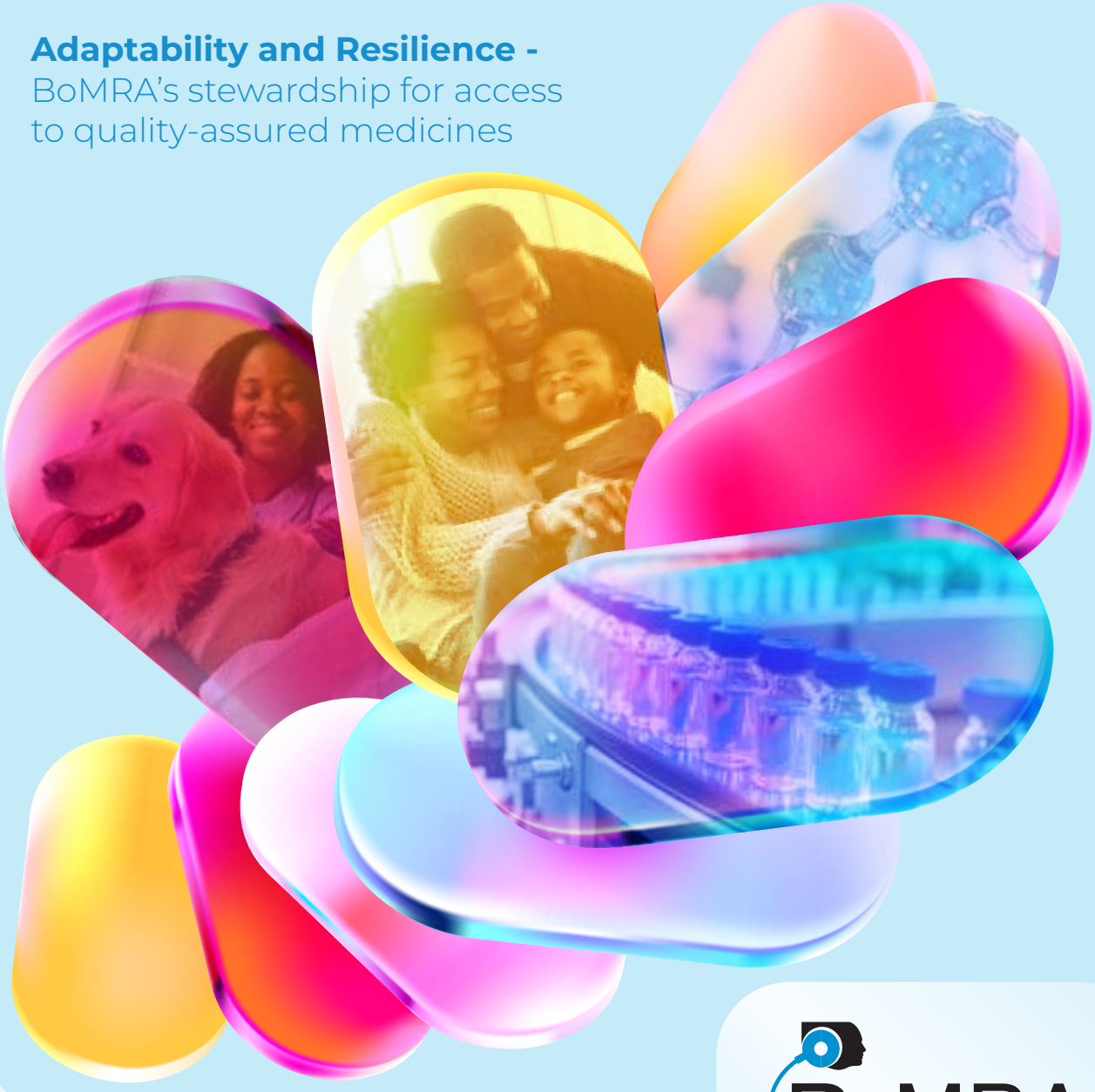
BOTSWANA MEDICINES REGULATORY AUTHORITY

ANNUAL REPORT

2025/2026

Adaptability and Resilience -
BoMRA's stewardship for access to quality-assured medicines



BoMRA
MEDICINES REGULATORY AUTHORITY

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Annual Report 2025/26

Botswana Medicines Regulatory Authority or BoMRA is responsible for ensuring the safety, efficacy and quality of medicines and related substances, which includes human, 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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BOMRA
PERFORMANCE

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Letter From The Board Chairperson

> **There are years in which governance is exercised through steady oversight, and there are years in which it is tested in real time, revealed through the choices leaders are required to make when circumstances become more demanding. The 2025/2026 financial year was unmistakably the latter.**

Botswana's operating environment shifted significantly during the reporting period. A new Government brought new national priorities, the fiscal environment tightened across the public sector, and medicine availability became one of the country's most pressing healthcare concerns. These developments presented new challenges for institutions across the health sector, including BoMRA. They did not alter our mandate. If anything, they reinforced why that mandate exists and why sound governance matters most when the environment becomes less certain.

Stewardship Through Change

Governance is often most visible during periods of stability. Its true value, however, is revealed when institutions must make difficult decisions without losing sight of their purpose. Throughout the year, the Board remained focused on providing strategic direction, disciplined oversight and responsible stewardship so that BoMRA could continue fulfilling its responsibility to protect public health while responding to a changing operating environment.

One lesson reinforced throughout the year was that good governance cannot be exercised in isolation from context. Effective oversight requires the Board to understand not only the organisation it governs, but also the environment within which that organisation operates. Throughout the year, we continually

returned to one guiding question: what must remain constant, regardless of the circumstances around us? That clarity of purpose became our North Star. It ensured that every governance decision, every discussion around priorities and every difficult trade-off remained anchored in BoMRA's core responsibility of protecting the health and wellbeing of the people of Botswana.

Built Layer by Layer

The theme of this Annual Report speaks to resilience built in layers, and from a governance perspective, it is a fitting reflection of the year under review. Strong institutions are not strengthened through a single achievement. They are built layer by layer through accountable governance, capable leadership, sound financial stewardship, effective partnerships and a culture anchored in the public interest. Each layer reinforces the next, creating an institution capable of adapting without compromising its standards. This year demonstrated the value of foundations laid over many years, allowing BoMRA to respond confidently when the system came under pressure.

The financial environment required careful judgement from both the Board and management. Fiscal constraints demanded disciplined prioritisation, and together we made a deliberate decision to protect the Authority's core regulatory responsibilities above all else. The systems responsible for safeguarding the quality, safety and efficacy of medicines remained our first priority, while some planned initiatives were deferred until circumstances allow for their implementation. This was not a departure from our long-term strategic vision. Rather, it reflected the discipline of good governance, recognising that effective stewardship is measured not by pursuing every opportunity at once, but by protecting the priorities that matter most.

Throughout the year, the Board remained equally mindful that public confidence is one of BoMRA's greatest responsibilities. Regulators do not exist to attract attention. They exist to provide assurance. Confidence is built through consistent oversight, transparent decision making and institutions that continue to perform reliably regardless of the challenges they face. While operational delivery rests with management, the Board's responsibility is to ensure that the governance framework supporting those operations remains robust, accountable and fit for purpose.

The reporting period also provided an important opportunity for the Board to reflect on its own effectiveness. We commissioned an independent Board evaluation to assess our governance practices, identify opportunities for improvement and strengthen our oversight responsibilities. Governance demands continuous learning, and the willingness to examine our own performance is an essential part of building an institution capable of meeting future challenges with confidence.

Against this backdrop, the milestones achieved during the year carry particular significance. The approval of the Medicines Regulatory Authority Act, 2025 provides BoMRA with a stronger legislative foundation and represents an important step towards achieving World Health Organization Maturity Level 3. Likewise, the SADCAS accreditation of the Quality Control Laboratory strengthens confidence in Botswana's technical capability while enhancing the Authority's standing within the region. These achievements are more than individual successes. They represent enduring institutional layers that will continue strengthening BoMRA long after this reporting period has concluded.

The Board also recognises that resilient institutions are strengthened through meaningful partnerships. During the year we continued engaging Government, development partners, regional regulatory authorities and the wider healthcare ecosystem, recognising that effective medicines regulation depends as much on collaboration as it does on technical excellence. Our governance review also highlighted opportunities to strengthen stakeholder engagement further, and this will remain an important area of focus as we continue building an Authority trusted not only for the quality of its regulation, but also for the strength of its relationships.

The Next Layer

As we look ahead, the Board's priorities are clear. We will continue strengthening governance systems, supporting implementation of the new legislative framework and maintaining oversight of the Authority's progression towards WHO Maturity Level 3 and beyond. Particular emphasis will be placed on leadership succession, strengthening internal assurance functions, developing organisational capability, advancing digital transformation and supporting long-term financial sustainability. Together, these priorities represent the next layers in building a stronger, more resilient regulatory authority equipped to meet the evolving needs of Botswana's healthcare system.

Ultimately, our responsibility extends beyond governance structures, legislation and institutional performance.

Letter From The Board Chairperson *(Continued)*

It reaches every patient who depends on medicines that are safe, effective and of assured quality, often without ever seeing the systems that safeguard them. That responsibility guided every decision the Board made throughout the year, and it will continue to guide those that follow.

I extend my sincere appreciation to my fellow Board members for their wisdom, diligence and unwavering commitment throughout what has been a demanding and defining period for the Authority. I am particularly grateful to those Board members whose terms conclude alongside mine. It has been a privilege to serve with colleagues whose integrity, sound judgement and shared commitment have strengthened both this Board and the institution it governs.

My gratitude also goes to the Chief Executive Officer, management and every member of the BoMRA team, whose professionalism and dedication enabled the Authority to continue serving the people of Botswana with integrity and purpose. I also thank the Honourable Minister, the Ministry of Health, Government, our development partners, healthcare professionals, industry stakeholders and every organisation that continues to strengthen Botswana's medicines regulatory system through collaboration and shared purpose.

As I conclude my tenure as Chairperson, I do so with confidence in the direction of this Authority and in the people who will continue leading it forward. Good governance is rarely measured by the decisions that attract the greatest attention. More often, it is reflected in the confidence people place in institutions that continue to protect them, year after year. BoMRA is a stronger institution today because its foundations have continued to deepen, its governance has continued to mature and its purpose has remained constant. It has been one of the greatest privileges of my professional life to contribute to that journey, and I leave knowing the next chapter will be built, as this one has been, layer by layer.

Dr. Kegomoditswe Biki Maphane
Chairperson

Chief Executive Officer's Report

Looking back on the past financial year, I find myself reflecting less on what we achieved than on what the year demanded of us. For BoMRA, 2025/26 was a year that tested our preparations, and I am proud of how this organisation responded.

The year unfolded against a backdrop of significant change. Botswana welcomed a new Government with new priorities, tighter fiscal conditions reshaped the public sector, and medicine shortages became one of the country's most pressing healthcare challenges. These developments did not alter our mandate; they altered the environment in which we had to deliver it.

When we concluded our previous Annual Report, I wrote about preparing the ground for a new strategic chapter. This year tested those preparations. The systems we had strengthened, the governance we had embedded and the partnerships we had cultivated became the foundations upon which we relied every day.

As Batswana say, pelo nngwe ga e agelwe motse: one heart cannot build a village. Sound governance, capable people, strong partnerships and disciplined stewardship helped us respond without compromising our standards. That, for me, is the defining story of this reporting period: we maintained institutional strength while adapting to circumstances beyond our control.

Responding When the System Was Under Pressure

Nothing illustrated this more clearly than the national medicines shortage. Global supply challenges have persisted since the COVID-19 pandemic, but their impact became far more pronounced this year, as fiscal pressures drove a significant increase in the sourcing of medicines from non-traditional suppliers.

For BoMRA, the challenge was straightforward, even if the solution was not: we had to facilitate access to medicines while maintaining the standards that protect public health. Rather than replacing established regulatory pathways, we strengthened them through additional safeguards, what I often describe as "layered interventions".

A pre-shipment inspection service was implemented on unregistered medicines to add independent verification at the country of export. At the same time, we intensified post-market surveillance and pharmacovigilance; enhanced surveillance enabled timely identification of quality concerns, allowing BoMRA to respond promptly.

Good regulation cannot wait for problems to reach patients. Every investment we make in digital capability, partnerships, laboratory excellence and legislative reform is ultimately about anticipating risk before it reaches the public.

Stewardship Through Constraint

The Authority also entered the first year of implementing its 2025–2030 Strategic Plan under considerably tighter financial conditions than anticipated. Our ambition was to accelerate growth by investing in people, systems and institutional capability; the operating environment required us to make different choices instead.

Rather than accelerating growth, our focus shifted to protecting capability. Certain projects were deferred and priorities revisited, not because our ambition had changed, but because protecting organisational capability had to come first. Cost containment is no longer a temporary response; it is now part of how we manage resources and make decisions.

Protecting the organisation also meant protecting our people and the institutional knowledge that takes years to build. The appointment of a Partnerships Manager strengthened our ability to secure donor funding, technical assistance and strategic collaboration, allowing critical capability-building to continue despite constrained budgets.

Together with disciplined financial management, these efforts enabled BoMRA to close the year with a surplus for two consecutive years, partly reflecting the timing of Government subvention payments, but also sustained cost containment and the growing contribution of development partners. The result is a financially stable Authority, better positioned to continue serving Botswana.

Strengthening the Layers That Endure

While much of the year required immediate operational decisions, we remained equally committed to strengthening the foundations that will support Botswana's regulatory system for years to come.
One of our most significant achievements was the successful passage of the Medicines Regulatory Authority Act, 2025, the culmination of years of consultation and technical refinement. The revised Act strengthens reliance, sustainable funding mechanisms, enforcement provisions and the regulation of traditional medicines, creating a stronger platform for our progress towards WHO Global Benchmarking Tool Maturity Level 3.

Another milestone of which we are particularly proud was the SADCAS accreditation of our Quality Control Laboratory to ISO/IEC 17025, validating years of investment in laboratory capability and providing independent assurance that our results meet internationally recognised standards. Together with our continued ISO 9001 certification, it reflects something we have worked towards consistently: quality is not simply something we expect from those we regulate: it must be evident in the way we regulate.

Responding to Change Without Losing Direction

The Government's renewed focus on medicinal cannabis required us to review legislative implications and regulatory frameworks; our role remains to support innovation while ensuring patient safety is never compromised. Artificial intelligence is also beginning to reshape regulatory science globally, and during the year we began to explore how we can incorporate AI into our digital strategy so the Authority remains prepared for emerging technologies while using them responsibly.

The Value of Partnership

Financial constraints reinforced an important lesson: no regulator succeeds alone. We turned deliberately towards partnerships, donor support and regional collaboration, which enabled us to continue developing our people, strengthen our technical capability and respond to emerging regulatory challenges even when internal resources were constrained.

Closer collaboration with neighbouring regulators remains equally important, since substandard and falsified medicines do not recognise national borders. As we say in Setswana, kgosi ke kgosi ka batho: leadership exists because of people. The same is true of institutions: our progress is shaped as much by the strength of our relationships as by what we achieve internally.

Chief Executive Officer's Report *(Continued)*

A Culture That Carries Us Forward

The milestones of this year matter, but they are not what gives me the greatest sense of pride. Despite sustained financial pressure and an increasingly demanding operating environment, our people continued to show up with professionalism, commitment and an unwavering focus on the public we serve. We protected jobs where we could, aggressively pursued partnerships to strengthen our talent pipeline, and continued leveraging external technical assessors to manage the product registration workload. Governance and culture are strengthened through consistent decisions made every day, often long before their value becomes visible. That culture remains one of BoMRA's greatest strengths.

Looking Ahead

Strong regulatory systems are shaped not by periods of stability, but by how they respond when circumstances become demanding. As we move into the next phase of our Strategic Plan, our direction remains clear: strengthening the legislative, technical and institutional foundations that support our journey towards WHO Global Benchmarking Tool Maturity Level 3, while contributing meaningfully to the strengthening of regulatory systems across Africa.

In the year ahead, our priorities include implementing the new Medicines Regulatory Authority Act and its supporting regulations, reducing application backlogs, strengthening reliance pathways, improving our digital services, deepening partnerships and expanding regional collaboration.
The healthcare landscape will keep evolving. New technologies, changing disease patterns and shifting national priorities will require us to remain agile without losing sight of our core purpose, a responsibility we embrace with confidence, and with humility.

Appreciation

I extend my sincere appreciation to our Board of Directors for their guidance and steadfast oversight throughout a demanding year, and to Government, our regional and international partners, healthcare professionals, industry stakeholders and all who continue to work alongside BoMRA in strengthening Botswana's regulatory system.

To the entire BoMRA team: thank you. This report speaks to legislation, laboratory accreditation, partnerships and financial stewardship, and behind every one of those achievements are people who remained committed to their work despite an exceptionally challenging year.

Last year, I wrote about preparing the ground for what lay ahead. This year, those foundations carried us through one of the most demanding periods in BoMRA's recent history, and we came through it without compromising our standards or losing sight of our purpose. That is the strongest foundation on which we will continue to build.

Dr. Seima Dijeng
Chief Executive Officer

Finance Director's Report

BoMRA achieved a total income of P123.3 million, reflecting steady growth from the prior year (2025: P116.0 million).

The period under review was one coloured by constrained fiscal conditions. Despite this, BoMRA achieved a total income of P123.3 million, reflecting steady growth from the prior year (2025: P116.0 million). This performance was underpinned by a combination of government subvention, donor funding, and strengthened regulatory fee collections, demonstrating the Authority's ongoing efforts to diversify revenue streams and enhance financial sustainability.

Government grants remained the primary funding source at P86.8 million, complemented by increased support from development partners and growth in regulatory fees to P7.3 million and P23.8 million respectively, indicating improved service uptake and regulatory effectiveness.

Income Streams

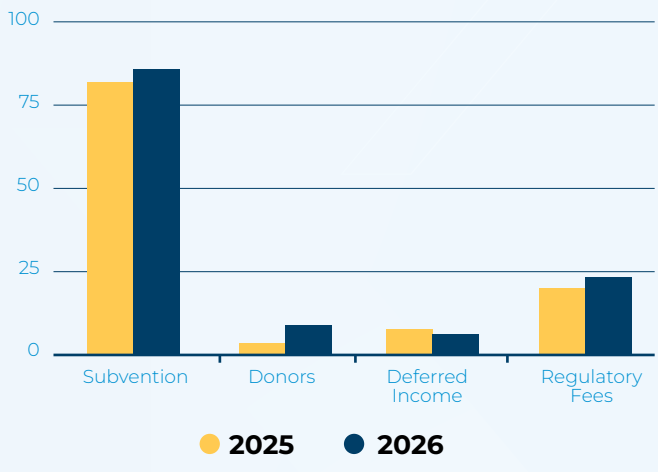


Figure 1: Income Streams

2026 Income Mix

Figure 2: 2026 Income Mix

In terms of expenditure, the Authority exercised prudent cost management, achieving a reduction in employee costs and governance expenditures compared to the prior year. Total expenses amounted to P106.4 million, reflecting disciplined resource allocation aligned with strategic priorities. As a result, BoMRA reported a total surplus of P16.7 million, a significant improvement from P5.16 million in the previous year. This, however, caused delayed implementation of some strategic projects, as subvention was received in the last week of the financial year.

Strengthening Liquidity and Operational Resilience

The Authority's liquidity position improved significantly, with cash and cash equivalents increasing to P34.1 million (2025: P13.2 million). This strong cash position reflects effective cash flow management and improved operational efficiency, enabling BoMRA to remain responsive to emerging National priorities and evolving regulatory demands.

Cash versus Current Liabilities

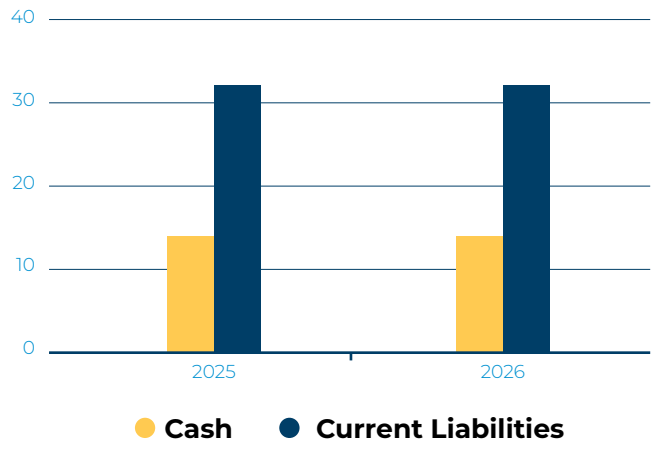


Figure 3: Cash vs Current Liabilities

Cash vs Current Ratios

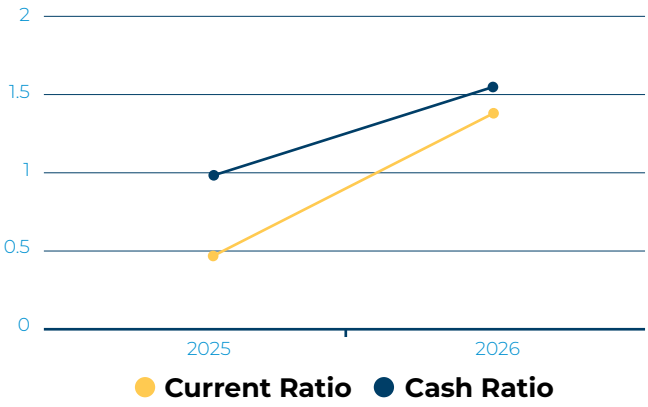


Figure 4: Current and Cash Ratios

Current ratio improved from 0.85x to 1.47x. Cash ratio improved from 0.42x to 1.31x.

Prudent Stewardship in a Constrained Environment

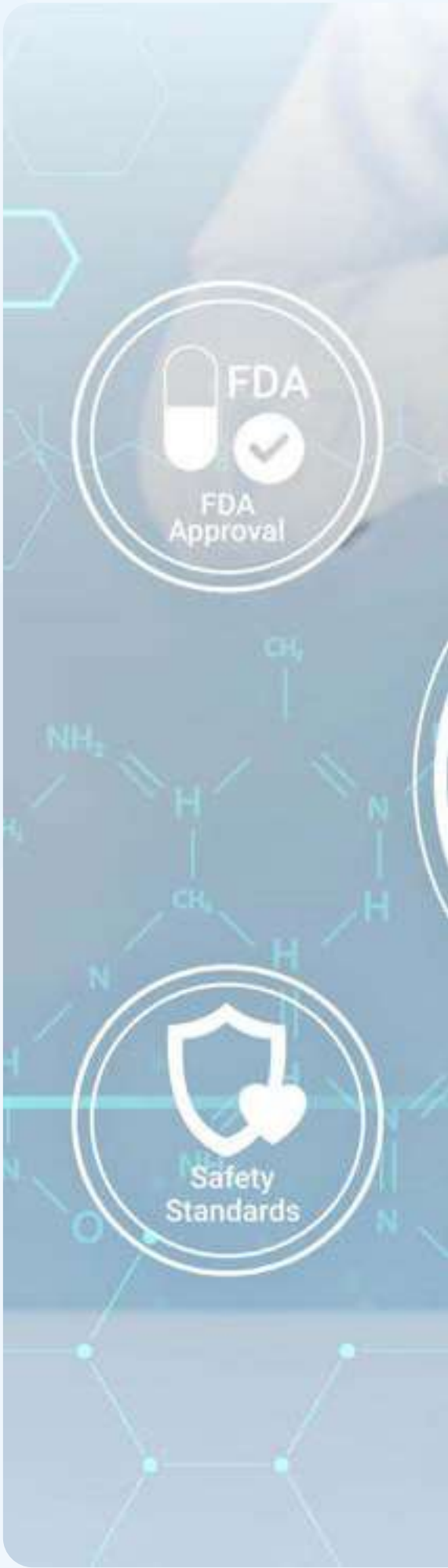
The Authority demonstrated adaptability in reallocating resources towards high-impact regulatory activities. Strategic prioritisation was critical in maintaining service delivery under constrained budgets, ensuring that regulatory operations that directly affect medicine quality, safety, and access were protected.

Cost containment measures, particularly in travel, training, and non-essential expenditure, enabled the Authority to sustain operations without compromising regulatory outcomes. At the same time, investments in essential assets and digital systems were maintained to support long-term efficiency and service improvement.

Investment in Systems and Infrastructure

The Authority continued to invest in infrastructure and systems that enhance regulatory efficiency and transparency. Capital expenditure during the year supported improvements in property, equipment, and digital platforms, contributing to the Authority's evolving operational capability. Notably, the continued rollout and utilisation of digital systems, including regulatory information management platforms, has strengthened process efficiency, reduced turnaround times, and improved stakeholder experience, which are critical components in ensuring access to quality-assured medicines.

Finance Director's Report *(Continued)*



Enhancing Accountability and Financial Governance

BoMRA maintained strong financial governance aligned with International Financial Reporting Standards (IFRS) and statutory requirements. The Board continues to place significant emphasis on internal controls, risk management, and ethical conduct, ensuring that financial resources are managed transparently and responsibly. Through these governance mechanisms, the Authority has maintained stakeholder confidence and ensured that financial management practices directly support regulatory effectiveness and public health outcomes.

