Botswana Medicines Regulatory Authority

Approved By: _____

Mr Bathusi Kgosietsile
Director - Product Evaluation and Registration

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1. Purpose

This guideline is intended to provide information and guidance to applicants and/or Marketing Authorisation holders on prescribed requirements and the process to be followed, in cases where a new registration or variation application for a veterinary medicinal product is submitted to the Botswana Medicines Regulatory Authority (BoMRA) for consideration through either the recognition or reliance procedure.

2. Scope

This guideline is applicable to all veterinary medicinal products, and not limited to only pharmaceutical, immunological, and complementary veterinary medicinal products.

3. Definitions and Abbreviations

3.1 Definitions

The following definitions shall apply:

3.1.1. Recognition - The act whereby BoMRA accepts the regulatory decision of another NRA or other trusted institution. Recognition shall be 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 subject to a mutual recognition agreement.

3.1.2. Reference regulatory authority - A national, regional, international regulatory body considered a trusted institution, whose regulatory work and/or regulatory decisions are relied or recognised upon by BoMRA to inform its own regulatory decisions.

3.1.3. Reliance - The act whereby BoMRA considers and gives significant weight to the assessments performed by another NRA or trusted institution in reaching its own regulatory decision. The BoMRA remains independent, responsible, and accountable for its regulatory decision, even when it relies on the work, decisions, and information of others.

3.1.4. Trusted Institution - For the purpose of this guidance document, it means an institution whose regulatory requirements, processes and capacity are comparable and / or meet BoMRA's expectations, with respect to the international standards for regulating veterinary medicinal products.

3.2 Abbreviations

The following abbreviations shall apply;

3.2.1 **API**- Active Pharmaceutical Ingredient
3.2.2 **BOMRA -** Botswana Medicines Regulatory Authority
3.2.3 **CCVB –** Canadian Centre for Veterinary Biologics
3.2.4 **CFIA –** Canadian Food Inspection Agency
3.2.5 **cGMP -** current Good Manufacturing Practice
3.2.6 **CTD** - Common Technical Document
3.2.7 **FPP -** Finished Pharmaceutical Products
3.2.8 **ICH -** International Council on Cooperation
3.2.9 **JVPA**- Japan Veterinary Products Association
3.2.10 **MA -** Marketing Authorisation
3.2.11 **MCAZ -** Medicines Control Authority of Zimbabwe
3.2.12 **NMRC -** Namibian Medicines Regulatory Council
3.2.13 **VICH -** International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
3.2.14 **ZAMRA** - Zambian Medicines Regulatory Authority

4. Reliance Process

4.1 Principles of Reliance

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

a) 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 recognized by BoMRA.
b) Unredacted assessment reports should be provided to BoMRA. Where variations have been instituted to the original dossier post MA, evidence of variation submission, assessment and approval from the reference regulatory authority should be provided.

4.2 Reliance - based assessment/evaluation

4.2.1 For new applications, BoMRA will perform a verification process to ensure that the product application submitted for registration or variation at BoMRA is the same as the product assessed and approved by the reference regulatory authority recognized by BoMRA.

4.3 Documentation Required for Reliance Process

4.3.1 All applications must be compiled in accordance with relevant guidance documents and, structured and submitted in line with Guideline on Submission of Applications for Registration and BOMRA timelines ***BOMRA/ER/MD/P04/G01.***

NB. The application cover letter to BOMRA should indicate the preferred evaluation pathway. If the preferred pathway is the reliance procedure, an applicant is required

to arrange for submission or submit unredacted assessment reports from the reference regulatory authority, as well as evidence of variation submission, assessment and approval where applicable.

4.3.2 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.

5. Recognition Process

5.1 Principles of Recognition

5.1.1 The recognition 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 recognized by BoMRA. Regulatory decisions from the trusted institutions, i.e., reference regulatory authorities, national, regional, and international bodies shall be recognized.

5.2 Recognition - based assessment / evaluation

5.2.1 For new applications, BoMRA will perform an abbreviated assessment process to ensure that the product application complies with some country specific requirements where possible. BoMRA will recognize the regulatory decision by the reference regulatory authority.

5.3 Documentation Required for Reliance Process

5.3.1 All applications must be compiled in accordance with relevant guidance documents and, structured and submitted in line with Guideline on Submission of Applications for Registration and BOMRA timelines ***BOMRA/ER/MD/P04/G01.***

NB. The application cover letter to BOMRA should indicate the preferred evaluation pathway. If the preferred pathway is the recognition procedure, an applicant is required to submit evidence of approval / issuance of MA in the form of approval letters or registration / MA certificates issued by the reference regulatory authority.

6. Reference Regulatory Authority

In accordance with the BoMRA Policy, Recognition and /or reliance on Information from Regional and International Veterinary Medicinal Products (VMP) Regulatory Agencies, **BOMRA/ER/VET/Policy No.1** the VMP NRAs from the following listed countries shall be considered for implementation of the reliance/recognition procedures:

6.1 For Registration / MA decisions

6.1.1 Founding members of the VICH:

a) EU CVMP

b) USFDA-Centre for Veterinary Medicines/US Dept of Agric- Centre for Veterinary Biologicals
c) Japan's JVPA

6.1.2 Standing members of the VICH:

a) Australia – APVMA
b) New Zealand
c) Canada -Veterinary Drugs Directorate/CFIA/CCVB
d) South Africa – SAHPRA
e) EU Member States
f) UK Veterinary Medicines Directorate (VMD)

6.1.3 SADC member states NRAs:

The Authority will recognise only registrations/MA issued from January 2017, for the following SADC member states, because the stated NRAs had comparable technical requirements for registration of VMPs.

a) MCAZ
b) TMDA
c) ZAMRA
d) NMRC

In case of variations, approvals from any year are acceptable for the above-mentioned authorities.

6.1.4 WHO Listed NRAs (ML3/ ML4)

6.1.5 Any other agencies with established MOUs with the Authority

6.2 For cGMP compliance

6.2.1 BOMRA shall recognize the evidence of cGMP compliance issued by and/or following cGMP inspections conducted by the same NRAs in 6.1 above as well as, those recognized for human medicines:

a) SRAs;
b) WHO and ICH (for those facilities manufacturing both human and veterinary formulations);
c) ZAZIBONA Member states as outlined above;
d) Uganda AMRH RCORE designation for inspections; and
e) Countries participating in the Pharmaceutical Inspection Co-operation Scheme (PIC/s).

6.2.2 Only valid cGMP certificates or cGMP approval letters shall be considered.

7. Review Process

7.1 Based on the information received from the recognized reference regulatory authority, review processes as outlined in clause 4.2 and 5.2 above, shall be conducted by BoMRA.

7.2 BoMRA still reserves the right to request more information or even make an independent decision to do full review after factoring in all the necessary information provided.