BOMRA
MEDICINES REGULATORY AUTHORITY

ANNUAL REPORT

2019

TABLE OF ACRONYMS

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BoMRA	DVS	DRU	FARC	HRC	MRSA	MOADFS	MOHW	NDP	PTC	PV	RC	PC	LC

KEY

1.Botswana Medicines Regulatory Authority

2. Department of Veterinary Services

3. Drugs Regulatory Unit

4.Finance Audit and Risk Committee

5.Human Resource Committee

6.Medicines and Related Substances Act

7.Ministry of Agricultural Development & Food Security

8.Ministry of Health and Wellness

9.National Development Plan

10. Procurement and Tender Committee

11. Pharmacovigilance

12.Registration Committee

13. Pharmacovigilance Advisory Committee

14. Licensing Committee

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INTRODUCING
BoMRA

Mandate
The Botswana Medicines Regulatory Authority (BoMRA) derives its mandate to regulate the supply chain of medicines for human and veterinary use, medical devices and cosmetics from the Medicines and Related Substances (8)Act 2013. BoMRA mandate is to among others:

- Ensure that all medicines and related substances, cosmetics and medical devices used in Botswana are in conformity with established criteria of quality, safety and efficacy.
- Ensure conformance to standards and adherence to best practice by all involved in the supply chain of medicines, medical devices and cosmetics.
- Ensure conformance to good laboratory practice by privately-owned medicine quality control laboratories through inspections and conducting tests and analysis of medicines.
- Ensure the safety and quality of cosmetics and medical devices by ascertaining that cosmetics and medical devices companies adhere to best practice standards.

STRATEGIC PLAN
Botswana Medicines Regulatory Authority (BoMRA), developed a Corporate Strategy to guide its operations and deliver on its mandate.

Consistent with the strategic intent of the Ministry of Health and Wellness, the BoMRA Corporate Strategy is aligned to the national planning priorities articulated in the National Development Plan 11, which also support the realisation of the aspirations of Vision 2036. The key strategic objectives of the Corporate Strategy 2019 - 2024 are to:

i. Reduce incidences of substandard, falsified, unregistered medical products and cosmetics.

ii. Improve awareness and Public Trust in the Medical Products and Cosmetics Regulatory System.

iii. Have a fully functional Regulatory System by 2024.

iv. Establish and implement an Institutional framework and good governance.

OUR STRATEGIC FOUNDATIONS
BoMRA has taken over a combination of functions that were previously performed under the Ministry of Health and Wellness as well as the Ministry of Agricultural Development and Food Security. Our strategic foundations are:

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

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

OUR VALUES

Integrity

Transparent and impartial environment with people who are trustworthy, disciplined and maintain confidentiality

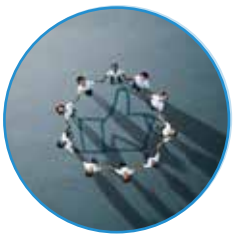
Customer Focus

Providing quality service and upholding standards.

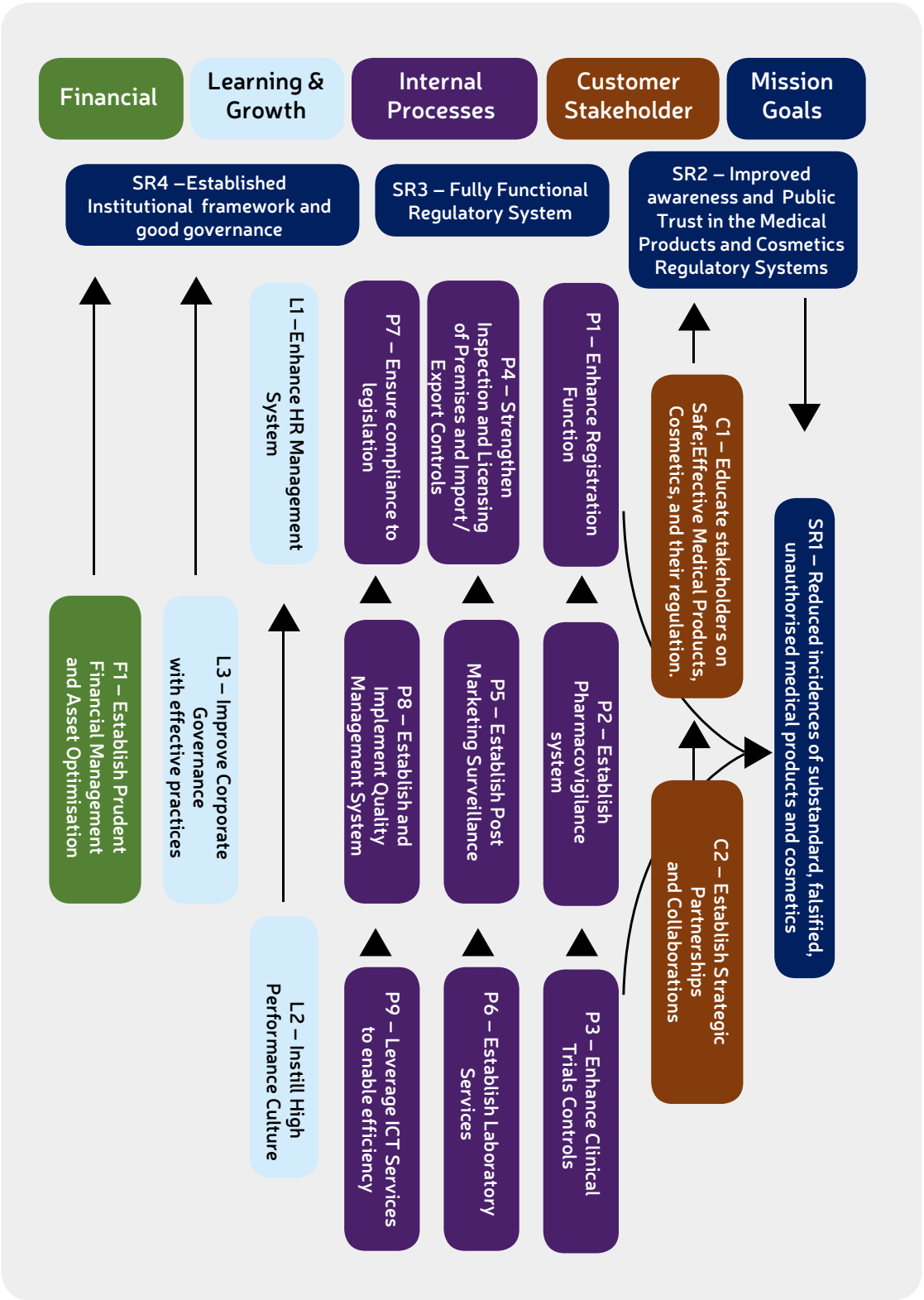
Efficiency

Working smart, applying innovative solutions and good judgement.

Team Work



Working together towards a common goal.


Financial
Learning & Growth
Internal Processes
Customer Stakeholder
Mission Goals
SR4 –Established Institutional framework and good governance
SR3 – Fully Functional Regulatory System
SR2 – Improved awareness and Public Trust in the Medical Products and Cosmetics Regulatory Systems
L1 –Enhance HR Management System
P7 – Ensure compliance to legislation
P4 – Strengthen Inspection and Licensing of Premises and Import/ Export Controls
P1 – Enhance Registration Function
C1 – Educate stakeholders on Safe;Effective Medical Products, Cosmetics, and their regulation.
SR1 – Reduced incidences of substandard, falsified, unauthorised medical products and cosmetics
F1 – Establish Prudent Financial Management and Asset Optimisation
L3 – Improve Corporate Governance with effective practices
P8 – Establish and Implement Quality Management System
P5 – Establish Post Marketing Surveillance
P2 – Establish Pharmacovigilance system
C2 – Establish Strategic Partnerships and Collaborations
L2 – Instill High Performance Culture
P9 – Leverage ICT Services to enable efficiency
P6 – Establish Laboratory Services
P3 – Enhance Clinical Trials Controls

BOARD CHAIRPERSON'S STATEMENT

Mr. Duncan Thela - Board Chairperson of the Medicines Regulatory Board

Although the Medicines and Related Substances Act (8) 2013 ("Act") was assented to by Parliament in July 2013, the Act was initially partially enacted and the Medicines Regulatory Board appointed in July 2016. Subsequent to the Board appointment, the Act was fully enacted and the Board initiated processes to establish BoMRA and appointed its first, employee; the Chief Executive Officer (CEO) in January 2018.

The CEO and the Board established the organizational structure, the head office and recruitment of the support structure for the CEO's office to enable a functional office that would then do the needful and ensure the actual establishment of BoMRA.

The Board, in line with principles of good governance, also established governance committees such as the Human Resources, Finance, Audit and Risk; and the Procurement and Tender committees, including their terms of reference. Technical committees were established later to assist and advise the Board on technical regulatory matters; in accordance with the Act.

I am happy to report that the Authority is now functional with most of the structures and governance instruments in place.

During the second part of the Financial Year 2018/19 the Board began an inclusive process to develop the Corporate Strategy of the Authority and we are pleased to report that a significant number of key stakeholders were involved in the process including: pharmaceutical industry, relevant regulatory and enforcement bodies such as Botswana Police Service and Botswana Unified Revenue Service, patient groups, health practitioner associations and groups, Ministry of Health and Wellness, and. Ministry of Agricultural Development and Food Security . The latter being involved to ensure alignment with the shareholder expectations.

The Board would like to acknowledge the assistance of the World Health Organisation (WHO) in facilitating the development of the Technical Strategy. The latter served as a key input into the Corporate Strategy 2019/24 and annual strategy implementation plan development process for BoMRA.

The Board would like to thank the Cabinet for facilitating our endeavor to review and amend the MRSA in order to ensure appropriate regulation of veterinary medicines and alignment with the African Union (AU) model Law amongst others.

