Botswana Medicines Regulatory Authority

Approved By:

Mr Bathusi Kgosietsile
Director - Product Evaluations and Registration

Date of Approval (DD/MM//YY)

This document is property of the Botswana Medicines Regulatory Authority (BOMRA). It is strictly confidential and may on no account be reproduced, copied, or divulged to any third party without prior authorization by BOMRA Management.

Revision status sheet

Page	Changes made	Issue No	Process owner's name	Date
10	Change of contact email from vetexemptions@bomra.co.bw to registration.vetmeds@bomra.co.bw	1.0	Director, Product Evaluation and Registration	28/05/2021
1	Change in the name of the approving Authority on the cover page	1.1	Director, Product Evaluation and Registration	16/10/2023
9	8.4(b)Inclusion of the turnaround times for processing of exemption applications	1.1	Director, Product Evaluation and Registration	16/10/2023

This document is property of the Botswana Medicines Regulatory Authority (BOMRA). It is strictly confidential and may on no account be reproduced, copied, or divulged to any third party without prior authorization by BOMRA Management.

Table of Contents

This document is property of the Botswana Medicines Regulatory Authority (BOMRA). It is strictly confidential and may on no account be reproduced, copied or divulged to any third party without prior authorization by BOMRA Management.

1. Purpose

The guideline is intended to facilitate access to essential veterinary medicinal products, in cases where there are no registered alternatives and to assist customers when preparing to submit the applications for exemption from registration of VMPs. It provides for the format and recommendations on the information to be included in the applications submitted to the Botswana Medicines Regulatory Authority (BoMRA).

2. Scope

This guideline is only applicable to applications for exemption from registration of conventional (pharmaceutical and immunological) and complementary veterinary medicinal products.

3. Abbreviations and Definitions

3.1 Abbreviations

For the purposes of this guidance document, the following abbreviations shall apply:

3.1.1 **BoMRA:** Botswana Medicines Regulatory Authority

3.1.2 **BVSC**: Botswana Veterinary Surgeons Council

3.1.3 **COE**: Code of Ethics for Veterinary Surgeons and Veterinary Paraprofessionals

3.1.4 **cGMP**: current Good Manufacturing Practices

3.1.5 **DPER**: Department of Product Evaluation and Registration

3.1.6 **DVS**: Department of Veterinary Services

3.1.7 **RMU**: Records Management Unit

3.1.8 **MRSA**: Medicines and Related Substances Act

3.1.9 **VMP(s)**: Veterinary Medicinal Product(s)

3.2 Definitions

For the purposes of this guidance document, the following definitions shall apply:

3.2.1 **Applicant:** a suitably qualified healthcare professional (Veterinary Surgeon/Pharmacist) requesting for the service.

3.2.2 **Motivation:** Justification for the application for exemption from registration of a VMP

3.2.3 **Patient-based Exemption** - An exemption applied for an individual patient.

3.2.4 **Wholesale-based Exemption** - An exemption applied for or granted to a wholesaler.

This document is property of the Botswana Medicines Regulatory Authority (BOMRA). It is strictly confidential and may on no account be reproduced, copied or divulged to any third party without prior authorization by BOMRA Management.

4. Introduction

In accordance with the provisions set out in Section 23 (1) of the Medicines and Related Substances Act (MRSA) of 2013, and the Medicines and Related Substances Regulations of 2019, No person shall import, export, manufacture, distribute, sell, promote, advertise, store, or dispense, any medicine, unless

a) the product is registered by the Authority, OR

b) the product is exempted from registration in terms of the Section 23, Subsection (3), (4) and (5) of the said Act.

Applicants are required to know that, importing, exporting, manufacturing, distributing, selling, promoting, advertising, storing, and/or dispensing of medicines, without the requisite approval from the Authority is an offence; Ref: MRSA, 2013 Section 23 (2), as read with any other laws of Botswana.

4.1 Objective

This guideline is intended to.

a) Enable BoMRA to effectively manage the processing of applications for exemptions from registration of VMPs,

b) Assist applicants in the preparation for the submission of applications for exemptions from registration of VMPs.