Impact and Value Delivered

The financial performance achieved during the year reflects more than fiscal discipline; it demonstrates the Authority's ability to translate limited resources into meaningful regulatory impact.

Through prudent financial stewardship, BoMRA has:

- Sustained regulatory operations amid fiscal constraints
- Strengthened financial resilience and liquidity
- Supported regulatory innovation and digital transformation
- Enabled continued access to safe, effective, and quality medicines

These outcomes reinforce the Authority's role as a responsive and adaptable regulator, capable of delivering its mandate even in challenging and uncertain conditions.

Looking Ahead

As BoMRA progresses into its next strategic cycle, the focus will remain on strengthening financial sustainability, enhancing revenue diversification, and maintaining disciplined expenditure management. Key priorities will include optimising the regulatory fee framework to support long-term sustainability, leveraging partnerships and donor funding to supplement core resources, deepening investments in digital transformation to improve efficiency and transparency, and strengthening financial planning to align with evolving regulatory demands.

Mr. Kitso Leburu
Director Finance and Administration


EMA
EMA Certification
Drug Evaluation
Approval Process
Quality Control

CORPORATE **GOVERNANCE**

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BOARD MEMBERS

1 **Dr. Kegomoditswe Biki Maphane**
Chairperson

2 **Dr. Lorato Mangadi**
(Vice-Chairperson)

3 **Dr. Ditiro Coyne**
(Member)

4 **Dr. Kobedi Segale**
(Member)

5 **Ms. Matshidiso Matome**
(Member)

Ms. Tiny Ralefala
(Member)

Ms. Mmama Mhlanga-Fichani
(Member)

Ms. Elizabeth Kelentse
(Member)

Mr. Modisa Kebonyemodisa
(Member)

Dr. Kefentse Motshegwa
(Ex-Officio - Director of Veterinary Services)

Dr. Oratile Mfokeng-Selei
(Ag) - Director Health Services

MANAGEMENT TEAM

Dr. Seima Dijeng
Chief Executive Officer

Dr. Parthasarathi Gurumurthy
Acting Chief Regulatory Officer

Ms. Zukiswa Raditladi
Director, Licensing and Enforcement

Mr. Bathusi Kgosietsile
Director, Product Evaluation and Registration

Mr. Kitso Leburu
Director, Finance and Administration

Ms. Shirley Pine
Director, Human Resources and Organisational Development

Mr. Lebogang Koitsiwe
Acting Director, Pharmacovigilance and Clinical Trials

Ms. Keletso George
Business Development and Partnerships Manager

Mr. Hlanganani Mhotsha
Strategy and Risk Manager

Mr. Kereng Baleki
Information and Technology Manager

Mr. Israel Kgosidiile
Public Relations Manager

Mr. Nonofo Thipe
Legal Counsel

Mr. Ishmael Motshabi
Quality Management Manager

Corporate Governance

Governance and Accountability

Act 29

MRSA 2025 assented 24 December 2025

81.5%

Independent Board effectiveness evaluation - "Good"

20

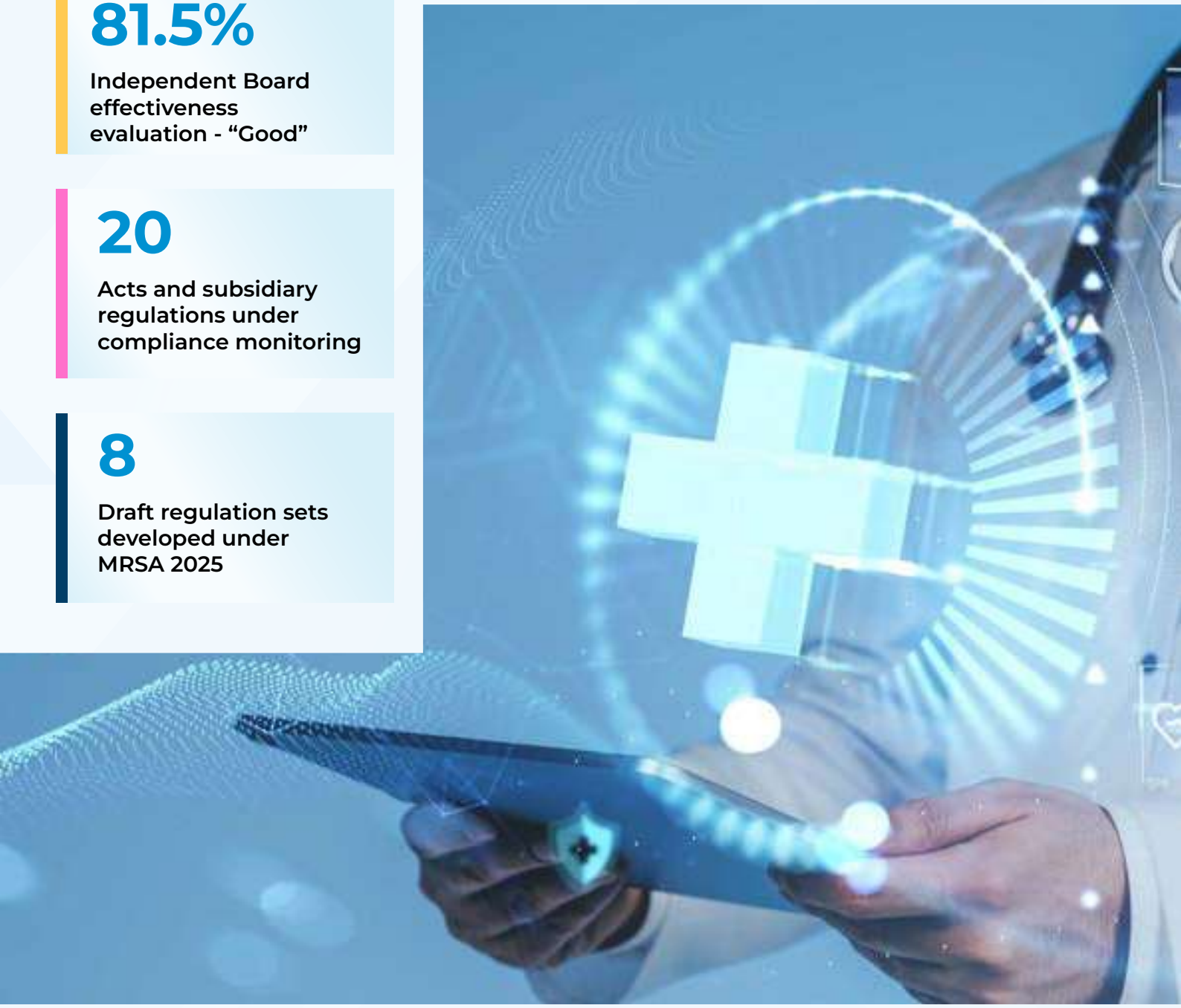
Acts and subsidiary regulations under compliance monitoring

8

Draft regulation sets developed under MRSA 2025

Board Structure

The Board is constituted under the Medicines and Related Substances Act and is responsible for the strategic direction of the Authority, oversight of management, and stewardship of the regulatory mandate. It discharges its duties directly and through six committees - three governance committees (Finance, Audit and Risk; Governance and Nominations; Human Resources) and three technical committees (Registration; Licensing and Enforcement; Pharmacovigilance and Clinical Trials) - supported by the Legal and Corporate Secretary, who also heads the Authority's legal function.



Board Members

Members who served during 2025/26, with skills coverage under section 7 of the MRSA:

Member	Skills (MRSA s7)	Term	Term Status in 2025/26	Committees
Dr. Kegomoditswe Biki Maphane (Chairperson)	Medicine	1 Oct 2021 – 30 Sep 2024; renewed	-	-
Dr. Lorato Mangadi (Vice-Chairperson)	Medicine	1 Oct 2021 – 30 Sep 2024; renewed	-	FARC
Dr. Ditiro Coyne (Member)	Veterinary Medicine	1 Oct 2021 – 30 Sep 2024; renewed	-	HRC
Dr. Kobedi Segale (Member)	Veterinary Medicine	1 Oct 2021 – 30 Sep 2024; renewed	-	LEC (Chair)
Ms. Matshidiso Matome (Member)	Pharmacy	1 Nov 2022 – 31 Oct 2025	Term concluded 31 Oct 2025	PVAC-CT (Chair)
Ms. Tiny Ralefala (Member)	Business Management	1 Nov 2022 – 31 Oct 2025	Term concluded 31 Oct 2025	FARC (Chair); GNC
Ms. Mmama Mhlanga-Fichani (Member)	Human Resources*	1 Nov 2022 – 31 Oct 2025	Term concluded 31 Oct 2025	HRC (Chair); GNC
Ms. Elizabeth Kelentse (Member)	Pharmacy	1 Nov 2022 – 31 Oct 2025	Term concluded 31 Oct 2025	RC (Chair); HRC
Mr. Modisa Kebonyemodisa (Member)	Law	1 Nov 2022 – 31 Oct 2025	Term concluded 31 Oct 2025	GNC (Chair)
Dr. Kefentse Motshegwa (Ex-Officio - Director of Veterinary Services)	Veterinary Medicine	Ongoing	Served throughout	-
Dr. Oratile Mfokeng-Selei (Ex-Officio - Ministry of Health)	Medicine	Ongoing	Served throughout	FARC

Table 1: Members who served during 2025/26

* Human resources expertise placed under "two other areas as may be determined by the Minister" per section 7. Committees: FARC - Finance, Audit and Risk; GNC - Governance and Nominations; HRC - Human Resources; RC - Registration; LEC - Licensing and Enforcement; PVAC - Pharmacovigilance and Clinical Trials.

Changes in Board Membership

The terms of five members - Ms. Matome, Ms. Ralefala, Ms. Mhlanga-Fichani, Ms. Kelentse and Mr. Kebonyemodisa - concluded on 31 October 2025, as disclosed in the 2024/25 Annual Report. The Chairperson formally appealed to the shareholder for continuity of Board composition ahead of the expiries. Successor appointments had not been made by year-end; the Board operated with reduced membership for the final five months of the year, the standing committees did not convene after 22 October 2025, and matters requiring oversight were reserved to the Board directly.

STRATEGIC INSIGHT

Board continuity is now a designed-in control

The October 2025 expiries showed the exposure created when multiple terms conclude in one cycle. The incoming governance suite embeds a Member Lifecycle Procedure - term-expiry tracking, early succession triggers, structured handover - and supports consideration of staggered terms in future appointment cycles.

Board and Committee Meetings

Structure	Sittings	Dates	Attendance
Board	7 (4 ordinary, 3 special)	· 2 Apr · 26 Jun · 9 Oct (Evaluation) · 29 Oct 2025 · 5 Mar · 23 Mar · 30 Mar 2026	100% at all sittings to 29 Oct 2025
FARC	3	· 19 Jun · 6 Aug · 21 Oct 2025	Full attendance
GNC	3	· 12 Jun · 18 Sep · 22 Oct 2025	Full attendance (one apology)
HRC	3	· 11 Jun · 30 Jul · 7 Aug 2025	Full attendance

Table 2: Members who served during 2025/26

Principal matters considered during the year:

- Passage of the new medicines legislation - Cabinet approval and Gazette publication of the Bill (29 October 2025), parliamentary engagement, and assent (24 December 2025).
- Product registration backlog clearance project: dedicated project manager, external assessor panel, twelve-month clearance target.
- WHO Maturity Level 3 Activity Implementation Plan and the subsidiary legislation programme.
- Track and Trace system architecture; laboratory capital renewal; procurement of outsourced internal audit services.
- Annual Performance Plan and provisional budget 2026/27;

Board Performance Evaluation

An independent Board performance evaluation for the year ended 31 March 2025 was facilitated by Business Direct (Pty) Ltd, covering the full Board, its six committees, the Chairperson, individual members, and assurance providers, assessed against King governance principles and the Botswana Code of Corporate Governance. The Board considered and adopted the report on 9 October 2025 and authorised an action plan on its recommendations.

Assessment Area	Score	Band
Overall	**81.5%**	**Good**
Board committees (average of six)	**85.4%**	**Good**
Individual members (average)	**86.7%**	**Good**
Full Board working as a body	**79.1%**	**Average**
Governance outcomes (effective control, ethical culture, performance, stakeholder legitimacy)	**83.1%, 83.1%, 83.1%, 76.9%**	**Good**

Table 3: Board Performance Evaluation

Highest-scoring areas were strategy (90.8%) and policy and guidance (90.3%). The assessment identified information and technology governance (72.8%) and stakeholder reporting and management (72.1%) as focus areas, with recommendations including strengthened whistleblowing processes, timely integrated reporting, and a clear Board mandate for IT governance. These recommendations inform the governance action plan and the instrument suite prepared for the incoming Board.

Governance Framework

The Authority applies the King IV Report on Corporate Governance as its adopted code, recording 80% application of recommended practices (112 of 140) at the most recent scored assessment - maintaining the baseline reported in 2024/25. A King V readiness framework covering all 150 recommended practices was established during the year; the first scored assessment will follow in FY2026/27, with adoption to be considered by the reconstituted Board.

A refreshed governance instrument suite was developed for tabling before the incoming Board: apex instruments at version 2.0 (Corporate Governance Framework, Board Charter, Delegation of Authority Framework), terms of reference for all Board, technical and management committees, five core governance procedures, and a consolidated Ethics and Integrity Framework.

Compliance with Laws and Regulations

Every statute applicable to the Authority is assessed, its obligations assigned to accountable units, and implementation tracked through the Legal Compliance Register (Issue 4.0, March 2026). No compliance breaches were recorded during the period; all identified obligations were under active monitoring at year-end. The Authority's litigation record was maintained: no legal case lost and no legal matter resulting in financial loss.

The compliance universe spans twenty Acts and their subsidiary regulations, by regulatory domain:

Regulatory Domain	Legislation	Priority
Core regulatory mandate	Medicines and Related Substances Act, 2013 (operative)	**High**
	Medicines and Related Substances Act, 2025 (Act 29 of 2025 - commencement pending)	**High**
	Statutory Instruments Act, 1984	Standard
Data, digital and information governance	Data Protection Act, 2024	**High**
	Access to Information Act, 2024	Elevated
	Cybercrime and Computer Related Crimes Act, 2018	Elevated
	Electronic Records (Evidence) Act, 2014	Standard
	Electronic Communications and Transactions Act, 2014	Standard
Financial stewardship and procurement	Public Procurement Act, 2021 and Public Procurement Regulations, 2023	**High**
	Financial Intelligence Act, 2022 and Regulations	**High**
	Financial Reporting Act and Financial Reporting (PIE) Regulations, 2016	**High**
	Income Tax Act	Elevated
	Public Audit Act	Elevated
	Economic Inclusion Act, 2021	Standard
Employment and people	Employment and Labour Relations Act, 2025	**High**
	Employment of Non-Citizens Act	Elevated
	Workmen's Compensation Act	Standard
Integrity and accountability	Corruption and Economic Crime Act	Elevated
	Criminal Procedure and Evidence (Controlled Investigations) Act, 2022	Standard
	National Archives Act	Standard

Table 4: The compliance universe spans twenty Acts and their subsidiary regulations, by regulatory domain

Priority reflects the risk assessment in the Legal Compliance Register.

STRATEGIC INSIGHT

Where the sharpest exposures sit - data and people

A regulator's own compliance record is part of its authority. The Data Protection Act, 2024 governs the pharmacovigilance, clinical trial and licensing data at the heart of the regulatory function - engagement with the Office of the Data Protection Commissioner was established during the year. The Employment and Labour Relations Act, 2025 reset employer obligations in a specialised-skills environment. Compliance effort is allocated accordingly.

Medicines and Related Substances Act, 2025 - A Wider Mandate

The **Medicines and Related Substances Act, 2025 (Act No. 29 of 2025)** was the year's defining legislative milestone: Cabinet approval and Gazette publication of the Bill on 29 October 2025; presentation to Parliament in November 2025; **assent on 24 December 2025.** The Act commences on a date to be appointed by the Minister by Gazette Order; the 2013 Act remained operative at year-end. Commencement readiness was delivered ahead of the Act: **all 125 sections across 23 Parts mapped to institutional obligations, and eight draft regulation sets developed -** general provisions, human medicines, veterinary medicines, medical devices, cosmetics, fees, clinical trials, and blood and blood products. At year-end, public engagement on the draft regulations was planned from April 2026, with submission to the Minister targeted for the end of 2026.

STRATEGIC INSIGHT

More than a new statute; a broader regulatory perimeter

The Act's architecture - visible in the eight regulation sets - extends structured lifecycle oversight across human and veterinary medicines, medical devices, cosmetics, clinical trials, and blood and blood products, strengthening the statutory foundation for the Authority's WHO Maturity Level 3 objective. At year-end, the Authority stood ready for the new framework while remaining fully compliant with the operative 2013 Act.

Cannabis and Hemp - Regulatory Readiness

In support of the national policy direction on cannabis and hemp, the Authority maintained a complete regulatory readiness package developed by the legal function: a position paper on cannabis as it relates to the Authority's mandate across medicines, medical devices and cosmetics; regulatory requirements established in line with international drug-control conventions and best practice; a gap analysis of the current legislative framework identifying the schedule amendments required; and draft statutory instruments - schedule amendments together with comprehensive draft cannabis regulations covering licensing, market authorisation, classification, packaging and labelling, laboratory testing and pharmacovigilance. On this basis, the Authority was positioned at year-end to regulate cannabis-containing medicines, medical devices and cosmetics once the national policy framework is settled.

Key Highlights

- Medicines and Related Substances Act, 2025 (Act No. 29 of 2025) assented to on 24 December 2025 - supported from Cabinet approval through parliamentary engagement to assent.
- Commencement readiness delivered: 125 sections across 23 Parts mapped; eight draft regulation sets spanning the full product mandate.
- Twenty Acts and their subsidiary regulations under structured compliance monitoring - no breaches recorded; litigation record maintained: no case lost, no financial loss.
- Independent Board evaluation adopted: 81.5% overall ("Good"), committees at 85.4%, individual members at 86.7%.
- Governance continuity managed through significant in-year Board membership changes, with a complete transition architecture prepared for the incoming Board.
- King IV application maintained at 80%; King V readiness framework established for scoring in FY2026/27.

Outlook for 2026/27

The year ahead will be a commencement year. The Authority will finalise the subsidiary legislation programme through public engagement and submission to the Minister; will prepare for commencement of the 2025 Act and the managed retirement of the 2013 framework; will undertake the first scored King V assessment, with adoption to be considered by the Board; will consolidate the reconstituted Board through its committee cycle and effectiveness programme; and will continue advancing toward WHO Maturity Level 3, targeted for March 2027.

Strategy Management

The 2025/26 financial year marks the inaugural year of implementation under the Corporate Strategic Plan 2025–2030. BoMRA enters this second strategic planning cycle not as a nascent institution finding its footing, but as a maturing regulatory authority with demonstrated systems, growing credibility and a clear vision for where it must go next. The results documented in this section confirm that the Authority has begun that journey with clarity and momentum.

Strategic Context and National Policy Alignment

BoMRA's Corporate Strategic Plan 2025 - 2030 is anchored within Botswana's national development architecture and draws its mandate from three interlocking frameworks:

Vision 2036	Commits Botswana to providing healthcare services of the highest attainable standard under Pillar 2: Human and Social Development. Every medicine BoMRA registers, every substandard product intercepted, and every licence issued is a direct and measurable contribution to this national aspiration.
NDP 12 & BETP (2025 - 2030)	Launched in August 2025, BETP designates BoMRA as a delivery institution within the Health and Wellness Social Sector pillar, holding the Authority accountable for specific, measurable KPIs including ML3 attainment, NCL operationalisation, legal framework reform and regional expansion.

2025 - 2030 Headline Targets

A Roadmap from ML1 to ML4 - Measured, Funded and Accountable. These six headline targets are embedded in NDP 12 and the Botswana Economic Transformation Programme, with dedicated capital and performance accountability. They define what BoMRA must deliver by 2030 and provide the strategic north star against which each year's Annual Performance Plan is measured.

#	Headline Target	Description	Target Year
1	WHO GBT Maturity Level 3	Full ML3 designation across all eight core regulatory functions. This is the foremost technical priority of the 2025 - 2030 period and the foundation of BoMRA's credibility as a well-functioning national regulatory authority.	2027
2	National Control Laboratory (NCL) Full Operationalisation	The NCL to be fully operational and delivering independent medicine quality testing services for Botswana and the region. Funded under a World Bank loan through BETP.	2027
3	MRSA 2025 Full Implementation	Complete implementation of the revised Medicines and Related Substances Act, including all subsidiary regulations, expanded regulatory scope and new product categories.	2027
4	Financial Sustainability - 50% IGR	Achieve 50% internally generated revenue (IGR) through a reformed fee structure and revenue diversification, critical for long-term regulatory independence and operational resilience.	2028
5	Institutional Capacity Expansion	Scope expansion to cover new areas of regulation introduced under the revised Act, supported by organisational redesign and targeted specialist recruitment.	2028
6	WHO GBT Maturity Level 4	Progression towards the next level of regulatory maturity, positioning BoMRA as a regional reference authority and potential WHO-listed National Regulatory Authority.	2030

Table 5: A Roadmap from ML1 to ML4 - Measured, Funded and Accountable.

FY 2025/26 Performance - Year 1 Results

BoMRA concluded the 2025/26 financial year with an overall weighted Balanced Scorecard (BSC) performance of 90.04% - firmly in the High Performance band. Of ten strategic objectives, six achieved High Performance, three registered Average Performance and one registered Low Performance. This result, achieved in the first year of a new and demanding five-year strategy simultaneously aligned to Vision 2036, NDP 12 and the BETP accountability framework, is a testament to the adaptability and resilience that define this reporting period.

Overall Performance Summary

OVERALL PERFORMANCE
90.04%
Average Weighted Score

IN PROGRESS 70 - 89%
3/10
Average Performance Objectives

ON TRACK ≥ 90%
6/10
High Performance Objectives

AT RISK < 70%
1/10
Low Performance Objectives

Strategic Pillar Performance

Impact Goal: Universal Coverage of Essential Health Services | Vision 2036 & NDP 12

High Performance
100%
Strong Consumer Safety

Average Performance
81%
Comprehensive Regulatory Oversight & Enforcement

High Performance
92.5%
Strong Partnerships & Collaborations

High Performance
96%
Effective Communications & Engagement

Average Performance
81%
Strong Organisational Capability

■ **High Performance ≥ 90%**

■ **Average Performance 70 - 89%**

■ **Low Performance < 70%**

Balanced Scorecard - Objective-Level Performance

The following table presents the full Balanced Scorecard performance for the 2025/26 financial year, reflecting the Authority's performance against all ten strategic objectives across the four BSC perspectives.

Perspective	Code	Strategic Objective	Target	Score	Weight	Wtd Score	Status
Client & Stakeholder	CS1	Promote Patient Safety	90%	100%	5%	5.000%	High Performance
	CS2	Develop Strategic Partnerships	90%	92%	5%	4.600%	High Performance
	CS3	Attain Stakeholder Trust & Confidw	90%	93%	5%	4.650%	High Performance
Financial	FN1	Achieve Financial Sustainability & Asset Optimisation	100%	95%	10%	9.500%	High Performance
Internal Process	IP1	Strengthen Regulatory Systems	95%	92%	50%	46.000%	High Performance
	IP2	Drive Digital Transformation	90%	78.6%	5%	3.930%	Average Performance
	IP3	Improve Corporate Governance & Performance	95%	72%	5%	3.600%	Average Performance
People	LT1	Build Leadership Capability	90%	96.5%	7%	6.755%	High Performance
	LT2	Enhance Results-Oriented Culture	90%	88.6%	4%	4.000%	Average Performance
	LT3	Develop a Talented & Engaged Workforce	90%	50%	4%	2.000%	Low Performance
AVERAGE WEIGHTED PERFORMANCE							90.035% | High Performance

Table 6: Balanced Scorecard - Objective-Level Performance

Key Achievements - FY 2025/26

The 2025/26 financial year delivered a number of milestone achievements with lasting significance for BoMRA's institutional trajectory, mandate delivery and strategic positioning. Each achievement is mapped to the relevant 2025–2030 headline target where applicable:

#	Achievement	Strategic Significance
1	**Consumer Safety - 100% (CS1)**	Perfect performance against the patient safety objective confirms that BoMRA's core regulatory functions - product registration, post-market surveillance and pharmacovigilance - are delivering at the highest standard. This is the most consequential performance result of the year.
2	**Strong Stakeholder Trust - 93% (CS3)**	A Net Promoter Score of +31% and a stakeholder satisfaction rate of 71% affirm that BoMRA's engagement approach is translating into measurable public and industry confidence.
3	**Financial Sustainability - 95% (FN1)**	Revenue growth of 25% and a cost-to-income ratio of 88% demonstrate strengthening financial resilience. The trajectory is positive and aligned to the 50% IGR target by 2028.
4	**Regulatory Systems - 92% (IP1)**	IP1 - the highest-weighted objective at 50% of the BSC - achieved 92%, contributing 46 weighted percentage points to the overall score. This confirms BoMRA's core regulatory infrastructure is performing at a high level and provides the evidentiary foundation for WHO GBT ML3 designation.
5	**Leadership Capability - 96.5% (LT1)**	Exceptional leadership performance confirms the quality and depth of the management cadre the Authority has built, providing a strong platform for the institutional and cultural transformation work ahead.
6	**NCL Operationalisation - 95% Complete**	The NCL reached 95% completion, with full operationalisation targeted for 2027. Funded under a World Bank loan through BETP, the NCL will eliminate reliance on contracted external laboratories and materially strengthen IP1 performance.
7	**Decentralisation Approved**	The approval of two regional offices - Francistown and Maun - under NDP 12 addresses the Authority's most significant regulatory enforcement gap and extends BoMRA's reach beyond Gaborone into informal markets, peri-urban areas and remote districts.
8	**MRSA Enactment**	The revised Medicines and Related Substances Act has been enacted, providing BoMRA with a strengthened and modernised legal mandate, expanded enforcement powers and broader regulatory scope. Full implementation of subsidiary regulations is targeted for 2027.
9	**Development Partner Funding - P6.3 million**	P6,318,325 in active donor funding from eight partners - including the Gates Foundation, Global Fund, UNICEF, Africa CDC and the Paul-Ehrlich-Institut - supports targeted capacity-building in pharmacovigilance, laboratory quality, clinical trials and vaccine safety surveillance.

