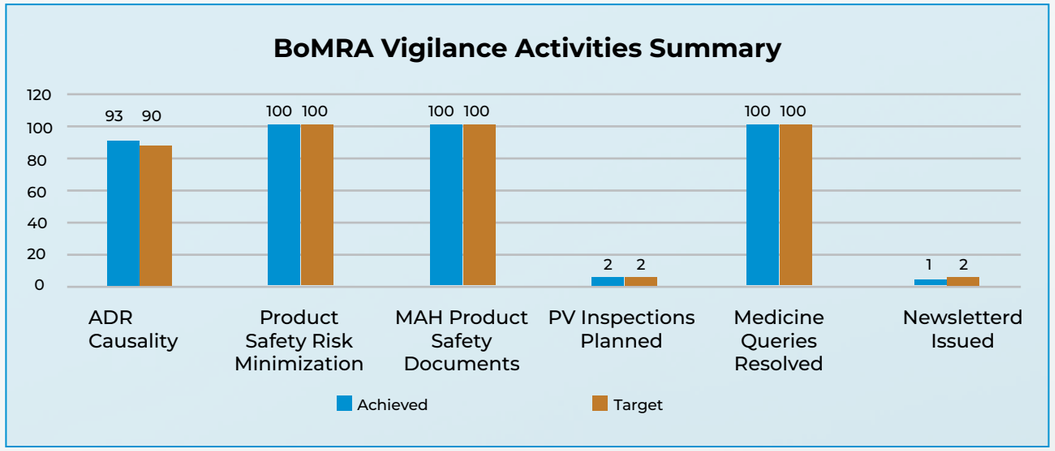


Figure 26: P2 - Establish Vigilance System:

Stakeholder engagements: Promoting Safe use of Medicines

Process	Number
Round Table	56
CMEs conducted	35
Public Health Program engagements (EPI & HIV/TB)	89
Drugs and Therapeutics Committee meetings	16
Patient Sensitizations	627
HCP stakeholder engagements	227
BRIMS engagements	30
Total number of HCP and patient stakeholder engagements	780

5,446 healthcare professionals were engaged in the reporting period.

45324 patients/public were sensitized on ADR reporting and safe use of medicines

Introduction of new AEFI reporting App

VigiMobile is a new application developed for reporting of Adverse Events Following Immunisation (AEFIs) and promote vaccine safety surveillance. Reporting of AEFIs promptly after detection will facilitate quick decisions, timely investigation and safety communication. VigiMobile is developed and supported by the WHO International Drug Monitoring programme based at Uppsala Monitoring Center, Uppsala, Sweden.

Figure 27: Training of Trainers on VigiMobile App at Lobatse March 2024

A training of trainers session was conducted for BoMRA pharmacovigilance staff and Expanded Immunization Programme (EPI) focal persons by WHO and Uppsala Monitoring Center with the following objectives:

- Reporting AEFIs on VigiMobile
- VigiFlow tools for AEFI analysis
- Develop implementation plan for the rollout of VigiMobile
- Refresher training on AEFI surveillance and serious AEFI investigation

VigiMobile is expected to address under-reporting and delayed turnaround times reports of AEFIs, and conduct of AEFI investigations.

Causality Assessment of ADRs/AEFIs:

Total number of reports received in the reporting period.

- 1,758 total reports received; 1,717 ADRs and 41 AEFIs
- Of the 1,717 ADRs 807 paper-based reports,

Figure 28: Training of HCPs in Kasane on VigiMobile App and AEFI surveillance

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PHARMACOVIGILANCE AND **CLINICAL TRIALS (PVCT)** [Continued]

611 e-reports and 299 Medsafety APP reports
- 37 AEFIs were paper-based reports and 4 from VigiMobile

Achievement: 93% of all ADRs/AEFIs reports received during the reporting period were assessed for causality. Causality assessment further helps identify safety signals and communicate the risk to promote safe use of medicines.

Product Safety Reporting by Marketing Authorisation Holders:

Achievement: 100% of Safety Variations and PSURs (Periodic Safety Update Reports) received were evaluated within the expected timelines, demonstrating compliance and efficiency in safety monitoring. No major safety concern and intervention was noted from the evaluated PSUR and Major Safety Variations. All PSURs and Safety Variations submitted were as per the guidelines provided to Marketing Authorisation Holders (MAHs) demonstrating regulatory compliance.

GVP Inspections - The Department conducted Good Pharmacovigilance Practices (GVP) inspections in collaboration with other regulatory bodies, contributing to the strengthening the regulatory compliance of MAHs.

The objective of the inspections were to:

a) Exchange of knowledge and expertise between BoMRA and regional regulatory Authority in an effort to harmonise regulatory requirements and processes.
b) Identification and adoption of best practices in GVP inspections.
c) Ensuring compliance by MAHs to Good Vigilance Practices. This activity will be expanded to conduct a baseline PV compliance for distributors, MAHs and Manufacturers.

Product Risk Minimisation initiatives: The Safety Signal on Tenofovir-containing products was identified, the causal association of Tenofovir and renal failure was established and the safety signal was communicated to relevant stakeholders. This informed and supported the change in the National HIV treatment guidelines.

Dear Healthcare Professional letters were published on safety concerns related to pseudoephedrine-containing products as well as Sodium Valproate (associated teratogenicity).

P3 - Enhance Clinical Trials Controls:

Clinical Trials Regulatory Compliance:

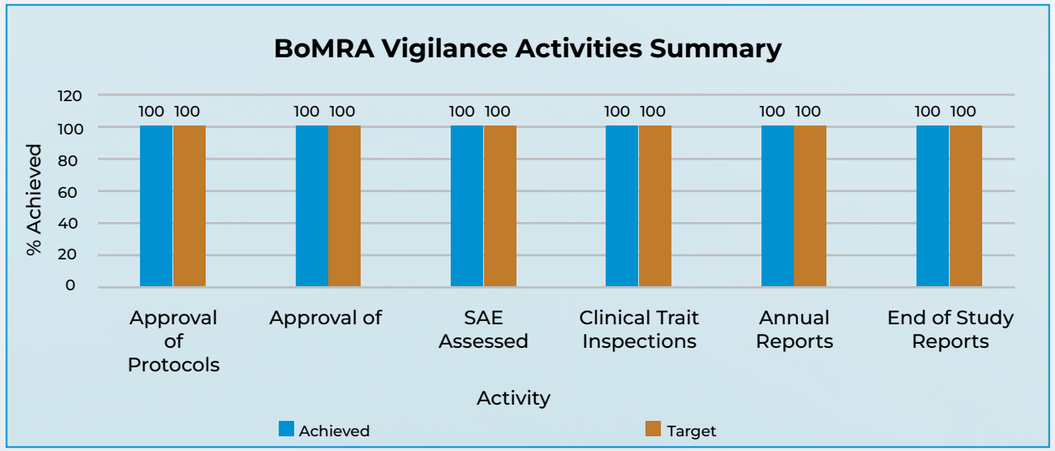

Figure 29: Clinical Trial Regulatory Compliance

Achievement: 100% compliance was observed in all clinical trial protocols, amendments, annual reports and Serious Adverse Events (SAEs) submissions to the Authority. Additionally, 5 GCP (Good Clinical Practice) inspections were conducted to ensure regulatory compliance to clinical trials in the country. Two GCP inspections were conducted regionally with other regulators (Medicines Control Agency Zimbabwe and Tanzania Medicines and Medical Devices Authority) to build capacity amongst the Clinical Trials unit staff, identification and adoption of best practices in GCP inspections, and exchange knowledge and expertise between BoMRA and regional regulatory Authority to harmonise regulatory requirements and processes.

SEARCH 2 PROJECT

The department is executing initiatives under the Southern Africa Regulatory for Clinical Research (SEARCH) 2 project, a European and Developing Countries Clinical Trials Partnership (EDCTP)-funded project. These initiatives are designed to enhance clinical trial processes in consortium countries and advance the organisations toward achieving Maturity Level 3 (ML3).

PHARMACOVIGILANCE AND **CLINICAL TRIALS (PVCT)** [Continued]

The SEARCH project addresses the identified challenges by aiming at capacity building and focusing on nationally and regionally-defined research and regulatory strengthening initiatives to increase country ownership and commitment to health research

The overall objectives include promoting collaboration and joint action between National Regulatory Authorities (NRAs) and National Ethics Committees (NECs) within and among participating Southern African countries namely: Botswana; Eswatini; Lesotho; Mozambique, Zambia, and Namibia, to improve the integrity of clinical trial oversight

The consortium will also develop technical expertise reinforcing regulatory systems at the national and regional level for supporting the conduct of clinical trials and strengthening frameworks and capabilities to ensure the safety, quality, and efficacy of medical products.

100% compliance was observed in all clinical trial protocols, amendments, annual reports and Serious Adverse Events (SAEs) submissions to the Authority.

The PMS strategy saw 88% implementation, with structured and unstructured PMS activities well-coordinated.

P5 - Establish Post Marketing Surveillance:

National Post Marketing Surveillance (PMS) Strategy:

Achievement: The PMS strategy saw 88% implementation, with structured and unstructured PMS activities well-coordinated. The first baseline for substandard and falsified products was established through risk-based sampling, with all samples tested meeting compendial standards.

Industry Compliance: A high level of product compliance was observed, with 531 registered products meeting regulatory requirements; some observations were noted for exempted products while they still met the minimum regulatory requirements.

Figure 30: Work Package's

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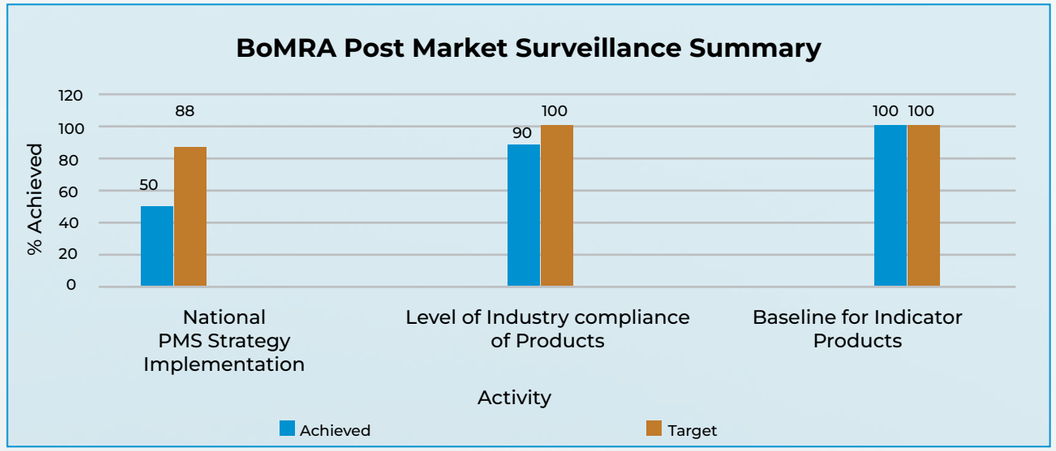

Figure 31: Post Market Surveillance Summary

Baseline for indicator products

The Post Marketing Surveillance (PMS) program's main objective is to promote access to safe and quality medical products leading to better patient outcomes. A baseline assessment for the substandard and falsified (SF) incidence in Botswana was conducted from 2021-2023 spanning over four financial years through structured and unstructured PMS. A total of 2,957 samples were collected, and 1341(45%) samples were subjected for confirmatory testing.

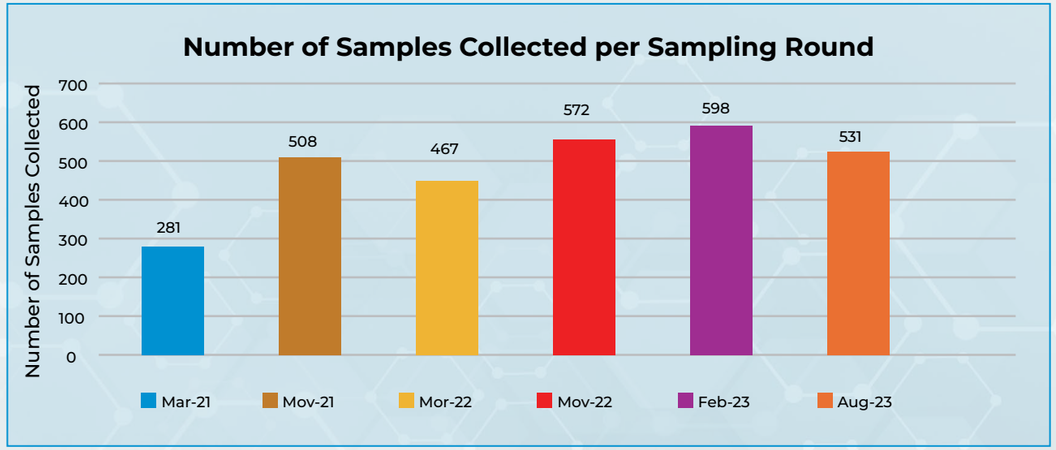

Figure 32: Number of Samples Collected per Sampling Round

PHARMACOVIGILANCE AND **CLINICAL TRIALS (PVCT)** [Continued]

A baseline for indicator products was established as ZERO as all samples passed i.e., they met the standards they were subjected to as per the Compendial Methods. Going forward the aim is to continue to strengthen the PMS Program by training and sensitization of the general public and healthcare professionals on the PMS activities. The authority is planning to implement the pharmaceutical traceability project in the country.