BoMRA continues to take part in regional regulatory activities in order to achieve harmonisation and to work with other regional regulatory bodies through ZAZIBONA. The latter is a voluntary group of regulators from Southern African Development Community (SADC) that works for the common goal of enhancing regulatory capacity and increasing access to medicines to the public in the member states.

I am, happy to report, on behalf of the Board, that we are satisfied with the progress of creating a fully functional regulatory Authority and performance of the BoMRA staff thus far.We have had an unqualified externalaudit covering the first 15 months of our operation with all audit findings having been addressed.

As the Board of Directors, we will continually endeavour to guide the operations of BoMRA through working closely with the BoMRA Team to ensure fulfilment of the Authority's mandate. The Board is committed to the five (5) year Corporate Strategy 2019/24 and will continue to facilitate and guide its implementation.

I would like to thank all our "parent Ministries" and other stakeholders for their continued and unwavering support and the BoMRA Team for work well done thus far.

Mr. Duncan Thela

BOARD CHAIRPERSON

CEO’S STATEMENT

Dr Stephen Ghanie – CEO

The year of 2018 shall forever become one of the most memorable years in the history of Botswana Medicines Regulatory (BoMRA) for it was the first year that the operations of the Authority were ignited. During the year, multiple activities took place, resulting in a relatively fast pace which helped set the tempo of the organisation.

In the same year of 2018, as recruitment started, we consulted with the pharmaceutical industry as key stakeholders over the fee structure for services to be provided as prescribed in the Medicines and Related Substances Act (No.8) (2013), both the Technical and Corporate Strategy development processes were kickstarted, BoMRA participated in the development by external partners of electronic tools for medicine safety reporting, and new employees attended a number of capacity building workshops and courses organised by the World Health Organisation (WHO), African Union (AU), and overseas partners.

We managed to fill the positions in the technical and support departments and where the required key skills were not available in the local market, the Authority resorted to imported skills. Filling the positions in the Quality department was critical at the beginning of the recruitment process as this quickly turned on the engine for process mapping and documentation throughout the organisation. The documentation of processes will ensure consistency of operations, consistency in service delivery, and provide a platform for continual improvement.

We are dependent on subventions from the parent Ministry of Health and Wellness. We observed budget underutilisation during the first year mainly due to delays in filling positions both at the laboratory and in other specific technical functions of the organisation. With respect to the laboratory, although we have a plan to build a fit-for-purpose facility on our plot, our short-term measure is to re-operationalise the drugs quality control laboratory situated at the Central Medical Stores.

The corporate strategy was completed at the beginning of 2019 and represents a final product from multiple engagements between management and the Board of Directors. Four strategic goals were set out over a five- year period, which are:

- Public education and trust in the regulatory system
- A fully functional regulatory system
- Institutional capacity developed
- Reduction of substandard and falsified medicines

Management believe that the achievement of these goals, underpinned by the values of Integrity, Customer Focus, Efficiency and Teamwork, will safeguard public health and facilitate business activity in the local pharmaceutical industry.
We will monitor and evaluate the value of our work over the strategic plan period and commit to effective regulation of medical products and cosmetics to ensure they meet the standards of quality, safety and efficacy.

The Authority received from Government a subvention totalling P41.9 million for the 15 months ended 31st March 2019. Total expenditure for this financial period amounted to P25 million, resulting in a surplus of P16.9 million. The reason for the surplus is the long recruitment lead time which slowed the implementation process.

Dr. Stephen Ghanie

CHIEF EXECUTIVE OFFICER

GOVERNANCE

Governing structure
The Medicines Regulatory Board (the Board), established under Section 6 of the MRSA, is the primary governing structure and is responsible for directing the affairs and operations of the Authority.

In accordance with the MRSA, the Board is mandated to supervise and control the administration and financial management of BoMRA and formulate policies for the purpose of providing guidance to BoMRA. In carrying out its mandate, the Board has the following duties and responsibilities, among others, as set out in the Board Charter:

i. Providing leadership and direction to Management of BoMRA.
ii. Overseeing the strategy, risk, performance and sustainability of BoMRA.
iii. Ensuring that the Authority's ethics are managed effectively.
iv. Managing reputational risk and BoMRA's relationship with Management, the Ministry of Health and Wellness and other stakeholders.

In terms of Section 7 (1) of the MRSA, the Board shall consist of Members appointed by the Minister of Health and Wellness, after consultation with the Minister of Agricultural Development and Food Security, and elected from amongst persons with expertise in law, pharmaceutical industry, business management, medicine, pharmacy, veterinary medicine and two other areas as determined by the Minister.

The Chief Executive Officer, the Director of Health Services and the Director of Veterinary Services are ex-officio Members of the Board.

Members appointed by the Minister hold office for three years and are eligible for reappointment for no more than two consecutive terms.

The Membership of the Board is presented in Table 1 below:

Table 1: Board of Directors

NAME	DESIGNATION	DATE OF APPOINTMENT	DATE OF EXPIRY OF TERM	TERM
Mr. Duncan Thela	Chairperson of the Board	1st June 2016	31st May 2019	3 years
Dr. Mbatshi Mazwiduma	Vice-Chairperson of the Board	1st June 2016	31st May 2019	3 years
Mr. Kagiso Balopi	Board Member	1st June 2016	31st May 2019	3 years
Mr. Meshack Baoleki	Board Member	1st June 2016	31st May 2019	3 years
Dr. Joyce Kgatlwane	Board Member	1st July 2018	30th June 2021	3 years
Dr. Tiroyaone Mampane	Board Member	1st June 2016	31st May 2019	3 years
Dr. Letlhogile Modisa	Ex- officio Board Member	1st June 2016	N/A	By virtue of his position
Dr. Gontle Moleele	Board Member	1st July 2018	30th June 2021	3 years
Ms. Shameela Pholo-Winston	Board Member	1st June 2016	31st May 2019	3 years
Dr. Khumo Seipone	Ex- officio Board Member	1st June 2016	N/A	By virtue of her position
Dr. Michael G. Sento	Board Member	1st July 2018	30th June 2021	3 years
Mr. Thapelo Tsheole	Board Member	1st June 2016	31st May 2019	3 years

Mr. Duncan Thela
Board Chairperson
Mr. Duncan Thela has a Bachelor of Pharmacy, Nottingham University (UK) and MBA from the University of Botswana. He is the Managing Director of Associated Fund Administrators Botswana (Pty) Ltd (AFA).

Mr. Thela is a well-rounded healthcare professional with a good understanding of the Botswana Healthcare System. From a regulatory perspective, Mr Duncan Thela served as a member of the Botswana Health Professions Council and is the former Chairman of the Botswana Drug Advisory Board. He is a member of the Human Resource Development Council - Health Sector Committee, Tourism, Health and Education Immigrants-Sector Specific Selection Board and member of the Business Botswana Health Sector Committee

Dr. Mbatshi Mazwiduma – Board Vice-Chairperson
Dr. Mbatshi Mazwiduma is a veterinary surgeon. His professional experience spans over 16 years with footprints in Botswana, New Zealand and Australia. Dr Mazwiduma is the founder and Director of VETPRO, a veterinary centre that provides specialised services in Agri business consulting and veterinary services throughout Botswana. He is also a member of the Veterinary Council, and deputy chairman of Botswana Veterinary Association.

Mr. Kagiso Balopi – Board Member
Mr. Kagiso Balopi holds a Bachelor of Accounting, University of Botswana, Management Development Program, University of Stellenbosch, and IIE, Pacific Institute. He is a Fellow Chartered Accountant (FCA) of the Botswana Institute of Chartered Accountants (BICA), a fellow member of the Association of Chartered Certified Accountants FCCA (UK), and a Certified Enterprise Risk Manager (CERM). His career spans over 16 years in Auditing, Accounting, and banking at various levels. He serves on the Boards of the Botswana Privatization Asset Holding (BPAH) and he is also a co-opted member of the Finance, Audit and Risk comittee for the Botswana Technology Research and Innovation (BITRI).He is also a member of the Institute of Directors Southern Africa (IODSA).

Ms. Shameela Pholo-Winston
Board Member
Ms. Shameela Pholo-Winston is a Human Resources Specialist and holds B.Soc.Sci (Hons) Industrial & Organisational Psychology from Rhodes University. With more than 15 years' experience, Ms. Pholo - Winston has successfully led transformation projects in private and public sector environments, cultivating organizational performance through alignment of strategy to organizational structures, policies and processes. Ms. Pholo - Winston served in the Human Resource Management field both as an executive and as a consultant in private practice. She continues to offer her services for the advancement of performance management in Botswana.

Dr. Tiroyaone Mampane – Board Member
Dr. Tiroyaone Mampane holds MBChB (MEDUNSA) (GIPS) and Corporate Governance & Project Management Certificate (University of Pretoria). Dr. Mampane is the founder and President of Boitekanelo College, a specialized health education academy. He has been at the helm of the college for over 10 years in charge of its Strategic direction, compliance and adherence to the regulatory framework. He previously worked at Princess Marina hospital as a medical practitioner. Dr. Mampane recently completed an Entrepreneurship Development Programme with Stanford Business school sponsored by De Beers Group.

Mr. Meshack Baoleki – Board Member
Mr. Meshack Baoleki holds an LLB from the University of Botswana, Post Graduate Certificate - Compliance Management, UCT and Graduate Certificate - Policy, Regulation & Management, WITS. He is the Managing Partner of Baoleki Attorneys - a transactional law firm specializing in corporate and commercial law. He has worked in the Telecommunications and Banking Industry, in charge of legal, compliance and regulatory affairs.

Mr. Thapelo Tsheole – Board Member
Mr. Thapelo Tsheole holds a Bachelor of Social Sciences (Single Major Economics) from the University of Botswana and a Master of Commerce (MComm) in Financial Markets from Rhodes University (RSA). Further, he holds a Masters in Business Administration (MBA) from the Graduate School of Business, University of Cape Town (RSA). He is the CEO of the Botswana Stock Exchange (BSE), having been appointed in January 2016.