Table 7: Key Achievements - FY 2025/26

Performance Challenges - 2025/26

While the overall 90.04% result is a strong inaugural performance, three objectives registered below target and demand focused management attention in 2026/27. These reflect structural challenges that require deliberate, sustained and systemic intervention:

Objective	Score	Strategic Significance
LT3 - Develop a Talented & Engaged Workforce	**50%**	The sole Low Performance result of the year. An employee Net Promoter Score of –31 signals structural disengagement manifesting as reduced productivity and risk of attrition. Root causes include unresolved workplace grievances, fragmented internal communications and the absence of a comprehensive wellbeing programme. A structured Culture Transformation Plan with measurable eNPS improvement targets is the priority intervention for 2026/27.
IP3 - Improve Corporate Governance & Performance	**72%**	Governance at 72% reflects the in-progress nature of critical governance infrastructure: the Combined Assurance Framework, the Ethics and Integrity Framework and the integrated Board reporting structure. Without these instruments, Board oversight is based on an incomplete assurance picture. All three are priority deliverables for 2026/27.
IP2 - Drive Digital Transformation	**78.6%**	The ISMS is at 75% implementation and the security posture score stands at 70% - both below target. The DIT Governance Framework and Data Governance Framework remain pending Board approval. BRIMS, BoMRA's core regulatory information management system, lacks a formally tested fallback procedure. The DIT Governance Framework is the highest-priority outstanding digital deliverable for 2026/27.

Table 8: Performance Challenges - 2025/26

Outlook - FY 2026/27 Priorities Toward Headline Targets

Year 2 of the Corporate Strategic Plan 2025–2030 is a year of consolidation, targeted remediation and deeper governance embedding. Each priority below is directly linked to the advancement of the six 2025–2030 headline targets:

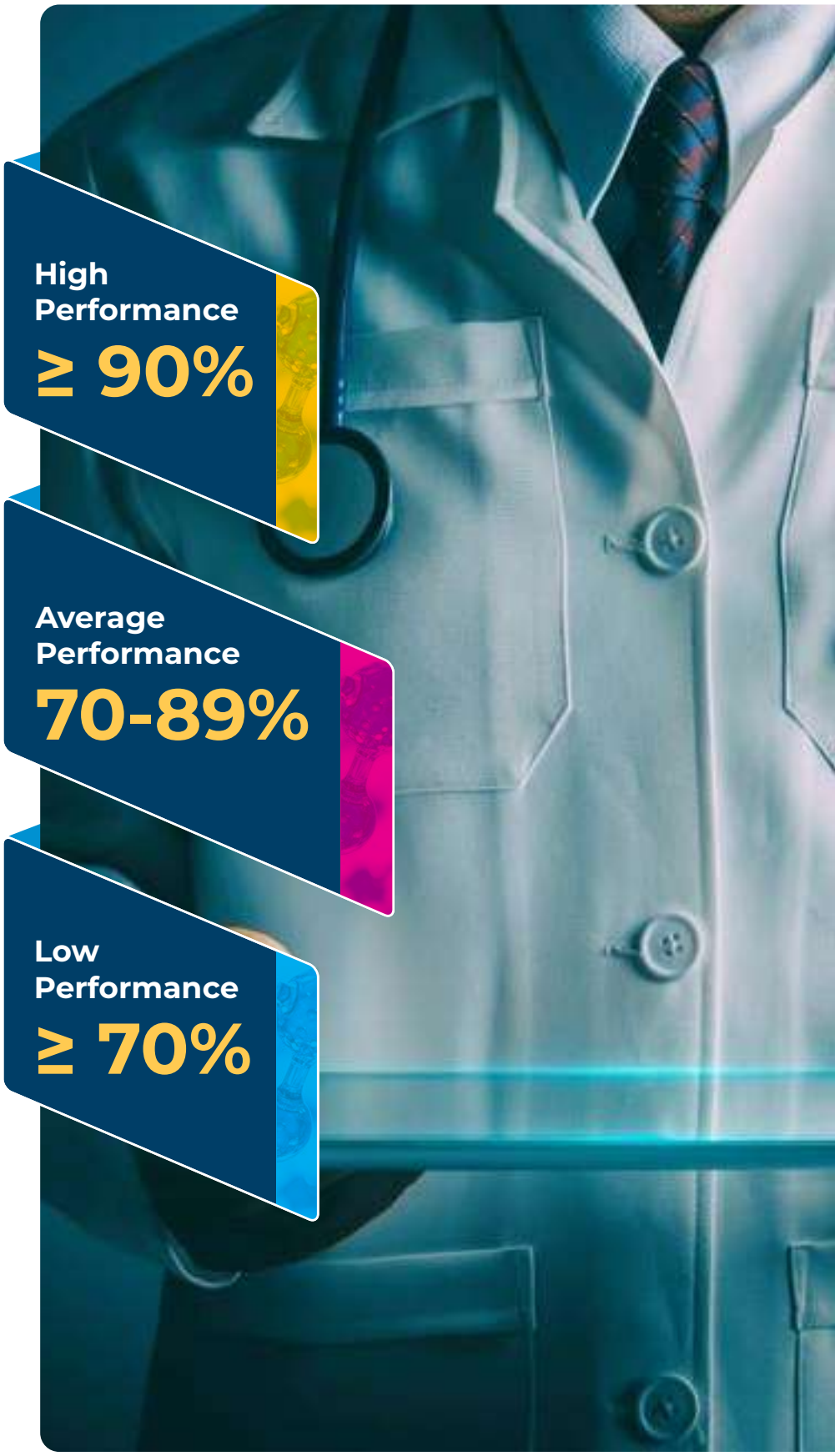
#	Priority	Action
1	**WHO GBT ML3 Attainment**	Coordinate self-assessment across all eight regulatory functions, build the evidence portfolio and submit for WHO designation. Commence baseline work for the ML4 trajectory.
2	**Culture Transformation**	Implement a structured Culture Transformation Programme targeting eNPS improvement, grievance resolution, performance management strengthening and employee wellbeing.
3	**Corporate Governance Completion**	Finalise and operationalise the Combined Assurance Framework, the Ethics and Integrity Framework and the integrated Board reporting structure.
4	**Digital Transformation**	Complete ISMS implementation, bring security posture to target, finalise and obtain Board approval of the DIT and Data Governance Frameworks.
5	**NCL Full Operationalisation**	Advance NCL completion to full operational status in alignment with the BETP milestone and World Bank loan deliverables.
6	**Financial Sustainability**	Grow IGR contribution through fee structure reform and revenue diversification towards the 50% IGR target by 2028.
7	**MRSA Full Implementation**	Progress implementation of all subsidiary regulations and new product categories under the revised MRSA.
8	**M&E Framework Embedding**	Embed the M&E Framework into the Q2 FY2026/27 APP cycle, validate all KPI indicators and produce the first annual M&E performance report.

Table 9: Outlook - FY 2026/27 Priorities Toward Headline Targets

Stewardship In Action

The 2025/26 financial year will be remembered as the year in which BoMRA moved from institutional establishment to strategic execution. A weighted performance score of 90.04% in the inaugural year of a demanding new strategic plan simultaneously aligned to Vision 2036, NDP 12 and the BETP accountability framework reflects the adaptability and resilience that define this chapter of the Authority's history. It reflects systems that are getting stronger, partnerships that are deepening, and a workforce that, despite the engagement challenges evidenced in the eNPS, continues to show up for the mission of protecting the public.
The six 2025–2030 headline targets from WHO GBT ML3 by 2027 to ML4 by 2030 are not aspirations. They are contractual commitments embedded in NDP 12 and BETP, with dedicated capital and performance accountability. The Authority enters Year 2 with clear priorities, funded plans and the institutional resolve to deliver against each one.

The stewardship of access to quality assured medicines is not a mandate that is ever fully discharged. It is renewed with every product registered, every inspection conducted, every safety signal detected, and every standard enforced. BoMRA is committed to that renewal - year after year - until every person in Botswana can be confident that the medicine they take is exactly what it is supposed to be, doing exactly what it is supposed to do.



Enterprise Risk Management & Business Continuity Management

Risk management and organisational resilience are structural enablers of BoMRA's ability to deliver its mandate consistently. The 2025/26 financial year marked a significant step forward in both Enterprise Risk Management and Business Continuity Management maturity - with foundational instruments completed, governance processes strengthened, and the Authority's risk landscape more actively managed than in any previous period.

Enterprise Risk Management - Framework & Governance

The ERM framework underwent a substantive review during the year, resulting in a revised Framework and updated Risk Appetite Statement, both aligned to ISO 31000:2018. These instruments are pending formal Board adoption, which is the primary governance milestone planned for Q1 FY2026/27. The year also saw completion of a Strategic Risk Assessment conducted with the Senior Management Team, establishing the Authority's critical risk profile directly linked to its ten Corporate Strategic Objectives. Below are achieved milestones.

Achievements	Key Outcome / Note
ERM Framework & Procedures Review	Revised framework aligned to ISO 31000; Risk Appetite Statement updated; Board adoption pending.
Risk Appetite & Tolerance Statement	Incorporated into revised framework; formal Board-level adoption scheduled for Q1 FY2026/27.
Strategic Risk Assessment	Senior Management Team workshop completed; 11 strategic risks identified and linked to BSC objectives.
Risk Champions Training	Training concluded September 2025; risk assessments completed across most departments and units.
Board & Senior Management Training	Delivered in Q4 2025/26; aligned leadership with ERM strategy ahead of full FY2026/27 roll-out.
Fraud Risk Management Policy Revision	Revised; scheduled for Senior Management approval in Q1 FY2026/27.
Independent External Assurance	To be revisited once ERM maturity improves post full framework implementation.

Table 10: Strategic Risk Assessment

Strategic Risk Mitigation Progress

5 of 11 Risks have been treated to acceptable level while the remaining 6 are at various levels of mitigation as outlined below.

Ref	Risk Description	Q3→Q4 Movement	Key Note
HR05	High Employee Attrition	Improved ↑	Improved from Cautionary (5). Performance management implementation and retention strategies effective; bench strength confirmed for critical roles.
HR06	Poor Role Fit	Improved ↑	Improved from Unacceptable (13). Enhanced performance management systems and one-on-one oversight mechanisms driving improvement.
HR01	Poorly Managed Organisational Change	Sustained →	Annual engagement plan in place; some activities deferred due to budget constraints. Risk maintained at Acceptable.
HR04	Insufficient Talent Bench Strength	Sustained →	Talent Management Framework and Localisation Policy operational; Talent Management Committee providing oversight.
LS06	Inadequate Medicinal Cannabis Framework	Sustained →	Medicinal Cannabis Commission established; cannabis ban lifted; draft regulations submitted; MRSA Bill inclusive of cannabis provisions.
CRO2	Substandard & Falsified / Unregistered Products	Sustained →	Inherent risk 25 (Critical); treated to Cautionary (3). MoU review ongoing; Stakeholder Engagement Plan active despite financial constraints.
F05	Financial Instability - Subvention Dependency	Sustained →	Cost Containment Plan in effect; MRSA Bill signed by the President (awaiting gazetting), unlocking enhanced fee-based revenue. Revised Plan under risk assessment.
HR08	Misalignment of Performance to Corporate Targets	Sustained →	PMS automation ongoing; contracting refresher completed; calibration report outstanding - expected in Q1 2026/27.
SR01	Business Disruption - Inadequate BCM	Sustained →	Incident & Crisis Management Procedure developed but not yet approved or tested. BCP approval scheduled for FY2026/27.
FS02	Lack of Power Backup at Laboratory	Sustained →	UPS non-functional; generator interrupted during load-shedding. Donor funding secured for new laboratory; risk active until new facility operational.
HR10	Internal Audit Manager Vacancy	Sustained →	No Internal Audit Plan executed. Implementation of Outsourcing still in progress. Remuneration alignment not actioned. Third line of defence not operational. Urgent resolution required.

Acceptable 0 - 5	Cautionary 6 - 10	Unacceptable 11 - 16	Critical 17 - 25

Table 11: Summarised movement and status of all strategic and priority business risks (Q4 2025/26)

BCM Milestone Progress

Business Continuity Management advanced materially in 2025/26. The year was characterised by the development and completion of the BCM documentation suite, the strengthening of IT resilience controls, and the training of Emergency Response Teams. The foundational work is complete; the focus for FY2026/27 is formal approval, testing and full operationalisation.

BCM Activity	Status	Detail
Corporate & Departmental BCPs	**Complete**	All Corporate, Departmental and Unit BCPs reviewed by Senior Management. Formal approval for implementation scheduled for Q2 2026/27.
Recovery Strategies	**Complete**	Recovery strategies developed and integrated into both Corporate and all Unit BCPs, supported by completed Incident and Crisis Management Procedures.
ISO 22301 Alignment	**Complete**	ISO 22301 standard procured and applied. All BCM documentation reviewed and confirmed aligned to the international Business Continuity Management standard.
IT Cybersecurity Controls	**Complete**	Multi-factor authentication, system redundancy and routine penetration testing implemented. All 2024/25 cybersecurity findings fully resolved - 100% closure rate achieved.
Vulnerability Assessment	**Complete**	Conducted in Q2 2025/26. Final report being prepared for submission. Findings will inform the 2026/27 BCM testing programme.
Emergency Response Teams	**Complete**	Fire Marshals and First Aiders trained in Q4 2025/26. Teams are equipped and ready for scenario testing in 2026/27.
Business Impact Assessments (BIAs)	**Complete**	All departmental and unit BIAs reviewed, finalised and ready for sign-off by respective heads following completion of the BCM toolkit.
BCM Testing Programme	**Planned**	Full-scope testing covering remote work simulation, ICT failure scenarios and Incident & Crisis Management team exercises planned for 2026/27.
Incident Reporting Form	**Complete**	Developed and finalised in Q4 2025/26 as a key operational tool for incident capture and escalation.
Incident & Crisis Management Procedure	**Pending Approval**	Procedure developed but not yet signed or approved. Testing cannot commence until approval is secured. Urgent action required in Q1 2026/27.

Table 12: BCM Milestone Progress

Information Technology Report

Strategic Overview

The 2025/26 reporting period marked a defining shift for BoMRA, from digitising individual processes towards organisation-wide digital transformation. Guided by the new Digital Transformation Strategy under the 2025–2030 Strategic Plan, the IT Unit moved beyond infrastructure maintenance to become a strategic enabler of regulatory efficiency, resilience and data-driven decision-making.

Performance Snapshot

Overall objective performance for "Drive Digital Transformation" was 78.6%, reflecting strong automation gains offset by an incomplete security rollout.

Measure	Target	Actual	Status
Process automation	90%	91%	Exceeded
Information Security Management System	100%	75%	Gap
Security posture	100%	70%	Gap
Overall objective performance	**-**	**78.6%**	**On track**

Table 13: Drive Digital Transformation

What Is Working Well

- Process automation reached 91% against a 90% target - regulatory workflows are now materially more efficient than in prior years.
- BRIMS Phase One is complete and operational, replacing fragmented manual processes with the foundation for integrated digital regulatory services.
- · Performance dashboards (Gates Foundation-supported) are live, giving management near real-time visibility into operations and enabling faster, evidence-based interventions.
- Governance foundations - the Digital Transformation Strategy, Data Management Framework and IT Corporate Governance Framework - are now in place, giving future investment clear direction and oversight.
- Alignment with the national BOHIE programme positions BoMRA to exchange health information securely with Government and healthcare partners.

What Is Not Working / Needs Attention

- Information security is the key gap: the Information Security Management System is only 75% implemented and security posture stands at 70%, both well short of the 100% target.
- The enterprise IT Security Policy - the framework meant to close this gap - is still awaiting Board approval and is therefore not yet in force.
- Outside BRIMS, a number of business areas still rely on manual workflows, email-based communication and paper documentation, limiting the reach of automation gains.
- Systems integration remains early-stage; dashboards and BRIMS operate as strong but largely separate capabilities rather than a fully unified data environment.

High-Level Assessment

IT delivered tangible, measurable progress this year - most notably exceeding its automation target and standing up BRIMS and real-time performance dashboards, both of which are already changing how the organisation works. The principal risk is cybersecurity: with security implementation at roughly three-quarters complete and the governing policy still pending Board sign-off, BoMRA carries residual exposure that should be prioritised in the year ahead. On balance, the Authority has moved from planning to visible delivery, and the coming year's priority is converting the strategic foundations built in 2025/26 - governance, data management and security - into fully operational, integrated capability.

Priorities for 2026/27

- Secure Board approval and operationalise the IT Security Policy; close the security posture gap.
- Progress BRIMS beyond Phase One and expand systems integration across regulatory functions.
- Operationalise the Data Management Framework to convert dashboards into organisation-wide analytics.
- Deepen BOHIE integration and explore AI-enabled regulatory intelligence.

Digital communication continued to transform the way BoMRA connects with stakeholders. Recognising the growing demand for accessible and timely information, the Authority increasingly utilised digital platforms to extend the reach of regulatory information, improve responsiveness and encourage two-way dialogue with stakeholders.

Human Resource - People & Culture

Ms Shirley Pine
Director Human Resources and Organisational Development

“At BoMRA, our people are not just contributors; they are the difference between a regulator that follows standards and one that sets them. 2025/26 was a year of resilience, governance maturity, and people investment, as we forge forward into 2026/27 to build a values-led, regulatory excellence, and future-fit organisation at BoMRA.”

Key Highlights of the Year

Despite nationwide fiscal constraints, rising service demand, and continued medicine shortages, BoMRA’s people function held the line and, in several areas, strengthened it. The Authority entered 2025/26 needing leadership depth it could rely on under pressure; it left the year with succession bench strength at 44.1%, ahead of the 40% target, built through a Leadership Development Programme pairing Directors and Senior Management with executive coaching. That investment shows up in the numbers: the Leadership Effectiveness Score rose from 54% to 56%, but its real value is regulatory continuity: fewer single points of failure meant assessment, inspection, and post-market surveillance functions continued uninterrupted through a year of sector-wide pressure.

That same discipline extended to how performance itself is governed. A fully automated Performance Management System, now running on a 5-point scale, brought consistency and audit-readiness to how staff are assessed, and average performance held at 90% across two consecutive cycles, evidence that stronger governance is translating into sustained delivery, not just administrative tidiness. For a regulator whose credibility rests on demonstrable process integrity, an auditable, values-anchored performance system is itself a governance safeguard, one that any external reviewer of BoMRA’s institutional controls can examine with confidence.

BoMRA also began holding itself to a regulator’s own standard of competence. The WHO Competency Framework was domesticated for regulatory roles, and the Authority’s first organisation-wide competency assessment returned 72% against a 70% target, with the resulting gaps now feeding directly into training plans, recruitment, probation, and performance development goals, rather than sitting in a report.

This matters beyond internal record-keeping: a workforce benchmarked against an international framework is a workforce whose dossier reviews, inspection findings, and regulatory decisions carry credibility with peer regulators and international partners.

Not every signal was positive, and the chapter is stronger for saying so. Employee advocacy (eNPS) remains a genuine concern. Culture diagnostics were used to isolate the drivers, which include recognition, leadership connection, and growth opportunity. Those findings are now shaping three concrete responses: the Nectar Recognition platform, the Leadership Development Programme, and planned Flexible Working Arrangements. Left unaddressed, disengagement is a regulatory risk as much as a people one: it is retained technical expertise, not policy alone, that keeps registration timelines and inspection schedules on track.

Values were re-anchored to the second Corporate Strategy (2025–2030) and built into Performance Contracts, so how results are achieved now carries the same weight as what is achieved, reinforced by a culture diagnostic score of 60%, flagged as a continuing-improvement area, and a workforce in which women hold 52% of positions, strengthening the inclusive leadership BoMRA draws on to make consistent, defensible regulatory decisions. On the talent pipeline that will carry the Authority forward, 23 employees are being supported through Bachelor's, Master's, and PhD studies supporting the newly operationalised Localisation Policy, a direct investment in sustainable, locally-anchored regulatory expertise, reflected in an 8:106 expatriate-to-local staff ratio, and one that reduces BoMRA's long-term dependence on external technical capacity.

Attrition fell by 5.12%, beating the 5% target, with 43% of vacancies filled through internal promotion and an internal service-pride score of 43, encouraging signs that the people carrying BoMRA's regulatory workload are choosing to stay and grow within it. A Talent Retention Strategy is now under development to protect that gain and because a resilient regulator depends on a healthy workforce, the Employee Assistance Programme expanded psychological, physical, and financial wellness support, backed by a management-sponsored Staff Wellness Club, safeguarding the institutional capacity BoMRA relies on to deliver its mandate without interruption.

Powered by Our Values and Culture

Our corporate values - Integrity, Excellence, Client Focus, Collaboration and Transparency - anchor our culture, defining how we live, how we lead, and how we deliver value at BoMRA.

Looking Ahead

The next cycle will focus on strengthening leadership effectiveness and succession planning for critical roles to ensure robust talent pipelines; implementing a comprehensive talent retention strategy; entrenching the desired culture through a structured culture transformation programme; embedding flexible working arrangements as a critical lever for employee wellbeing; and leveraging technology and artificial intelligence to improve how we work and deliver efficiency. Together, these priorities continue to close the engagement gap identified, building on a year in which governance, performance, and capability foundations were significantly strengthened.

Quality Management Report

Introduction

The Quality Management Unit (QMU) is the function within the Botswana Medicines Regulatory Authority (BoMRA) mandated to establish, maintain, and continually improve the Authority's quality management system, ensuring that regulatory processes and decisions are delivered consistently and in line with international best practices. In this capacity, the Unit underpins BoMRA's credibility as a regulator and serves as a key enabler of the Authority's strategic journey towards the maintenance of ISO 9001:2015 certification, attainment of ISO/IEC 17025:2017 for Competence of Testing and Calibration Laboratories accreditation and WHO Global Benchmarking Tool (GBT) maturity level 3 attainment, translating to a stable, well-functioning and integrated national regulatory system.

Corporate Governance & Performance

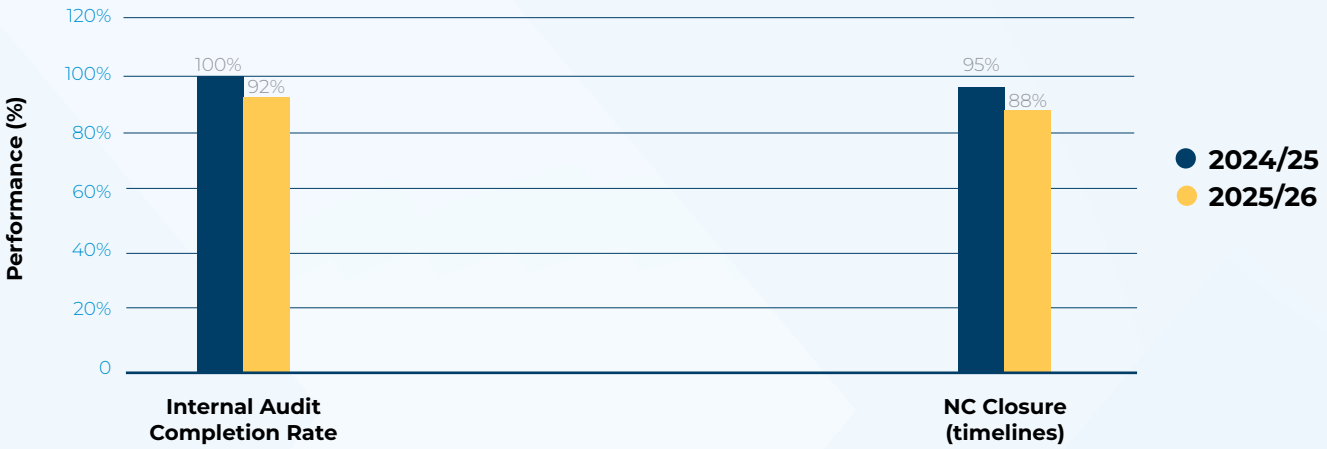
Improve Corporate Governance & Performance measures the extent to which the Authority's management systems are actively governed, assured, and continually improved, evidenced by the consistent operation of two core assurance mechanisms: the internal audit programme and external assessment programmes, which provide independent oversight of the QMS, and subsequently the non-conformity management process, which ensures that gaps identified through the two mechanisms are systematically tracked to closure.