Product Quality Complaints

A total of 82 product quality complaints were received and all were investigated and necessary actions initiated within turnaround times.

Product Recall

Three product recalls were initiated and completed within turnaround times.

Global Fund Project

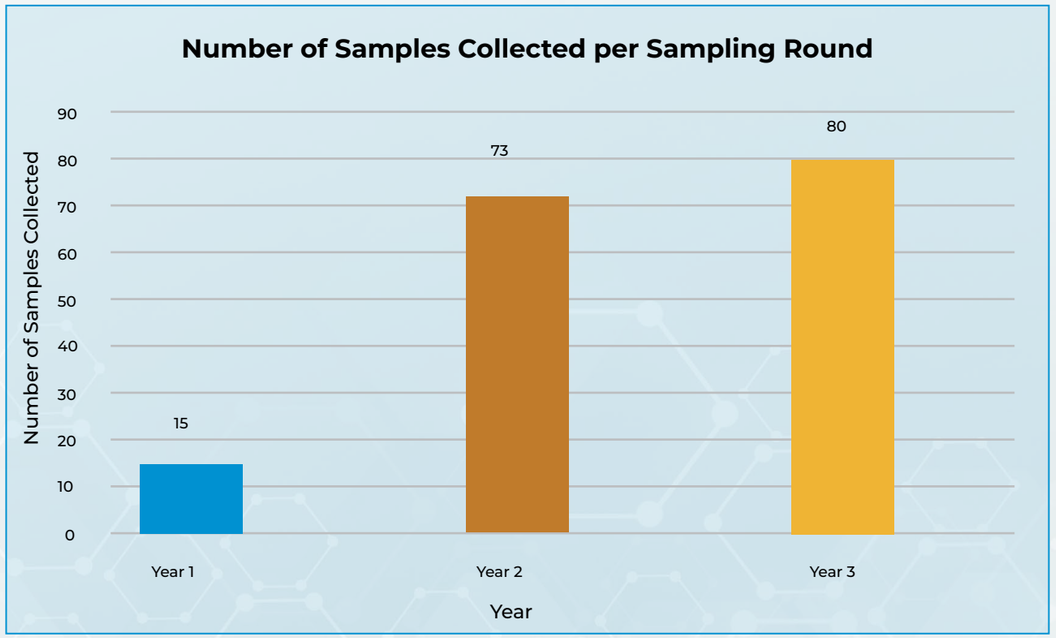

Figure 33: Global Fund Project Implementation

For the reporting period 2023-2024, i.e year 2 and half of year 3 of the project, 80% implementation has been achieved.The project shall be completed in the next reporting period following completion of key activities, all of which are underway and progressing according to plan.

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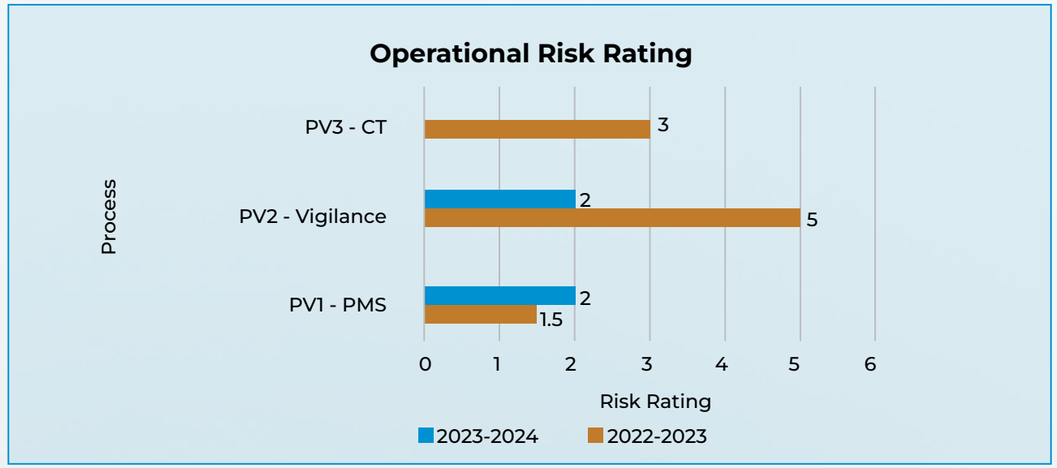
Figure 34: Operational Risk Rating



Enterprise Risk Management

The overall operational risk rating has improved from cautious to acceptable levels for this financial year.

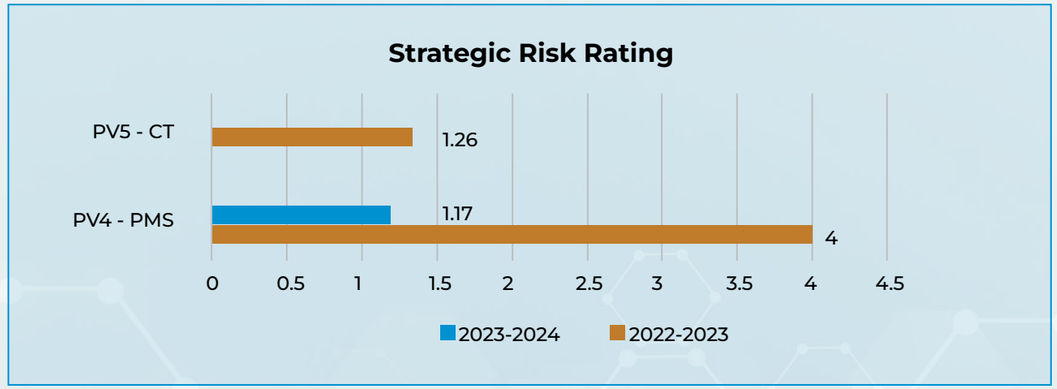


Figure 35: Strategic Risk Rating

The overall strategic risk rating has improved from cautious to acceptable levels for this financial year for PV 4 Post Market Surveillance and maintained acceptable levels for PV5 Clinical Trials.

