Botswana Medicines Regulatory Authority

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Table of Contents

Revision status sheet

Page	Changes made	Issue No	Process Owner (Title)	Initiated By (Name)	Reviewed By (Name)	Date
	Changed the document title from "GMP reliance policy" to "Guideline for Good Recognition and Reliance Practices."	1.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	31/03/2026
	3.1.2 Added Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement. 3.1.3 Replaced Stringent Regulatory Authority with the WHO-listed Authority 3.1.4 Updated the definition of ZAZIBONA 1.2 removed as it was already provided for in the conclusion	1.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	31/03/2026
	Removal of recognition on Regulatory authorities that participate in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S). This was part of the SRA definition. Expanded the reliance criteria	1.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	31/03/2026

	Addition of number of assessment cycles 4.2.2 revised to expand the recognition criteria 5.0- The review timeline revised to align with the Authority document review timeline 6.0- References updated current WHO guidance	1.0	Manager – Inspections and Licensing	Raymond Manikisa	Maikaego N. Moreri	31/03/2026

1. Preamble

The Botswana Medicines Regulatory Authority (BoMRA) was established through the Medicines and Related Substances Act of 2013 and continues to operate under provisions of the Medicines and Related Substances Act, 2025. The Act provides for the regulation of medicines, medical devices, and cosmetics to protect and promote public and animal health by ensuring their quality, safety, and efficacy.

2. Purpose

2.1 This guideline establishes the criteria, principles, and processes under which the Authority may recognise and/or rely upon the regulatory decisions, assessments, or inspections conducted by other National Regulatory Authorities (NRAs) or recognised international organisations.

2.2 The objective of this guideline is to enhance regulatory efficiency, optimize resource utilisation, avoid unnecessary duplication of regulatory activities, and facilitate timely access to quality, safe, and efficacious medical products.

3. Scope

3.1 This guideline applies to foreign-based manufacturers seeking Good Manufacturing Practice (GMP) compliance recognition by BoMRA.

3.2 The guideline outlines the mechanisms and procedures for implementation of reliance pathways, including the submission, review, and evaluation of GMP inspection information from recognized authorities.

3.3 It further provides guidance to manufacturers on:

a) The applicable reliance pathways for GMP inspection requests;
b) The documentation requirements for reliance-based assessments; and
c) Their responsibilities in facilitating timely and complete information sharing with the Authority.

3.4 This guideline shall be read in conjunction with the Guideline for Good Manufacturing Practice- ***BOMRA/IL/IL/P08/G01*** and other applicable BoMRA regulatory instruments.

4. Laws, Regulations, Policies and Guidelines Applied

4.1 These guidelines were developed using principles from the following:

a) Medicines and Related Substances Act, 2025, (MRSA)
b) Medicines and Related Substances Regulations, 2019
c) WHO current Good Manufacturing Practice (cGMP) guidelines

4.2 Legal Considerations

4.2.1 *MRSA 2025, Section 7 (a)(i): The Authority shall ensure that all regulated products manufactured in, imported into, or exported from, Botswana are registered and conform to established criteria of quality, safety and efficacy.*

4.2.2 *MRSA 2025, Section 7 (ii): The personnel, premises and practices employed to manufacture, promote, procure, store, distribute and sell regulated products comply with defined codes of practice and other requirements*

4.2.3 *MRSA 2025, Section 7 (a)(iii): The Authority shall ensure implementation of risk-based approaches in prioritising regulatory activities or decisions and develop and publish risk assessment tools and matrices.*

4.2.4 *MRSA 2025, Section 7 (e); The Authority shall ensure to inspect or cause to be inspected, all manufacturing premises, exporters, importers, wholesalers, distributors, clinics and hospital pharmacies, retail pharmacies, dispensaries and other outlets where medical products are dispensed or stored, for compliance with good practice.*

4.2.5 *MRSA 2025, Section 7 (j): Inspect foreign manufacturing premises, clinical research organisations, and testing premises seeking marketing authorisations, and testing premises seeking marketing authorisation for their products, for compliance with good manufacturing practices.*

4.2.6 *MRSA 2025, Section 7 (m): The Authority shall collaborate with other national, regional and international institutions on regulated products*