Three independent bodies assessed/audited different parts of BoMRA's management system during the reporting period together providing external, corroborated assurance that the QMS is in place and continually improving.

Internal Audits and Corrective actions

As part of its assurance and control framework, and to ensure the effectiveness of governance and assurance processes, BoMRA schedules and conducts internal audits and subsequently addresses the audit findings.

Internal Audit & Non-Conformity Management



Internal audit completion & NC closure rate, 2024/25 vs 2025/26

92% Internal audits completed	**46** Non-conformities raised & tracked in 2025/2026	**88%** Closed within stipulated timelines

Figure 5: Internal Audit & Non-Conformity Management

External Audits and Assessment

In addition to its periodic ISO 9001 assessment, BoMRA undertook a WHO Global Benchmarking Tool assisted self-benchmarking exercise and pursued accreditation against ISO/IEC 17025.

WHO GBT Assisted Self-Benchmarking	SADCAS ISO/IEC 17025 Accreditation	BSI ISO 9001 Surveillance Audit
August 2025: All regulatory functions were assessed, and the Licensing Establishment function provisionally attained Maturity Level 3.	September 2025: The laboratory was assessed and accredited against ISO/IEC 17025:2017.	November 2025: The surveillance audit recorded no non-conformities and identified four opportunities for improvement.

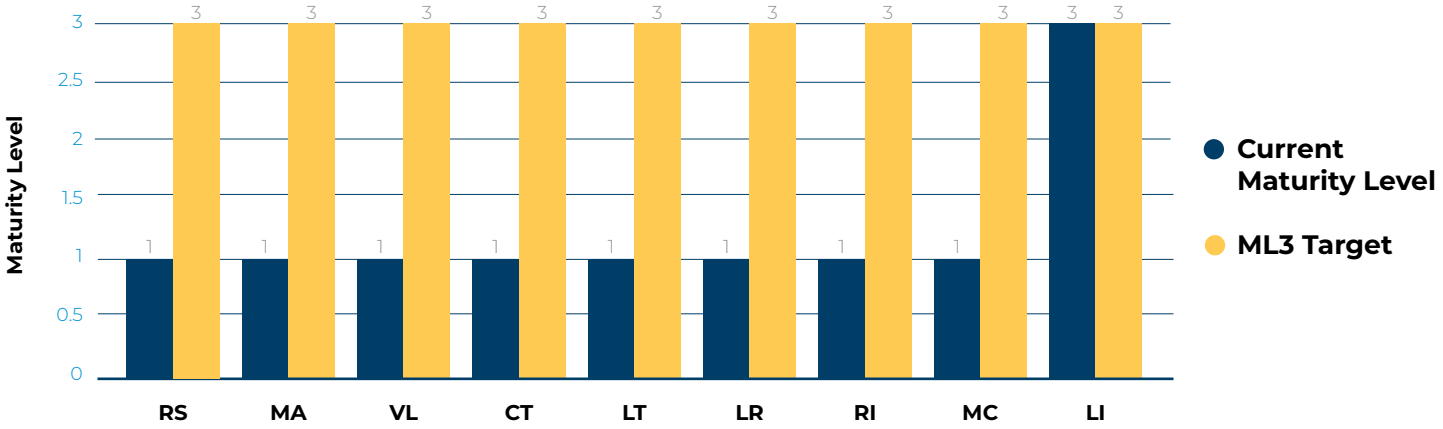
Table 14: External Audits and Assessment

WHO Global Benchmarking (WHO GBT)

As the nation, through BoMRA, is striving towards WHO Maturity Level 3, building on a resilient national regulatory system, BoMRA has embarked on being assessed and monitored by WHO.

Maturity Level Progress

GBT Maturity Level Progress by Function (2025/2026)

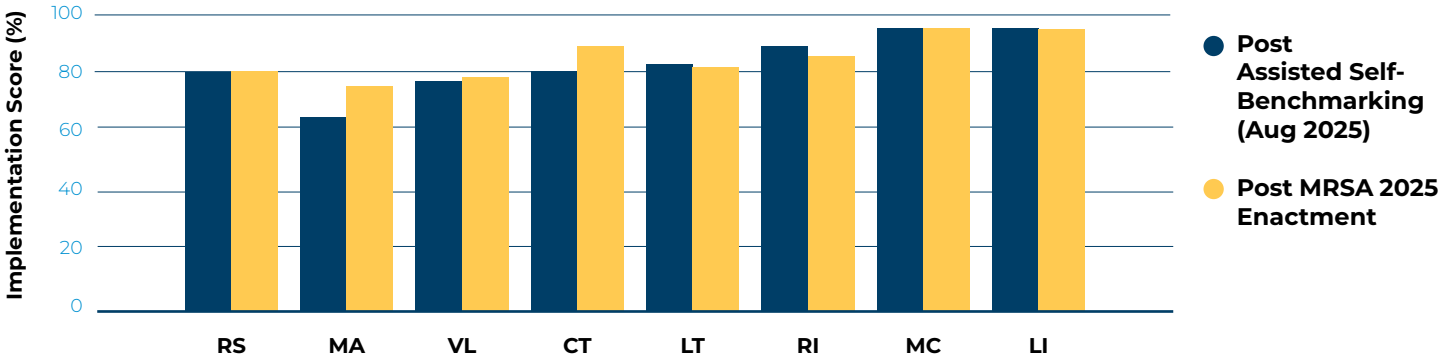


Overall, the NRA is on ML1, Licensing Establishment (LI) has provisionally reached ML3, whilst the other eight functions remain at ML1.

Figure 6: GBT Maturity Level Progress by Function (2025/2026)

Implementation Scores by Function

GBT Implementation Scores by Function



82% average implementation score, attributed to the enactment of the MRSA 2025.

41 Legal IDPs closed via the Medicines and Related Substances Act (MRSA), 2025	**170** IDPs raised in 2025/26 (down from 310 in 2024/25)	**82%** Average WHO GBT implementation score

Figure 7: GBT Implementation Scores by Function

Key Enablers of Progress

- Legislative foundation: MRSA 2025 and MRSA Regulations
- WHO relationship
- Partnerships: CIP Network
- Internal systems
- Accountability
- Continual training and capacity building

QMS Improvements	ML3 Critical Success Factors	Strengthening Audit & Assurance
Enhance automation of quality processes via BRIMS to enable: Legislative foundation: • Receipt of customer service evaluations • Receipt and management of complaints • Real-time IDP process control • Impact-oriented KPI redesign • Integrated assurance model	• Expedite legislation and critical legal instruments, such as regulations and guidelines • Enhance partnerships to ensure impactful, critical GBT requirements, such as ethics committees, are in place	• Build a pool of internal auditors capable of assessing various management systems within the Authority • Build capacity to enable competency in effective, structured RCA • Restore internal audit coverage to 100% • Closer tracking of NC (non-conformity) closure timelines • Sustain external assurance outcomes

Table 15: Key Enablers of Progress

Overall, BoMRA strengthened its quality management and regulatory systems during 2025/2026, laying a solid foundation for continued improvement and accelerated progress towards WHO Maturity Level 3 in 2026/2027.

The 2025/2026 financial year demonstrated the resilience and continued strengthening of BoMRA's Quality Management System. During this period, the Authority maintained ISO 9001:2015 certification, attained ISO/IEC 17025:2017 laboratory accreditation, completed 92% of planned internal audits, achieved timely closure of 88% of non-conformities within stipulated timelines, and improved its average WHO Global Benchmarking Tool implementation score to 82%. The enactment of the Medicines and Related Substances Act, 2025 also enabled the closure of 41 legal Institutional Development Plan gaps, while the Licensing Establishment function provisionally attained Maturity Level 3.

Towards WHO Maturity Level 3, building a stable, well-functioning, and integrated National Regulatory Authority and beyond "advanced level of performance with a proven commitment to continuous improvement."

Business Development and Partnerships

Strategic Partnerships: Progress and Impact in 2025/26

Partnerships Delivering Strategic Value

During 2025/26, BoMRA expanded and deepened its strategic partnership portfolio, progressing five priority partnerships: two new strategic partnerships and three strengthened collaborations. New partnerships were established with Poland's national regulatory authority and the World Bank through the Health Emergency Preparedness, Response and Resilience (HEPRR) Project. Existing collaborations with the African Union Development Agency (AUDA-NEPAD), the European Directorate for the Quality of Medicines and HealthCare (EDQM) and Germany's Federal Institute for Drugs and Medical Devices (BfArM) were strengthened during the year.

Together, these partnerships generated tangible value for BoMRA through mobilisation of financial resources, access to specialist technical expertise, strengthened regulatory and laboratory capability, and deeper participation in regional and international regulatory networks. They demonstrate how strategic collaboration can accelerate institutional development and strengthen BoMRA's ability to deliver on its public health mandate.

Our Partnership Mandate

The Business Development and Partnerships Unit enables BoMRA to strengthen regulatory performance through strategic collaboration. By cultivating partnerships with national regulatory authorities, development partners, multilateral organisations, academia, and industry, the Unit mobilises technical expertise, financial resources, and institutional cooperation that enhance the Authority's ability to fulfil its public health mandate.

The Unit advances BoMRA's Strong Partnerships and Collaborations strategic pillar and Strategic Objective CS2 by ensuring that partnerships are aligned with organisational priorities and deliver measurable value.

Progress and Results in 2025/26

Established in November 2025, the Business Development and Partnerships Unit spent its inaugural year building a structured approach to partnership management while advancing priority collaborations. During the reporting period, two new strategic partnerships were established and three existing partnerships were strengthened, creating tangible opportunities for capability development, resource mobilisation and stronger regulatory performance.

Deepening Continental Collaboration on Medicines Safety

BoMRA's existing collaboration with the African Union Development Agency (AUDA-NEPAD) was strengthened through the introduction of the African Union Smart Safety Surveillance (AU-3S) programme. Under the Pharmacovigilance Unit, BoMRA operationalised the programme and secured USD 199,994 in funding. This expanded collaboration strengthens access to continental medicines-safety intelligence, technical expertise and regional information sharing, enhancing the Authority's ability to identify, assess and respond to emerging safety risks and support evidence-based regulatory decisions.

The Pharmacovigilance Unit's First Prize at the International Society of Pharmacovigilance (ISoP) Africa Chapter Meeting for Botswana's Adverse Drug Reaction Monitoring Centre model further demonstrated BoMRA's growing contribution to regional regulatory practice.

Deepening International Collaboration for Laboratory Capability

BoMRA strengthened its established laboratory collaborations with Germany's Federal Institute for Drugs and Medical Devices (BfArM) and the European Directorate for the Quality of Medicines and HealthCare (EDQM). Through the BfArM collaboration, GHPP LabTrain 2.0, funded by Germany's Federal Ministry of Health, commenced implementation for 2026-2028. In parallel, collaboration with EDQM, supported through the Team Europe Initiative, advanced internal audit capability and specialised testing competencies.

Together, these strengthened partnerships expand BoMRA's access to international technical expertise, strengthen laboratory competencies and quality-management systems, and support alignment with international quality standards. They also build technical readiness for the planned expansion of BoMRA's laboratory services under HEPRR.

Establishing a New Bilateral Regulatory Partnership

During the reporting period, BoMRA established a new bilateral partnership with Poland's national regulatory authority through the signing of a Memorandum of Understanding. Structured technical exchanges were initiated in clinical-trials oversight and marketing authorisation. The partnership gives BoMRA direct access to the experience of an established European regulator, accelerates institutional learning and supports implementation of the Authority's regulatory reliance agenda.

Establishing a New Partnership for Regulatory Resilience through HEPRR

A defining strategic milestone was the establishment of a new partnership with the World Bank through the Health Emergency Preparedness, Response and Resilience (HEPRR) Project. Following declaration of project effectiveness, the programme transitioned from preparation to implementation. The project is financed through a USD 40 million World Bank loan to the Government of Botswana and is implemented jointly by the Ministry of Health, Botswana Public Health Institute, Central Medical Stores and BoMRA. BoMRA will utilise USD 13.5 million under the Access to Quality Health Commodities component.

Within BoMRA's allocation, USD 9.6 million is earmarked for construction, equipping and operationalisation of the National Drug Quality Control Laboratory (NDQCL). The programme also provides for regional regulatory offices, expansion of medicines safety and quality monitoring centres, enhancement and interoperability of the Botswana Regulatory Information Management System (BRIMS), and development of the National Health Products Registry.

The strategic result during 2025/26 was the transition from project preparation to implementation, unlocking multi-year investment in critical regulatory infrastructure, laboratory capability and digital systems. This creates a stronger platform for emergency preparedness, decentralised regulatory services, post-market surveillance and sustained access to quality-assured health products.

Building a Sustainable Partnership Function

Alongside external partnership progress, BoMRA established the foundations required to manage partnerships as a strategic organisational capability. During the Unit's inaugural year, departmental strategies and annual work plans, partnership policies and procedures, stakeholder mapping tools, engagement mechanisms and resource mobilisation approaches were developed.

These foundations strengthen BoMRA's ability to identify, prioritise, manage and measure partnerships against organisational objectives and provide a platform for demonstrating the technical, financial and institutional value generated through collaboration.

Value Delivered through Partnerships

Across the portfolio, the two new partnerships and three strengthened collaborations delivered value by expanding access to technical expertise and regulatory knowledge, strengthening medicines-safety surveillance and laboratory capability, supporting regulatory reliance, and mobilising external resources for critical infrastructure and digital transformation. They also strengthened BoMRA's regional and international networks, creating opportunities for continued institutional learning and collaboration.

Looking Ahead

The progress achieved in 2025/26 demonstrates the growing strategic role of partnerships in advancing BoMRA's mandate. Five priority partnerships were progressed during the year: two new strategic partnerships were established and three existing collaborations were strengthened. Collectively, they expanded access to technical expertise, financial resources, regulatory intelligence, and institutional learning.

The strengthened AUDA-NEPAD partnership introduced the AU-3S programme and secured USD 199,994 for medicines-safety surveillance, while deeper collaboration with EDQM and BfArM advanced laboratory capability. New partnerships with Poland and the World Bank expanded opportunities for regulatory learning and unlocked significant investment in regulatory infrastructure, laboratory capacity and digital systems through HEPRR. In parallel, the establishment of the Business Development and Partnerships Unit created the institutional foundation for a more structured, accountable and value-focused approach to collaboration.

Public Relations and Stakeholder Report

At the heart of BoMRA's mandate is the statutory need to sustain public trust in the National medicines regulatory system. This also means building trust, often through strategic engagement. This responsibility is founded on three pillars: BoMRA's statutory mandate under the Medicines and Related Substances Act, its strategic commitment to regulatory excellence, and its contribution to achieving the health and governance aspirations of Botswana's Vision 2036.

The Public Relations & Stakeholder Engagement Unit serves as a critical link between the Authority and the public, stakeholders, institutions and partners it serves. The Unit ensures that BoMRA's regulatory work is understood, supported and connected to the broader public health priorities of Botswana. This is achieved through structured engagement, timely communication and responsive stakeholder management.

In this context, the stakeholder engagement function extends beyond information sharing, or public education; it is a strategic enabler that promotes transparency, supports informed decision-making, strengthens institutional credibility and enables collaboration in protecting public health.

The 2025/2026 reporting period presented a unique operating environment. Against a backdrop of national fiscal constraints, evolving government priorities and medicine supply challenges, stakeholder engagement became more important than ever. As the Authority adapted its operations to facilitate timely access to quality, safe and effective medicines, it was equally important to ensure that healthcare professionals, industry, government, development partners, patients and the public remained informed, engaged and confident in BoMRA's regulatory decisions.

In response, the department adopted a deliberate, resource-conscious engagement approach focused on continuity of mandate delivery. Rather than allowing fiscal pressures to limit public education and stakeholder confidence-building, the Unit prioritised high-impact platforms, shared stakeholder networks and community-based structures that could extend BoMRA's reach while supporting the Authority's responsibility to safeguard public health.

Sustaining Mandate Delivery Through Intentional Community Awareness Structures

One of the most significant interventions during the reporting period was the establishment of strong, practical and community-facing awareness structures designed to support community-driven medicines safety education. Through the Tirelo Sechaba Programme, BoMRA worked with community-based participants to expand awareness of its mandate, adverse events following immunisation and adverse drug reaction reporting, while building local capacity to communicate medicine safety messages in communities.

The Tirelo Sechaba training was implemented from October to November 2025 across multiple districts and communities, including Mahalapye, Palapye, Serowe, Bobonong, Selibe-Phikwe, Tonota, Nata, Francistown, Tutume and Masunga. Its purpose was to address awareness gaps identified through baseline findings, which showed limited public understanding of adverse event and adverse drug reaction reporting, and to equip participants with the knowledge, tools and confidence to sensitise the public on BoMRA's mandate and reporting channels.

The programme used interactive and scenario-based learning, group work and practical reporting exercises. Participants developed tailored awareness plans for their respective communities and received supporting materials such as AEFI and ADR reporting posters, vaccine factsheets, reporting books, brochures and promotional materials. This ensured that the engagement was not a once-off awareness activity, but a structured intervention capable of translating regulatory information into community-level action.

The intervention yielded important results. Participants demonstrated increased awareness of pharmacovigilance and reporting mechanisms, developed actionable community awareness plans and created a foundation for sustained data collection, follow-up surveys and stronger partnerships. By investing in community-based messengers, BoMRA extended its public education reach beyond formal institutional settings and strengthened the link between regulation, reporting behaviour and public health protection.

Throughout the year, BoMRA continued to strengthen relationships with its stakeholders through open dialogue, timely communication and strategic partnerships. By listening, responding and collaborating, the Authority reinforced its commitment to accountability while supporting Botswana's broader healthcare objectives. Every engagement was guided by a single purpose: ensuring that regulatory excellence translates into improved public health outcomes.

Collaboration: A Strategic Enabler

BoMRA recognises that effective regulation cannot be achieved in isolation. The Authority's success depends on productive relationships with government institutions, healthcare providers, industry, academia, development partners, patients, media and the communities it serves. These relationships provide valuable insights into emerging challenges, evolving stakeholder expectations and opportunities to strengthen regulatory performance.

During the reporting period, stakeholder engagement remained an integral part of organisational governance and decision-making. Feedback gathered through consultations, technical meetings, public engagements, conferences, exhibitions, digital platforms and routine interactions informed operational priorities and contributed to continuous improvement across the Authority.

The Board and Executive Management continued to regard stakeholder engagement as an essential governance function that supports transparency, accountability and institutional resilience. Stakeholder perspectives were regularly considered alongside organisational priorities, ensuring that strategic decisions remained responsive to national needs while supporting the Authority's long-term vision under the 2025–2030 Strategic Plan.

This collaborative approach proved particularly valuable during the implementation of the Human Medicines Assessment Backlog Clearance Plan and ongoing efforts to facilitate access to essential medicines, where regular engagement with applicants, Marketing Authorisation Holders, healthcare professionals and government institutions helped improve understanding of regulatory processes and expectations.

Strengthening Public Confidence Through Communication

Providing accurate, timely and evidence-based information remains central to BoMRA's public health mandate. Throughout the year, the Public Relations and Stakeholder Engagement function continued to translate complex regulatory information into clear, accessible communication that empowered stakeholders to make informed decisions.

The Authority maintained consistent communication across multiple platforms, ensuring information reached diverse audiences in ways that were relevant and accessible. These included:

- Corporate website updates and regulatory notices
- Timely public information through social media platforms
- Media engagement through press releases, interviews and public announcements
- Stakeholder circulars and regulatory updates
- Public awareness campaigns and exhibitions
- Scientific and technical publications
- Direct engagement with healthcare professionals, industry and development partners

As medicine availability became an even greater national priority in this period - and with heightened pressure - communication efforts focused on providing clarity around regulatory processes, assessment timelines, medicine registration initiatives and the Authority's role in facilitating access while safeguarding quality, safety and efficacy. These proactive communication efforts strengthened public understanding of BoMRA's mandate while reinforcing confidence that regulatory decisions remained science-based, transparent and aligned with the public interest.

Deepening Partnerships for Better Health Outcomes

BoMRA continued to foster strong partnerships across Government, regional regulatory bodies, international organisations and the healthcare sector. Collaboration remained a cornerstone of regulatory effectiveness, enabling knowledge exchange, regulatory harmonisation and capacity building. During the year, the Authority hosted and participated in several technical engagements with local and international partners, sharing regulatory expertise while learning from regional and global best practices. These engagements not only strengthened Botswana's regulatory ecosystem but also positioned BoMRA as an increasingly respected partner within Africa's evolving medicines regulatory landscape.

The Authority further maintained close collaboration with the Ministry of Health, healthcare institutions, law enforcement agencies, customs authorities, professional associations, academia and development partners to support coordinated regulatory interventions aimed at protecting public health.

Leveraging Digital Communication

Through the Authority's website and social media platforms, BoMRA shared medicine safety information, regulatory updates, public notices, stakeholder advisories, awareness campaigns and organisational milestones. These platforms enabled the Authority to engage wider audiences while ensuring information remained accessible regardless of geographic location.

Digital engagement also provided valuable insights into stakeholder information needs, allowing communication strategies to become increasingly data-informed and audience-focused. The continued growth of BoMRA's digital platforms further demonstrated the value of digital communication as a mandate-delivery tool. Increased activity across the corporate website and social media channels such as Facebook, X and LinkedIn expanded the Authority's ability to disseminate regulatory information quickly, reach stakeholders beyond physical engagement settings and reinforce public understanding of medicines' safety, reporting mechanisms and regulatory decisions.

In a constrained operating environment, these platforms provided a cost-effective channel for maintaining visibility, supporting transparency and ensuring that critical public health information remained accessible to healthcare professionals, industry, patients, communities and the general public.

Internal website survey findings further reinforced the importance of strengthening BoMRA's digital platforms as part of mandate delivery. While respondents generally viewed the website's visual appearance and layout as acceptable, the feedback also highlighted areas requiring improvement, particularly website performance, navigation, speed and responsiveness. These insights provided a practical evidence base for refining the Authority's digital communication channels so that regulatory notices, medicine safety information, stakeholder advisories and public education content can be accessed more efficiently by staff and external stakeholders.

Website area assessed	Key survey indication	Mandate-delivery implication
Visual appearance	The majority of respondents rated the website as average, with some rating it above expectations.	Maintaining a professional digital presence supports institutional credibility and public trust.
Performance against expectations	Most responses were concentrated around average and poor ratings.	Improved performance is necessary to ensure timely access to regulatory information and services.
Navigation	Navigation was largely rated average or poor.	Clearer navigation can help stakeholders find notices, reporting channels and guidance more quickly.
Design and layout	Design and layout received comparatively stronger feedback, with ratings spread across average and above expectations.	Good design supports accessibility and improves the user experience for diverse stakeholders.
Speed and responsiveness	Speed and responsiveness emerged as the weakest area, with most respondents rating it poor.	Improving responsiveness is critical for reliable access to time-sensitive public health and regulatory information.

Table 16: Internal website survey findings

The survey, therefore, positioned the website not only as an information platform, but as an operational enabler that must continuously evolve to support transparency, stakeholder confidence and efficient access to regulatory services. Going forward, the lessons from the survey will inform ongoing improvements to digital content, platform usability and data-driven communication planning.

Supporting Organisational Resilience

The reporting period reaffirmed that effective communication is critical during times of uncertainty. As fiscal pressures and medicine supply challenges required the Authority to adapt its priorities, stakeholder engagement played a pivotal role in maintaining confidence among government, industry, healthcare providers and the public.

Transparent communication around regulatory priorities, legislative developments and operational initiatives helped build understanding of the Authority's evolving role while reinforcing trust in its ability to continue delivering on its statutory mandate despite constrained resources. This transparent approach supported organisational resilience by ensuring stakeholders remained informed partners in BoMRA's journey towards a stronger and more responsive regulatory system.

Listening to Stakeholders

Meaningful engagement is built on listening as much as communicating. BoMRA continued to create opportunities for stakeholders to share their experiences, concerns and expectations through consultations, technical working sessions, regulatory meetings and digital engagement platforms. These interactions provided valuable insights into emerging regulatory challenges while enabling the Authority to continuously improve its services.

Stakeholder feedback informed several operational improvements during the year, including enhancements to communication materials, greater transparency around regulatory processes and increased engagement on matters affecting applicants and healthcare professionals. By embedding stakeholder feedback into everyday decision-making, BoMRA strengthened the culture of continuous improvement and demonstrated its commitment to responsive, people-centred regulation.

Looking Ahead

As the Authority continues to implement its 2025–2030 Strategic Plan, stakeholder engagement will remain a strategic pillar supporting organisational growth and regulatory excellence.

The Authority will continue investing in innovative communication approaches, digital engagement, evidence-based public education and collaborative partnerships that strengthen transparency and accountability. Greater emphasis will also be placed on integrated stakeholder intelligence, enabling the organisation to anticipate emerging issues, better understand stakeholder expectations and continuously improve service delivery.