Dr. Gontle Moleele
Board Member
Dr. Gontle Moleele is a practicing physician and endocrinologist, based at Bokamoso Private Hospital, where she is also the hospital Superintendent. She has sat on several boards including MRI Botswana and the University of Botswana School of Medicine Advisory Board. She currently chairs the Joint Medical and Surgical Board of the Botswana Health Professions Board.

Dr. Michael G. Sento
Board Member
Dr. Michael Sento is a qualified veterinary surgeon with experience spanning over 21 years in private practice. Away from the surgery room, Dr Sento is a passionate small stock farmer and keen promoter of organic farming practices. He previously held a board membership of the Botswana Vet Council.

Dr. Joyce Kgatlwane
Board Member
Dr. Joyce Kgatlwane is a pharmacist and an academic. Her career spans over 28 years, where she worked in various hospitals in Botswana. Dr. Kgatlwane previously worked for Botswana Harvard AIDS Institute Partnership, PEPFAR and her areas of research include medicines utilisation, antibiotics use, adherence to medicines, medication errors, adverse medicines reactions and reporting. She contributed to the curriculum review and development of the advancement at the Institute of Health Sciences and the University of Botswana respectively.

She served as a member of the Pharmacy Board under the Botswana Health Professions Council. She is also a member of HIV Management Guidelines Committee, Palliative Care Advisory Committee, National Health Research Committee and one of the founders of the Medicine Utilisation Research in Africa. In the area of medicine regulation, Dr. Kgatlwane worked at the Drugs Regulatory Unit as part of internship and She received training on dossier evaluation. She also received training on pharmacovigilance. Dr. Kgatlwane obtained a Bachelor of Pharmacy from the University of Otago (New Zealand), PharmaD from the University of Florida (USA) and Masters of Public Health from the University of Texas School of Public Health (USA)

Dr. Letlhogile Modisa
Board Member
Dr. Letlhogile Modisa is the Director of Veterinary Services in the Ministry of Agricultural Development and Food Security. He is the Vice President of the OIE regional Commission for Africa.

Dr Stephen Ghanie
Chief Executive Officer
Dr. Stephen Ghanie is the Chief Executive Officer of BoMRA.A veterinarian by profession, Dr. Ghanie's academic footprints include veterinary medicine, meat science, strategic management and general management. He has worked as a veterinary public health practitioner occupied various executive positions at Botswana Meat Commission and became the first citizen country manager at Parmalat Botswana

Corporate Governance
The Board values good corporate governance practices and in pursuit of ensuring that it maintains the highest standards of governance and ethics, has adopted the King III Code of Corporate Governance as a base standard with a planned gradual movement toward the King IV Code of Corporate Governance.

The Board has appointed Committees to assist in its efficient functioning, which Committees include the Finance, Audit and Risk Committee; Human Resources Committee; Procurement and Tender Committee; Registration Committee; Licensing Committee and Pharmacovigilance Committee. The Board is guided by the Act, the Government and other Legislation and has further developed a charter to guide its proceedings. Furthermore, the Board formulates the Terms Of Reference for its sub-committees which it regularly reviews.

The Corporate and Legal Counsel carries out the Board Secretarial function and provides support on governance and administrative matters.

Strategy Implementation
The Strategy will be implemented during the period 2019 – 2024. The Board will ensure implementation of the Strategy through the approval of the annual performance plans and quarterly performance reports by Management.

Board meetings and sitting allowances
The Board is required to hold at least 6 meetings a year, as per Section 14 of the MRSA. At any meeting of the Board a quorum shall be constituted by not less than one half of the members of the Board. In the event of an equality of votes, the Chairperson shall have the casting vote.

The Board held six meetings for the financial year 2018/19, with the record of attendance as shown in table 2 Below:

The Board held six meetings for the financial year 2018/19, with the record of attendance as shown in table 2 Below:

Table 2: Board meetings Held in 2018/19

	BOARD MEETING DATE BOARD MEMBER	24th July 2018	27th Sep. 2018 (special)	23rd Oct. 2018	27th Nov. 2018 (Special)	06th Dec. 2018	5th March 2019	Total Meetings Attended
1.	Mr. Duncan Thela	✓	✓	✓	✓	✓	✓	6/6
2.	Dr. Mbatshi Mazwiduma	✓	A	✓	✓	A	✓	4/6
3.	Mr. Kagiso Balopi	✓	✓	✓	A	A	✓	4/6
4.	Mr. Meshack Baoleki	✓	✓	✓	✓	✓	✓	6/6
5.	Dr. Joyce Kgatlwane	✓	✓	A	✓	✓	A	4/6
6.	Dr. Tiroyaone Mampane	✓	A	✓	✓	A	A	3/6
7.	Dr. Letlhogile Modisa	A	✓	✓	A	✓	✓	4/6
8.	Dr. Gontle Moleele	✓	✓	✓	A	✓	A	4/6
9.	Ms. Shameela Pholo-Winston	✓	✓	✓	✓	✓	✓	6/6
10.	Dr. Khumo Seipone	A	-	-	-	-	-	0/1
11.	Dr. Michael G. Sento	✓	A	✓	✓	✓	✓	5/6
12.	Mr. Thapelo Tsheole	A	A	✓	A	A	A	1/6

KEY

Present	✓	Apology	A	Not Applicable	-

Committees
The Board may appoint committees to assist in carrying out its function as permitted by the MRSA at Section 16 and in keeping with good corporate governance practices. The Board appointed five committees being the Finance, Audit and Risk Committee (FARC), the Human Resources Committee (HRC), the Procurement and Tender Committee (PTC), the Licensing Committee (LC), the Registration Committee (RC) and the Pharmacovigilance Advisory Committee (PAC) to assist in the execution of its functions.

The membership of the committees is shown in table 3:

Table 3:Membership of Committees

	FARC	HRC	PTC	RC	PC	LC
Chairperson	Mr. Kagiso Balopi	Ms. Shameela Pholo-Winston	Mr. Meshack Baoleki	Dr. Joyce Kgatlwane	Dr. Gontle Moleele	Dr. Michael G. Sento
Committee Member	Dr. Mbatshi Mazwiduma	Dr. Gontle Moleele	Mr. Kagiso Balopi	Dr. Tendani Gaolathe	Mr. Richard Leepo	
Committee Member	Mr. Meshack Baoleki	Dr. Letlhogile Modisa	Dr. Gaseitsewe Sento	Mrs. Lesego Moetedi	Dr. Tjedza Matenge	
Committe Member			Dr. Joyce Kgatlwane	Dr. Goabaone Pono	Dr. Kerapetse Sehularo	
Committee Member				Dr. Batshanani Busang	Mrs. Matshe-diso Matome	
				Dr. Samantha Letsholo	Dr. Lebapots-we Tlale	
				Dr. Celda Molake	Ms. Ratanang Balisi	

Finance, Audit and Risk Committee
The committee's objectives are the following:
i. to consider, monitor, oversee and make recommendations to the Board on matters related to the Authority's financial reporting and risk management
ii. to review the effectiveness of the Authority's internal control framework
iii. to monitor and review the effectiveness of the internal audit function
iv. to annually assess the effectiveness of the external audit process

Table 4:Finance Audit and Risk Committee Meetings for 2018/19

Committee Member		Date	Date	Total Meetings
		9th Oct 2018	14th Feb 2019	
1	Mr. Kagiso Balopi	✓	✓	2/2
2	Dr. Mbatshi Mazwiduma	✓	✓	2/2
3	Mr. Meshack Baoleki	✓	✓	2/2

KEY	
Present	✓

Human Resources Committee (HRC)
The committee is responsible for the following:
i. To consider, monitor, oversee and make recommendations to the Board regarding the Authority's human resources management and compensation philosophy.
ii. The identification and assessment of potential Board candidates and making recommendations to the Board and the Minister for approval.

Table 5:Human Resources Committee Meetings for 2018/19

	Committee Member	Date	Date	Total Meetings	
		4 June 2018	6 August 2018	23 January 2019	
1	Ms. Shameela Pholo-Winston	✓	✓	✓	3/3
2	Dr. Gontle Moleele	✓	✓	✓	3/3
3	Dr. Letlhogile Modisa	A	A	✓	1/3
4	Dr. Khumo Seipone	A	✓	-	1/2

KEY

Present	✓	Apology	A	Not Applicable	-

Procurement and Tender Committee
The objectives of the Procurement and Tender Committee are:

i. To adjudicate and approve tenders in accordance with the Procurement Policy within its limit of approval.

Table 6:Procurement and Tender Committee Meetings for 2018/19

	Committee Member	Date	Date	Date	Total Meetings
		22th May 2018	23rd August 2018	18th Dec 2018	
1	Mr. Meshack Baoleki	✓	✓	✓	3/3
2	Mr. Kagiso Balopi	✓	✓	✓	3/3
3	Dr. Gaseitsewe Sento	✓	✓	✓	3/3
4	Dr. Joyce Kgatlwane	✓	✓	A	2/3

KEY

Present	✓	Apology	A

Registration Committee
The objective of the Registration Committee is to ensure that registered medicines meet the provisions of the MRSA, Regulations, Policies, Standards, the set conditions and requirements for registration.

The Registration Committee was constituted on the 5th of March 2019. The committee did not sit during the financial period under review.

Pharmacovigilance Advisory Committee
The objectives of the Pharmacovigilance Advisory Committee are to guide pharmacovigilance functions and conduct of clinical trials. The committee makes decisions on risk benefit assessments of the medicines registered in Botswana based on the quality, safety and efficacy of the medicines. The Pharmacovigilance Advisory Committee was constituted on the 5th of March 2019. The Committee did not sit during the financial period under review.