The year under review demonstrates significant progress across BoMRA's strategic objectives related to pharmacovigilance, clinical trial controls, and post-marketing surveillance.

High compliance rates, effective implementation of strategies, and collaborative efforts with other regulatory bodies have contributed to advancing BoMRA's regulatory capabilities and positioning towards Maturity Level 3. The continuous improvement in these areas suggests a strong foundation for further enhancements in regulatory oversight and public health protection.

ANNUAL FINANCIAL **STATEMENTS**

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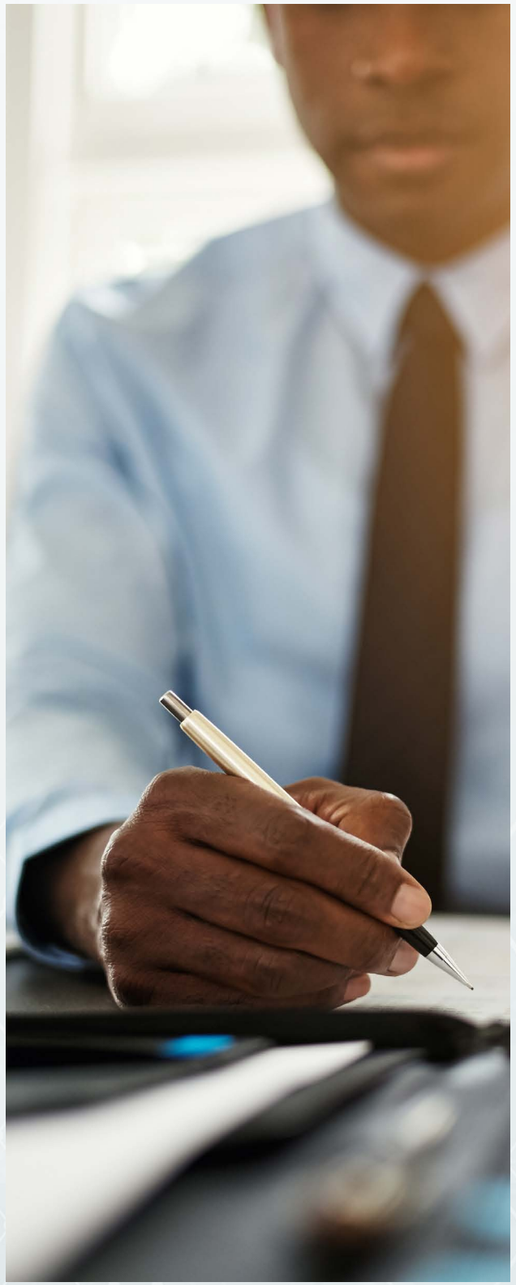
GENERAL INFORMATION

FOR THE YEAR ENDED 31 MARCH 2024



BOARD MEMBERS

- Dr. Kegomoditswe Biki Maphane (Chairperson)
- Dr. Lorato Mangadi-Mokama (Vice Chairperson)
- Dr. Kobedi Segale (Board Member)
- Ms. Mmama Mhlanga-Fichani (Board Member)
- Dr. Ditiro Coyne (Board Member)
- Ms. Elizabeth Kelentse (Board Member)
- Ms Matshidiso Matome (Board Member)
- Ms. Tiny Ralefala (Board Member)
- Mr Modisa Kebonyemodisa(Board Member)

ACTING CHIEF EXECUTIVE OFFICER
Dr. Seima Dijeng

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.

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STATEMENT OF RESPONSIBILITY BY THE BOARD OF DIRECTORS

FOR THE YEAR ENDED 31 MARCH 2024

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 2025 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 93 to 95.

The annual financial statements set out on pages 96 to 106, which have been prepared on the going concern basis, were approved by the board on 26 November 2024 and were signed on their behalf by:

MODISA KEBONYEMODISA
Chairperson

Chief Executive Officer

INDEPENDENT AUDITOR'S REPORT

FOR THE YEAR ENDED 31 MARCH 2024

Grant Thornton

To the Members of the Medicines Regulatory Authority (The Authority)

Report on Annual Financial Statements

Opinion

We have audited the annual financial statements of Medicines Regulatory Authorities (The Authority) ("The Authority") set out on pages 7 to 25, which comprise the statement of financial position as at 31 March 2024, and the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and notes to the financial statements, including a material accounting policy information.

In our opinion, annual financial Statements give a true and fair view of, the financial position of the Medicines Regulatory Authority (The Authority) as at 31 March 2024, 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 Regulatory Authority (The Authority) 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 Authority for Accountants Code of Ethics for Professional Accountants (Parts 1,3 and 4A) (IESBA Code) and other independence requirements applicable to performing audits of 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.

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INDEPENDENT AUDITOR'S REPORT

FOR THE YEAR ENDED 31 MARCH 2024

Grant Thornton

Other information

The Directors are responsible for the other information. The other information comprises the information included in the document titled "Medicines Regulatory Authority (The Authority) Annual Financial Statements for the year ended 31 March 2024", 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. Other information does not include the annual 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 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 we have obtained prior to the date of this auditors 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 International Financial Reporting Standards and the requirements of the Medicines Regulatory Authority (The Authority) 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.

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 skepticism 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.

INDEPENDENT AUDITOR'S REPORT

FOR THE YEAR ENDED 31 MARCH 2024

Grant Thornton

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Authority's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the members of the board 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.
- Obtain sufficient appropriate audit evidence regarding the financial information of the activities within the Authority to express an opinion on the annual financial statements. We are responsible for the direction, supervision and performance of the audit. We remain solely responsible for our audit opinion.

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.

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 21 (3) (a) and (b) of the Medicines and Related Substances Act, 2013.

- We have received all the information and explanations which to the best of our knowledge and belief were necessary for the performance of our duties as auditors.
- The accounts and related records of the Authority have been properly maintained.
- The Authority has complied with all the financial provisions of the Act, which it is their duty to comply with.
- The financial statements of the Authority were prepared on a basis consistent with that of the preceding year and represents a true and fair view of the transactions and financial affairs of the Authority.