Ultimately, BoMRA's commitment extends beyond regulatory compliance. It is about building enduring relationships founded on trust, openness and shared responsibility for protecting public health. Through meaningful engagement, the Authority will continue creating value for its stakeholders while advancing its vision of becoming a responsive, internationally recognised medicines regulatory authority that improves access to quality-assured medicines and safeguards the health of every Motswana.

Stakeholder Engagement and Highlights

Minister Of Health, Dr. Stephen Modise, pays courtesy call to BoMRA

In a significant step towards strengthening the healthcare regulatory framework, the Minister of Health, Dr. Stephen Modise paid a courtesy call to BoMRA. Accompanied by the Permanent Secretary Professor Oathokwa Nkomazana and the Director of Health Services Dr. Oratile Mfokeng-Selei the visit was an opportunity for the Minister to meet with the dedicated staff of the BoMRA, engage in discussions with the Board and Executive Team, and gain insight into the operations and challenges faced by the Authority in its mission to regulate medicines, ensure public health safety, and promote access to quality healthcare in the country.

The Honourable Minister was received with great enthusiasm by the BoMRA staff, who expressed their appreciation for the opportunity to engage with the Minister directly. This meeting was particularly important as it marked the first time the Minister was able to meet the team in person, offering a valuable chance to connect and discuss the vital work being carried out by the Authority.

Engaging with Staff and Executive Leadership:

During the visit, the Minister participated in a “Meet and Greet” session with BoMRA staff, which allowed him to personally interact with the team and better understand their roles, challenges, and aspirations. He commended the BoMRA staff for their hard work and commitment to ensuring that the nation’s medicines regulatory processes are aligned with best practices globally.

> The Minister also took the opportunity to engage with the BoMRA’s Board led by the Chairperson Dr. Kegomoditswe Biki Maphane and the Chief Executive Officer Dr. Seima Dijeng and the Executive Team, participating in discussions that focused on a range of crucial issues, including financing, capacity building, and the overall scope of the Authority’s mandate. A key point of discussion was the need for sufficient funding to allow for the Authority to effectively carry out its responsibilities and expand its capacity to meet growing healthcare demands.

BoMRA Achieves ISO/IEC 17025:2017 Accreditation, marking a major milestone in advancing regulatory excellence

The Botswana Medicines Regulatory Authority (BoMRA) is proud to announce that its National Quality Control Laboratory has been awarded the internationally recognised ISO/IEC 17025:2017 accreditation by the Southern African Development Community Accreditation Service (SADCAS). This follows a rigorous and comprehensive assessment of BoMRA's laboratory systems, technical competence, and operational processes.

This achievement represents a momentous milestone in BoMRA's continued commitment to excellence in regulatory science and laboratory quality assurance. The accreditation confirms that the Authority's laboratory meets global standards for accuracy, reliability, and impartiality in testing strengthening its role in safeguarding public health.

"This accreditation strengthens our credibility, enhances trust among our stakeholders, and reinforces the quality and reliability of our scientific work," said Dr. Seima Dijeng, Chief Executive Officer of BoMRA. "It is a milestone that positions the Authority firmly on the path toward greater institutional maturity. Indeed, BoMRA is on an active journey towards achieving WHO Maturity Level 3 status, and this accomplishment serves as a major step forward. We are building robust systems, strengthening governance, and ensuring that our regulatory processes meet international benchmarks."

> "In applauding BoMRA for this achievement, Ms. Christine Gadzikwa, Chief Executive Officer of SADCAS, highlighted the significance of this accreditation for both Botswana and the region. She stated, "We congratulate BoMRA for meeting the stringent requirements of ISO/IEC 17025:2017. This accreditation affirms the laboratory's technical competence and commitment to quality. For SADCAS, it is always a proud moment to support national regulatory systems in strengthening the quality infrastructure necessary to protect public health. We look forward to continued collaboration as BoMRA expands its testing capabilities and upholds the highest standards of laboratory practice."

The Ministry of Health also commended BoMRA for this major advancement. Speaking on behalf of the Ministry, Dr. Rex Segadimo said, "We congratulate BoMRA on this exceptional achievement. Ensuring that our national regulatory authority meets international standards is vital for the protection of public health and the credibility of Botswana's health system. This accreditation strengthens patient safety by giving assurance of the quality and reliability of the test results issued by the BoMRA laboratory.

BoMRA cracks down on illegal medicines in Kazungula: over 500 unregistered products seized

The Botswana Medicines Regulatory Authority (BoMRA), in collaboration with other law enforcement agencies, intensified efforts to safeguard public health through a coordinated operation in Kazungula and Kasane.

During the operation in Kazungula, a total of 512 unregistered medicinal products were confiscated from four shops and two street vendors found in possession of the illegal goods. These actions constitute a direct violation of Section 23 (1) parts (a), (b), (e), (f), and (h) of the Medicines and Related Substances Act, 2013, which prohibits the possession, sale, and distribution of unregistered medicines.

This decisive enforcement action underscores BoMRA's ongoing commitment to ensuring that only safe, effective, and quality-assured medicines are made available to the public. Working closely with other law enforcement partners, BoMRA continues to strengthen the fight against the circulation of unregulated health products a threat that puts communities at serious risk.

As part of its ongoing mandate, BoMRA will continue to intensify market surveillance, raise public awareness, and strengthen collaboration with other law enforcement as well as border control authorities to prevent the importation and sale of counterfeit and substandard medical products. The protection of public health remains BoMRA's top priority. We urge members of the public to purchase medicines only from licensed pharmacies and authorised health facilities.

> BoMRA remains steadfast in its mission to safeguard the nation from falsified and unsafe health products and will continue to conduct robust operations to uphold the highest standards of pharmaceutical regulation in Botswana.

BoMRA deepens Strategic Partnership with University Of Botswana School Of Pharmacy

Gaborone, Botswana – BoMRA continues to demonstrate its commitment to strengthening the country's pharmaceutical sector through a collaborative partnership with the University of Botswana (UB). As part of a Memorandum of Understanding (MoU) signed between the two institutions, BoMRA is actively supporting teaching, research, education, and experiential learning to build a robust pipeline of skilled pharmaceutical professionals in Botswana.

This strategic collaboration was further solidified at the 43rd UB Graduation Ceremony 2025, where BoMRA proudly sponsored awards for the top three graduating students from the School of Pharmacy. The awards recognise academic excellence and commitment to the pharmaceutical profession.

- **First Prize:**
  Chamo, Keletso - P5,000 P5,000
- **Second Prize:**
  Madza, Eugette, Ngasoh, Ngwebuin - P2,500
- **Third Prize:**
  Tsayang, Angel Mpho - P1,000

Dr. Parthasarathi Gurumurthy, Acting Chief Regulatory Officer of BoMRA, emphasised the long-term vision behind the Authority's sustained support: "This is not just a Memorandum of Understanding - this is a commitment to developing Botswana's pharmaceutical sector through strategic investments in our future professionals. These learners represent the next generation of regulatory scientists, pharmacists, and innovators who will serve our country and region."

Professor David Norris, Vice Chancellor of the University of Botswana, expressed his gratitude during the ceremony, "We are immensely thankful for BoMRA's unwavering support. Their investment in our students' success is a clear reflection of their commitment to national development and academic excellence. Partnerships like these allow us to align our educational outcomes with industry needs."

BoMRA's sponsorship of awards and ongoing collaboration with UB are part of a broader initiative to advance Botswana's capacity in pharmaceutical regulation, public health, and promoting access to safe medicines. As the partnership continues to evolve, BoMRA remains committed to supporting UB and the School of Pharmacy in producing competent, skilled, and innovative pharmaceutical professionals who will contribute to the nation's health sector and beyond.

Botswana Medicines Regulatory Authority (BoMRA) joins 10th Anniversary Campaign For Safer Use Of Medicines

Everyone has a role to play in monitoring medicines safety. By reporting suspected side effects, you and I can help make medicines safer for everyone. That's the core message of this year's #MedSafetyWeek campaign, now in its tenth year.

BoMRA is one of 130 partner organisations worldwide taking part in this campaign, which runs from 3-9 November 2025. Together, we are encouraging patients, families, and healthcare professionals to report any suspected side effects because each report can help protect others.

Medicines save lives and improve the health of millions of people globally. Sometimes they can also cause unintended side effects. By reporting suspected side effects when they do occur, regulators can take actions to make medicines safer. Regulatory agencies around the world such as BoMRA use reports from patients and healthcare professionals to monitor the safety of medicines and respond to any potential risks. Unfortunately, research indicates that only about 5-10% of all suspected side effects are reported.

> "This means that what we see is only the tip of an iceberg, and that it may take longer to identify important safety issues. By raising awareness through #MedSafetyWeek, we want more people to know that their report, no matter how seemingly trivial they may seem, matters," says Dr Seima Dijeng, CEO of BoMRA.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ACTING CHIEF REGULATORY OFFICER REPORT

Dr. Parthasarathi Gurumurthy
Acting Chief Regulatory Officer

The 2025/26 financial year marked a defining chapter in BoMRA's journey towards regulatory excellence. As the inaugural year of implementing the 2025–2030 Corporate Strategic Plan, the year required the Authority to respond decisively to an evolving landscape characterised by fiscal constraints, global supply chain uncertainties, increasing demand for timely access to essential medicines, and a rapidly changing legislative environment. Against this backdrop, the Regulatory Office remained steadfast in fulfilling its mandate to protect and promote public and animal health by ensuring that medicines, medical devices and cosmetics available in Botswana meet the highest standards of quality, safety and efficacy.

The theme of this year's Annual Report, "Adaptability and Resilience: BoMRA's Stewardship for Access to Quality Assured Medicines," aptly reflects the environment in which we operated. Throughout the year our focus extended beyond maintaining compliance to ensuring that scientific rigour, risk-based decision-making and operational agility enabled uninterrupted oversight despite competing demands and constrained resources. Our ability to prioritise high-impact activities, embrace innovation and strengthen collaborative partnerships ensured that public health remained at the centre of every decision we took.

Advances in regulatory science, increasing reliance on international cooperation, digital transformation, and heightened expectations for faster access to quality-assured medical products continue to redefine how national regulatory authorities (NRAs) discharge their mandates. These developments reaffirm the need to balance timely access with robust scientific evaluation and vigilant post-market oversight. As a science-based regulator, BoMRA continued to align its practices with internationally recognised standards and the World Health Organization Global Benchmarking Tool (GBT) framework while adapting these approaches to Botswana's healthcare context.

Advancing BoMRA's Regulatory Mandate

The Regulatory Division serves as the technical cornerstone of the Authority, providing leadership across the full lifecycle of medicines, medical devices and cosmetics. It discharges this responsibility through the evaluation and registration of medical products, the licensing of regulated entities, the inspection of manufacturing and distribution facilities, safety monitoring of medical products (pharmacovigilance), clinical trial oversight, market surveillance and control, and laboratory testing and analysis.

During the reporting period, particular emphasis was placed on strengthening our systems while maintaining the integrity, consistency and transparency of scientific decision-making. Risk-based approaches allowed the Division to direct resources towards areas of greatest public health significance without compromising quality, an approach that proved especially valuable in responding to medicine shortages and to increased demand for expedited decisions affecting essential medicines.

A significant milestone during the year was continued preparation for the implementation of the Medicines and Related Substances Act, 2025, which was assented to on 24 December 2025. The Act has not yet been brought into operation, and the Medicines and Related Substances Act, 2013 accordingly remained the operative legislative instrument throughout the year under review. The 2025 Act considerably broadens BoMRA's regulatory mandate, and the development of subsidiary regulations and implementation readiness activities represent a transformational step towards a more

modern, responsive and comprehensive regulatory system capable of addressing emerging public health needs.

Equally important was the Authority's commitment to achieving WHO GBT Maturity Level 3. This internationally recognised benchmark remains central to strengthening Botswana's National Regulatory System and confidence in the Authority's regulatory decisions, both nationally and internationally. In August 2025, the World Health Organization conducted an assisted self-benchmarking exercise to assess the Authority's readiness for formal benchmarking and the authority is preparing to achieve this milestone consistent with our corporate strategic plan.

Delivering Regulatory Excellence Through Strategic Priorities

Despite operating within a constrained fiscal environment, the Division recorded significant progress across several strategic priorities, focusing on efficiency while preserving scientific integrity across all core functions.

Assessments continued to facilitate timely access to essential medicines and health products through efficient scientific review supported by risk-based evaluation methodologies and, where appropriate, reliance mechanisms. These approaches improved responsiveness and enhanced consistency in decision-making.

The Division strengthened inspection and licensing activities aimed at assuring compliance with Good Manufacturing Practice (GMP) and other internationally recognised quality standards across the medical products supply chain. GMP inspections remain fundamental for assuring that medicines supplied to Botswana are consistently manufactured in accordance with internationally accepted quality standards. During the reporting period, BoMRA strengthened oversight of pharmaceutical manufacturers through both its national GMP inspection programme and participation in the ZaZiBoNa collaborative initiative.

Post-market surveillance and pharmacovigilance activities strengthened our ability to detect, assess and respond to safety concerns. Enhanced monitoring of adverse events, product quality defects and emerging safety signals ensured that decisions remained evidence-based and responsive to evolving risks, across both human and veterinary medicines. During 2025/26, BoMRA established three additional adverse drug reaction monitoring centres (AMCs), expanding its safety monitoring programme across the country.

Recognising that excellence cannot be achieved in isolation, the Division deepened collaboration with national stakeholders, regional authorities and international partners. Participation in joint initiatives and reliance-based approaches enabled knowledge sharing, capacity development and harmonisation of standards, improving efficiency while maintaining high levels of public health protection.

Digital transformation remained an important enabler. Continued investment in regulatory information management systems and digital platforms improved transparency, streamlined processes and enhanced the stakeholder experience, positioning the Authority for greater operational efficiency in the years ahead.

Responding to Challenges and Building Resilience
Like many authorities globally, BoMRA operated within an increasingly complex environment of competing priorities and resource limitations. Fiscal constraints required careful prioritisation to ensure that limited resources were directed where they would have the greatest public health impact. Growing application volumes, evolving technologies and rising stakeholder expectations placed additional demands on capacity.

Global supply disruptions and local medicine shortages heightened the need for agile responses capable of facilitating timely access to essential medicines while maintaining robust quality assurance. Balancing efficiency with scientific rigour required continuous adaptation of our processes without compromising patient safety.

We responded by adopting risk-based approaches, strengthening reliance on trusted international decisions, enhancing digital systems and reinforcing collaboration with local and international partners. These interventions enabled continuity of operations and demonstrated the resilience of BoMRA's systems in the face of uncertainty.

The year also underscored the importance of investing in human capital and institutional capability. Continued professional development of our staff, knowledge sharing and technical capacity building remain essential to sustaining scientific excellence in an increasingly specialised field. Despite resource constraints, BoMRA continued to strengthen competencies among regulatory officers with support from technical partners and funded projects.

Looking Ahead

As BoMRA enters the second year of implementing its 2025–2030 Corporate Strategic Plan, the CRO's office remains firmly committed to strengthening Botswana's National Regulatory System through innovation, collaboration and continuous improvement.

Priority will be placed on operationalising the Medicines and Related Substances Act, 2025, upon its commencement, finalising subsidiary legislation, accelerating digital transformation, strengthening reliance mechanisms and advancing towards WHO GBT Maturity Level 3. Continued enhancement of post-market surveillance, inspection capacity, pharmacovigilance systems and regulatory intelligence will further reinforce our ability to respond effectively to emerging public health challenges.

The evolving healthcare landscape presents both opportunities and responsibilities. New technologies, advanced therapies, increasingly complex supply chains and expanding regional cooperation demand systems that are agile, evidence-based and internationally connected. My office will continue to embrace these opportunities while remaining anchored in the Authority's core mandate of protecting public health.

I extend my sincere appreciation to the Board, the Chief Executive Officer, Executive Management, members of the technical teams, our expert evaluators, technical committees, healthcare professionals, regulated industry, development partners and all stakeholders whose dedication and collaboration continue to strengthen Botswana's regulatory system. Their collective commitment enabled the Authority to navigate a demanding year while maintaining public confidence in our decisions.

Together, we will continue building a modern, resilient and internationally recognised authority that delivers timely access to safe, efficacious and quality-assured medical products for the people of Botswana.

Dr. Parthasarathi Gurumurthy
Acting Chief Regulatory Officer

Product Evaluation And Registration Report

Mr. Bathusi Kgosietsile
Director Product Evaluation and Registration

The Product Registration Department is responsible for the scientific assessment and registration of medicines, medical devices, in vitro diagnostics (IVDs), complementary medicines and other regulated health products. The Department ensures that products placed on the Botswana market meet established standards of quality, safety and efficacy while supporting timely access to essential medical products. Its mandate contributes directly to the Authority's strategic objectives of strengthening regulatory efficiency, improving public health protection and enhancing stakeholder confidence through risk-based and reliance regulatory approaches.

The Department recorded strong performance during the 2025/26 financial year, exceeding strategic targets despite increasing application volumes. Veterinary was the most increased at 420% of applications received, compared to the previous year, followed by complementary at 200% while for Medical Devices, applications increased by 110%.

Meanwhile, Human Medicines increased slightly by 2%. Furthermore, there was a significant cumulative historical assessment backlog, which led to the implementation of a project for Backlog clearance. Increased use of reliance mechanisms and improved stakeholder engagement contributed to enhanced regulatory efficiency while maintaining high standards for quality, safety and efficacy of health products.

Key Performance Indicators

Year-on-Year Comparison
Registration committee approvals 2024/25 vs 2025/26

	NEW APPLICATIONS				VARIATIONS			RENEWALS
	HM	COMPs	VET	MD	HM	COMPs	VET	HM
2024/2025								
TOT PRESENTED	217	7	10	40	1707	16	1	125
TOT APPROVED	217	5	9	40	1707	16	1	125
TOT REJECTED	0	2	0	0	0	0	0	0
2025/2026								
TOT PRESENTED	221	21	52	84	543	13	28	670
TOT APPROVED	214	21	52	84	541	13	28	670
TOT REJECTED	7	0	0	0	2	0	0	0

Above table depicts summary of applications that were considered for a final regulatory decision comparing the reporting period with the previous year.

Applications Considered For Registration

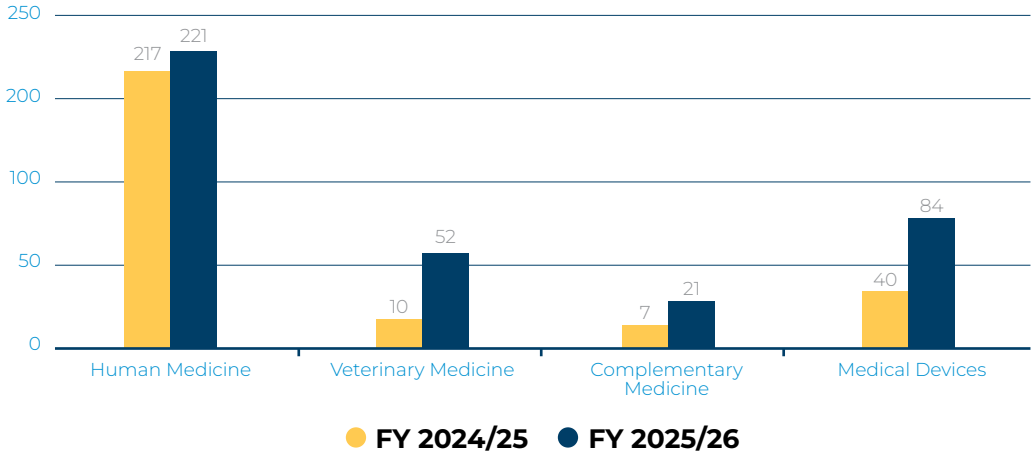


Figure 8: Applications Considered For Registration

Key Highlights

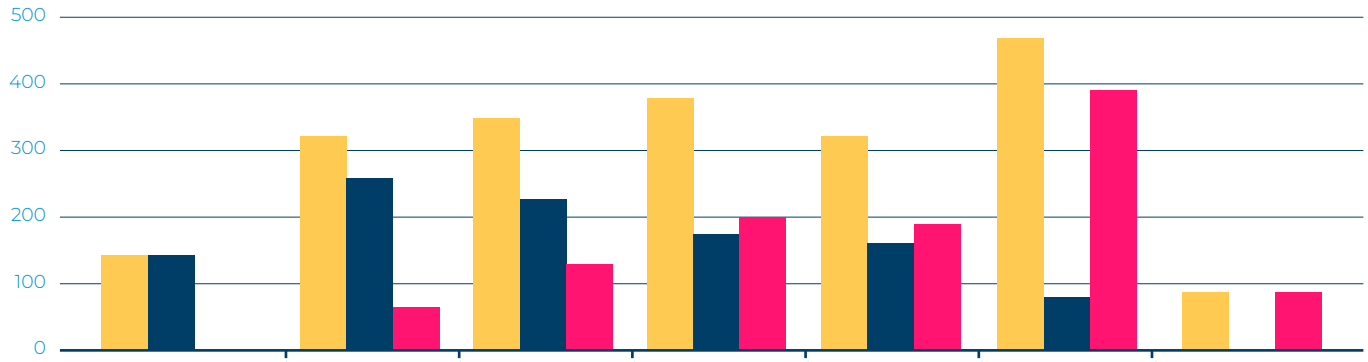
- Human Medicines remained relatively stable, increasing slightly from 217 to 221 applications
- Veterinary Medicines recorded the highest growth, increasing from 10 to 52 applications (420% increase)
- Complementary Medicines tripled from 7 to 21 applications
- Medical Devices more than doubled from 40 to 84 applications (110% increase)

These results indicate strong expansion in regulatory activity outside the traditional human medicines portfolio, particularly in veterinary medicines and medical devices.

Product Split Registered (2025/26)

Cumulative Years Consolidated (Human Medicine)

New Applications - HM



	2020	2021	2022	2023	2024	2025	2026 (March)
Received new application	157	331	355	372	345	461	89
Closed new application	157	272	222	175	156	60	1
Pending new application	0	59	133	197	189	401	88

Received new application | Closed new application | Pending new application

Figure 9: Product Split Registered (2025/26)

Cumulative Received vs Closed - Veterinary

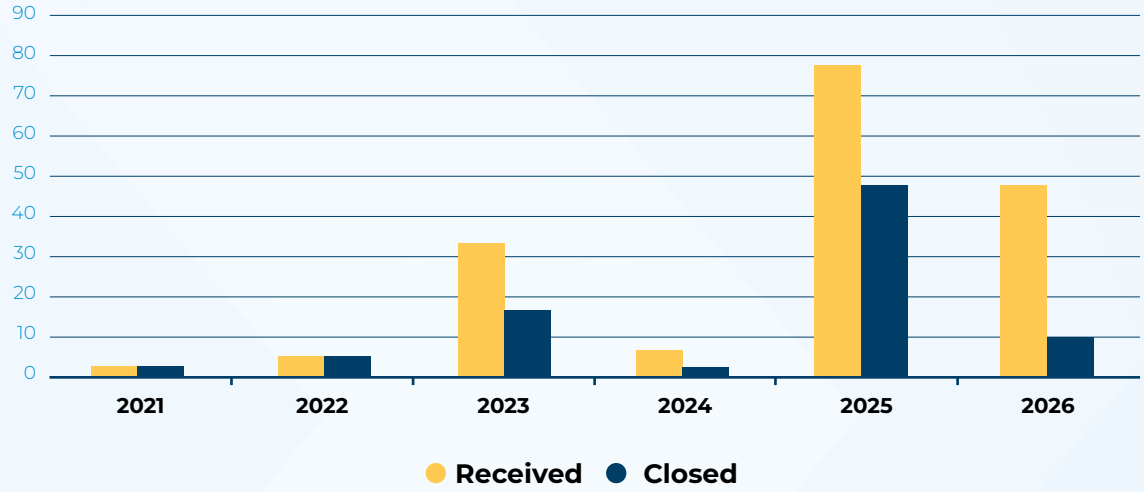


Figure 10: Cumulative Received vs Closed - Veterinary

Cumulative Received vs Closed - Complementary

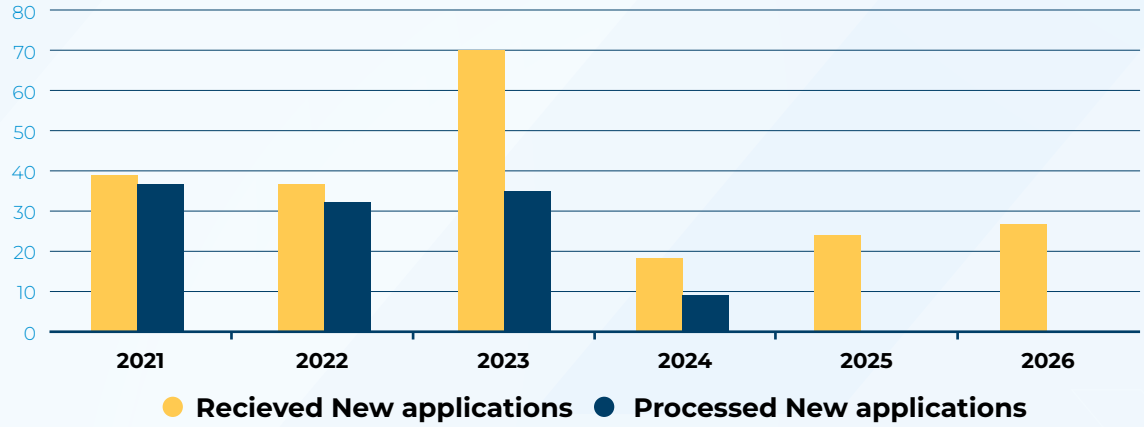


Figure 11: Cumulative Received vs Closed - Complementary

Received Cumulative vs Closed - Medical Devices

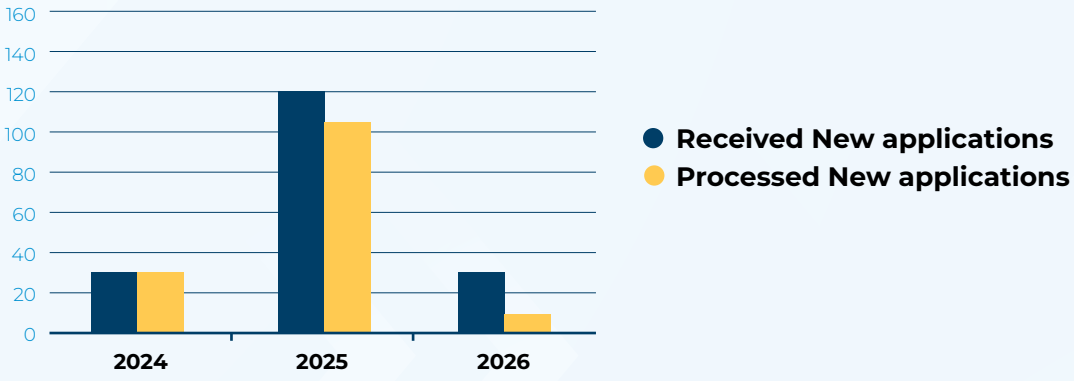


Figure 12: Received Cumulative vs Closed - Medical Devices

Cosmetics

The graph below shows the number of cosmetic notifications submitted through the notification portal since inception to date.