Licensing Committee
The mandate of the Licensing Committee is administrative, to set Guidelines and have oversight of the licensing criteria. The licensing decisions are made at Department level. The Committee is yet to be fully constituted and did not sit in the financial period under review.

HUMAN CAPITAL

HUMAN CAPITAL REPORT

Our Human Capital management philosophy is guided by the goals and priorities of BoMRA's strategic plan, high performance, growth, and a positive employee experience. BoMRA strives to attract and retain top talent that is diversified (skills, competencies and background) and will facilitate achievement of its strategic objectives. In this regard, BoMRA is committed to implementing a talent management strategy, performance-based rewards and recognition policy, and provides a range of employee support and consultative services as well as professional development and training programmes.

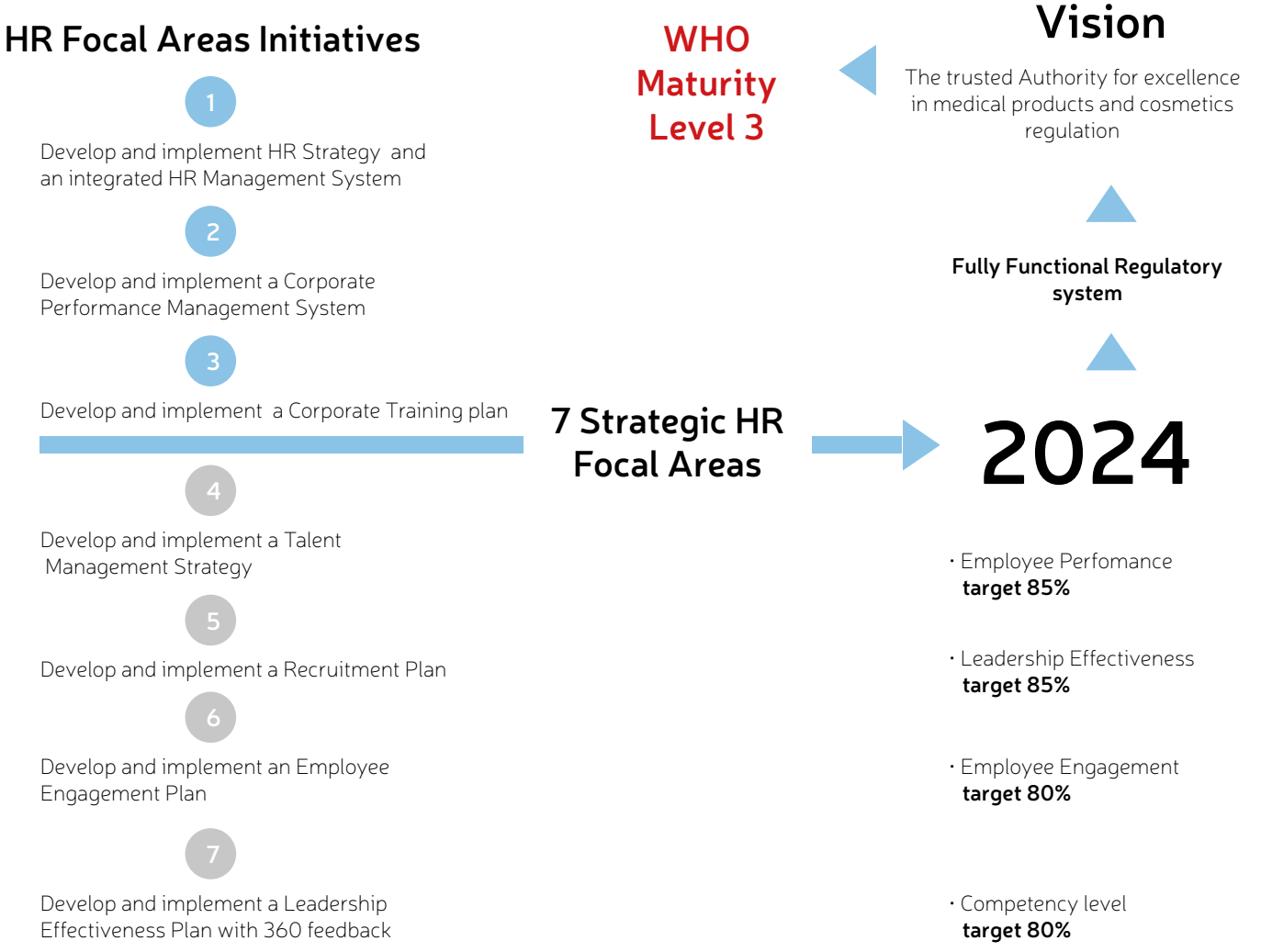
Our Human Capital ensures that the Authority is appropriately resourced with the right talent for high performance. The team promotes and facilitates the maintenance of a culture of superior performance, collaboration (team-work), employee engagement and inclusiveness where work is meaningful, employees are valued and their achievements celebrated.

STRATEGIC GOALS AND INITIATIVES

The Human Resource (HR) function is a business partner that provides a facilitatory and advisory role to the Authority and is focused on the strategic goal of continually strengthening our integrated human resource management.

A comprehensive Integrated Human Resource Management Strategy aligned to the Corporate Strategy will be developed and implemented during the Financial Year 2019/20. The HR Strategy initiatives will serve as part of our road map that will guide our efforts towards developing a fully functional regulatory system.

The Strategy Initiatives are depicted below:

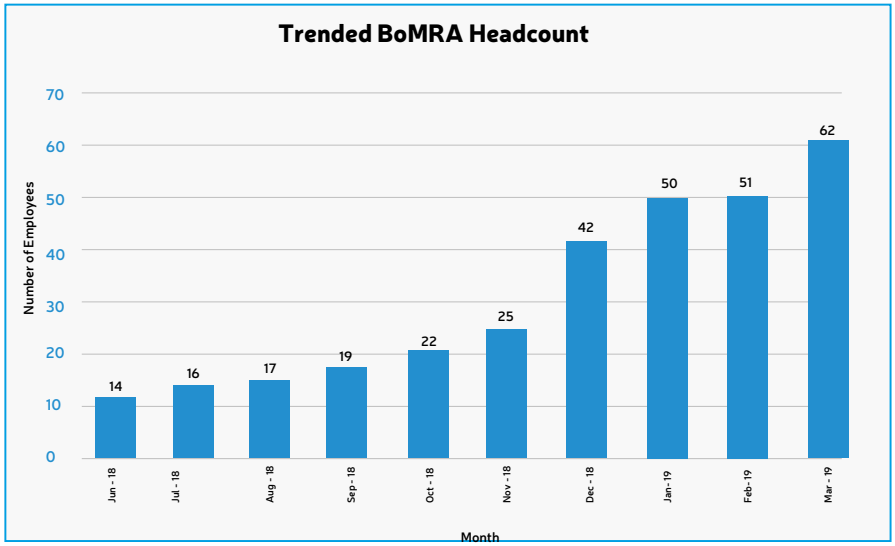


YEAR-TO-DATE ACTIVITIES

As a newly formed organsation the following activities were our focal areas during the Financial Year 2018/19

- Recruitment and probation performance management.
- Development of the Integrated HR strategy.
- Employee engagement activities that were aimed at inculcating the values of BoMRA.
- Capacity building workshops and courses.

Figure 1 – Headcount trend as at March 2019



The total headcount of **62** represent **3** employment categories as follows:
Pensionable – **36**
Fixed Term Contract – **17**
Temporary – **9**

Dr. Stephen Ghanie
C.E.O

Lydia Maleho
P.A to C.E.O

Dr. Sinah Selelo
Chief Technical Advisor

Dr. Nkaelang Modutlwa
Director - P.E & R

Dr. Parthasarathi Gurumurthy
Director - Post Marketing Surveillance & Clinical Trials

Dr. Seima Dijeng
Director - Inspection & Licensing

Latelang Chakalisa
Corporate & Legal Counsel

Harold Kuvenga
Director:Finance & Admin

Kelame Morwalela
Internal Audit Manager

Israel Kgosidiile
Public Relations Manager

Padmine Rammidi
H.R Manager

Zukiswa Raditladi
Quality Manager

Harold Kuvenga
Director:Finance & Admin

Dikeledi Koketso
Finance Manager

Desmond Ramodisa
Procurement Manager

Dennis Theleso
I.T Business Partner

Kagiso Masala
Records Supervisor

Laowabo Seganabeng
Admin Coordinator

Rosaliah Gunda
Accountant

Doreen July
Receptionist

Oaitse Radisweng
Records Assistant

Kenalemang Ratlhako
Accounts Assistant

Bathoni Mpape
Driver / Messenger

Zukiswa Raditladi
Quality Manager

Keolopa Gabobofane
Quality Officer

Eunicah Abotseng
SHE Officer

POST MARKETING SURVEILLANCE & CLINICAL TRIALS

Dr. Parthasarathi Gurumurthy
Director - Post Marketing Surveillance & Clinical Trials