Grant Thornton

27 Nov 24

Grant Thornton
Firm of Certified Auditors
Practicing Member: Madhavan Venkatachary (CAP 0017 2024)

Gaborone

ABOUT BOMRA | PERFORMANCE | CORPORATE GOVERNANCE | REGULATORY PERFORMANCE | ANNUAL FINANCIAL STATEMENTS

STATEMENT OF SURPLUS OR DEFICIT AND COMPREHENSIVE INCOME

FOR THE YEAR ENDED 31 MARCH 2024

	Notes	2024	2023
		P	P
Revenue	3	**90,647,614**	57,772,128
Regulatory fees	4	**17,886,656**	16,586,242
Total Income		**108,534,270**	74,358,369
Employee costs	5	**(74,789,384)**	(61,967,061)
Governance expenses		**(1,134,798)**	(1,147,678)
Depreciation and amortisation expenses	5	**(7,967,433)**	(7,810,953)
Publicity and awareness expenses		**(4,598,719)**	(3,983,687)
Travel and accommodation costs		**(7,920,911)**	(4,387,253)
Operating expenses		**(19,627,238)**	(13,880,094)
Total Expenses		**(116,038,484)**	(93,176,726)
Operating (deficit) / surplus		**(7,504,214)**	(18,818,357)
Investment income	6	**-**	5,876
Finance costs	7	**(468,937)**	(615,513)
Total Operating (deficit) / surplus for the year		**(7,973,151)**	(19,427,994)
Other comprehensive income		**-**	-
Total comprehensive (deficit) / surplus for the year		**(7,973,151)**	(19,427,994)

STATEMENT OF FINANCIAL POSITION

FOR THE YEAR ENDED 31 MARCH 2024

	Notes	2024	2023
		P	P
ASSETS			
Non-current assets			
Right-of-use asset	9	**4,579,398**	6,673,202
Property and equipment	10	**35,966,725**	35,597,349
Intangible assets	11	**6,335,678**	5,019,342
		46,881,802	47,289,892
Current assets			
Trade and other receivables	12	**4,111,023**	2,518,211
Cash and cash equivalents	13	**20,724,234**	28,895,054
		24,835,256	31,413,265
Total assets		**71,717,058**	78,703,157
RESERVES AND LIABILITIES			
Reserves			
Accumulated (Deficit) surplus		**(3,797,252)**	4,175,898
		(3,797,252)	4,175,898
Non-current liabilities			
Lease liabilities	9	**3,212,426**	6,008,404
Deferred income	14	**41,877,965**	40,513,575
		45,090,390	46,521,979
Current liabilities			
Lease liabilities	9	**2,758,916**	2,444,745
Deferred income	14	**7,618,575**	10,906,664
Trade and other payables	15	**20,046,429**	14,653,871
		30,423,920	28,005,280
Total reserves and liabilities		**71,717,058**	78,703,157

STATEMENT OF CHANGES IN RESERVES

FOR THE YEAR ENDED 31 MARCH 2024

	Accumulated Deficit	Total
Year ended 31 March 2023	**P**	**P**
Balance at 01 April 2022	23,603,892	23,603,892
Deficit for the period	(19,427,994)	(19,427,994)
Balance at 31 March 2023	**4,175,898**	**4,175,898**
Year ended 31 March 2024	**P**	**P**
Balance at 01 April 2023	4,175,898	4,175,898
Deficit for the period	(7,973,151)	(7,973,151)
Balance at 31 March 2024	**(3,797,253)**	**(3,797,253)**

STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED 31 MARCH 2024

	Notes	2024	2023
		P	P
Cash flows from operating activities:			
(Deficit) / Surplus for the year		**(7,973,151)**	(19,427,994)
Adjustments for:			
Depreciation and amortisation		**7,967,433**	7,810,953
Loss on disposal of property and equipment		**3,326**	(70,178)
Interest income		**-**	(5,876)
Finance costs		**468,937**	615,513
Operating income before reinvestment in working capital		**466,545**	(11,077,582)
Changes in working capital			
Increase in accounts receivables		**(1,592,812)**	(794,422)
Increase in accounts payable		**5,392,558**	3,403,577
Finance costs		**(468,937)**	(615,513)
Net cash (outflow) / inflow from operating activities		**3,797,354**	(9,083,940)
Cash flows from investing activities:			
Purchase of property and equipment	10	**(5,545,373)**	(4,350,234)
Purchase of intangible assets	11	**(2,035,724)**	(2,815,400)
Proceeds on disposal of property and equipment		**18,428**	404,106
Interest income		**-**	5,876
Net cash outflow from investing activities		**(7,562,669)**	(6,755,652)
Cash flows from financing activities:			
Payment of lease liabilities		**(2,481,807)**	(2,142,786)
(Decrease) / Increase in specific grants		**(3,288,088)**	8,111,631
Increase in deferred government grant		**1,364,389**	1,070,111
Net cash inflow from financing activities		**(4,405,506)**	7,038,955
Net movement in cash and cash equivalents		**(8,170,821)**	(8,800,637)
Cash and cash equivalents at beginning of year		**28,895,054**	37,695,691
Cash and cash equivalents at end of year	13	**20,724,233**	28,895,054

MATERIAL ACCOUNTING POLICIES

FOR THE YEAR ENDED 31 MARCH 2024

1 PRINCIPAL ACCOUNTING POLICIES

The material 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 SIGNFICANT JUDGEMENTS AND SOURCE 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.

MATERIAL ACCOUNTING POLICIES (continued)

FOR THE YEAR ENDED 31 MARCH 2024

1.2 SIGNFICANT JUDGEMENTS AND SOURCE 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.

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MATERIAL ACCOUNTING POLICIES (continued)

FOR THE YEAR ENDED 31 MARCH 2024

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 16 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.

Credit risk

Details of credit risk are included in the financial instruments and risk management (note 16).

Derecognition

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

MATERIAL ACCOUNTING POLICIES (continued)

FOR THE YEAR ENDED 31 MARCH 2024

1.5 FINANCIAL INSTRUMENTS (CONTINUED)

Accounts receivables (continued)

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 16 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.

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.

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MATERIAL ACCOUNTING POLICIES (continued)

FOR THE YEAR ENDED 31 MARCH 2024

1.6 LEASES (CONTINUED)

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

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

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

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

The Authority remeasures the lease liability (and makes a corresponding adjustment to the related right-of-use asset) when:
- there has been a change to the lease term, in which case the lease liability is remeasured by discounting the revised lease payments using a revised discount rate;
- there has been a change to the lease payments due to a change in an index or a rate, in which case the lease liability is remeasured by discounting the revised lease payments using the initial discount rate.