Listed Cosmetics

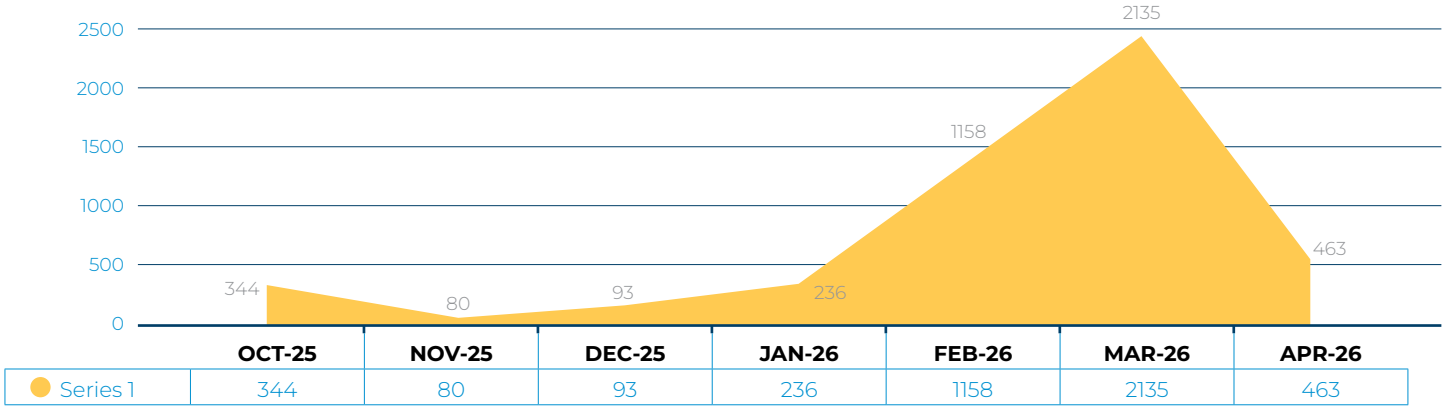


Figure 13: Number of cosmetic notifications submitted through the notification portal since inception to date.

Summary of Cosmetic Notification Activity

The cosmetic notification data demonstrates significant fluctuations in the number of cosmetic notifications submitted over the reporting period, with a total of 4,509 notifications submitted through the notification portal between October 2025 and April 2026.

Key Observations

Cosmetic notification activity showed progressive growth from January 2026, with approximately 80% of all notifications being submitted between February and April 2026.

Key Highlights

Major Achievements

- Implementation of backlog clearance, mostly occurred due to reduction of timelines.
- Expanded the use of reliance and recognition pathways, accelerating registration of priority medicines
- Improved stakeholder engagement through quarterly industry meetings and publication of updated regulatory guidance
- Implemented electronic dossier tracking and dashboard monitoring

Performance Summary

Indicator	Target	Actual	Performance
Eligible Applications Processed through Reliance Pathway	90%	100%	Exceeded Target
Regulatory Compliance	90%	100%	Exceeded Target
Backlog Reduction			
Service Standards			

Table 17: Performance Summary

Outlook for 2026/27

The Department will focus on:

- Eliminating the remaining historical assessment backlog
- Full implementation of combined screening and scientific assessment
- Expansion of reliance and abridged review pathways
- Strengthening regulation of medical devices, veterinary medicines and complementary medicines

Looking ahead, the Department is well positioned to achieve full digital transformation and further improve access to safe and effective medical products in the coming financial year.

Licensing and Enforcement Report

Ms. Zukiswa Raditladi
Director, Licensing and Enforcement

The Department of Licensing and Enforcement is responsible for the inspection and licensing of premises along the supply chain of all regulated products as well as the import-export control of regulated products moving in international trade. Furthermore, the Department is mandated with testing and analysis of medicines, for the determination of their compliance with standards of quality. The Department is also responsible for the general enforcement of the Medicines and Related Substances Act and regulations thereof.

Through risk-based regulatory oversight, the Department ensures that regulated entities comply with applicable legal and technical requirements, thereby safeguarding the quality, safety, efficacy and performance of medical products throughout their lifecycle. Its functions encompass the licensing of manufacturers, wholesalers, retailers, healthcare institutions, medical device establishments, veterinary medicine premises, and other regulated facilities, together with border control, laboratory testing, market oversight, and regulatory enforcement.

In alignment with the BoMRA Strategic Plan 2025–2030, the Department contributes to Strengthening Regulatory Systems, protecting public and animal health, securing the integrity of the medical products supply chain, facilitating access to quality-assured medical products, and promoting compliance through transparent, risk-based, and internationally benchmarked regulatory practices.

Key Performance Indicators

Regulatory Compliance: Premises

Premises compliance is a key indicator of the effectiveness of BoMRA's inspection and licensing programme. During the 2025/26 financial year, the Authority maintained a compliance target of 90%. A total of 473 premises were assessed for licensing, of which 443 met the prescribed licensing requirements, resulting in an overall compliance rate of 93.7%. This represents an improvement over the 93.2% achieved during the 2024/25 financial year and exceeded the Authority's compliance target.

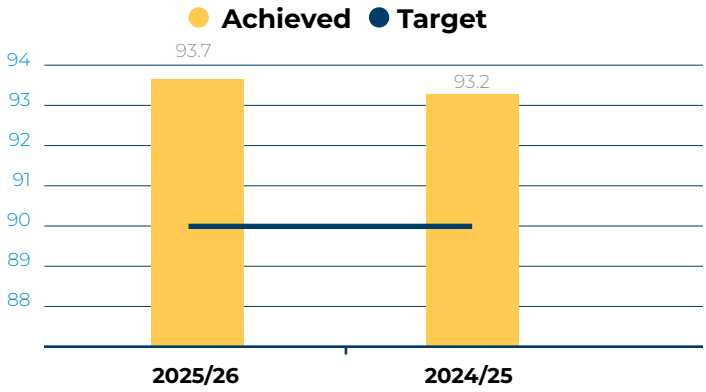


Figure 14: Premises Compliance Performance Against Target

The improvement reflects the continued effectiveness of BoMRA's risk-based inspection and licensing programme, despite the expansion of the regulatory framework to include Schedule IV and complementary medicines distributors. Details of inspection and licensing activities that contributed to this performance are presented under Section 3.

Regulatory Compliance: Products

Product compliance is a key performance indicator that measures the Department's effectiveness in ensuring that medical products available on the Botswana market, and those entering the country through donation programmes, comply with applicable regulatory requirements for quality, safety and labelling. During the 2025/26 financial year, the Department achieved an overall product compliance level of 79% against an annual target of 90%.

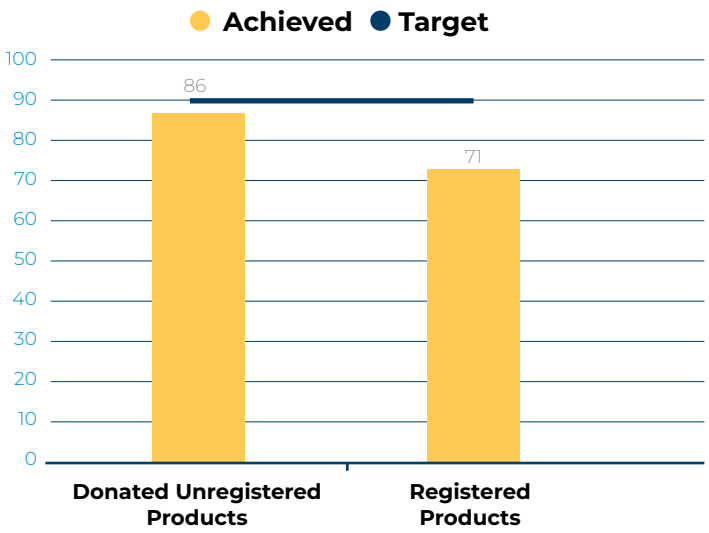


Figure 15: Product Compliance Performance Against Target

Compliance among donated medical products was higher than that observed for registered medical products, reflecting the effectiveness of pre-release regulatory assessment. However, where non-compliance was identified in donated products, the deficiencies generally posed a greater potential risk to product quality and patient safety. These included expired products, breaches in cold chain integrity, inadequate product information, particulate matter in injectable products and products unsuitable for the intended patient population.

In contrast, the principal deficiencies identified among registered medical products related to statutory labelling requirements, including the absence of BoMRA registration numbers, schedule classification numbers and manufacturing dates. While these deficiencies have a lesser direct impact on product quality, they reduce product traceability, may affect the availability of critical information required for safe use, and constitute non-compliance with regulatory requirements.

The Department will continue to strengthen post-market surveillance, importer and supplier engagement, and risk-based quality assurance interventions to improve product compliance across both registered and unregistered medical products. Detailed findings relating to these activities are presented under Section 4.

Regulatory Oversight of Licensed Establishments

Premises Inspections

During the 2025/26 financial year, the Department conducted 594 premises inspections, comprising 459 licence renewal inspections and 135 new premises inspections. This represents a 21% increase compared to the previous financial year, reflecting increased regulatory activity and continued growth within Botswana's regulated medical products sector.

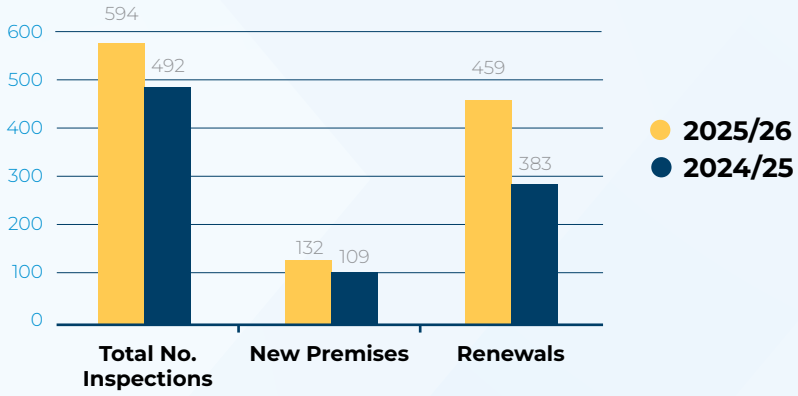


Figure 16: Premises Inspections

Retail establishments accounted for approximately 74% of inspections, followed by wholesale facilities (15%), Good Manufacturing Practice inspections (7%) and within-group practice pharmacies (4%).

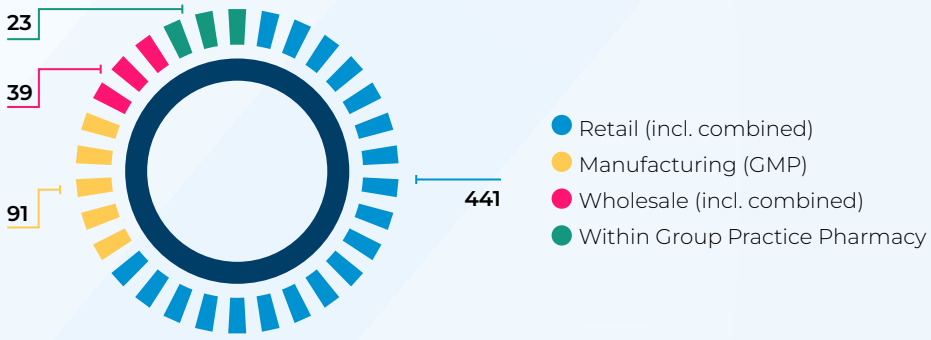


Figure 17: Distribution of facilities inspected by category, 2025/26

Human medicines premises accounted for 75% of inspections, veterinary medicinal product premises 24%, and medical device premises less than 1%, marking the commencement of medical device premises regulation following implementation of the Medicines and Related Substances Act, 2025.

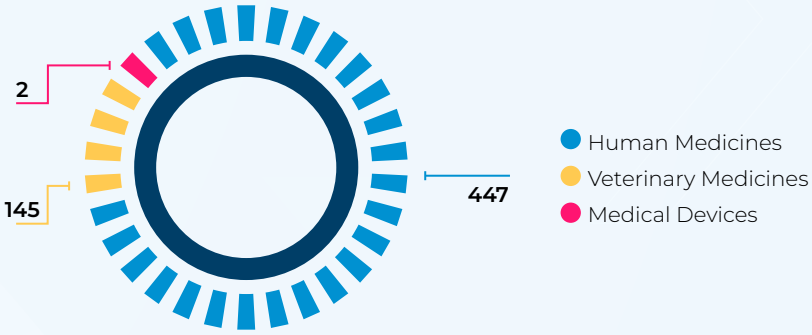


Figure 18: Inspections by product stream, 2025/26

The increase in inspection activity reflects BoMRA's strategic focus on strengthening regulatory oversight through risk-based inspections, promoting compliance across the regulated supply chain, and supporting a growing healthcare market while safeguarding public and animal health.

Good Manufacturing Practice (GMP) Inspections and Regulatory Reliance

Good Manufacturing Practice (GMP) inspections remain a key regulatory tool for assuring that medicines supplied to Botswana are consistently manufactured in accordance with internationally accepted quality standards. During the 2025/26 financial year, BoMRA strengthened oversight of pharmaceutical manufacturers through both its national GMP inspection programme and participation in the ZAZIBONA collaborative initiative, reinforcing its commitment to regulatory excellence, regional harmonisation and reliance.

BoMRA National GMP Inspection Programme

During the reporting period, BoMRA conducted 30 GMP assessment activities, comprising 27 on-site inspections and 3 desk reviews of pharmaceutical manufacturing facilities supporting licensing and product registration decisions.

The inspections identified a number of manufacturers that demonstrated compliance with current Good Manufacturing Practice (cGMP) requirements, while other facilities were required to implement Corrective and Preventive Actions (CAPAs) before regulatory decisions could be finalised. Follow-up of CAPA implementation remains an important component of BoMRA's risk-based regulatory approach, ensuring that identified deficiencies are effectively addressed before market authorisation or continued supply is permitted.

Regional Collaboration through ZaZiBoNa

BoMRA continued to contribute to regional pharmaceutical manufacturing oversight through active participation in the ZaZiBoNa collaborative medicines registration initiative. During the reporting period, the Authority participated in 31 regional GMP assessment activities, including joint inspections and desk reviews undertaken with partner National Regulatory Authorities.

Participation in the ZaZiBoNa programme enables BoMRA to leverage regional technical expertise, reduce duplication of inspections and strengthen reliance on shared regulatory assessments. During the reporting period, collaborative inspections supported regulatory decision-making for pharmaceutical manufacturing facilities supplying medicines to Botswana and contributed to the continued registration of 95 medicinal products across participating countries.

Overall, the combined national and regional GMP programmes strengthened regulatory oversight of pharmaceutical manufacturing, promoted harmonisation of regulatory standards within the Southern African Development Community (SADC), and supported timely access to quality-assured medicines. The continued application of risk-based inspections and regional reliance mechanisms reflects BoMRA's strategic commitment to building an efficient, internationally aligned regulatory system while safeguarding public and animal health.

Licensing of Establishments

During the reporting period, the Department concluded 469 licensing activities, comprising 443 licences issued and 26 licence variations. The licences issued included 370 licence renewals and 73 pre-licensing approvals. The sustained increase in pre-licensing approvals reflects continued growth in new regulated establishments entering the market and is consistent with the increase observed in new premises inspections during the reporting period.

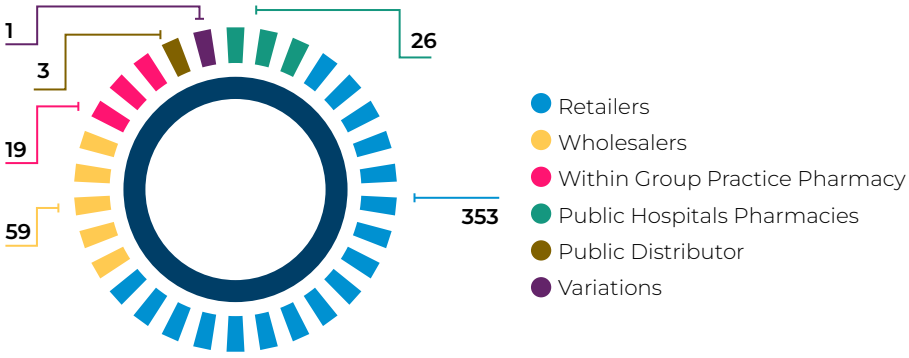


Figure 19: Licensing activities by type, 2025/26

Retail establishments continued to account for the majority of licensing activities, reflecting the structure of Botswana's regulated medicines sector. Growth in pre-licensing approvals demonstrates continued expansion of regulated healthcare establishments while maintaining compliance with prescribed licensing standards.

The continued increase in licensing activity demonstrates the expansion of Botswana's regulated healthcare sector and reflects BoMRA's commitment to delivering efficient, risk-based licensing services that facilitate market entry while ensuring compliance with the Medicines and Related Substances Act and applicable regulatory standards. These efforts support the Authority's strategic objective of strengthening regulatory systems, promoting compliance, and ensuring that regulated products are handled only by suitably licensed establishments.

Supply Chain Quality Assurance

Compliance Monitoring of Registered Medical Products

Post-market compliance monitoring was undertaken through physical inspection of registered medical products sampled from BoMRA-authorised retail outlets.

A representative sample of frequently imported registered medical products was assessed, with 71% found to comply with statutory labelling requirements. The principal deficiencies related to the absence of BoMRA registration numbers, schedule classification numbers and manufacturing dates.

Compliance of Unregistered Donated Products

The Department assessed consignments of unregistered donated medical products before authorising their release into Botswana's healthcare system.

During the reporting period, 480 medical products were assessed, of which 412 (86%) were released for use while 68 (14%) were rejected or quarantined because they did not meet applicable regulatory requirements. The principal causes of rejection included cold chain failures, inadequate product information and labelling, expired products, contraindications, particulate contamination and insufficient supporting documentation.
Overall, the product compliance programme demonstrates BoMRA's commitment to ensuring that both registered products already available on the market and donated medical products entering the country comply with applicable regulatory standards. These activities strengthen product traceability, support informed and safe use of medical products, and protect public and animal health by preventing non-compliant products from reaching patients.

Pre-Shipment Inspection Programme

BoMRA introduced the Pre-Shipment Inspection (PSI) programme in August 2025 to strengthen regulatory oversight of imported medicines, mitigate public health risks associated with substandard or falsified products, and improve cost efficiency in the verification of imported medical products.

Phase 1 of the programme focused on wholesale-level unregistered medicines imported from India, a key source market for Botswana's pharmaceutical supply chain. The implementation framework included the appointment of an inspection service provider, control, and the engagement of three accredited laboratories to support sampling and product testing activities.

During Phase 1 implementation, the programme delivered the following outputs:

a) 23 consignments inspected
b) Across 55 product lines
c) A further 85 samples analysed through partner laboratories, at approximately 20% of the cost of regional laboratory testing services

The PSI programme represents a significant enhancement of BoMRA's risk-based regulatory approach by shifting quality assurance earlier in the supply chain and reducing the likelihood of non-compliant products entering the Botswana market.

Import-Export Control

Permit Issuance

During the reporting period, the Department issued 7,780 import, export and transit permits, representing a 1.21% increase compared to the previous financial year.

Permit processing efficiency also improved significantly, with compliance to service turnaround times increasing from 81% to 91%, primarily due to implementation of the BRIMS IMPEX module. In October 2025, issuance of permits for medical devices commenced. By the end of the reporting period, a total of 313 medical device permits had been issued.

This marks the first six months of implementation of medical device import and export control within BoMRA's regulatory framework and expands the scope of regulated products under the permit system.

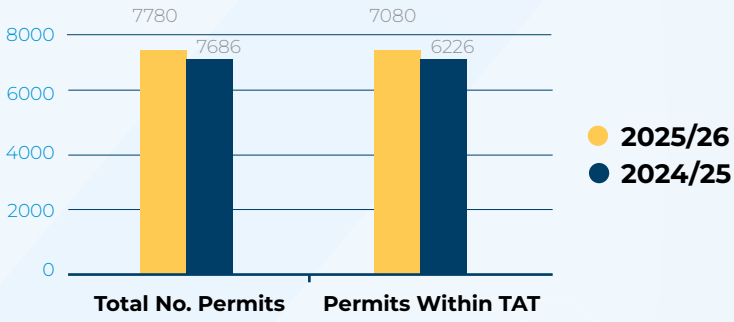


Figure 20: Comparison of permit volumes and turnaround time performance

Furthermore, a notable increase was observed in human and veterinary exemption permits, which rose from 429 permits in 2024/25 to 1,209 permits in 2025/26. This increase is largely attributed to higher volumes of medicine consignments entering Botswana during the reporting period, including donations and emergency supply imports linked to medicine shortages experienced in the healthcare system.

Prevention, Detection and Response to Regulatory Non-Compliance

Detection of Regulatory Non-Compliance

The Department continued to implement a risk-based enforcement programme through surveillance, inspections and joint enforcement operations.

A total of 64 offences were detected during the reporting period, representing a 20% reduction compared to the previous financial year.

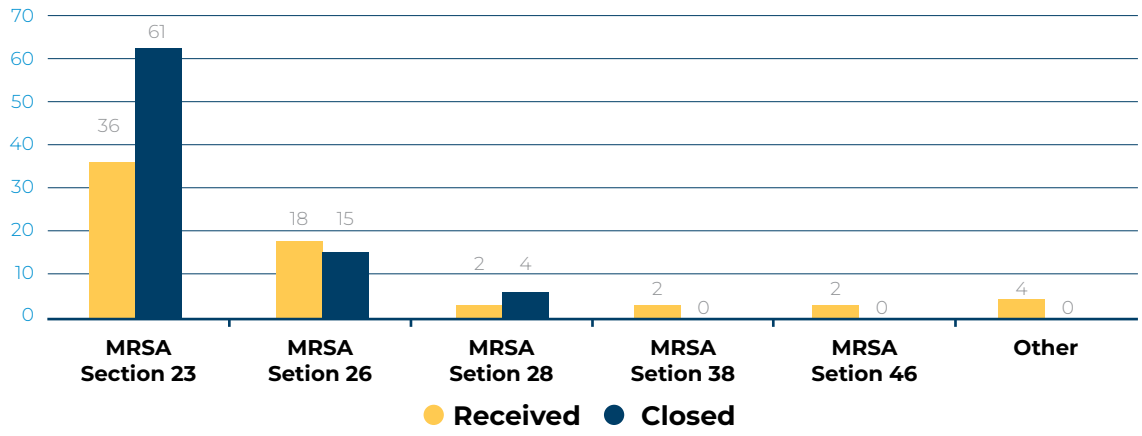


Figure 21: Comparison of MRSA Violations Over the Two-Year Period

Although offences involving unregistered medicines remained the most common, reductions in several offence categories demonstrate improving compliance across the regulated sector. Emerging non-compliance associated with prescription medicines and unauthorised promotion highlights the need for continued surveillance and stakeholder engagement.