5. General Principles

The content of this guideline should be read in conjunction with the MRSA, 2013 and the Medicines and Related Substances Regulations of 2019 and other relevant guidelines.

6. General guidance on the process

6.1 The applicant should complete the relevant Exemption Application Form.

NB. All sections of the Exemption Application Form should be correctly and accurately completed. The customer should follow instructions given on the form.

6.2 Exemptions from registration of VMPs only applies in special circumstances where there are no registered alternatives. NB. The prescribing / requesting practitioner should have exhausted the provisions set out in section 2.12.8 of the Code of Ethics for Veterinary Surgeons and Veterinary Paraprofessionals (BVSC/COE).

6.3 In cases where there are registered alternatives, and the request/application is because the registered alternatives are not available for sale on the Botswana market, the applicant should provide evidence of such unavailability from the manufacturer, applicant or sole distributors of the registered alternatives, and the need of the unregistered product.

This document is property of the Botswana Medicines Regulatory Authority (BOMRA). It is strictly confidential and may on no account be reproduced, copied or divulged to any third party without prior authorization by BOMRA Management.

6.4 Exemption Applications can either be individual prescription based, wholesale dealer-based, veterinary hospital/clinic-based or clinical trial-based,

a) **Individual prescription-based exemption:** applications for exemption of medicine(s) on a prescription issued by a registered veterinary surgeon or veterinary paraprofessional for administration to an animal or group of animals for treatment of a clinical condition they have diagnosed following an appropriate clinical examination (as guided by the BVSC/COE). For this type of exemption applications, the applicant is the prescribing practitioner.

b) **Wholesale dealer-based exemption:** application for exemption of medicine(s) initiated by the wholesale dealer solely to ensure a continued supply of essential, required medicines in cases where there is no registered alternative, or where the registered alternatives are not available on the Botswana market. For this type of applications, the applicant is the suitably qualified person recognised/registered as the responsible person (pharmacist or veterinarian) supervising the operations of that business.

c) **Veterinary hospital/clinic-based exemption:** applications for exemption of medicine(s) initiated by a registered veterinary hospital/clinic for use (administration or dispensing) in an animal or group of animals under their care in the clinic or hospital. (as guided by the BVSC/COE). For this type of exemption applications, the applicant is the registered veterinary surgeon registered as the responsible person supervising the operations of that business.

d) **Clinical trial-based exemption:** applications for exemption of medicine(s) initiated by a recognised research institution or organisation solely for the purpose of conducting research work in animals. For this type of exemption applications, the applicant is the registered veterinary surgeon who is the responsible principal investigator or responsible for the welfare of the animal participants in that research or study.

6.5 The applicant should ensure that all the required, correct information is provided. This includes the supporting documents as outlined in section 8 below.

6.6 All documents should be in English.

6.7 In the event, an applicant intends to amend a discrepancy in an already issued exemption letter, the applicant should provide a letter detailing the requested amendment, and the original letter that was issued.

Note: All VMP exempted medicines will be imported by recognized registered/licensed importer (wholesaler).

7. Considerations for the different types of VMPs

7.1 Pharmaceutical VMPs

a) The VMP indicated for use in food producing animals should not contain any of the prohibited pharmaceutical active substances included in the Medicines and Related Substances (Prohibition of Use of Certain Medicines in Animals) Order 2020, SI 76 of 2020, and /or in any other local or international legislation.

This document is property of the Botswana Medicines Regulatory Authority (BOMRA). It is strictly confidential and may on no account be reproduced, copied or divulged to any third party without prior authorization by BOMRA Management.

b) Applications for exemption from registration of VMPs indicated for food producing animals and containing prohibited pharmaceutical active substances included in the SI 76 of 2020, and /or in any other local or international legislation shall not be authorised.

c) If one intends to import a product containing prohibited pharmaceutical active substances included in the SI 76 of 2020, and /or in any other local or international legislation, should seek clearance to do so, by the Director of Veterinary Services.

d) Any other VMP containing the prohibited active substances, if indicated in accordance with the exceptional provisions in the SI 76 of 2020, and not for use in food producing animals may be approved if the evidence provided is considered adequate to demonstrate so. NB. Any risks or consequential impact associated with extra label use of such VMP in food producing animals is the responsibility of the Animal Health practitioner.