4.2.7 *MRSA 2025, Section 35 (3): The Authority shall, in considering the market authorisation application consider whether;*

a) The availability of the regulated product is in the public interest
b) The regulated product is safe, of acceptable quality, efficacious or acceptable performance
c) The premises and manufacturing operation comply with prescribed good manufacturing practices or quality assurance requirements
d) The product complies with any other prescribed requirements

4.2.8 *MRSA 2025, Section 55 (1); A person issued with a clinical trial authorisation under this part may manufacture, assemble, import or export any investigation product in compliance with the good manufacturing practices and international quality standards*

4.2.9 *MRSA 2025, section 58 (1); A person shall not manufacture, sell, supply, export, import, distribute, dispense or store a regulated product unless he or she is authorised or licensed by the Authority in accordance with good manufacturing practices and international quality standards*

4.2.10 *MRSA 2025, section 58 (2); A person who wishes to apply for an authorisation or licence under subsection (1) shall apply to the Authority in such form and manner and upon payment of such a fee as prescribed.*

4.2.11 *MRSA 2025, section 58 (7)(a); The Authority shall carry out necessary inspections to verify compliance with prescribed requirements and standards of good practice.*

4.2.12 *MRSA 2025, Section 109 (1): The Authority may make or adopt regulatory decisions based on reports, information or decisions made by another regulatory authority or trusted institution in reaching in own decisions.*

4.2.13 *MRSA 2025, Section 109 (2): The Authority may enter into mutual agreements, mutual recognitions with other regulatory authorities for the purposes of facilitating performance and regulatory decision making.*

5. Definitions and Abbreviations

5.1 Definitions

5.1.1 **Reliance** - The act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information derived from others.

5.1.2 **Recognition** - The acceptance of the regulatory decision of another regulator or trusted institution. Recognition is based on evidence of conformity that the regulatory requirements of the reference regulatory authority is sufficient to meet the regulatory requirements of BoMRA. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.

5.1.3 **WHO Listed Authority** - is a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking (GBT) and a performance evaluation process.

5.1.4 **ZAZIBONA** - a collaborative medicines registration initiative in Southern Africa focusing on dossier assessments and current Good Manufacturing Practice (cGMP) inspections

5.2 Abbreviations

5.2.1 **APQR** - Annual product quality review
5.2.2 **AMA** - African Medicines Agency
5.2.3 **BoMRA** - Botswana Medicines Regulatory Authority
5.2.4 **CAPA** - Corrective Actions and Preventative Actions
5.2.5 **cGMP** – current Good Manufacturing Practices
5.2.6 **MRSA –** Medicines and related substances act, 2025
5.2.7 **SADC** - Southern African Development Community
5.2.8 **WHO** – World Health Organization
5.2.9 **WHO GBT-** WHO Global Benchmarking Tool
5.2.10 **WLA**- WHO Listed Authority

6. Criteria for Recognition and/or Reliance

6.1 General

6.1.1 GMP inspections are conducted to verify that manufacturing operations comply with the approved marketing authorisation and WHO GMP requirements, ensuring the consistent production and supply of quality, safe, and efficacious medical products.

6.1.2 The Authority may apply reliance principles to support risk-based regulatory decision making and reduce duplication of inspection, where sufficient assurance of GMP compliance has been demonstrated.

6.1.3 Reliance shall be applied in a manner that ensures:

a) Maintenance of regulatory sovereignty and accountability

b) Protection of public and animal health;

c) Transparency, consistency, traceability of decisions; and

d) Efficient use of regulatory resources

6.1.4 In determining the applicability of reliance or recognition, the Authority shall consider:

a) Legal and Regulatory Framework

i. Availability of legal provisions enabling reliance

ii. Existence of confidentiality arrangements or Memoranda of Understanding (MoUs)

iii. Compatibility of regulatory frameworks between BoMRA and the reference authority.

b) Regulatory Authority Maturity

i. Preferably, WHO GBT Maturity Level 3 and above.

ii. Participation in recognised regional, continental and international regulatory networks (e.g., ZAZIBONA, AMA, WLA frameworks)