Additional offences detected included mishandling of habit-forming medicines, illegal compounding activities, poor record keeping, and the sale of counterfeit medicines. Analysis of offender categories indicates that 34% of offenders were BoMRA-licensed entities, compared to 31% in the previous financial year. These infringements were largely linked to non-compliance with licensing conditions under Section 26(1)(a) and (b) of the Act. A notable 35% reduction in offences involving other categories of offenders, including street vendors and general dealers, was also observed. This reflects the impact of sustained enforcement operations targeting informal and unregulated distribution channels.

The overall enforcement outcomes demonstrate BoMRA's continued commitment to strengthening the prevention, detection, and response framework for regulatory non-compliance. While a reduction in total offences was observed, emerging offence types highlight the need for ongoing surveillance, targeted inspections, and sustained public education to address evolving risks in the medicines supply chain.

Enforcement Actions

Appropriate regulatory actions were taken against non-compliant entities in accordance with the Medicines and Related Substances Act.

During the reporting period, fines amounting to P124,900.00 were issued and paid through the Botswana Police Service, reinforcing compliance across the regulated supply chain.

These actions form part of BoMRA's broader compliance enforcement strategy, aimed at deterring non-compliance and reinforcing adherence to regulatory requirements across the supply chain.

Disposal of Unwanted Regulated Products

The Department safely disposed of 20,747 unwanted regulated products seized through joint enforcement operations and concluded investigations. This is a 33% decrease compared to the previous financial year.

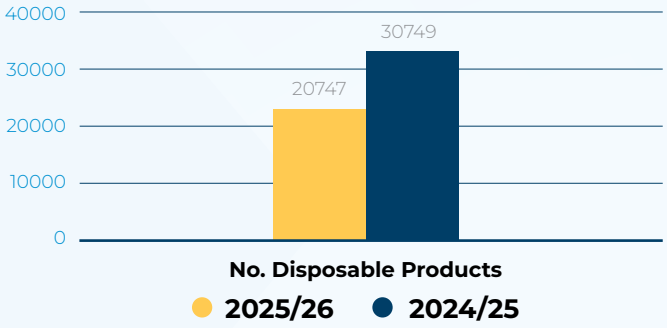


Figure 22: Comparison of Disposed Unwanted Products Over the Two-Year Period

The estimated street value of the disposed products amounted to P603,259.62, demonstrating the continued impact of enforcement interventions in disrupting the illegal trade in medical products.

The seized products primarily comprised prescription-only and Schedule medicines obtained from illegal markets, including products such as cough syrups containing codeine, topical corticosteroid creams, phosphodiesterase inhibitors, appetite stimulants, and veterinary vaccines.

Laboratory Services and Quality Assurance

The BoMRA Laboratory provides the scientific evidence that underpins regulatory decision-making through the testing and analysis of medical products submitted under post-market surveillance, pre-distribution verification, quality defect investigations, enforcement activities and other regulatory programmes. By verifying compliance with established quality standards, the laboratory plays a critical role in detecting substandard and falsified medical products, supporting regulatory interventions and protecting public and animal health.

During the 2025/26 financial year, the laboratory continued to strengthen its technical capability, improve operational efficiency and enhance the quality and reliability of its testing services through implementation of a Laboratory Quality Management System in accordance with ISO/IEC 17025:2017. These improvements resulted in expanded in-house analytical capability, significantly improved turnaround times and successful attainment of the ISO/IEC 17025:2017 accreditation.

Key Performance Indicators

Sample Analysis

During the 2025/26 financial year, the BoMRA Laboratory analysed 440 medical product samples, representing 100% of all samples received during the reporting period.

Although this represents a decrease from the 508 samples analysed during the 2024/25 financial year, the reduction does not reflect diminished laboratory performance. Rather, it is attributable to fewer post-market surveillance sampling initiatives undertaken during the year, with only one national sampling exercise conducted as regulatory priorities shifted to supporting the national response to medicine shortages. In addition, the comparatively higher workload reported in 2024/25 included a number of samples carried forward from previous reporting periods.

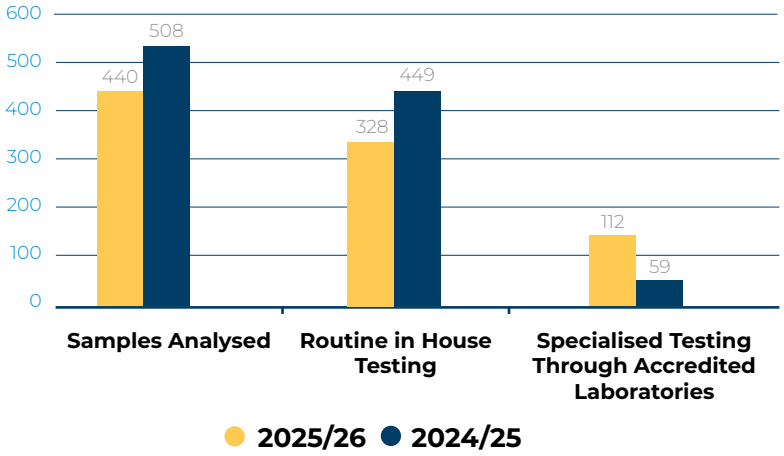


Figure 23: Laboratory Sample Analysis Trend

Of the total samples analysed, 328 samples (75%) were tested in-house, while 112 samples (25%) were subcontracted to accredited partner laboratories. The increase in subcontracted samples reflects the deliberate expansion of the product categories and dosage forms subjected to regulatory quality testing, particularly specialised dosage forms such as injectable preparations, oral liquids, ointments and suspensions, for which certain analytical capabilities are still being developed within the BoMRA Laboratory. The use of accredited external laboratories ensures that these products continue to be assessed against the required quality standards while maintaining the integrity and reliability of regulatory decisions.

At the same time, the laboratory significantly strengthened its in-house analytical capability through optimisation of the Laboratory Quality Management System, enhanced analyst competency and expansion of its testing scope. These improvements have enabled a greater proportion of routine analyses to be performed internally, strengthened BoMRA's scientific capacity and supported more timely regulatory decision-making, while strategic subcontracting continues to provide access to specialised analytical expertise where required.

Turnaround Time Performance

The laboratory achieved a significant improvement in operational efficiency during the 2025/26 financial year, reducing the average sample analysis turnaround time from 210 working days in 2023/24 to 30 working days in 2025/26.

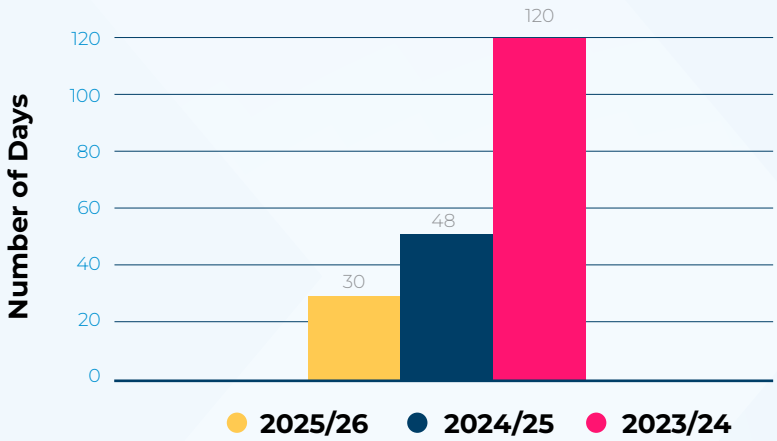


Figure 24: Laboratory Performance Against Established Turnaround Times

This achievement was driven by the successful implementation of the Laboratory Quality Management System, optimisation of analytical workflows, improved resource planning, strengthened document control and enhanced staff competency through targeted technical training.

To further improve service delivery, the laboratory introduced a risk-based staggered turnaround time model, with service standards determined by sample volume and analytical complexity. While the laboratory has adopted a maximum turnaround time of 80 working days for complex or high-volume workloads, the laboratory substantially outperformed this service standard, achieving an average turnaround time of 30 working days.

The substantial reduction in turnaround time has enhanced the Authority's ability to make timely, evidence-based regulatory decisions relating to product registration, post-market surveillance, quality defect investigations, import quality assurance and enforcement actions. Faster availability of laboratory results has also strengthened regulatory responsiveness, enabling more effective protection of public and animal health through timely identification and management of quality-related risks.

Analytical Scope

The laboratory analysed a broad range of dosage forms during the 2025/26 financial year, reflecting the diversity of medical products regulated by BoMRA and the expanding scope of regulatory quality assurance activities. Oral solid dosage forms remained the predominant category of samples analysed, accounting for the majority of the laboratory workload. These comprised 362 tablet samples and 4 capsule samples, representing products routinely monitored through post-market surveillance, quality complaint investigations and pre-distribution verification programmes.

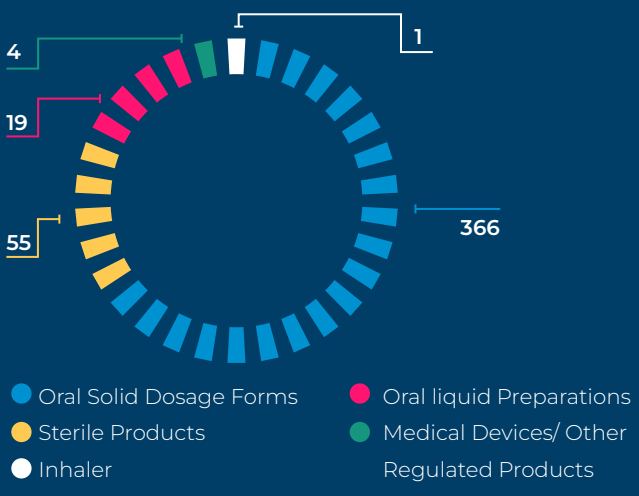


Figure 25: Distribution of Samples Analysed by Dosage Form

Analytical Scope (Continued)

In addition to routine oral solid dosage forms, the laboratory analysed a range of more technically demanding products including injectable preparations and intravenous infusions, as well as oral liquid preparations comprising syrups, suspensions and solutions. In addition, specialised products such as inhalation products and other regulated products, including gloves and soap, were subjected to quality assessment.

The inclusion of a broader range of dosage forms demonstrates the continued expansion of BoMRA's regulatory testing programme beyond routine oral solid dosage forms to encompass products requiring more specialised analytical techniques. Where analytical capability was not yet available in-house, testing was undertaken through accredited partner laboratories to ensure that all products were assessed against the required quality standards. This approach strengthens regulatory oversight across the medical products supply chain while supporting the progressive expansion of the laboratory's analytical capability.

Quality Management and Accreditation

A major milestone during the reporting period was the successful implementation of the Laboratory Quality Management System and the attainment of ISO/IEC 17025:2017 accreditation by the Southern African Development Community Accreditation Service (SADCAS).

Following an external assessment conducted on 22–23 September 2025, the laboratory was granted accreditation on 18 October 2025, marking a significant achievement in the Authority's journey towards strengthening scientific excellence and internationally benchmarked regulatory laboratory services. Accreditation provides independent assurance that the laboratory operates in accordance with internationally recognised standards for technical competence, impartiality and consistent operation. It strengthens confidence in laboratory results, supports regulatory reliance and enhances the credibility of regulatory decisions made by BoMRA.

The accreditation was particularly valuable during a period of national medicine shortages, when increased importation of donated and unregistered medical products required timely laboratory verification. The availability of an internationally accredited regulatory laboratory strengthened BoMRA's ability to verify product quality and provided greater confidence that regulatory decisions regarding product release were supported by internationally recognised scientific evidence.

Implementation of the Laboratory Quality Management System also resulted in streamlined laboratory processes, improved traceability, enhanced documentation, strengthened analyst competency and expansion of the laboratory's analytical capability. During the reporting period, the laboratory expanded its in-house testing capability from one validated analytical capability to six analytical techniques, enabling a greater proportion of regulatory samples to be analysed internally while reducing reliance on external laboratories for routine testing.

The laboratory remains committed to maintaining its accreditation through continual improvement, regular internal audits, participation in proficiency testing programmes and ongoing staff development to ensure the continued delivery of reliable, high-quality analytical services in support of BoMRA's regulatory mandate.

Pharmacovigilance And Clinical Trials Report

Mr Lebogang Koitsiwe
Acting 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, approving and overseeing clinical trials, conducting post-marketing surveillance for quality, and preventing substandard and falsified medicines from entering the supply chain in Botswana.

During the 2025/2026 reporting period, BoMRA commenced implementation of its Second Strategic Plan (2025–2030), following the successful completion of its maiden (2019–2024) and transition (2024–2025) Strategic Plans. The Second Strategic Plan provides a framework for delivering the Authority's regulatory mandate in alignment with the National Development Plan 12, Botswana Economic Transformation Programme, Sustainable Development Goals as well as the World Health Organization's Global Benchmarking Tool towards a fully functional and trusted Authority.

Key Performance Indicators

The Department surpassed its target for promoting patient and animal safety, achieving a 13.8% increase in safety reporting against the set target of 10%. Overall, the PVCT regulatory compliance composite was 96.67% of the target set at 95%, comprising activities towards strengthening regulatory systems, promoting patient and animal safety, and enhancing regulatory compliance through effective safety monitoring (vigilance), clinical trial oversight, and post-marketing surveillance.

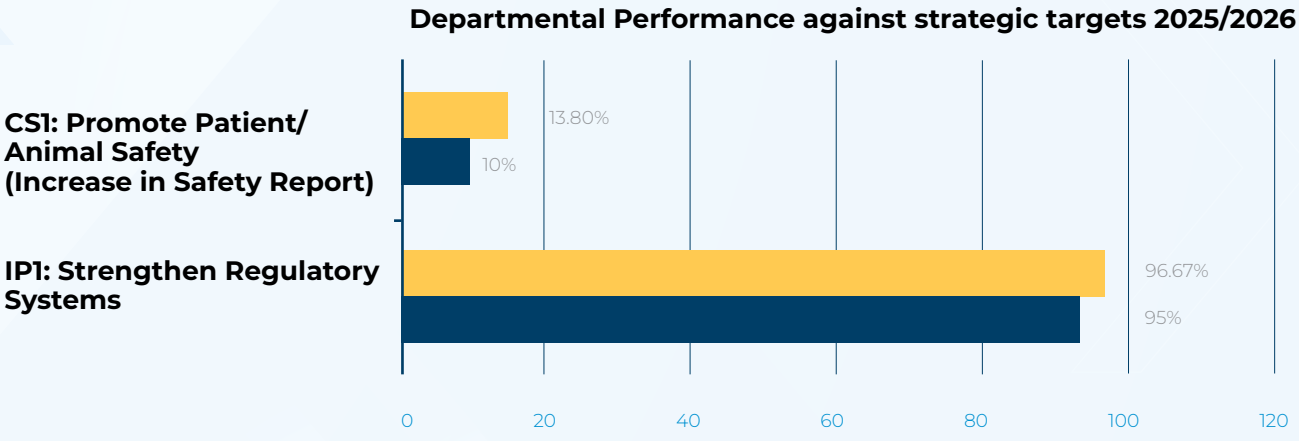


Figure 26: Composite score for PVCT performance against strategic targets for key activities

A 13.8% increase in number safety reports is indicative of the robust stakeholder engagement activities conducted by department, for the reporting period the authority has received a total of 1783 reports which translates to 685 reports per million population, this directly contributes the risk benefit balance medicines used in the territory.

A composite score of 96.67% for PV and CT at IP1 indicates that the department is positively contributing the overall mandate of the authority, System, structures and process are in place and ensure that medicinal products use in the territory meet the set criteria for quality, safety and efficacy.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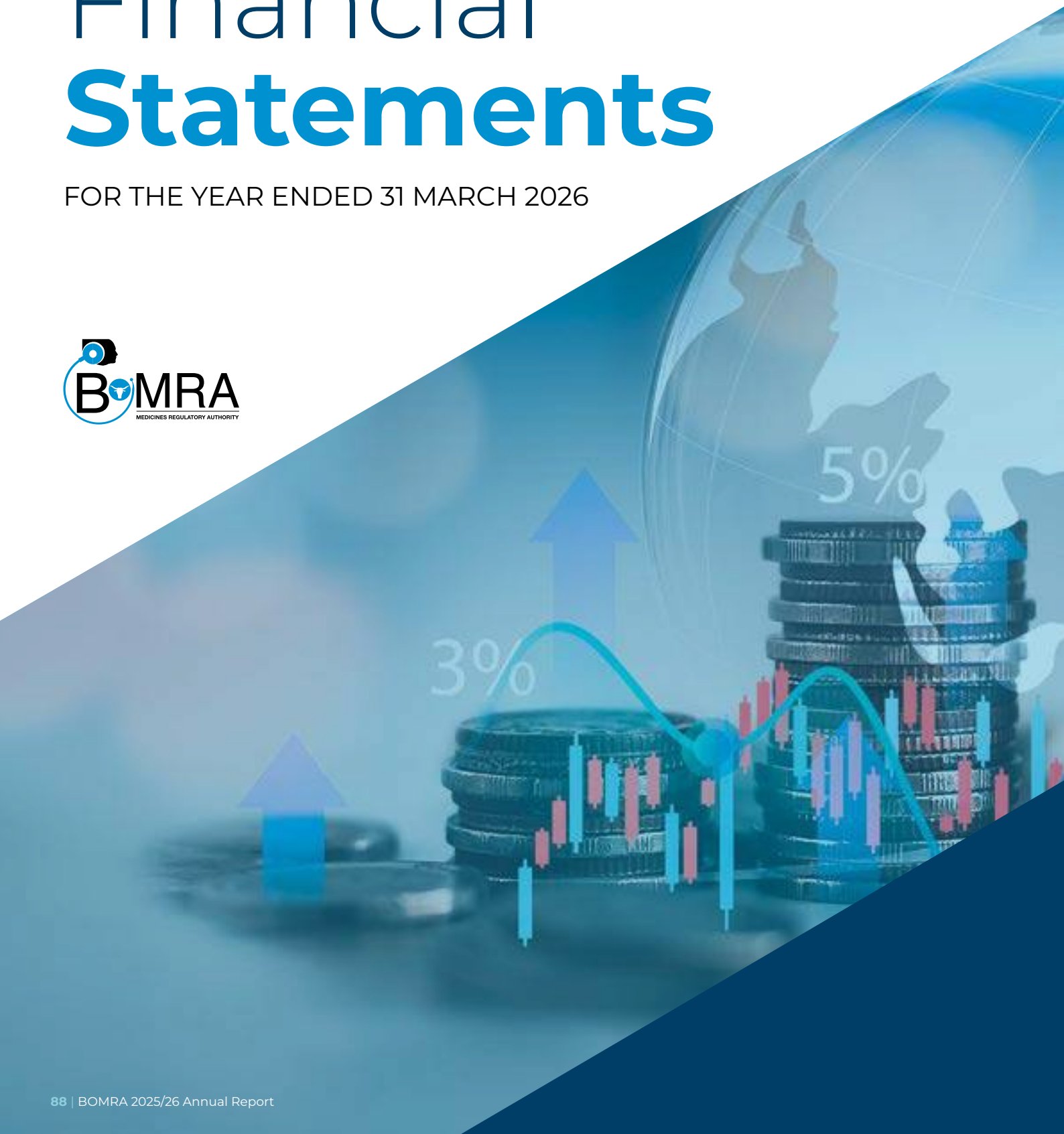
Annual Financial **Statements**

FOR THE YEAR ENDED 31 MARCH 2026



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GENERAL INFORMATION

FOR THE YEAR ENDED 31 MARCH 2026

	Appointed	Expired
Dr. Kegomoditswe Biki Maphane (Chairperson)	01/10/24	29/05/26
Dr. Lorato Mangadi-Mokama (Vice Chairperson)	01/10/24	29/05/26
Dr. Kobedi Segale (Board Member)	01/10/24	29/05/26
Ms. Mmama Mhlanga-Fichani (Board Member)	01/10/22	31/10/25
Dr. Ditiro Coyne (Board Member)	01/10/24	29/05/26
Ms. Elizabeth Kelentse (Board Member)	01/11/22	31/10/25
Ms. Matshidiso Matome (Board Member)	01/11/22	31/10/25
Ms. Tiny Ralefala (Board Member)	01/11/22	31/10/25
Mr. Modisa Kebonyemodisa(Board Member)	01/11/22	31/10/25
Dr. Kefentse Motshegwa (Board Member)	13/04/23	29/05/26
Dr. Oratile Mfokeng-Selei (Board Member)	24/06/24	
Dr. Mpapho Motsumi (Chairperson)	29/05/26	
Dr. Lebapotswe Tlale (Board Member)	29/05/26	
Mr. Kago Mokotedi (Board Member)	29/05/26	
Mr. Duncan Thela (Board Member)	29/05/26	
Ms. Keitumetse Kgasudi (Board Member)	29/05/26	
Ms. Koketso Molefhe-Motalaote (Board Member)	29/05/26	
Dr. Leruo Keokilwe (Board Member)	29/05/26	
Ms. Lesego Maedza (Board Member)	29/05/26	
Dr. Kobedi Segale (Board Member)	29/05/26	

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.

STATEMENT OF RESPONSIBILITY BY THE BOARD OF DIRECTORS

FOR THE YEAR ENDED 31 MARCH 2026

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 2027 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 92-94.

The annual financial statements set out on pages 95 to 118, which have been prepared on the going concern basis, were approved by the board on 09 September 2026 and were signed on their behalf by:

Chairperson of the Board

Chief Executive Officer

Independent Auditor's Report

FOR THE YEAR ENDED 31 MARCH 2026

Grant Thornton

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

Report on audit of the annual financial statements

Opinion

We have audited the annual financial statements of Medicines Regulatory Authority ("The Authority") set out on pages 95 to 118, which comprise the statement of financial position as at 31 March 2026, and the statement of surplus or deficit and other comprehensive income, statement of changes in reserves and statement of cash flows for the year then ended, and notes to the financial statements, including 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 2026, and its financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards issued by the International Accounting Standards Board and the requirements of the Medicines and Related Substances Act, 2013.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Annual Financial Statements section of our report. We are independent of the Authority in accordance with the International Ethics Standards 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.

Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current period. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon.

We have no key audit matters to report.

Other information

The members of the Board are responsible for the other information. The other information comprises the information included in the document titled "Medicines Regulatory Authority (The Authority) Annual Financial Statements for the year ended 31 March 2026", which includes the statement of responsibility by the Board of Directors and the detailed income statement, 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.

Independent Auditor's Report

FOR THE YEAR ENDED 31 MARCH 2026

Grant Thornton

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 auditor's report, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

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

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

In preparing the annual financial Statements, the members of the Board are responsible for assessing the Authority's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the members of the Board either intend to liquidate the Authority or to cease operations, or have no realistic alternative but to do so.

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

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 repor 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.
- 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 members of the Board.