7.2 Immunological or Biological VMPs

a) The VMP indicated for the treatment or prevention of a notifiable disease / pathogen for which there is a national control program, as stipulated by the Director of Veterinary Services from time to time, are not eligible for exemption from registration.

b) Applications for exemption from registration for immunological or biological VMPs that exist on the DVS list of notifiable diseases / pathogens for which there are national control programs shall not be authorised.

c) All other immunological VMPs not covered by the provisions in 7.2.1 and 7.2.2 above, may be approved only if the application for exemption is accompanied by a clearance / approval letter from the Director of Veterinary Services.

7.3 Complementary VMPs

a) Complete information of the active and non-active ingredients of complementary VMP should be provided.

b) The complementary VMPs should not contain any active substances prohibited for use in VMP formulations.

c) The responsibility is on the applicant to provide the required information and evidence to demonstrate that the complementary VMPs, commonly known as supplements, are:

   a) manufactured in accordance with acceptable cGMP standards.

   b) safe for use in the animal species indicated.

   c) of good/acceptable quality.

8. VMP Exemption Application Packages

A complete application should be submitted as follows:

8.1 Individual Prescription-based Exemptions:

This document is property of the Botswana Medicines Regulatory Authority (BOMRA). It is strictly confidential and may on no account be reproduced, copied or divulged to any third party without prior authorization by BOMRA Management.

a) Duly completed Application Form for Application for Exemption from Registration of VMPs - Individual Prescription (BOMRA/ER/VET/P03/F01)

b) A valid prescription

8.2 Wholesale dealer-based Exemptions:

a) Duly completed Application Form for Exemption from Registration of VMPs – Wholesale / Vet. Clinic / Research Institute (BOMRA/ER/VET/P03/F02)

b) Motivation: evidence of unavailability of registered alternatives and need for the unregistered product in Botswana Market

c) Product Label and package insert.

d) Evidence of registration in source country and registration in VICH founding or observer member states (SAHPRA included), the following NRAs of SADC member states (issued from January 2017): Zimbabwe, Tanzania, Zambia, and Namibia.

e) Valid cGMP Certificate from country of origin.

f) In the case of sterile injectable pharmaceutical and immunological VMPs, the certificate or evidence of cGMP compliance of the VMP manufacturer should be from an Stringent Regulatory Authorities, ICH/VICH member states, members of PIC/s, WHO (for those facilities manufacturing both human and veterinary formulations), SADC member states stated above, and Uganda (AMRH RCORE designation for inspections) If the sterile product applied for, is manufactured by the manufacturing site that already exist on the Veterinary Medicines Register, or that has been exempted before, a cGMP certificate will be waived.

g) Proof of payment

8.3 Veterinary Hospital/Clinic-based Exemptions:

a) As provided for wholesale dealer-based exemptions

8.4 Clinical Trials-based Exemptions:

a) Duly completed Application Form for Exemption from Registration of VMPs – Wholesale / Vet. Clinic / Research Institute (BOMRA/ER/VET/P03/F02)

b) Evidence of approval of the study using a VMP by the relevant Authorities (BoMRA and DVS)

c) Label and package insert of the Investigational VMP.

d) Investigator's brochure or SmPC of the reference product

e) cGMP certificate of the manufacturer, where applicable

f) proof of payment

NOTE:

This document is property of the Botswana Medicines Regulatory Authority (BOMRA). It is strictly confidential and may on no account be reproduced, copied or divulged to any third party without prior authorization by BOMRA Management.

a) The provisions of section 7 above, should be observed for all the types of VMP exemption applications. Necessary documents should be appended to the application packages defined above, e.g., DVS clearance/approval letter for Immunological VMPs and pharmaceutical VMPs containing prohibited substances.

b) The turnaround time for processing of an exemption application is 48 working hours.

c) If an applicant is requested to submit/provide additional information, a response should be provided within 48 hours from the time sending/receipt of communication from the Authority.

d) If no response is submitted, or the Applicant failed to adequately resolve the issues communicated within the stipulated timeline, the application will be recommended for rejection unless motivation for extension is provided, which should not be for a period > than 10 working days.