When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right-of-use asset.

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

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

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

1.7 RESERVES
Accumulated surplus under reserves represent excess of income over expenditure.

1.8 EMPLOYEE BENEFITS
Short-term employee benefits

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

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

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

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.

MATERIAL ACCOUNTING POLICIES (continued)

FOR THE YEAR ENDED 31 MARCH 2024

1.9 GOVERNMENT GRANTS (CONTINUED)

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

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

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

1.10 REGULATORY FEES

Authority provides regulations in order to provide regulation services. The Authority receives fees in advance for the provision of services. All contracts are fixed price and short-term. The Authority sends a written response at a specific point in time when an application has gone through decision-making. Consequently, revenue is recognised at a specific point when the application has been fully processed. Revenue is measured based on the consideration to which the Authority expects to be entitled in a contract with a customer and excludes amounts collected on behalf of third parties.

Revenue recognition follows a five-step model framework as follows:

Step1: Identify the contract(s) with a customer.
Step 2: Identify the performance obligations in the contract.
Step 3: Determine the transaction price.
Step 4: Allocate the transaction price to the performance obligations in the contract.
Step 5: Recognise revenue when (or as) the entity satisfies a performance obligation

1.11 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 2024

2 NEW STANDARDS AND INTERPRETATIONS

2.1 Standards and interpretations effective and adopted in the current year

In the current year, the company has adopted the following standards and interpretations that are effective for the current financial year and that are relevant to its operations:

Standard/ Interpretation:	Effective date: Years beginning on or after	Expected impact:
Deferred tax related to assets and liabilities arising from a single transaction: - Amendments to IAS 12	01 January, 2023	Unlikely there will be a material impact
Disclosure of accounting policies: -Amendments to IAS 1 and IFRS Practice Statement 2.	01 January, 2023	Unlikely there will be a material impact
Definition of accounting estimates:- Amendments to IAS 8	01 January, 2023	Unlikely there will be a material impact
IFRS 17 Insurance Contracts	01 January, 2023	Unlikely there will be a material impact

2.2 Standards and interpretations not yet effective or relevant

The following standards and interpretations have been published and are mandatory for the company's accounting periods beginning on or after 1 April 2024 or later periods:

Standard/ Interpretation:	Effective date: Years	Expected impact:
Classification of Liabilities as Current or Non-Current:- Amendment to IAS 1	01 January, 2024	Unlikely there will be a material impact
Leases on sale and leaseback: - Amendment to IFRS 16	01 January, 2024	Unlikely there will be a material impact
Amendments to supplier finance arrangements:- Amendments to IAS 7 and IFRS 7	01 January, 2024	Unlikely there will be a material impact
Lack of exchangeability: - Amendments to IAS 21	01 January, 2024	Unlikely there will be a material impact
Income Taxes: - Amendments to IAS12	01 January, 2024	Unlikely there will be a material impact

NOTES TO THE FINANCIAL STATEMENTS (continued)

FOR THE YEAR ENDED 31 MARCH 2024

	2024	2023
	P	P
3 REVENUE		
Grant received from Government of Botswana	**81,935,651**	49,953,072
Grants received from EDCPT and Global Fund	**2,835,943**	1,833,893
Amortisation of deferred income	**5,876,019**	5,985,162
	90,647,614	57,772,128
RECONCILIATION OF GOVERNMENT GRANT RECEIVED		
Grant received from Government of Botswana	**89,176,060**	57,008,346
Amount utilised to acquire assets	**(7,240,409)**	(7,055,274)
	81,935,651	49,953,072
4 REGULATORY FEES		
Regulatory fees - Registration	**15,284,271**	14,451,658
Other regulatory fees	**2,143,587**	1,928,637
Other income	**458,798**	205,947
	17,886,656	16,586,242

NOTES TO THE FINANCIAL STATEMENTS (continued)

FOR THE YEAR ENDED 31 MARCH 2024

	2024	2023
	P	P
5 OPERATING SURPLUS		
Operating surplus/(deficit) for the year is stated after charging (crediting) the following, amongst others:		
Auditors' remuneration		
Audit fees	**90,862**	85,438
Employee costs		
Salaries, wages and other benefits	**59,880,346**	49,455,974
Recruitment and consultancy costs	**216,625**	419,295
Pension scheme contribution	**4,668,478**	3,708,939
Gratuity expense	**5,847,235**	4,741,179
Leave pay expense	**3,394,901**	3,053,641
Professional and other subscriptions	**781,798**	588,032
	74,789,384	61,967,061
Depreciation		
Depreciation of property and equipment	**5,154,243**	5,064,926
Depreciation of right-of-use asset	**2,093,803**	2,093,803
Amortisation of intangible assets	**719,387**	652,224
	7,967,433	7,810,953
6 INVESTMENT INCOME		
Interest income		
Investments in financial assets:		
Other financial assets	**-**	5,876
7 FINANCE COSTS		
Lease liabilities	**468,937**	615,513
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).		

NOTES TO THE FINANCIAL STATEMENTS (continued)

FOR THE YEAR ENDED 31 MARCH 2024

	2024	2023
	P	P
9 LEASES (COMPANY AS LESSEE)		
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 2024		
Cost		
Balance at beginning of the year	**16,063,045**	16,063,045
Additions	**-**	-
Balance at end of the year	**16,063,045**	16,063,045
Depreciation		
Balance at beginning of the year	**9,389,843**	7,296,040
Charge for the year	**2,093,803**	2,093,803
Balance at end of the year	**11,483,647**	9,389,843
Net book value at 31 March 2024	**4,579,398**	6,673,202
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.		
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	**2,950,744**	2,950,744
Two to five years	**6,787,066**	6,787,066
	9,737,810	9,737,810
Less finance charges component	**(3,766,469)**	(1,284,661)
	5,971,342	8,453,149
Non-current liabilities	**3,212,426**	6,008,404
Current liabilities	**2,758,916**	2,444,745
	5,971,342	8,453,149

NOTES TO THE FINANCIAL STATEMENTS (continued)

