Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

Approved By:

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Director – Product Evaluations and Registration

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Revision status sheet

Page	Changes Made	Issue No.	Process Owner (Title)	Reviewer's name	Date
5.	Deletion of SRA countries since they are referred to as WHO-Listed	2.0	Dossier Assessor	Olivia Lekuni	11/11/2025
7	Addition of Responsibility and Authority, Records and References	2.0	Dossier Assessor	Olivia Lekuni	11/11/2025
4, 5	Inclusion of AMA Continental Listing procedure	2.0	Director – DPER	Olivia Lekuni	05/08/2025
1	Changed owner of process name	1.0	Director – DPER		01/09/2023
1.	Change in the title of the document to include 'recognition'	1.0	Director – DPER		01/09/2023
5	Section 3 revised to include definitions	1.0	Director – DPER		01/09/2023
5	Redefined the purpose and scope of the document	1.0	Director – DPER		01/09/2023
6-10	Rearranged presentation of information in the guideline and redefined countries BoMRA relies on	1.0	Director – DPER		01/09/2023
10	Inclusion of statement on variation application processing	1.0	Director – DPER		01/09/2023
7	Inclusion of WHO listed Authorities	1.0	Director – DPER		06/11/2023

1. Purpose

This guideline is intended to provide information and guidance to applicants/MA holder on the prescribed requirements and process to be followed, in cases where a new registration or variation application is submitted to BOMRA with the applicant/MA holders requesting a recognition/reliance-based evaluation.

2. Scope

This guideline covers reliance activities for medicines, vaccines, blood and blood products.

3. Definitions and Abbreviations

3.1 Definitions

The following definitions shall apply;

3.1.1 **Reliance** - The act whereby the BoMRA takes into account and gives significant weight to assessments performed by another NRA or trusted institution in reaching its own decision. BOMRA remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others.

3.1.2 **Recognition** - Recognition involves accepting the regulatory decision of another NRA or other trusted institution. It shall be based on evidence that the regulatory requirements of the reference authority **are equivalent to or sufficiently align with** those of BoMRA. Recognition may be unilateral or mutual and, in the latter case, may form the basis of a mutual recognition agreement.

3.1.3 **Reference regulatory authority** - A national, regional and international authority, or a trusted institution, whose regulatory work and or regulatory decisions are relied upon by a regulatory authority to inform its own regulatory decisions.

3.2 Abbreviations

The following abbreviations shall apply;

3.2.1 **AMA** – African Medicines Agency
3.2.2 **BOMRA** – Botswana Medicines Regulatory Authority
3.2.3 **CRP** – Collaborative Registration Procedure
3.2.4 **MA** – Market Authorization
3.2.5 **NRA** – National Regulatory Authority
3.2.6 **PQ** – Pre-qualification
3.2.7 **SRA** – Stringent Regulatory Authority
3.2.8 **WHO** – World Health Organisation
3.2.9 **WLA** - WHO Listed Authorities

4. Principles of Reliance-Based Evaluation

Reliance-based evaluation will be based on the following principles:

Reliance is applicable for both new registration and variation applications. The application submitted for registration to BoMRA should be the same as the most updated product on record at the **Reference regulatory authority**. Approval letters of variations post registration of the product from the relied authority should be provided with the variation applications.

4.1 BOMRA's Reference Regulatory Authorities

To qualify for a reliance evaluation pathway, an application must have been approved through:

a) PQ CRP

b) SRA/WLA CRP

c) Zazibona collaborative procedure

d) AMA Continental Listing Procedure

e) World Health Organization Pre-qualified products

f) The following ZAZIBONA member states:

1. Zambia,
2. Zimbabwe,
3. Tanzania,
4. Namibia
5. South Africa.

For f) above, the registrations from the year 2016 to date shall be considered to factor in alignment of regulatory requirements through the Zazibona collaborative registration procedure.
In case of variations, approvals from any year are acceptable for the above-mentioned authorities.

g) WHO Listed Authorities

4.2. Documentation Required For Reliance Process

All applications must be submitted in line with Guideline on Submission of Applications for Registration and BOMRA timelines - *BOMRA/ER/MD/P04/G01* and a cover letter to BOMRA indicating the pathway they are interested in. In addition, applicants are required to submit required documents in line with the pathway (see links above).

Additionally, all applicants should provide requirements as outlined in Section 1.10.5 of the CTD format with respect to the sameness of the API and FPP information.

4.3 Review Process

Based on the information received from the recognized authority, an abridged review shall be conducted by BoMRA. BoMRA still reserves the right to request more information or make an independent decision to do full review after factoring in all the necessary information provided.

5 Responsibility and Authority

5.1 Dossier Assessors are responsible for the effective implementation of this guideline.

5.2 Manager, Human Medicines is responsible for overseeing implementation and for review of this guideline.

5.4 The Records Supervisor is responsible for maintenance of Product Files and Outgoing Mail Log.

5.5 Director – Product Evaluation Registration is responsible for reviewing and validating the guideline.

6 Records

6.1 Dossier

6.2 DPER Metadata Log BOMRA/FA/RC/P01/F05

7 References

7.1 WHO-website

7.2 Zazibona website