Lebogang Koitsiwe
P.V Officer

Wapapha Nthomiwa
P.V Officer

Tebogo Mokotedi
P.V Officer

Elizabeth Kelentse
P.V Officer

Dr. Thabang Phetlhe
P.V Officer

PRODUCT EVALUATION & REGISTRATION TEAM

Dr. Nkaelang Modutlwa
Director - Product Evaluation & Registration

Tendayi Roy Chihaka
Manager - Complementary Medicines & Cosmetics

Nyasha Maregere
Manager - Evaluation & Registration

Ethel Sebua
Dossier Assessment Specialist

Ntsetselele Kago
Dossier Assessment Specialist

Cynthia Oatlhotse
Dossier Assessment Specialist

Olivia Lekuni
Dossier Assessment Specialist

Kefilwe Mothabane
Dossier Assessment Specialist

Charlton Tsopota
Dossier Assessment Specialist

Innocent Ravengai
Dossier Assessment Specialist

Kesolofetse Keakile
Dossier Assessment Specialist

Tumo Pelekekae
Dossier Assessment Specialist

PRODUCT EVALUATION & REGISTRATION TEAM

Maikaego Moreri
Dossier Assessment Specialist

Dr. Moagi Mogomotsi
Dossier Assessment Specialist

Sarah Dipula
Dossier Assessment Specialist

Itumeleng Zimba
Dossier Assessment Specialist

PUBLIC RELATIONS & STAKEHOLDER ENGAGEMENT TEAM

Israel Kgosidiile | **Itumeleng S. Modibedi-Ledimo**

Public Relations Manager

Public Education & Stakeholder Management Officer

Latelang Chakalisa
Corporate & Legal Counsel

Nonofo Thipe
Legal Officer

Amantle Diare
Enforcement Officer

Bashi Ntshonono
Enforcement Officer

INSPECTION & LICENSING TEAM

Dr. Seima Dijeng
Director - Inspection & Licensing

Patrick Kgori
Regulatory Officer

Leah Kanaimba
Regulatory Officer

Dr.Ndindonga Mosimane
Regulatory Officer

Tshegofatso Chilume
Regulatory Officer

Gilbert Sekgophana
Regulatory Officer

Tshetsana Senau
Regulatory Officer

Dr.Raymond Manikisa
Regulatory Officer

Gaone Matlhare
Regulatory Officer

Serwaledi Phetlhu
Regulatory Officer

Matshediso Ramotshabi
Regulatory Officer

Oreeditse Moloi
Lab Analyst Officer

Unaswi Oratile
Lab Analyst Officer

Diketso Kanyenvu
Lab Analyst Officer

Gogontle D. Rapelana
Lab Analyst Officer

Tuduetso Mmolai
Import & Export Officer

HUMAN & CAPITAL TEAM

Padmine Rammidi
Human Resource Manager

Kutlwano Thipe
Human Resource Officer

QUALITY

QUALITY MANAGEMENT SYSTEM REPORT

BoMRA is committed to implementing a Quality Management System (QMS) in order to coordinate and direct the organisation's activities and adequately execute its regulatory mandate. In implementing QMS we expect to continually improve the efficiency and effectiveness of our processes and thereby meet and exceed our customer needs and stakeholder requirements.

Our Quality Management Unit has thus been mandated to facilitate the implementation of the Quality Management System throughout the organisation in order for BoMRA to achieve International Organisation of Standardisation (ISO) certification and accreditation. This will assist BoMRA in achieving its Vision of being "The trusted Authority for excellence in medical products and cosmetics regulation"

In addition to achieving operational excellence, BoMRA will continually improve on its Safety, Health and Environment management (SHE) to ensure that all matters relating to safety of operations, the health of employees, and the environments in which they work in are conducive to promoting high performance, innovation and continuous improvement

STRATEGIC GOALS AND INITIATIVES

Within the Corporate Strategy period 2019-2024, BoMRA aims to be ISO9001 certified and to be accredited against ISO/IEC17025 and ISO/17020.

Two strategic initiatives have been identified for the Annual Strategic plan period of 2019/2020.

1. Development of a Quality Management System for all the functions of the Authority. This will facilitate delivery of quality services to both our external and internal clients, and stakeholders.

2. Institutionalisation of a Quality Culture throughout the organisation since the Authority is newly established and to ensure successful implementation of QMS.

YEAR-TO-DATE ACTIVITIES

During the period ending 31st March 2019, the following activities were undertaken:

- **Process Documentation:**
  A total of 63 key processes were mapped for all the BoMRA's functional areas, 12 were documented and approved and 28 are at different stages of development.The process documentation includes, amongst others, policies, standard operating procedures (SOPs) and other work tools.

- **QMS Internal Audits:**
  An internal Audit has been done on all functions that had completed process documentation and feedback provided.

- **Inculcating a Quality Culture:**
  Quality Champions have been trained per department in order to help inculcate a quality culture.

- **Risks and Opportunities Management:**
  A risk-based thinking approach as well as risk and opportunities management are being promoted and related guiding procedures have been developed.

- **SHE inspections:**
  SHE inspections were made, deficiencies closed and a SHE culture is being inculcated.

PRODUCT EVALUATION & REGISTRATION

Our Product Evaluation & Registration function ensures that medicines and other healthcare products are appropriately registered and authorized for marketing in Botswana.In essence our processes ensure that these products are safe and fit for purpose and meet quality standards.

Our Product Evaluation and Registration teams carry out the initial assessment of registration document(s), with the assistance of collaborating SADC partners ("ZAZIBONA") as deemed appropriate, and submit their assessment reports to the Registration Committee, which has been established and delegated Authority to approve registration by the Board.

Veterinary Medicines

BoMRA has not yet commenced registration of veterinary medicines as the MRSA is still being amended to include veterinary medicines regulation. Some of the activities are currently being done jointly with the Department of Veterinary Services

Medical Devices

BoMRA has not yet commenced registration of medical devices as the MRSA is still being amended to include medical devices regulation.

Cosmetics

The MRSA is still being amended to improve the regulation of cosmetics. However, we have adopted a temporary cosmetic clearance procedure to facilitate continuance of trade and availability of these products.

STRATEGIC GOALS AND INITIATIVES

BoMRA is enhancing some of the medicines registration processes inherited from the Ministry of Health and Wellness – Drugs Regulatory Unit (DRU).

Our Annual Strategy Plan for Financial Year 2019/20 is to:

- Review and enhance all registration processes, standards and structures.
- Implement a registration backlog reduction plan – backlog inherited from DRU.
- Develop and implement World Health Organisation (WHO) Institutional Develop Plans (IDPs) and achieve Maturity Level 3 by 31st March 2024 for the Registration function.

YEAR-TO-DATE ACTIVITIES

- Training of dossier specialists to facilitate application for registration reviews
- Assessment of medicine registration dossiers (applications for registration), including those from local manufacturers and for essential medicines.
- Assessment of post-registration variations
- Clearance of cosmetic products registration
- Appointment of the Registration Committee, which started holding bi-monthly registration meetings.

POST MARKETING SURVEILLANCE & CLINICAL TRIALS

POST MARKETING SURVEILLANCE & CLINICAL TRIALS REPORT

BoMRA aims to understand, reduce and prevent medicines and related products' adverse effects or related problems through:

- Documenting and analysing submitted reports of adverse reactions and taking appropriate action for confirmed adverse reactions, which action may include temporary or permanent withdrawal of marketing authorisation of a product
- Implementing and coordinating a national pharmacovigilance programme, which is a program aimed at sensitising stakeholders, facilitating documentation and reporting of medical products' adverse reactions, random sampling and testing of products for quality and safety.
- Promoting rational and safe use of medicines by all stakeholders
- Approval of clinical trials of new, current and variant medicines and related medical products.
- Providing unbiased medicines information to all stakeholders.

STRATEGIC GOALS AND INITIATIVES

The Post Marketing Surveillance and Clinical Trials function was recently Established and will pursue the following initiatives during Financial Year 2019/20

1. Establish the structure, processes and standards for the function.
2. Develop a pharmacovigilance strategy and plan leading to development of a national medicine safety monitoring centre.
3. Develop and implement a health practitioner education programme that supports the promotion of both compliance and growth of a research culture and pharmacovigilance.
4. Contribution to strengthening of the legislative framework for reporting of adverse reactions by health practitioners.

YEAR-TO-DATE ACTIVITIES

- A baseline assessment of the Pharmacovigilance (PV) system in Botswana was done to identify its gaps, strengths, and weaknesses – BoMRA is developing a PV plan to address weaknesses identified
- Technical assistance was sought from WHO and Uppsala Monitoring Center and to develop a web based reporting tool (ICT Application) for adverse drug or medicine reaction
- Newly appointed PV Officers have been trained or upskilled to ensure their performance

LEGAL & ENFORCEMENT

OUR PURPOSE

The Legal and Enforcement Unit, under the direction of the Legal and Corporate Counsel, is responsible for providing BoMRA with legal services and undertaking the enforcement of the MRSA and related legislation. The Unit further provides Board secretarial services to the Medicines Regulatory Board.

Legal

During the Financial Year 2018/19, BoMRA commenced a review and amendment of the MRSA and drafting subsidiary legislation to align the MRSA to current practices in the industry, meet the international medicines regulatory standards and adequately address the Authority's mandate to regulate veterinary medicines, among others. This process is ongoing and is expected to be concluded during 2019/20.

Enforcement

In order to actualize its enforcement mandate, BoMRA works and collaborates with other Law Enforcement Agencies in Botswana, including the Botswana Police Service and Botswana Unified Revenue Service.

We conducted various successful enforcement operations resulting in the confiscation of non-registered, counterfeit, substandard and falsified medicines that were either disposed or retained as evidence for prosecution. All persons who were found to be in possession of such goods were duly fined or referred for prosecution.

STRATEGIC GOALS

Our key strategic initiatives, under Legal and Enforcement, as outlined in the Corporate Strategy 2019 – 2024 are:

- Ensure Compliance to the MRSA and related legislation
- Improve Corporate Governance through adoption of good governance and best practice.

These initiatives are aimed at ensuring that the appropriate resources and structures are in place and optimised to ensure adherence to the MRSA and that the Board and the Authority maintain good corporate governance practices.

During the Financial Year ending 31 March 2019, we focused on staff recruitment and providing support to the Board and its committees as well as development of Board governance tools (Charter and Committee Terms of Reference), since the Authority was in its formative period.

INSPECTORATE & LICENSING

OUR PURPOSE

In pursuance of its inspection and licensing mandate BoMRA conducts pre–licensing and annual post licensing premises inspections to ensure compliance with Good Manufacturing practices (GMP), Good Distribution Practices (GDP), Good Laboratory Practice (GLP) and Good Pharmacy Practices (GPP) by facilities involved in manufacturing and distributing human and veterinary medicines. In addition, BoMRA controls the import and export of medicines throughout the supply chain.