6.2 Reliance

6.2.1 BoMRA may rely on GMP inspections conducted by recognised regulatory authorities for the same manufacturing site, manufacturing block, production line, and dosage form, provided that the inspection scope is directly relevant to the product and manufacturing process under assessment. This reliance is unilateral and is implemented through desk assessment of inspection reports issued by:

a) WHO-Listed Authorities as published and periodically updated by the WHO, including any subsequent revisions

b) Regulatory authorities within the SADC region (i.e., South Africa Health Products Regulatory Authority, Medicines Control Authority of Zimbabwe, Zambia Medicines Regulatory Authority, and Tanzania Medicines and Medical Devices Authority), including inspection outcomes arising from recognised mechanisms such as the WHO Prequalification Programme and the ZAZIBONA initiative.

c) Other regulatory authorities e.g. Ghana FDA

6.2.2 The manufacturer shall provide complete, accurate, and unredacted documentation to support the desk assessment. This shall include, but is not limited to:

a) Inspection reports issued by recognised regulatory authorities.

b) Reviewed CAPA plans and evidence of implementation.

c) Valid GMP certificates.

d) Annual Product Quality Review (APQR) reports; and

e) Relevant batch manufacturing and packaging records.

This list is indicative and not exhaustive. The Authority may request additional information where necessary.

6.2.3 Notwithstanding the above, BoMRA reserves the right to determine the appropriate inspection modality, including the requirement for an on-site or remote (virtual) inspection, based on risk assessment.

6.2.4 Manufacturing facilities located within WLA jurisdictions may be considered for continued reliance through desk assessment, provided that:

a) A valid GMP certificate is maintained

b) Routine inspections are conducted by the WLA within an acceptable timeframe (generally not exceeding three (3) to four (4) years.

c) There is no evidence of non-compliance, regulatory action, or product quality concerns

6.2.5 Manufacturing facilities inspected and approved by recognised SADC regulatory authorities and other authorities may be considered for pre-approval and routine/approval renewal through desk assessment, provided that:

a) The inspection and approval are not older than two (2) years; and

6.2.6 The scope of inspection covers the product under evaluation.

6.2.7 The validity of GMP clearance granted through desk assessment shall not exceed the validity period of the referenced GMP certificate or two (2) years, whichever is shorter, unless otherwise justified based on risk.

6.2.8 For manufacturing facilities located outside WLA jurisdictions, reliance shall be limited to a maximum of two (2) consecutive cycles. Thereafter, an on-site inspection shall be conducted.

6.2.9 Reliance decisions shall be documented, justified, and retained to ensure traceability.

6.2.10 Reliance shall not be applied where:

a) The inspection scope is not relevant to the product under assessment
b) There are unresolved critical or major deficiencies
c) Documentation is incomplete, unreliable, or redacted
d) There are concerns regarding data integrity,
e) There is evidence of significant regulatory action, product recalls, or quality defects.

6.3 Recognition

6.3.1 The Authority recognises, on a unilateral basis, GMP inspection outcomes and regulatory decisions from the following bodies:

a) WHO Prequalification Programme based on its global mandate, application of harmonised WHO GMP standards, and transparency of inspection outcomes.

b) Regional and continental collaborative initiatives such as ZAZIBONA and AMA based on the Authority's participation in joint assessments and reliance on shared regulatory outputs.

6.3.2 Facilities inspected and approved through the above mechanisms may be considered for GMP approval through recognition and reliance pathways, and may not routinely require an onsite inspection, provided that;

a) The scope of inspection is relevant to the product, manufacturing site and process under evaluation

b) The inspection outcome is current and demonstrates an acceptable level of GMP compliance

c) There is no evidence of significant non-compliance, regulatory action, or product quality concerns.

6.3.3 Recognition may form the basis for reliance and shall be operationalised through regulatory assessment in accordance with Section 6.2

6.3.4 Recognition does not preclude the Authority from conducting further assessment or inspection where deemed necessary based on risk assessment.

7. References

7.1 WHO Good reliance practices in regulatory decision-making for medical products: high-level principles and considerations – WHO TRS 1033, 2021, Annex 10

7.2 WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions- WHO TRS 1010, 2018, Annex 9