9. Validity of VMP Exemption Letters

9.1 All VMP Exemption Letters are valid for the quantity for which they are approved, and for 6 months from date of issue; validity of import permits ref: MRSA, 2013 Section 50 subsection 2.

9.2 The only exception is for Individual Prescription-based Exemptions, where the Exemption Letters are valid for the quantity for which they are approved as guided by the validity of a prescription, ref: MRSA, 2013 Section 40, Subsection 1 (as read with MRSR, 2019 section 40 (1)) and 2, which specifies the following:

a) A prescription for a Schedule 1A, Schedule 1B or Schedule 1C medicine is valid for only thirty days and shall not be dispensed more than once in succession.

NB. All Schedule 1- 4 VMPs will follow this provision.

b) A prescription for a Schedule 2 medicine may be repeated a maximum of six times and is valid, for initial dispensing, for a period of three months from the date of prescription.

NB. All veterinary medicinal products scheduled as POM, VPS and GSM will follow this provision.

10. Payments

10.1 In accordance with the SI 163 of 2019, Schedule 5, the applicable application fees are as follows:

a) Individual prescription-based exemptions: Free

b) Wholesale dealer-based exemptions: P350 per medicine

c) Veterinary hospital/clinic-based exemptions: P50 per medicine

d) Clinical Trials-based exemptions: P150 per medicine

This document is property of the Botswana Medicines Regulatory Authority (BOMRA). It is strictly confidential and may on no account be reproduced, copied or divulged to any third party without prior authorization by BOMRA Management.

10.2 All payments should be made at the bank, electronic transfer, or the BoMRA Accounts Office.

10.3 BOMRA Bank Details are as follows:

Account holder:	Botswana Medicines Regulatory Authority
Bank:	First National Bank (FNB)
Business Cheque Account no.:	62747456417
Branch:	Gaborone Industrial
Brach Code:	281667

10.4 A copy of the proof of payment should be submitted to BoMRA, together with the Wholesale-based Exemption Application.

11. Submission of Exemption Applications

11.1 The applicant should email the fully completed application form and supporting documentation to BOMRA using the email address; vetexemptions@bomra.co.bw

11.2 The customer should make sure to use the correct email address for submission of their application to enable timely processing of their requests.

11.3 Where the customers are unable to email their application, they may submit at BoMRA's RMU. NB. Customers are strongly encouraged to submit their applications via email.

12. Handling of VMPs obtained through the Exemption Procedure.

12.1 All VMPs obtained through the exemption procedure should be kept in their original packaging material, and at storage conditions recommended on the label by the manufacturer and in accordance with good storage practices.

12.2 Just like any other registered or listed VMPs, the applicant is required to keep purchase, sales, and where applicable, usage records of exempted products in accordance with the legislation.

12.3 The applicants are required to monitor and report to BoMRA any quality defects, and adverse events (safety or efficacy related) for all exempted VMPs in their custody.

13 References for Lists of Prohibited Active Substances

13.1 Medicines and Related Substances (Prohibition of Use of Certain Medicines in Animals) Order 2020, SI 76 of 2020 and,

13.2 Other international regulations like:

a) EC Commission Regulation 37 of 2010

b) Council Directive 96/22/EC of 1996

c) Council Directive 96/23/EC of 1996

d) EU Register of Feed Additives pursuant to Regulation (EC) No 1831/2003

This document is property of the Botswana Medicines Regulatory Authority (BOMRA). It is strictly confidential and may on no account be reproduced, copied or divulged to any third party without prior authorization by BOMRA Management.