Independent Auditor's Report

FOR THE YEAR ENDED 31 MARCH 2026

- 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 preclude 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

Grant Thornton
Firm of Certified Auditors
Practising Member: Madhavan Venkatachary (CAP 0017 2026)

09 September 2026

Gaborone

STATEMENT OF SURPLUS OR DEFICIT AND COMPREHENSIVE INCOME

FOR THE YEAR ENDED 31 MARCH 2026

	Notes	2026	2025
		P	P
Revenue	3	99,503,713	94,988,891
Regulatory fees	4	23,803,283	21,029,970
Total income		**123,306,996**	**116,018,861**
Employee costs	5	(72,666,405)	(78,488,209)
Governance expenses		(1,537,993)	(2,038,688)
Depreciation and amortisation expenses	5	(8,853,810)	(8,652,760)
Publicity and awareness expenses		(2,538,866)	(2,408,467)
Travel and accommodation costs		(3,871,623)	(3,593,203)
Operating expenses		(16,948,402)	(15,446,509)
Total expenses		**(106,417,099)**	**(110,627,834)**
Operating (deficit) / surplus		**16,889,897**	**5,391,027**
Investment income		25,993	-
Finance costs	6	(136,921)	(230,869)
Total operating (deficit) / surplus for the year		**16,778,969**	**5,160,158**
Other comprehensive income		-	-
Total comprehensive (deficit) / surplus for the year		**16,778,969**	**5,160,158**

STATEMENT OF FINANCIAL POSITION

FOR THE YEAR ENDED 31 MARCH 2026

	Notes	2026	2025
		P	P
ASSETS			
Non-current assets			
Right-of-use asset	8	7,940,240	2,046,576
Property and equipment	9	31,757,348	36,369,805
Intangible assets	10	6,432,272	6,943,804
		46,129,860	**45,360,185**
Current assets			
Government grant and other receivables	11	3,930,611	13,604,992
Cash and cash equivalents	12	34,087,112	13,212,248
		38,017,723	**26,817,240**
Total Assets		**84,147,583**	**72,177,425**
RESERVES AND LIABILITIES			
Reserves			
Revaluation reserves		-	-
Accumulated (deficit) surplus		18,141,875	1,362,906
		18,141,875	**1,362,906**
Non-current liabilities			
Lease liabilities	8	5,423,821	-
Deferred income	13	34,638,384	39,275,734
		40,062,205	**39,275,734**
Current liabilities			
Lease liabilities	8	2,545,597	2,817,775
Deferred income	13	7,624,162	11,983,011
Trade and other payables	14	15,773,744	16,737,999
		25,943,503	**31,538,785**
Total reserves and liabilities		**84,147,583**	**72,177,425**

STATEMENT OF CHANGES IN RESERVES

FOR THE YEAR ENDED 31 MARCH 2026

	Accumulated	
	Surplus	**Total**
Year ended 31 March 2025	**P**	**P**
Balance at 01 April 2024	(3,797,253)	(3,797,253)
Surplus for the period	5,160,158	5,160,158
Balance at 31 March 2025	**1,362,905**	**1,362,905**
Year ended 31 March 2026	**P**	**P**
Balance at 01 April 2025	1,362,905	1,362,905
Surplus for the period	16,778,969	16,778,969
Balance at 31 March 2026	**18,141,874**	**18,141,874**

STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED 31 MARCH 2026

	Notes	2026	2025
		P	P
Cash flows from operating activities:			
(Deficit) / surplus for the year		16,778,969	5,160,158
Adjustments for:			-
Depreciation and amortisation		8,853,810	8,652,760
Profit on disposal of property and equipment		(5,882)	6,760
Interest income		(25,993)	-
Finance costs		136,921	230,869
Operating income before reinvestment in working capital		**25,737,825**	**14,050,546**
Changes in working capital			
Decrease/ (Increase) in Government grant and other receivables		9,674,381	(9,493,969)
Increase in accounts payable		(964,255)	(3,308,430)
Finance costs		(136,921)	(230,869)
Net cash inflow from operating activities		**34,311,031**	**1,017,278**
Cash flows from investing activities:			
Purchase of property and equipment	9	(1,366,158)	(6,191,806)
Purchase of intangible assets	10	(38,960)	(1,261,198)
Proceeds on disposal of property and equipment		7,077	10,457
Interest income		25,993	-
Net cash outflow from investing activities		**(1,372,048)**	**(7,442,547)**
Cash flows from financing activities:			
Payment of lease liabilities	8	(3,067,918)	(2,848,922)
Increase in specific grants	13	(4,358,850)	4,364,436
Decrease in deferred government grant	13	(4,637,351)	(2,602,231)
Net cash outflow from financing activities		**(12,064,118)**	**(1,086,716)**
Net movement in cash and cash equivalents		**20,874,863**	**(7,511,986)**
Cash and cash equivalents at beginning of year		13,212,247	20,724,233
Cash and cash equivalents at end of year	12	**34,087,111**	**13,212,247**

MATERIAL ACCOUNTING POLICIES

FOR THE YEAR ENDED 31 MARCH 2026

1. MATERIAL 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.

MATERIAL ACCOUNTING POLICIES (Continued)

FOR THE YEAR ENDED 31 MARCH 2026

1.2 SIGNFICANT JUDGEMENTS AND SOURCE OF ESTIMATION UNCERTAINTY (CONTINUED)

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

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

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

1.3 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.

MATERIAL ACCOUNTING POLICIES (Continued)

FOR THE YEAR ENDED 31 MARCH 2026

1.3 PROPERTY AND EQUIPMENT (CONTINUED)

The useful lives of items of property, plant and 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
Plant and Machinery	Straight line	10 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.

Capital work in progress represents assets under construction or development that are not yet available for their intended use. Capital work in progress is carried at cost and is not depreciated until the related asset is completed and available for use, at which point it is transferred to the appropriate category of property and equipment and depreciation commences.

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

MATERIAL ACCOUNTING POLICIES (Continued)

FOR THE YEAR ENDED 31 MARCH 2026

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 (note11).

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

Trade and Other payable

Classification
Trade and other payables,excluding amounts received in advance, are classified as financial liabilities subsequently measured at amortised cost.

Trade payable and other payable include amounts which have been denominated in Euro, South African Rand and US Dollar. Foreign exchange gains or losses are recognised in profit or loss.

MATERIAL ACCOUNTING POLICIES (Continued)

FOR THE YEAR ENDED 31 MARCH 2026

1.5 FINANCIAL INSTRUMENTS (CONTINUED)

Trade and Other payable (CONTINUED)

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 Trade and other 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 6).

Trade other 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.

Translation of foreign currencies transactions
A foreign currency transaction is recorded, on initial recognition in Pula, by applying to the foreign currency amount the spot exchange rate between the functional currency and the foreign currency at the date of the transaction. Foreign currency monetary items are translated at the end of the reporting period using the closing rate.

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.

MATERIAL ACCOUNTING POLICIES (Continued)

FOR THE YEAR ENDED 31 MARCH 2026

1.6 LEASES (CONTINUED)

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 Authority has the right to substantially all of the economic benefits from the use of the asset as well as the right to direct the use of the asset.

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

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

Lease payments included in the measurement of the lease liability comprise fixed lease payments and variable lease payments that depend on an index or a rate, initially measured using the index or rate at the commencement date of the lease. Variable lease payments that do not depend on an index or a rate are recognised in profit or loss in the period in which they are incurred and are not included in the measurement of the lease liability.

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 6).

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
At the commencement date of the lease, the Authority recognises a right-of-use asset measured at cost. The cost of the right-of-use asset comprises the amount of the initial measurement of the lease liability, any lease payments made at or before the commencement date less any lease incentives received, any initial direct costs incurred by the Authority.

MATERIAL ACCOUNTING POLICIES (Continued)

FOR THE YEAR ENDED 31 MARCH 2026

1.6 LEASES (CONTINUED)

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

Subsequent to initial recognition, the right-of-use asset is measured at cost less accumulated depreciation and accumulated impairment losses and is adjusted for any remeasurement of the lease liability.

The right-of-use asset is depreciated on a straight-line basis over the shorter of the lease term and the 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.

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.

MATERIAL ACCOUNTING POLICIES (Continued)

FOR THE YEAR ENDED 31 MARCH 2026

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:

Step 1: 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 2026

2 NEW STANDARDS AND INTERPRETATIONS

2.1 Standards and interpretations effective and adopted in the current year

In the current year, the Authority 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:
Amendments to IFRS 16-Lease Liability in sale and Leaseback The amendment specifies subsequent measurement requirements for sale and leaseback transactions.	Annual periods beginning on or after 1 January 2024	No material impact
Amendments to IAS 1-Presentation of Financial Statements Non current liabilities with covenants introduces additional disclosures for liabilities with covenants within 12 months of the reporting period. These disclosures are to enable financial statement users to understand the risks of the loans becoming repayable within 12 months of the reporting date.	Annual periods beginning on or after 1 January 2024	Unlikely there will be a material impact
Amendments to IAS 7-Satement of Cash Flows and IFRS 7 Financial instruments. Supplier finance arrangements, amendment to IAS & IFRS 7 is done to address the disclosure requirements to enhance the transparency of supplier finance arrangements and their effects on a company's liabilities cash flows and exposure to liquidity risk.	Annual periods beginning on or after 1 January 2024	Unlikely there will be a material impact
Amendments to IAS 21-Lack of Exchangeability Specifies how an entity should assess whether a currency is exchangeable and how it should determine a spot exchange rate when exchangeability is lacking. An entity's objective in estimating the spot exchange rate is to reflect the rate at which an orderly exchange transaction would take place at the measurement date between market participants under prevailing economic conditions.	Annual periods beginning on or after 1 January 2024	Unlikely there will be a material impact

NOTES TO THE FINANCIAL STATEMENTS

FOR THE YEAR ENDED 31 MARCH 2026

2 NEW STANDARDS AND INTERPRETATIONS (CONTINUED)

2.2 Standards and interpretations not yet effective or relevant

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

Standard/ Interpretation:	Effective date: Years beginning on or after	Expected impact:
Contracts Referencing Nature-dependent Electricity (Amendments to IFRS 9 and IFRS 7)	01 January, 2026	Unlikely there will be a material impact
IFRS 18 Presentation and Disclosure in Financial Statements	01 January, 2027	Unlikely there will be a material impact
Amendments to IFRS 10 and IAS 28: Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	Deferred until further notice (IASB	Unlikely there will be a material impact
IFRS 19 Subsidiaries without Public Accountability: Disclosures	01 January, 2027	Unlikely there will be a material impact
Amendments to IFRS 1 First-time Adoption of International Financial	01 January, 2026	
Amendments to IFRS 7 Financial Instruments: Disclosures	01 January, 2026	Unlikely there will be a material impact
Amendments to IFRS 9 Financial Instruments	01 January, 2026	Unlikely there will be a material impact
Amendments to IAS 10 Statement of Cash flows	01 January, 2026	Unlikely there will be a material impact
Amendments to IFRS 9 and IFRS 7: Amendments to the Classification and Measurement of Financial Instruments	01 January, 2026	Unlikely there will be a material impact
Amendments to IFRS 10 Consolidated Financial Statements	01 January, 2026	Unlikely there will be a material impact

NOTES TO THE FINANCIAL STATEMENTS

(Continued)

FOR THE YEAR ENDED 31 MARCH 2026

	2026	2025
	P	P
3 REVENUE		
Grant received from Government of Botswana	86,498,679	85,761,556
Grants received from EDCPT and Global Fund	5,667,000	2,844,964
Grants received from BMG Fund	862,077	51,247
Grants received from The Africa Union Development Agency-(Auda- NEPAD)	768,386	-
Amortisation of deferred income	5,707,572	6,331,125
	99,503,713	**94,988,891**
RECONCILIATION OF GOVERNMENT GRANT RECEIVED		
Grant received from Government of Botswana	87,568,900	93,214,560
Amount utilised to acquire assets	(1,070,221)	(7,453,004)
	86,498,679	**85,761,556**
4 REGULATORY FEES		
Regulatory fees - Registration	16,295,194	18,422,034
Other regulatory fees	6,509,203	2,560,788
Other income	998,886	47,148
	23,803,283	**21,029,970**
5 OPERATING SURPLUS		

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

Auditors' remuneration		
Audit fees	111,516	96,341
Employee costs		
Salaries, wages and other benefits	59,451,785	64,024,722
Recruitment and consultancy costs	216,845	181,846
Pension scheme contribution	4,738,549	4,984,793
Gratuity expense	5,972,741	6,412,233
Leave pay expense	1,712,372	2,205,451
Professional and other subscriptions	574,114	679,163
	72,666,405	**78,488,209**
Depreciation		
Depreciation of property and equipment	5,977,420	5,771,510
Depreciation of right-of-use asset	2,325,898	2,228,176
Amortisation of intangible assets	550,492	653,073
	8,853,810	**8,652,760**
6 FINANCE COSTS		
Lease liabilities	**136,921**	**230,869**

NOTES TO THE FINANCIAL STATEMENTS

(Continued)

FOR THE YEAR ENDED 31 MARCH 2026

	2026	2025
	P	P

7 TAXATION

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

8 LEASES (AUTHORITY 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 2026		
Cost		
Balance at beginning of the year	15,758,399	16,063,045
Additions	8,219,561	328,499
Lease modification	-	(633,144)
Balance at end of the year	**23,977,961**	**15,758,399**
Depreciation		
Balance at beginning of the year	13,711,822	11,483,646
Charge for the year	2,325,898	2,228,176
Balance at end of the year	**16,037,721**	**13,711,822**
Net book value at 31 March 2026	**7,940,239**	**2,046,577**

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		
Within one year	2,986,446	2,909,417
Two to five years	5,786,433	-
	8,772,879	2,909,417
Less finance charges component	(803,461)	(91,643)
	7,969,418	2,817,775
Non-current liabilities	5,423,821	-
Current liabilities	2,545,597	2,817,775
	7,969,418	**2,817,775**
Amounts recognised in the statement of cash flows		
Total cash outflow for leases	3,067,918	2,848,922
	3,067,918	**2,848,922**

NOTES TO THE FINANCIAL STATEMENTS (Continued)

FOR THE YEAR ENDED 31 MARCH 2026

9 PROPERTY, PLANT AND EQUIPMENT

	Land (valuation)	Motor Vehicles (cost)	Computer Equipment (cost)	Furniture & Fixtures (cost)	Office Equipment	Plant and Machinery (cost)	Laboratory Equipment (cost)	Leasehold Improvements (cost)	Laboratory Work in Progress (cost)	Total (cost/ valuation)
Year ended 31 March 2026	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**
Cost or valuation										
Balance at beginning of the year	21,000,000	4,070,054	11,892,916	2,711,946	1,640,850	415,132	15,173,272	1,229,635	1,690,290	**59,824,095**
Additions		-	1,167,316	29,165	169,677	-		-	-	**1,366,158**
Disposals	-	-	(51,057)	-	-	-	-	-	-	**(51,057)**
Balance at end of the year	**21,000,000**	**4,070,054**	**13,009,175**	**2,741,112**	**1,810,526**	**415,132**	**15,734,461**	**1,229,635**	**1,690,290**	**61,700,385**
Depreciation										
Balance at beginning of the year	-	1,810,770	9,618,705	1,141,345	1,309,319	65,730	8,386,451	1,121,970	-	**23,454,290**
Charge for the year	-	374,656	1,530,197	270,631	172,692	39,438	3,545,826	43,980	-	**5,977,420**
Disposals depreciation	-	-	(49,862)	-	-	-	-	-	-	**(49,862)**
Balance at end of the year	**-**	**2,185,426**	**11,099,041**	**1,411,977**	**1,482,011**	**105,167**	**12,493,466**	**1,165,950**	**-**	**29,943,037**
Net book value at 31 March 2026	**21,000,000**	**1,884,628**	**1,910,135**	**1,329,135**	**328,515**	**309,965**	**3,240,995**	**63,685**	**1,690,290**	**31,757,348**
Year ended 31 March 2025										
Cost or valuation										
Balance at beginning 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**
Additions		1,100,000	520,349	49,920	39,528	-	4,482,009	-	-	**6,191,806**
Disposals	-	-	(53,547)	-	-	-	-	-	-	**(53,547)**
Balance at end of the year	**21,000,000**	**4,070,054**	**11,892,916**	**2,711,946**	**1,640,850**	**415,132**	**15,173,272**	**1,229,635**	**1,690,290**	**59,824,095**
Depreciation										
Balance at beginning of the year	-	1,474,463	7,732,477	874,382	1,111,609	26,292	5,522,086	977,801	-	**17,719,110**
Charge for the year	-	336,307	1,922,558	266,963	197,710	39,438	2,864,365	144,169	-	**5,771,510**
Disposals depreciation	-	-	(36,330)	-	-	-	-	-	-	**(36,330)**
Balance at end of the year	-	1,810,770	9,618,705	1,141,345	1,309,319	65,730	8,386,451	1,121,970	-	**23,454,290**
Net book value at 31 March 2025	**21,000,000**	**2,259,284**	**2,274,211**	**1,570,601**	**331,531**	**349,402**	**6,786,821**	**107,665**	**1,690,290**	**36,369,805**

NOTES TO THE FINANCIAL STATEMENTS

(Continued)

FOR THE YEAR ENDED 31 MARCH 2026

	Computer Software (cost)	Computer software work in progress (cost)	(cost)
	P	P	P
10 INTANGIBLE ASSETS			
Year ended 31 March 2026			
Cost			
Balance at beginning of the year	4,328,304	5,403,927	9,732,231
Additions	-	38,960	38,960
Balance at end of the year	**4,328,304**	**5,442,887**	**9,771,191**
Depreciation			
Balance at beginning of the year	2,788,428	-	2,788,428
Charge for the year	550,492	-	550,492
Balance at end of the year	**3,338,920**	**-**	**3,338,920**
Net book value at 31 March 2026	**989,384**	**5,442,887**	**6,432,272**
Year ended 31 March 2025			
Cost			
Balance at beginning of the year	4,328,304	4,142,729	8,471,033
Additions	-	1,261,198	1,261,198
Balance at end of the year	**4,328,304**	**5,403,927**	**9,732,231**
Depreciation			
Balance at beginning of the year	2,135,355	-	2,135,355
Charge for the year	653,073	-	653,073
Balance at end of the year	**2,788,428**	**-**	**2,788,428**
Net book value at 31 March 2025	**1,539,876**	**5,403,927**	**6,943,803**

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

NOTES TO THE FINANCIAL STATEMENTS

(Continued)

FOR THE YEAR ENDED 31 MARCH 2026

		2026	2025
		P	P
11	**GOVERNMENT AND OTHER RECEIVABLES**		
	Government grant and other receivables	908,181	11,419,987
	Lease deposit	171,375	171,375
	Provision for doubtful debt	(847,623)	-
	Non-financial instruments		
	Prepayments	3,684,096	1,991,463
	Staff advances	14,581	22,167
	Total Government and other receivables	**3,930,611**	**13,604,992**
	Financial instrument and non-financial instrument components of receivables		
	At amortised cost	231,934	11,591,362
	Non-financial instruments	3,698,677	2,013,629
		3,930,611	**13,604,992**
12	**CASH AND EQUIVALENTS**		
	Cash and cash equivalents consist of:		
	Bank balances	34,087,112	13,212,248
	Short-term investments	-	-
		34,087,112	**13,212,248**

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 2026

	2026	2025
	P	P

13 DEFERRED INCOME

The Authority received a total amount of P86,498,679 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	39,275,734	41,877,965
Assets purchased during the year	1,070,221	3,728,894
Amortisation of grant related to assets	(5,706,377)	(6,313,908)
Adjustment on asset retirement	(1,195)	(17,217)
Assets Revaluation Reserve	-	
At the end of year	**34,638,383**	**39,275,734**
Grants related to specific projects		
Opening balance	11,983,011	7,618,575
Grants received for specific projects	2,938,613	7,319,167
Grants used for specific projects operating expenditure	(6,475,928)	(2,329,514)
Grants disbursed to other beneficiaries	-	-
Assets purchased during the year for specific projects		
Amortisation of specific projects grant related to assets	(821,535)	(625,216)
At the end of year	**7,624,160**	**11,983,011**
Total Deferred Income	**42,262,544**	**51,258,745**

14 TRADE AND OTHER PAYABLES

Financial instruments Trade and Other Payables:		
Payable to suppliers	4,443,213	4,020,127
Payable to Related Parties	254,670	189,915
	4,697,883	**4,210,042**
Non-Financial instruments:		
Provision for gratuity	3,827,569	5,139,020
Provision for leave pay	7,248,291	7,388,937
	11,075,861	**12,527,957**
	15,773,744	**16,737,999**

Exposure to liquidity risk

Refer to note 15 Financial instruments and financial risk management for details of liquidity risk exposure and management.

NOTES TO THE FINANCIAL STATEMENTS

(Continued)

FOR THE YEAR ENDED 31 MARCH 2026

	2026	2025
	P	P

15 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			
Government grant and other receivables	11	231,934	11,591,362
Cash and cash equivalents	13	34,087,112	13,212,248
		34,319,046	**24,803,610**
Categories of financial liabilities			
Liabilities as per statement of financial position			
Trade & Other payable	14	4,697,883	4,210,042
		4,697,883	**4,210,042**

CAPITAL 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 2026, the Authority did not have any borrowings. The Authority's operations are currently being sustained by the Government of Botswana.

FINANCIAL RISK MANAGEMENT

Overview

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

NOTES TO THE FINANCIAL STATEMENTS

(Continued)

FOR THE YEAR ENDED 31 MARCH 2026

15 FINANCIAL INSTRUMENTS AND RISK MANAGEMENT (CONTINUED)

Credit risk

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

The Authority is exposed to credit risk on 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.

		2026			2025		
		Gross carrying amount	Credit loss alloance	Amortised cost/fair value	Gross carrying amount	Credit loss allowance	Amortised cost/fair value
Government grant and other receivables	11	231,934	-	231,934	11,591,362	-	11,591,362
Cash and cash equivalents	12	34,087,112	-	34,087,112	13,212,248	-	13,212,248
		34,319,046	**-**	**34,319,046**	**24,803,610**	**-**	**24,803,610**

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 Authority manages its liquidity risk by effectively managing its working capital, capital expenditure and cash flows, ensuring it maintains adequate cash and cash equivalents to settle 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.

NOTES TO THE FINANCIAL STATEMENTS

(Continued)

FOR THE YEAR ENDED 31 MARCH 2026

15 FINANCIAL INSTRUMENTS AND RISK MANAGEMENT (CONTINUED)

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 discounted contractual amounts

2026

		Less than 1 year	2 to 5 years	Total	Carrying amount
Current liabilities					
Trade & other payable	14	4,697,883	-	4,697,883	**4,697,883**
		4,697,883	**-**	**4,697,883**	**4,697,883**

2025

		Less than 1 year	2 to 5 years	Total	Carrying amount
Current liabilities					
Trade & other payable	14	4,210,042	-	4,210,042	4,210,042
		4,210,042	**-**	**4,210,042**	**4,210,042**

16 RELATED PARTIES

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

Relationships	
Medicines Regulatory Board	Refer to general information for a list of Medicines Regulatory Board (Page 90).
Members of Key Management	Dr. Seima Dijeng (Chief Executive Officer) Mr. Kitso Leburu (Director: Finance and Administration) Mr Bathusi Kgosietsile (Director: Product Evaluation and Registration) Dr. Parthasarathi Gurumurthy (Director: Pharmacovigilance and Clinical Trials) Ms. Shirley Pine (Director: Human Resources and Organisational development) Ms. Zukiswa Raditladi (Director: Inspections & Licensing)
Main Financier	Government of the Republic of Botswana

NOTES TO THE FINANCIAL STATEMENTS

(Continued)

FOR THE YEAR ENDED 31 MARCH 2026

16 RELATED PARTIES (CONTINUED)

	2026	2025
Related party transactions	**P**	**P**
Compensation to directors and other key management		
Salaries and other short term benefits	7,530,501	8,601,843
Gratuity	2,209,601	1,693,977
	9,740,102	**10,295,820**
Grant received		
Government of Republic of Botswana	87,568,900	93,214,560
Transactions with other parastatals		
Botswana Telecommunication Corporation - telephone	1,472,053	1,525,462
Botswana Power Corporation - electricity	725,138	525,392
Sitting allowance		
Medicines Regulatory Board	1,314,800	1,337,200
Related party balances		
Amounts included in other payables regarding related parties		
Botswana Telecommunication Corporation - telephone	177,348	165,739
Botswana Power Corporation- electricity	67,246	-
Botswana Unified Revenue Services -WHT	10,076	24,176

17 GOING CONCERN

The annual financial statements have been prepared on the basis of accounting policies applicable to a going concern. This basis presumes that funds will be available to finance future operations and that the realisation of assets and settlement of liabilities, contingent obligations and commitments will occur in the ordinary course of business.

The directors believe that the Authority has adequate financial resources to continue in operation for the foreseeable future and accordingly the annual financial statements have been prepared on a going concern basis. The members of the Board are satisfied that the Authority is in a sound financial position to meet its foreseeable cash requirements. The directors are not aware of any new material changes that may adversely impact the Authority. The directors are also not aware of any material non-compliance with statutory or regulatory requirements or of any pending changes to legislation which may materially affect the Authority.

18 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. The Authority will continue as a going concern and continue with its operations for the forseeable future without the existence of a material uncertainity about the ability to continue as agoing concern.

DETAILED INCOME STATEMENT

FOR THE YEAR ENDED 31 MARCH 2026

		2026	2025
		P	P
Revenue			
Amortisation of deferred income		5,707,572	6,331,125
Grant received from the Government of Botswana		86,498,679	85,761,556
Other grants received		7,297,463	2,896,211
	3	**99,503,713**	**94,988,891**
Other operating income			
Other operating income	4	23,803,283	21,029,970
Operating expenses			
Amortisation and depreciation	5	(8,853,810)	(8,652,760)
Auditors remuneration - external auditors	5	(111,516)	(96,341)
Bank charges		(195,277)	(210,905)
Computer expenses		(2,178,970)	(1,904,800)
Consultancy fees		(355,445)	(1,368,084)
Consulting and professional fees - legal fees		-	-
Consumables		(401,960)	(344,585)
Donations		(14,100)	(14,500)
Employee costs	5	(72,666,405)	(78,488,209)
Governance costs		(1,426,477)	(1,942,347)
Insurance		(744,458)	(531,669)
Motor vehicle expenses		(711,539)	(582,576)
Postage		(89,916)	(41,330)
Printing and stationery		(161,226)	(327,919)
Publicity and awareness		(900,978)	(1,670,108)
Records management		(128,757)	(87,133)
Repairs and maintenance		(991,333)	(733,369)
Security		(534,601)	(502,707)
Seminars and conferences		(1,623,788)	(723,858)
Short term lease		(98,669)	(102,673)
Staff welfare		(390,618)	(258,125)
Technical expenses		(4,553,497)	(4,688,091)
Telephone and fax		(2,737,577)	(3,063,126)
Training		(1,014,050)	(90,127)
Travel and accommodation		(3,871,623)	(3,593,203)
Utilities		(812,889)	(609,291)
Bad Debt Expense		(847,623)	-
		(106,417,099)	**(110,627,834)**
Operating surplus/(deficit)		**16,889,897**	**5,391,027**
Investment income	6	25,993	-
Finance costs	7	(136,921)	(230,869)
Surplus / (deficit) for the year		**16,778,969**	**5,160,158**

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

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BOMRA
MEDICINES REGULATORY AUTHORITY