The above activities were transferred from the Ministry of Health and Wellness Drugs Regulatory Unit to BoMRA in December 2018.

BoMRA licensed a few new veterinary facilities since most were already licensed by the Department of Veterinary Services. BoMRA will take over the licensing renewals of veterinary premises from January 2020.

No public facilities were inspected during the period under review. BoMRA will engage with the Ministry of Health and Wellness Inspectorate Unit in order initiate inspections of public facilities from January 2020.

Imports and Exports of Habit-Forming Drugs

BoMRA continues to facilitate the import/export controls for habit-forming drugs (HFD's), in line with the International Narcotics Control Board (INCB) guidelines, through the issuance of Import and Export permits for narcotic and psychotropic medicines. The INCB is the United Nations office responsible for the control of narcotic and psychotropic medicines in international trade and allocates country quotas and monitors consumption of such products.

General Imports and Exports

Import and export of human medicines is carried out through the authorization of purchase orders presented to BoMRA by wholesale distributors. These purchase orders are verified against the medicines register to ensure only registered medicines are imported into the country.

The Authority will be piloting a new system for issuance of import permits, first with veterinary medicines in July 2019 and same will be rolled-out for human medicines. The system is expected to improve the tracing of medicines as they are imported into the country and provide further information as to the quantities imported at any given time.

Through collaboration with Port Health in the Ministry of Health & Wellness and the Botswana Unified Revenue Service the Authority has established presence at Ports of Entry to facilitate verification of incoming and outgoing consignments. It is anticipated that these relationships will be formalised and strengthened through memorandum of understanding (MoUs) in the next financial year.

STRATEGIC GOAL AND INITIATIVES

BoMRA will continue to strengthen its inspection and licensing function, to improve import/export controls for medicines registered for use in Botswana.

We will focus on the following during Financial Year 2019/20:

- Review and documentation of inspection and licensing, import/export controls processes, structures and standards.
- Development and implementation of an inspection framework and more efficient and effective inspection programmes.

YEAR-TO-DATE ACTIVITIES

In the period ending 31st March 2019, the following key activities were undertaken by the department:

- Capacity building through training on GMP/GDP.
- Inspection and licensing of pharmaceutical operations
  - o Human medicine facilities inspections and licensing
  - o Veterinary medical products premises inspections and licensing
- Process documentation for the function
- Issuance for Habit Forming Drugs import permits
- Development of veterinary medical products databases and management of their importation
- Authorisation of human medicines imports from various wholesale distributors
- GMP Desk review process (for ZAZIBONA work sharing commitments)
- Benchmarking with other regulators

PUBLIC EDUCATION & STAKEHOLDER ENGAGEMENT

The Public Education and Stakeholder Engagement department is responsible for engagement with both external and internal stakeholders. This engagement is guided by the Public Relations (PR) and Stakeholder Engagement strategy. The PR strategy further establishes the lines, responsibilities and standards for the organisation's communication and engagement across all stakeholders. The key stakeholders are as follows:

Practitioners

Providing unbiased information on medical products and a platform for medical safety reporting.

Public

Promoting well being and Educating the public by providing information that helps them make informed choices regarding human and animal health products.

STAKEHOLDERS & VALUE PROPOSITION

Law Enforcement

Enriching law enforcement operations by providing relevant technical support, information and evidence.

Industry

Enabling the medical Industry to go to market with safe, quality and effective medical products and cosmetics, as well as protecting the market from effects of illegal trade

Our Staff

An enabling environment for high performance, growth and opportunity to make a positive impact on customers and stakeholders served

Public education and interactions with key internal and external stakeholders, are coordinated and managed by the PR and Stakeholder Engagement department. Its objectives are underpinned by the 2019 – 2024 BoMRA strategic goal of Improved Awareness and Public Trust in the medical products and cosmetics regulatory system.

We are committed to providing effective, internal and external communication and stakeholder engagement via print and online platforms and to delivering information in a way that suits all types of stakeholders, taking into account the local socio-economic factors.

STRATEGIC GOALS AND INITIATIVES

The PR unit will pursue the following goals during the strategy plan period:

1.Promote active stakeholder participation through extensive engagement and involvement in all matters affecting stakeholders and the Authority
2.Layout the foundation to communicate in a friendly, expert and direct way to stakeholders addressing all communication needs
3.Further, drive active community involvement through the implementation of a CSI strategy.
4.Provide and support an enabling environment for a High-Performance Culture.

YEAR-TO-DATE ACTIVITIES

The following activities took priority during the 2018-2019 period:

1.Roadshows.
Roadshows were held in all the major villages and towns in the country leading to the official launch of the Authority on the 11th July 2019. The purpose of the roadshows was to create awareness to the nation about the existence and mandate of BoMRA. These roadshows were well attended and the engagement with the public was high.

2.Participation in the **Annual Science and Technology Week, Botswana Consumer Fair, and World Aids Day.**
The aim of participating in the commemorations was to increase brand awareness to both the youth and the general public.

3.Corporate Social Responsibility at Bamalete Lutheran Hospital in Ramotswa.

4.Activity on print, online and social media.

The different platforms targeted different stakeholders and included content in the form of video footage, audio recordings and photos. These were shared with the aim of promoting brand awareness, gaining first-hand accounts and insights from all stakeholder groups, and building trusted partnerships with stakeholders.

5.Radio participation

BoMRA's public educations efforts have also included appearances on radio.

In October 2018, the BoMRA team participated in a live broadcast interview on Yarona FM to discuss topics such as the role of the Authority in medicines regulation and complementary medicines.

In November 2018 the team participated in a radio programme on Gabz FM to talk about the role of BoMRA and its contribution towards the mainstream NDP 11 and Vision 2036.

FINANCIAL STATEMENTS

General Information

Country of incorporation and domicile	Botswana
Nature of business and principal activities	Mr. Duncan Thela (Chairperson) Dr. Mbatshi Mazwiduma (Vice Chairperson) Dr. Gontle Moleele (Board Member) Dr. Joyce Kgatlwane (Board Member) Mr. Kagiso Balopi (Board Member) Mr. Meshack Baoleki (Board Member) Dr. Michael G. Sento (Board Member) Ms. Shameela Pholo-Winston (Board Member) Mr. Thapelo Tsheole (Board Member) Dr. Tiroyaone Mampane (Board Member) Dr. Letlhogile Modisa (Ex- officio Board Member) Dr. Khumo Seipone (Ex-officio Board Member) (Resigned 31/08/2018)
Chief Executive Officer	Dr. Stephen Ghanie (Ex-officio Board Member)
Board secretary	Mrs. Latelang Chakalisa
Business address	Plot 112 International Finance Park Gaborone
Postal address	Private Bag 2 Gaborone Botswana
Bankers	First National Bank Botswana Limited
Auditor	RSM Botswana Certified Auditors RSM House Plot 39 Commerce Park Gaborone

Contents

The reports and statements set out below comprise of the financial statement of the Authority (BoMRA) for the fifteen months ended 31 March 2019.

Medicines Regulatory Board Responsibilities and Approval of the Financial Statements

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

The financial statements are prepared in accordance with International Financial Reporting Standards and are based upon appropriate accounting policies consistently applied and supported by reasonable and prudent judgements and estimates.

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

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

The Board has reviewed the Authority's cash flow forecast for the year to March 31, 2020 and, in light of this review and the current financial position, it is satisfied that the Authority has adequate resources to continue in operational existence for the foreseeable future.

The external auditors are responsible for independently auditing and reporting on the Authority's financial statements. The financial statements have been examined by the Authority's external auditors and their report is presented on pages 45 to 47

The financial statements set out on pages 48 to 66, which have been prepared on the going concern basis, were approved by the Board on "29 August 2019 and were signed on their behalf by:

Chairperson

Chief Executive Officer

RSM Botswana
P.O. Box 1816, Gaborone, Botswana
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T +267 3912805 F +267 3959638
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www.rsm.co.bw

INDEPENDENT AUDITOR'S REPORT

To the Minister of Health and Wellness

Report on the Audit of the Financial Statements

Opinion

We have audited the annual financial statements of Botswana Medicines Regulatory Authority (the Authority) set out on pages 47 to 48, which comprise the statement of financial position as at 31 March 2019, and the statements of surplus or deficit and other comprehensive income, changes in reserves and cash flows for the period then ended, and notes to the financial statements, including significant accounting policies.

In our opinion, the annual financial statements present fairly, in all material respects, the financial position of the Authority as at 31 March 2019, and its financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards.

Basis for opinion

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

Other Information

The Board is responsible for the other information that is issued with the financial statements on which we have issued our audit report. The other information comprises the chairperson's statement on page 7 the Chief Executive Officer's Statement on Page 9 reports of various departments of the Authority on pages 10 to 39 and the Detailed Income Statement on page 68.

Our opinion on the annual financial statements does not cover the other information and we do not express any form of assurance conclusion thereon. In connection with our audit of the financial statements, our responsibility is to read the other information. We consider whether other information is consistent with the financial statements or our knowledge obtained in the audit. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of directors for the Financial Statements

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

In preparing the annual financial statements, members of the Board are responsible for assessing the Authority's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless they have no realistic alternative but to let discontinue the Authority's operations.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with International Standards on Auditing (ISAs) will always detect a material misstatement when it exists.Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

• Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions,misrepresentations, or the override of internal control.

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

• Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the members of the Board.

• Conclude on the appropriateness of the Board's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Authority's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the 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 financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the Board regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit. We also provide the Board with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

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

Report on other legal and regulatory requirements
Further, in accordance with Section 21 (3) of the Medicines and Related Substances Act, 2013 (the Act), in our opinion:
1. The Authority in terms of Section 21(3) (a) of the Act provided us with the necessary information and explanations for us to perform our duties as auditors.

