Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

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1 Purpose

The guideline provides guidance on the format and content of the applications for renewal of registration of veterinary medicinal products. It is intended to assist the applicant in the preparation of the submission documentation for renewal of registration of VMPs.

2 Scope

This guideline applies only to applications for renewal of registration of all VMPs.

3 Abbreviations and Definitions

3.1 Abbreviations

The following abbreviations shall apply.

3.1.1 API:	Active Pharmaceutical Ingredient
3.1.2 APIMF:	Active Pharmaceutical Ingredient Master File
3.1.3 BoMRA:	Botswana Medicines Regulatory Authority
3.1.4 CEP:	Certification of suitability of European Pharmacopoeia monographs
3.1.5 CPP / CoPP:	Certificate of Pharmaceutical Product
3.1.6 CTD:	Common Technical Document
3.1.7 EMA:	European Medicines Agency
3.1.8 FPP:	Finished Pharmaceutical Product
3.1.9 GMP:	Good Manufacturing Practice
3.1.10 VICH:	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Veterinary Use

3.2 Definitions

The following definitions shall apply.

3.2.1 Renewal

The process of extending the period of validity of the Marketing Authorisation at the end of the stipulated 5 years from initial registration, or previous extension.

3.2.2 Applicant

The person or entity that applies for renewal of registration.

3.2.3 Benefit Risk balance

A concept used to make regulatory decisions which focus on minimising risks and optimising benefits throughout the lifecycle of a medicinal product. It will promote and protect animal and public health as well as enhance safety to the target animal, user, consumer and the environment by avoiding unnecessary risks. Benefit-Risk balance of a medicinal product can change and there is a need for re-assessment.

4. General Principles

4.1 As per the provisions set out in the Medicines and Related Substances Act (MRSA), Market Authorization holders shall submit renewal applications for all their veterinary medicinal products registered with Botswana Medicines Regulatory Authority, before the lapse of five (5) years from the date of registration of the product.

4.2 An application for the renewal of registration shall be submitted at least six (6) months before the expiry of the validity period of registration.

4.3 This guideline provides requirements of the Active Substance (AS) and Finished Product (FP) information that should be submitted to support applications for renewal of registration.

4.4 The renewal process includes verification of the product compliance with conditions of registration and current regulatory standards, assessment of the consistency of the quality of the registered Finished Product, and its manufacturing process(es) over the identified period, and acceptability of the product's benefit-risk-balance.

4.5 The content of this guideline should be read in conjunction with relevant information described in other existing VICH, EMA reference documents and guidelines, as well as, relevant BoMRA Registration Guideline.

5 Documents to be submitted

Applications should contain the documents listed below:

I. Full electronic dossier (CD) in CTD format (except for complementary VMPs) including the following, either as annexures or in the dossier:

   a. Cover letter

   b. Duly signed and dated application form *BOMRA/ER/VET/P10/F02* (e-copy).

   a. Evidence of current (within 3 years) GMP inspections for Active Substance and Finished Product manufacturers (including dates, National Regulatory Authority and outcome).
   b. All available certifications related to the product (CEP/CPQ, CPPs/COPPs and Registration certificates). Declaration for deregistration(s) and reasons, if applicable.
   c. Summary of Product Characteristics, Labelling and Package Leaflet: An approved version of the SmPC, Product Labelling (outer and inner labels) and Patient Information Leaflet in English.
   d. Quality Information Summary (Word and pdf versions)

   e. BoMRA Renewal Application Form (Word version) *BOMRA/ER/VET/P10/F02* - Completed as directed in Appendix I of this guideline

II. List of all post marketing authorisation / variation application submitted to the Authority post

Appendix 1: Guidance on completion of Renewal Form

This section provides guidance on completion of the renewal application form *BOMRA/ER/VET/P10/F02* which should be submitted with the renewal application.

To complete the Remarks section:

a) For variations, state the variation number, provide evidence as an attachment or refer to the section in the updated dossier with the requested information. Variation approvals for the pending variations should be stated and appended to the renewal's application form.

b) Provide any clarity on submitted information in this section. Each new version of documents should allow traceability to the registered dossier and approved variations.

Item	Registered dossier	Renewal Submission[1]	Remarks[2,3] *Guidance Notes for completion of form*
Product Registration number			*State all the BOV numbers including the different pack sizes*
INN Name, strength and pharmaceutical form			
Applicant (Company name, physical address and contact numbers)			
Manufacturer(s) of Active Substance(AS), with physical address			*Including unit and/or block numbers and contact numbers.* *List each AS separately.* *List separately if different steps are performed by different sites e.g. packaging, quality control.*
Number/version of each APIMF or CEP associated with the FP			*List separately for each AS*
			List separately for each AS. *FP manufacturer's API specifications should be provided in this section.* *Updated specifications should be provided in the updated dossier*
Retest period/shelf life and storage conditions of Active Substance(s)			*Updated stability data should be provided if proposed retest period/shelf life and storage conditions are different from approved shelf life.* *Provide outcome(s) on any commitments made at registration or variation.*

Product description (visual appearance)			*Describe form, colour, CCS etc*
Manufacturing site(s) of FP, with physical address			*Including unit and/or block numbers and contact numbers.* *List separately if different steps are performed by different sites e.g. packaging, quality control*
Batch size(s) of FP			*State different batchs sizes*
Primary and secondary packaging material(s) and pack size(s)			*Describe the construct, shape, dimension, and pack size of the CCS*
Shelf-life of FP and storage conditions			*Updated stability data should be provided if proposed shelf life and storage conditions are different from approved shelf life.* *Provide outcome(s) on any commitments made at registration or variation* *Shelf life and storage conditions should be in line with current regulatory requirements e.g. long-term stability data at 30 °C for products stored at room temperature*

[1] If there has been no update of the dossier then indicate "N/A" (not applicable).

[2]State variation number or provide evidence as attachment or refer to the section in the updated dossier with the requested information.

[3]Provide any clarity on submitted information in this section. Each new version of documents should allow traceability to the registered dossier and approved variations.