FOR THE YEAR ENDED 31 MARCH 2024

10 PROPERTY, PLANT AND EQUIPMENT

	Land (valuation)	Motor vehicles (cost)	Computer equipment (cost)	Furniture and fixtures (cost)	Office equipment (cost)	Plant and machinery (cost)	Laboratory Equipment (cost)	Leasehold Improvements (cost)	Laboratory Work in Progress (cost)	Total (cost/ valuation)
	P	P	P	P	P	P	P	P	P	P
Year ended 31 March 2024										
Cost or valuation										
Balance at beginning of the year	21,000,000	2,970,054	8,442,412	2,116,553	1,442,627	-	9,689,496	1,086,697	1,665,990	48,413,828
Additions	-	-	3,226,062	545,473	189,700	415,132	1,001,767	142,938	24,300	5,545,373
Transfers	-	-	-	-	-	-	-	-	-	-
Disposals	-	-	(242,360)	-	(31,005)	-	-	-	-	(273,365)
Balance at end of the year	**21,000,000**	**2,970,054**	**11,426,114**	**2,662,026**	**1,601,322**	**415,132**	**10,691,263**	**1,229,635**	**1,690,290**	**53,685,836**
Depreciation										
Balance at beginning of the year	-	1,165,017	5,904,064	638,655	870,092	-	3,476,203	762,449	-	12,816,480
Charge for the year	-	309,446	2,050,565	235,727	270,977	26,292	2,045,883	215,352	-	5,154,243
Disposals depreciation	-	-	(222,152)	-	(29,460)	-	-	-	-	(251,612)
Balance at end of the year	**-**	**1,474,463**	**7,732,477**	**874,382**	**1,111,610**	**26,292**	**5,522,086**	**977,801**	**-**	**17,719,110**
Net book value at 31 March 2024	**21,000,000**	**1,495,591**	**3,693,637**	**1,787,644**	**489,713**	**388,841**	**5,169,177**	**251,834**	**1,690,290**	**35,966,726**
	P	P	P	P	P	P	P	P	P	P
Year ended 31 March 2023										
Cost or valuation										
Balance at beginning 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
Additions	-	768,189	1,717,572	84,021	86,798	-	940,409	28,243	725,003	4,350,234
Disposals	-	(1,130,070)	(214,627)	-	-	-	-	-	-	(1,344,697)
Balance at end of the year	21,000,000	2,970,054	8,442,412	2,116,553	1,442,627	-	9,689,496	1,086,697	1,665,990	48,413,828
Depreciation										
Balance at beginning of the year	-	1,473,997	4,169,760	428,473	592,187	-	1,625,691	472,214	-	8,762,323
Charge for the year	-	516,025	1,920,069	210,181	277,905	-	1,850,511	290,235	-	5,064,926
Disposals depreciation	-	(825,005)	(185,765)	-	-	-	-	-	-	(1,010,770)
Balance at end of the year	**-**	**1,165,017**	**5,904,064**	**638,655**	**870,092**	**-**	**3,476,203**	**762,449**	**-**	**12,816,480**
Net book value at 31 March 2023	21,000,000	1,805,037	2,538,348	1,477,898	572,535	-	6,213,293	324,248	1,665,990	35,597,349

NOTES TO THE FINANCIAL STATEMENTS (continued)

FOR THE YEAR ENDED 31 MARCH 2024

11 INTANGIBLE ASSETS

	Computer software (cost)	Computer software work in progress (cost)	Total (cost)
	P	P	P
Year ended 31 March 2024			
Cost			
Balance at beginning of the year	3,877,415	2,557,894	6,435,309
Additions	450,888	1,584,836	2,035,724
Balance at end of the year	**4,328,304**	**4,142,729**	**8,471,033**
Depreciation			
Balance at beginning of the year	1,415,967	-	1,415,967
Charge for the year	719,387	-	719,387
Balance at end of the year	**2,135,355**	**-**	**2,135,355**
Net book value at 31 March 2024	**2,192,949**	**4,142,729**	**6,335,678**
Year ended 31 March 2023			
Cost			
Balance at beginning of the year	3,291,184	328,726	3,619,909
Additions	586,232	2,229,168	2,815,400
Balance at end of the year	3,877,415	2,557,894	6,435,309
Depreciation			
Balance at beginning of the year	763,744	-	763,744
Charge for the year	652,224	-	652,224
Balance at end of the year	1,415,967	-	1,415,967
Net book value at 31 March 2022	2,461,448	2,557,894	5,019,342

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.

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NOTES TO THE FINANCIAL STATEMENTS (continued)

FOR THE YEAR ENDED 31 MARCH 2024

	2024	2023
	P	P
12 ACCOUNTS RECEIVABLE		
Accounts receivable	**579,360**	369,771
Lease deposit	**171,375**	171,375
Non-financial instruments		
Prepayments	**3,273,168**	1,938,178
Staff advances	**87,120**	38,888
Total trade and other receivables	**4,111,023**	2,518,211
Financial instrument and non-financial instrument components of receivables		
At amortised cost	**750,735**	541,146
Non-financial instruments	**3,360,288**	1,977,065
	4,111,023	2,518,211

The average credit period is 90 days. Accounts receivables which are less than 6 months past due are not considered to be impaired. No interest is levied on these debtors, they are not secured and have not been rescheduled. The carrying value of accounts receivables approximates their fair values due to their short-term nature. The accounts receivables past due but not impaired were Nil, (2023,P Nil).

13 CASH AND EQUIVALENTS

Cash and cash equivalents consist of:		
Bank balances	**20,724,234**	28,895,054
	20,724,234	28,895,054

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.

NOTES TO THE FINANCIAL STATEMENTS (continued)

FOR THE YEAR ENDED 31 MARCH 2024

	2024	2023
	P	P
14 DEFERRED INCOME		
The Authority received a total amount of P 89,176,060 as a Government grant during the reporting period Grants related to assets are recognised 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	**40,513,575**	39,443,464
Assets purchased during the year	**7,240,409**	7,055,274
Amortisation of grant related to assets	**(5,854,266)**	(5,651,235)
Adjustment on asset retirement	**(21,753)**	(333,927)
At the end of year	**41,877,965**	40,513,575
Grants related to specific projects		
Opening balance	**10,906,664**	2,795,033
Grants received for specific projects	**1,196,511**	9,945,524
Grants used for specific projects operating expenditure	**(4,484,599)**	(1,833,893)
Grants disbursed to other beneficiaries	**-**	-
At the end of year	**7,618,575**	10,906,664
Total Deferred Income	**49,496,540**	51,420,239
15 ACCOUNTS PAYABLE		
Financial instruments:		
Payable to suppliers	**6,105,468**	5,859,878
Provision for gratuity	**6,071,163**	3,327,255
Provision for leave pay	**7,869,798**	5,466,738
	20,046,429	14,653,871
Categorisation of accounts payable		
At amortised cost	**20,046,429**	14,653,871
Exposure to liquidity risk		
Refer to note 16 Financial instruments and financial risk management for details of liquidity risk exposure and management.		