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

RSM Botswana.

RSMBotswana
Certified Auditors:
Practicing member: P Muonde
Membership number: 2007 0052

Date: 6th September2019
Gaborone

Statement of Surplus or Deficit and Other Comprehensive Income

Figures in Pula	Note(s)	2019 15 months
Revenue	3	41,836,456
Other operating income	4	14,875
Total income		41,851,331
Employee costs	5	(15,266,963)
Governance expenses		(629,805)
Depreciation, amortisation and impairment expenses	5	(2,504,880)
Publicity and awareness expenses		(998,646)
Travel and accommodation costs		(1,541,202)
Other operating expenses		(3,306,675)
Operating surplus	5	**17,629,051**
Finance costs	6	(751,195)
Operating surplus before taxation		**16,877,856**
Taxation	7	-
Total operating surplus for the period		**16,877,856**
Other comprehensive income		**-**
Total comprehensive surplus for the year		**16,877,857**

Statement of Financial Position as at March 31, 2019

Figures in Pula	Note(s)	2019
Assets		
Non-current assets		
Equipment	8	6,150,180
Intangible assets	9	841,232
Right-of-use asset	10	12,601,566
		19,592,978
Current Assets		
Other receivables	11	338,732
Cash and cash equivalents	12	45,948,409
		46,287,141
Total assets		**65,880,119**
Reserves and liabilities		
Reserves		
Accumulated surplus		16,877,857
Liabilities		
Non-current liabilities		
Lease liability	13	12,257,608
Deferred income	14	6,991,171
		19,248,779
Current liabilities		
Deferred income	14	24,231,765
Lease liability	13	1,269,635
Other payables	15	4,252,083
		29,753,483
Total liabilities		**49,002,262**
Total reserves and liabilities		**65,880,119**

Figures in Pula	Accumulated surplus	Total reserves
Surplus for the period	16,877,856	16,877,856
Total surplus for the period	**16,877,856**	**16,877,856**
Balance at March 31, 2019	**16,877,856**	**16,877,856**

Note(s)

Figures in Pula	Note(s)	2019
Cash flows from operating activities		
Cash generated	16	23,519,316
Finance cost	6	(751,195)
Net cash inflows from operating activities		**22,768,121**
Cash flows from investing activities		
Purchase of equipment	8	(6,220,928)
Purchase of intangible assets	9	(903,631
Net cash outflows from investing activities		**(7,124,559)**
Cash flows from financing activities		
Lease payments for principal portion of lease liability		(918,088)
Deferred income from government grant		31, 222,935
Net cash from financing activities		**30,304,847**
Net increase in cash and cash equipments		**45,948,409**
Cash and cash equivalents at the end of the period	12	**45,948,409**

1. Significant accounting policies

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

1.1 Basis of preparation

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

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

1.2 Significant judgements and sources of estimation uncertainty

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

Key sources of estimation uncertainty

Impairment of financial assets

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

Impairment testing

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

Useful lives of equipment

The Board 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 the 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 estimates of residual values are affected by market conditions for similar used items, technological advances, pattern of use and government practices. 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 in the statement of financial position.

1.3 Leases

The Board elected to early-adopt IFRS 16 - 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 the premises for a period of time in exchange for consideration. There has not been any changes to the terms and conditions of the contracts. The lease term is determined as the non- cancellable period of the lease together with the period covered by the option to extend the lease that the Board is reasonably certain it will exercise.

The Board elected not to apply IFRS 16 Leases to short-term leases and lease for which the underlying asset is of low value.

Right-of-use asset – lessee

At commencement date of the lease. the Authority recognises a right-of-use asset and a lease liability in the statement of financial position. The right-of-use asset is recognised at cost. The cost of the asset comprises the amount of the initial measurement of the lease liability, any lease payments made at or before the commencement date and any direct costs incurred by the Authority.

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

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

The right-of use asset is subsequently measured at cost less accumulated depreciation and any accumulated impairment losses. The right-of-use asset is depreciated from the commencement date of the lease contract to the earlier of the useful life of the right-of-use asset or the end of the lease term.

1.4 Equipment

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

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

Equipment is initially measured at cost. Cost includes all of the expenditure which is directly attributable to the acquisition of the asset.

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

Equipment is subsequently stated at cost less accumulated depreciation and any accumulated impairment losses, except for land which is stated at cost less any accumulated impairment losses.

1.4 Equipment (continued)

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 company. Leased assets are depreciated in a consistent manner over the shorter of their expected useful lives and the lease term. Depreciation is not charged to an asset if its estimated residual value exceeds or is equal to its carrying amount. Depreciation of an asset ceases at the earlier of the date that the asset is classified as held for sale or derecognised.

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

Item	Depreciation method	Average useful life
Furniture and fittings	**Straight line**	**10 years**
Motor vehicles	**Straight line**	**5 years**
Office equipment	**Straight line**	**5 years**
Computer equipment	**Straight line**	**3-5 years**

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

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

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

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

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

1.5 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.

Reassessing the useful life of an intangible asset with a finite useful life after it was classified as indefinite is an indicator that the asset may be impaired. As a result the asset is tested for impairment and the remaining carrying amount is amortised over its useful life.

Amortisation is provided to write down the intangible assets, on a straight line basis, to their residual values as follows:

1.5 Intangible assets (continued)

Item	Useful life
Computer software	6 years

1.6 Financial instruments

Financial instruments held by the Authority are classified in accordance with the provisions of IFRS 9 Financial Instruments.

Broadly, the classification possibilities, which are adopted by the Authority ,as applicable, are as follows:

Financial assets which are debt instruments:

- Amortised cost. (This category applies only when the contractual terms of the instrument give rise, on specified dates, to cash flows that are solely payments of principal and interest on principal, and where the instrument is held under a business model whose objective is met by holding the instrument to collect contractual cash flows); or

Financial liabilities:

- Amortised cost; or

Note 17 Financial instruments and risk management presents the financial instruments held by the Authority based on their specific classifications.

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

Other receivables

Classification

Other receivables, excluding prepayments, are classified as financial assets subsequently measured at amortised cost (note 11).

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 other receivables.

Recognition and measurement

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

They are subsequently measured at amortised cost.

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

Credit risk

Details of credit risk are included in the other receivables note (note 11) and the financial instruments and risk management note (note 17).

Derecognition

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

1.6 Financial instruments (continued)

Other payables

Classification

Other payables (note 15), excluding amounts received in advance, are classified as financial liabilities subsequently measured at amortised cost.

Recognition and measurement

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

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

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

If trade and other payables 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 and other payables expose the Authority to liquidity risk and possibly to interest rate risk. Refer to note 17 for details of risk exposure and management thereof.

Derecognition

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

Cash and cash equivalents

Cash and cash equivalents comprise cash on hand and demand deposits. Cash and bank balances are stated at carrying amount which is deemed to be fair value.

Derecognition

Financial assets

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

Financial liabilities

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

1.7 Tax

Current tax assets and liabilities

No provision 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).

1.8 Impairment of assets

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

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

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

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

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

1.9 Reserves

Accumulated surplus under reserves represents excess of income over expenditure.

1.10 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 the amounts not yet remitted to the plan at the reporting date.

1.11 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 revenue 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 entity with no future related costs is recognised as income of the period in which it becomes receivable.

1.11 Government grants (continued)

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 revenue in the statement of surplus or deficit separately.

Committed funds for specific projects are recognised at fair value in the statement of financial position as deferred income liability. These form part of cash and cash equivalents at the reporting date. Subsequently, as the expenses of the specific projects are financed, the liability is amortised to the statement of surplus or deficit.

1.12 Other operating income

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

1.13 Translation of foreign currencies

Foreign currency 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.

At the end of the reporting period, foreign currency monetary items are translated using the closing rate.

Exchange differences arising on the settlement of monetary items or on translating monetary items at rates different from those at which they were translated on initial recognition during the period or in previous financial statements are recognised in surplus or deficit in the period in which they arise.

When a gain or loss on a non-monetary item is recognised to other comprehensive income and accumulated in equity, any exchange component of that gain or loss is recognised to other comprehensive income and accumulated in equity. When a gain or loss on a non-monetary item is recognised in surplus or deficit, any exchange component of that gain or loss is recognised in surplus or deficit.

Cash flows arising from transactions in a foreign currency are recorded in Pula by applying to the foreign currency amount the exchange rate between the Pula and the foreign currency at the date of the cash flow.

Figures in Pula	2019

2. First-time adoption of International Financial Reporting Standards

The Authority has applied IFRS 1, First-time adoption of International Financial Reporting Standards, to provide a starting point for the reporting under International Reporting and Accounting Standards.

These financial statements are the Authority's first IFRS financial statements as this is its first period of operation. There are therefore no transition requirements applicable.

3. Revenue

Grant received from the Government of Botswana	41,175,100
Amortisation of deferred income	661,356
	41,836,456

4. Other operating income

Tender fees	7,375
Regulatory fees	7,500
	14,875

5. Operating surplus

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

Employee costs

Salaries, wages and other short-term benefits	11,597,7151
Recruitment costs	1,249,530
Post-employment benefits	541,330
Termination benefits	1,878,388
Total employee costs	**15,266,963**

Depreciation and amortisation	
Depreciation of equipment	598,716
Depreciation of right-of-use asset	1,843,765
Amortisation of intangible assets	62,399
Total depreciation and amortisation	**2,504,880**

6. Finance costs

Finance leases	751,195

7. Taxation

No provision 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).

