LABORATORY TESTING SERVICES

The lab is responsible for the analysis of medicines and related substances as well as medical devices placed on the market to determine their fitness for purpose and verify manufacturer claims on their quality, efficacy and safety.

Testing and reporting of results as well as results validity are important outputs for a successful laboratory operation. The laboratory achieves this through implementation of a laboratory quality management system based on the principles of ISO/IEC 17025 and the WHO accreditation guidelines across three sections of microbiology, physiochemistry and medical devices analysis. The laboratory informs key decisions on products marketing.

PHARMACOVIGILANCE

According to WHO, Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem. The aims of PV are to enhance patient care and patient safety in relation to the use of medicines; and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicine.

Medicines are intended for treatment and management of diseases, however there are possibilities of occurrences of adverse drug reactions or side effects. An Adverse Drug Reaction is a harmful/toxic and unintended response which occurs at doses normally used in humans/animals for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. A side-effect is any effect caused by a drug other than the intended therapeutic effect, whether beneficial, neutral or harmful. The term 'side-effect' is often used interchangeably with 'ADR' although the former usually implies an effect that is less harmful, predictable and may not even require discontinuation of therapy

We monitor safety of medicines, medical devices and cosmetics by collecting, detecting and assessing adverse drug reactions that may occur while on treatment of any disease.
The public is encouraged to report all adverse drug reactions to Health care providers i.e Nurses, Doctors, Pharmacists, Dentists, Veterinary Doctors etc.

POST MARKETING SURVEILLANCE

Post Marketing Surveillance (PMS) is the practice of ensuring the quality of a medicine or medical device after it has been released on the market to ensure that quality is maintained as well as reduce sub-standard/falsified medicines in the market.

CLINICAL TRIALS CONTROL

Clinical trials are a systematic study in human beings or animals in order to establish the safety, efficacy and identify or verify the effects or adverse reactions of medicines.

Clinical trials involving the use of medicines that are conducted in Botswana are regulated in terms of sections 56 and 57 of the Medicines and Related Substance Act of 2013 and its regulations

PUBLIC EDUCATION AND STAKEHOLDER ENGAGEMENT

We value the contribution and participation of all key stakeholders in medicine regulations.

We continuously strive to improve public awareness and trust in the medical products and cosmetics regulatory system and establish Strategic Partnerships and Collaborations.
with key stakeholders.

The Public Education and Stakeholder Engagement unit is responsible for implementation of the stakeholder engagement plan initiatives that educate and empower different stakeholders on safe, quality and effective medicines, medical products and cosmetics and their regulation.

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Botswana Medicines Regulatory Authority

INTRODUCING
BOTSWANA MEDICINES REGULATORY AUTHORITY (BoMRA)

INTRODUCTION

The Botswana Medicines Regulatory Authority BoMRA was established through the Medicines and Related Substances Act of 2013. The MRSA authorizes BoMRA to perform functions given by the shareholder – The Government of Botswana.

The MRSA of 2013 replaced the repealed Drugs and Related Substances Act No. 18 of 1992 which was previously enforced by the Drug Regulation Unit (DRU) under the Ministry of Health and Wellness.BoMRA has taken over a combination of functions that were previously performed under the Ministry of Health and Wellness and the Ministry of Agricultural Development and Food Security.

MANDATE

The Authority's order is to:

- Ensure that all medicines and related substances used in Botswana are in conformity with established criteria of quality, safety and efficacy.
- Uphold standards for the regulatory functions value chain and ensure adherence to best practice
- Conduct tests and analysis of medicines and inspection of privately-owned laboratories to ensure good laboratory practice as the cornerstone of compliance.
- Ensure the safety of cosmetics and medical devices (that is, ascertaining that cosmetics and medical devices companies follow regulations to keep cosmetics and personal care products as safe as possible.

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.

VALUES

- Integrity
- Customer Focus
- Efficiency
- Team Work

OUR VALUE PROPOSITION

INDUSTRY : We enable the Industry to go to market with products that meet set standards of safety, quality and efficacy.

We protect the market from the effects of illegal international trade. (Imports/Exports)

PUBLIC: We promote well - being of the nation and encourage the use of safe and effective medical products and cosmetics.

We protect the public from harmful and substandard medical products and cosmetics.

We educate the public by providing information that will help it make informed choices regarding human and animal health products.

PRACTITIONERS: We provide unbiased information to practitioners and a platform for medical safety reporting.

LAW ENFORCEMENT: We enrich other law enforcement sectors by providing relevant technical support, information and evidence.

INTERNAL: We provide an enabling environment for High Performance, growth and opportunity to make a positive impact on customers and stakeholders served.

OUR SERVICES

PRODUCT REGISTRATION

The Department of Product Evaluation and Registration is responsible for reviewing applications submitted for registration of human and veterinary medicines (including complementary medicines for human and veterinary use), cosmetics and medical devices. This review is aimed at ensuring timely access to safe, high quality and effective medical products intended for marketing, sale and distribution in Botswana.

It is also responsible for the review of post registration amendments made to any registered medical product. The department maintains registers for all the approved products and these registers are accessible to the public. It also provides impartial and objective information to the public/stakeholders with regards to the registration process. The department develops guidelines and make them accessible to potential applicants to serve as guidance during the application process.

Registration Procedure

Interested applicants can submit their applications to BoMRA offices. The procedure is as follows;

- Medicine application dossiers are received, screened for completeness.
- The application is evaluated for quality, safety and efficacy. A detailed evaluation report is generated.
- Completed reports and recommendation are forwarded to the Registration Committee for consideration.
- The Committee's decision is communicated to the applicant.
- Products approved by the Committee are allocated a registration number and entered the Medicines Register

INSPECTIONS AND LICENSING OF PREMISES

This Department is responsible for verifying compliance of medicines supply chain in Botswana with both national and international requirements in the provision of safe, high efficacy and quality products.

Premises and outlets (e.g. pharmacies) that manufacture, store, distribute and dispense medicines are routinely inspected and licensed.Inspection and licensing services are conducted throughout the year depending on the level of compliance while license renewals are done annually. Only outlets that meet the set standards are issued with permits or licenses to operate.

IMPORT/EXPORTS CONTROL

The responsibility of the unit is to assess all import/export requests from registered importers/exporters to ensure that medicines meet importing and exporting country requirements. In issuing import and export permits the unit monitors the flow of habit-forming medicines into and out of Botswana to ensure that allocated quotas are not exceeded in any calendar year. The unit also reports national consumption of these drugs to the International Narcotics Control Board (INCB).