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NOTES TO THE FINANCIAL STATEMENTS (continued)

FOR THE YEAR ENDED 31 MARCH 2024

		2024	2023
		P	P
16 FINANCIAL INSTRUMENTS AND RISK MANAGEMENT			
Categories of financial instruments			
Categories of financial assets			
	Note (s)	**Amortised cost**	**Amortised cost**
Assets as per the statement of financial position			
Accounts receivables	12	**750,735**	541,146
Cash and cash equivalents	13	**20,724,234**	28,895,054
		21,474,968	29,436,200
Categories of financial liabilities			
Liabilities as per statement of financial position			
Accounts payable	15	**20,046,429**	14,653,871
Finance lease obligations	9	**5,971,342**	8,453,149
		26,017,771	23,107,020

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 2024, 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 institutions with high credit ratings.

NOTES TO THE FINANCIAL STATEMENTS (continued)

FOR THE YEAR ENDED 31 MARCH 2024

16 FINANCIAL INSTRUMENTS AND RISK MANAGEMENT (CONTINUED)

Credit risk (Continued)

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

		2024			2023		
		Gross carrying amount	Credit loss allowance	Amortised cost/fair value	Gross carrying amount	Credit loss allowance	Amortised cost/fair value
Accounts receivable	12	4,111,023	-	4,111,023	2,518,211	-	2,518,211
Cash and cash equivalents	13	20,724,234	-	20,724,234	28,895,054	-	28,895,054
		24,835,256	**-**	**24,835,256**	31,413,265	-	31,413,265

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.

2024

		Less than 1 year	2 to 5 years	Total	Carrying amount
Non-current liabilities					
Lease liabilities		**-**	**3,212,426**	**3,212,426**	**3,212,426**
Current liabilities					
Accounts payable	10	20,046,429	-	20,046,429	**20,046,429**
Lease liabilities	9	2,758,916	-	2,758,916	**2,758,916**
		22,805,345	**3,212,426**	**26,017,771**	**26,017,771**

2023

	Less than 1 year	2 to 5 years	Total	Carrying amount
Non-current liabilities				
Lease liabilities	-	6,008,404	6,008,404	6,008,404
Current liabilities				
Accounts payable	14,653,871	-	14,653,871	14,653,871
Lease liabilities	2,444,745	-	2,444,745	2,444,745
	17,098,616	6,008,404	23,107,020	23,107,020

NOTES TO THE FINANCIAL STATEMENTS (continued)

FOR THE YEAR ENDED 31 MARCH 2024

17 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.

Medicines Regulatory Board	Refer to general information for a list of Medicines Regulatory Board (Page-1).
Members of Key Management	Dr. Seima Dijeng (Acting Chief Executive Officer) Ms Ropafadzai Hove (Chief Regulatory Officer) Mr. Harold Kuvenga (Director: Finance and Administration) Mr Bathusi Kgosietsile (Director: Product Evaluation and Registration) Dr. Parthasarathi Gurumurthy (Director: Pharmacovigilance and Clinical Trials) Ms. Shirely Pine (Director Human Resourcers and Organisational development) Ms. Zukiswa Raditladi (Acting Director Inspections & Licensing)
Main Financier	Government of the Republic of Botswana

	2024	2023
Related party transactions	**P**	P
Compensation to directors and other key management		
Salaries and other short term benefits	**8,761,310**	7,000,594
Gratuity	**2,346,963**	1,853,930
	11,108,274	8,854,524
Grant received		
Government of Republic of Botswana	**89,176,060**	57,008,346
Transactions with other parastatals		
Botswana Telecommunication Corporation - Telephone	**1,351,524**	1,282,267
Botswana Power Corporation- Electricity	**554,441**	510,076
Sitting allowance		
Medicines Regulatory Board	**514,432**	368,329
Related party balances		
Amounts included in other payables regarding related parties		
Botswana Telecommunication Corporation - Telephone	**708,123**	70,941
Botswana Power Corporation- Electricity	**-**	45,219
Botswana Unified Revenue Services - Paye & WHT	**85,010**	1,046,776

NOTES TO THE FINANCIAL STATEMENTS (continued)

FOR THE YEAR ENDED 31 MARCH 2024

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.

DETAILED INCOME STATEMENT

FOR THE YEAR ENDED 31 MARCH 2024

		2024	2023
		P	P
Revenue			
Amortisation of deferred income		5,876,019	5,985,162
Grant received from the Government of Botswana		81,935,651	49,953,072
Other grants received		2,835,943	1,833,893
	3	**90,647,614**	57,772,128
Other operating income			
Other operating income	4	17,886,656	16,586,242
Operating expenses			
Amortisation and depreciation	5	(7,967,433)	(7,810,953)
Auditors remuneration - external auditors	5	(90,862)	(85,438)
Bank charges		(139,020)	(130,490)
Computer expenses		(3,366,023)	(2,105,002)
Consultancy fees		(1,814,275)	(999,909)
Consulting and professional fees - legal fees		(57,456)	(90,142)
Consumables		(1,353,040)	(440,997)
Donations		(82,500)	(25,000)
Employee costs	5	(74,789,384)	(61,967,061)
Governance costs		(986,481)	(972,098)
Insurance		(365,106)	(304,553)
Motor vehicle expenses		(737,212)	(638,904)
Postage		(125,299)	(34,375)
Printing and stationery		(394,375)	(278,615)
Publicity and awareness		(2,322,120)	(2,131,688)
Records management		(107,878)	(291,993)
Repairs and maintenance		(1,188,874)	(735,519)
Security		(383,565)	(423,419)
Seminars and conferences		(2,194,099)	(1,826,999)
Short term lease		(76,690)	(51,236)
Staff welfare		(1,503,443)	(1,188,574)
Technical expenses		(3,865,160)	(1,875,223)
Telephone and fax		(2,298,390)	(2,208,275)
Training		(1,273,634)	(1,474,174)
Travel and accommodation		(7,920,911)	(4,387,253)
Utilities		(635,252)	(583,421)
		(116,038,484)	(93,061,310)
Operating surplus/(deficit)		**(7,504,214)**	(18,702,940)
Investment income	6	**-**	5,876
Finance costs	7	(468,937)	(615,513)
Surplus / (Deficit) for the year		**(7,973,151)**	(19,312,578)

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

Notes

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Notes

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