Figures in Pula	2019

8. Equipment

	Cost	Accumulated depreciation	2019 Carrying value
Computer equipment	3,439,041	(366,677)	3,072,364
Furniture and fixtures	616,658	(21,371)	595,287
Motor vehicles	2,396,033	(178,577)	2,217,456
Office equipment	297,164	(32,091)	265,073
Total	**6,748,896**	**(598,716)**	**6,150,180**

Reconciliation of equipment - 2019

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

Carrying amounts of equipment acquired by government grant

The following assets were acquired by means of government grants:

Computer equipment	3,072,364
Furniture and fixtures	595,287
Motor vehicles	2,217,456
Office equipment	265,073
	6,150,180

Figures in Pula	2019

9. Intangible assets

			2019
	Cost	Accumulated amortisation	Carrying value
Computer software	903,632	(62,399)	841,232

Reconciliation of intangible assets - 2019

	Opening balance	Additions	Amortisation	Total
Computer software	-	903,632	(62,399)	841,232

Carrying amount of intangible assets acquired by means of government grant

Intangible assets consist of server software, accounting and payroll system software. The software was obtained by means of a government grant and initially recognised at fair value. It has subsequently been measured using the cost model.

Software acquired	841,232

10. Right-of-use assets

Carrying amount of right-of-use assets	
Cost of right of use assets	14,442,831
Initial direct costs incurred	2,500
Depreciation for the period	(1,843,765)
	12,601,566

11. Other receivables

Lease deposits	231,195
Non-financial instruments:	
Prepaid expenses	107,537
Total trade and other receivables	**338,732**

Split between non-current and current portions

Current assets	338,732

Categorisation of other receivables

Other receivables are categorised as follows in accordance with IFRS 9: Financial Instruments:

At amortised cost	231,195
Non-financial instruments	107,537
	338,732

Figures in Pula	2019

11. Other receivables (continued)

Exposure to credit risk

The Authority does not offer services on credit. There is therefore no inherent credit risk exposure to the Authority, being the risk that the Authority will incur financial loss if clients fail to make payments as they fall due. No losses will be incurred on lease deposits as the Authority can set off amounts receivable against lease payments due.

12. Cash and cash equivalents

Cash and cash equivalents consist of:

Bank balances	45,948,409

13. Lease liability

The Authority leases the premises from which it operates. The lease contract stipulates a non-cancellable term of five (5) years, with an option to extend for three (3) years. The Board is reasonably certain to exercise the option.

Interest rates are linked to the banks' prime at the contract date. This rate is indicative of the lessors incremental borrowing rate.

Carrying amount of lease liability	
Present value of lease payments unpaid at lease inception	14,442,831
Interest expense on lease liabilities	751,196
Total cash outflow for leases	(1,666,784)
Present value of minimum lease payments	**13,527,243**

Present value of minimum lease payments due	
- within one year	1,269,635
- in second to fifth year inclusive	7,208,455
- later than five years	5,049,153
	13,527,243

Minimum lease payments due	
- within one year	2,100,148
- in second to fifth year inclusive	9,504,495
- later than five years	5,365,487
	16,970,130
Less: Future finance charges	(3,442,887)
	13,527,243

Figures in Pula	2019

14. Deferred income

The Authority received a total amount of P72,531,424 as a government grant during the reporting period. P24,231,765 of this amount was received in the 4th quarter for the refurbishment of a Drugs Quality Control Testing Laboratory. This specific grant remained unutilised at the reporting date. Amounts of P6,748,895 and P903,631 were used to acquire equipment and software for use by the Authority. The Authority also received capital assets from the government valued at P527,968. Grants related to assets are recognised using the deferred income method.

The grant received has been deferred per the reconciliation below.

Government grants - related to non-current assets	
Assets purchased during the year	7,124,560
Assets received from government of Botswana	527,967
Amortisation of grant related to assets	(661,356)
	6,991,171
Government grants - related to specific projects	
Grant received for the development of a laboratory	24,231,765

15. Other payables

Financial instruments:	
Post-employment benefits payable	801,949
Short-term employee benefits	2,728,360
Other payables	721,774
	4,252,083

Exposure to liquidity risk

Refer to note 17 Financial instruments and financial risk management for details of liquidity risk exposure and management.

16. Cash generated from operations

Surplus for the year	16,877,856
Adjustments for:	
Depreciation and amortisation	2,504,882
Finance costs	751,195
Changes in operating funds:	
Other receivables	(338,732)
Other payables	4,252,083
Deferred income - non cash grant related to assets	(527,968)
	23,519,316

Figures in Pula	2019

17. Financial instruments and risk management

Categories of financial instruments

Categories of financial assets

2019

	Note(s)	Amortised cost	Total
Trade and other receivables	11	231,195	231,195
Cash and cash equivalents	12	45,948,409	45,948,409
		46,179,604	**46,179,604**

Categories of financial liabilities

2019

	Note(s)	Amortised cost	Total
Trade and other payables	15	3,364,435	3,364,435
Finance lease obligations	13	13,050,728	13,050,728
		16,415,163	**16,415,163**

Capital risk management

The Authority's objective when managing capital (which includes reserves, working capital and cash and cash equivalents) is to safeguard its ability to continue as a going concern in order to perform its mandate. The Board is of the view that these objectives are being met. During the period ended 31 March 2019, the Authority did not have any borrowings. The Authority's operations are currently being sustained by the Government of Botswana.

Figures in Pula	2019

17. Financial instruments and risk management (continued)

Financial risk management

Overview

The Authority is exposed to the following risks from its use of financial instruments:

- Credit risk;
- Liquidity risk; and
- Market risk (currency risk and interest rate risk).

Credit risk

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

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 trade receivables. All its current operations are on a cash basis.

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

			2019
		Gross carrying amount	Amortised cost / fair value
Other receivables	11	231,195	231,195
Cash and cash equivalents	12	45,948,409	45,948,409
		58,781,170	**58,781,170**

Figures in Pula	2019

17. Financial instruments and risk management (continued)

Liquidity risk

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

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

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

2019

		Less than 1 year	2 to 5 years inclusive	Over 5 years	Total	Carrying amount
Non-current liabilities						
Finance lease liabilities		-	7,208,923	5,049,153	12,258,076	12,258,076
Current liabilities						
Other payables	13	4,252,083	-	-	4,252,083	4,252,083
Finance lease liabilities	13	1,269,635	-	-	1,269,635	1,269,365
Deferred income- specific projects		24,231,765	-	-	24,231,765	24,231,765
		29,753,483	-	-	**42,011,559**	**42,011,289**

Foreign currency risk

The Authority is exposed to foreign currency risk as a result of certain transactions which are denominated in foreign currencies. Transactions denominated in foreign currency were minimal in the period under review, limited to consultation and memebership subscriptions. The foreign currencies in which the Authority deals primarily are US Dollars and South African Rand.

The Authority does not have any significant foreign currency risk exposure. No amounts were receivable or payable that are denominated in foreign currency.

Figures in Pula	2019

17. Financial instruments and risk management (continued)

Interest rate risk

Fluctuations in interest rates impact on the value of lease liabilities, giving rise to interest rate risk. The debt of the Authority comprises of finance leases, which bear interest at floating interest rates.

Interest rate sensitivity analysis

The following sensitivity analysis has been prepared using a sensitivity rate which is used when reporting interest rate risk internally to key management personnel and represents management's assessment of the reasonably possible change in interest rates. All other variables remain constant. The sensitivity analysis includes only financial instruments exposed to interest rate risk which were recognised at the reporting date.

At March 31, 2019, if the interest rate (prime rate) had been 0.5% per annum- higher or lower during the period, with all other variables held constant, surplus for the year would have been P 67,636 lower or higher.

Figures in Pula	2019

18. Related parties

The Authority was established by the Medicines and Related Substances Act of 2013 and is therefore related to the Government of the Republic of business.

Relationships

Medicines Regulatory Board	Refer to page 12-15 for general information and list of the Medicines Regulatory Board.
Members of Key Management Board	Stephen Ghanie (Chief Executive Officer) Harold Kuvenga (Director: Finance and Administration) Sinah Selelo (Chief Technical Officer) Nkaelang Modutlwa (Director: Product Evaluation and Registration) Seima Dijeng (Director: Inspections and Licensing) Latelang Chakalisa (Corporate and Legal Counsel)
Main financier	Government of the Republic of Botswana

Related party balances

Amounts included in Other Payables regarding related parties	
Botswana Telecommunications Corporation - Telephone	19,869
Botswana Power Corporation - Electricity	22,665

Related party transactions

Capital grant received	
Government of the Republic of Botswana - assets transferred	527,968
Government of the Republic of Botswana - grant received	72,531,424
Transactions with other parastatals	
Botswana Telecommunications Corporation - Telephone	312,999
Botswana Power Corporation - Electricity	292,273

Sitting allowances

Medicines Regulatory Board	158,737
Compensation to key management	
Short-term employee benefits	3,438,259
Gratuity	1,234,544
Leave pay	370,531
	5,043,334

19. Comparative figures

No comparative figures have been presented as these are the first financial statements of the Authority. The Authority commenced operations in January 2018. The reporting period is therefore longer than a year.

Figures in Pula	Note(s)	2019 15 months
Revenue		
Grant received from the government of Botswana		41,175,100
Amortisation of deferred income		661,356
	3	**41,836,456**
Other operating income		
Other operational income	4	14,875
Operating expenses		
Amortisation and depreciation		(2,504,880)
Bank charges		(16,381)
Certification costs		(8,248)
Computer-related expenses		(530,905)
Consumables		(130,729)
Employee costs		(15,266,963)
Governance costs		(629,805)
Insurance		(77,599)
Motor vehicle expenses		(45,182)
Printing and stationery		(262,764)
Professional fees		(8,000)
Publicity and awareness		(998,646)
Repairs and maintenance		(174,664)
Security		(150,376)
Subscriptions		(291,789)
Telephone and fax		(459,615)
Training		(785,463)
Travel and accommodation		1,541,202
Utilities		(339,068)
		(24,222,279)
Operating surplus	5	**17,629,052**
Finance costs	6	(751,195)
Surplus for the year		**16,877,857**

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