Botswana Medicines Regulatory Authority

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Date of Approval (DD/MM//YY)

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1. Preamble

1.1. Botswana Medicines Regulatory Authority (BOMRA) was established through an Act of Parliament, the Medicines and Related Substances Act of 2013. The Authority regulates the supply chain of medicines, medical devices, and cosmetics in Botswana to promote human and animal health to ensure their quality, safety and efficacy.

1.2. To achieve this, the Authority has developed a set of guidelines to provide guidance on the retailing of veterinary medicinal products (VMP) in Botswana.

2. Purpose

The purpose of these guidelines is:

2.1 To ensure that business operators are well informed on what should be presented to BOMRA to facilitate the license approval process.

2.2 To define categories of veterinary medicines and vaccines to be stored and dispensed by VMP retailers

2.3 To define the minimum requirements for operating a VMP retailer

2.4 To ensure proper storage and handling of veterinary medicinal products.

3. Laws, Regulations, Policies and Guidelines Applied

These guidelines were developed in accordance with the various laws, regulations, policies and guidelines governing veterinary medicinal products, practices and services. These guideline does not replace nor supersede any aspect as described in any one of the Acts or the Regulations within the Acts. The laws, regulations, policies and guidelines applied are listed below:

a) Medicines and Related Substances Act, 2013, and Medicines and Related Substances Regulations, 2019

b) Diseases of Animals Act

c) Veterinary Surgeons Act 2008

d) OIE Terrestrial Animal Health Code-28/06/2019 Chapter 6.10

e) WHO Good distribution practices for Pharmaceutical Products TRS 957 2010 Annex 5

f) WHO Good storage practices for pharmaceuticals TRS 908 2003, Annex 9

3.1 Legal Considerations

a) In terms of *MRSA 26 (1)* No person shall practice as a pharmacist or operate a pharmacy or a dispensary on any premises unless:

a) The person has applied for and been issued with a license in respect of the said premises for operating the pharmacy or dispensary.

b) The premises, in the case of a pharmacy, are under the continuous supervision of a pharmacist; and

c) In the case of a dispensary, the person is authorised in writing by the Director of Health Services or the Director of Veterinary Services as the case may be, to dispense.

b) A person who wishes to sell medicines shall apply to the Authority, in the prescribed form accompanied by such fee as may be prescribed.

c) A dispenser or user of veterinary medicinal products shall keep, in the prescribed form, records of all transactions or activities relating to the medicines they dispense (*Sec 29 (1) of the MRSA, 2013*).

4 Definitions

4.1 **Adverse Drug Reactions (ADR)** - noxious and unwanted reaction to drugs that occurs at a dose used in animals for diagnosis, treatment or prophylaxis.

4.2 **Authority**-means the Botswana Medicines Regulatory Authority established under section 3 of the MRSA 2013.

4.3 **Authorised Dispenser**- shall mean a registered Pharmacist and a Veterinary Paraprofessional as defined in the category authorised to dispense by the BVSC or any other paraprofessional or Veterinary Surgeon authorised in accordance with section 26 (1c) of the MRSA, 2013.

4.4 **Authorised Person**- means any person given the responsibility for ensuring the medicine requirements are in compliance with the laws and regulations in force in Botswana

4.5 **Authorised Prescriber**- shall mean a registered Veterinary Surgeon, a registered Veterinary Paraprofessional as defined in the category authorised to prescribe by the BVSC or any other registered paraprofessional authorised in accordance with section 39 of the MRSA, 2013.

4.6 **Counterfeit Product**-means a medicine, cosmetic, related substance that is fraudulently mislabelled with respect to identity and/or source. Both branded and generic products can be counterfeited, and counterfeit products may include products with correct ingredients, with the wrong ingredients, without active ingredients, with insufficient quantity of active ingredients or with fake packaging.

4.7 **Dispensary**- means any premises in which an authorised dispenser stores, handles, and dispenses medicine listed under these guidelines.

4.8 **Immunological Medicinal Veterinary Product** - A veterinary medicinal product with an immunological mode of action, i.e. it induces immunity to the active substance(s) contained in a product.

4.9 **Medicated feed**- means a premix and animal feeds

4.10 **Qualified Person**- means a person registered with the relevant professional body to undertake work or practise within a specific technical field or area meeting the minimum requirements in the guidelines

4.11 **Paraprofessional**- means a person other than a Veterinary surgeon authorised by the Veterinary Surgeon Council to carry out designated duties relating to veterinary medicine under the supervision of a veterinary surgeon

4.12 **Premix-** means a mixture of one or more active pharmaceutical substances, solely intended for mixing into animal food for production animals.

4.13 **Pharmacist**- a person registered as a Pharmacist under the Botswana Health Professions Act.

4.14 **Vaccine**- Includes all products designed to stimulate active immunisation of animals against disease, without regard to the type of microorganism or microbial component or toxin from which they may be derived or that they contain.

4.15 **Veterinary Medicinal Product**- means any product with approved claims to having a prophylactic, therapeutic or diagnostic effect or to alter physiological functions when administered or applied to an animal

4.16 **VMP Retailer**-a dispensary, pharmacy and general dealer that is licensed and approved by BoMRA to handle and sell veterinary medicinal products.

4.17 **Veterinary Surgeon**- a person registered as a Veterinary surgeon under the Veterinary Surgeons Act.

5 Abbreviations

5.1 **BHPC** - Botswana Health Professions Council

5.2 **BOMRA** - Botswana Medicines Regulatory Authority

5.3 **BVSC** - Botswana Veterinary Surgeons Council

5.4 **DVS** - Department of Veterinary Services

5.5 **EU** - European Union

5.6 **GSP** - Good Storage Practices

5.7 **GSM** - General Sales Medicine

5.8 **MRSA** - Medicines and Related Substances Act

5.9 **MRSR** - Medicines and Related Substances Regulations

5.10 **TRS** - Technical Report Series

5.11 **OIE** - Office International des Epizooties

5.12 **POM-V**- Prescription Only Veterinary Medicine

5.13 **VMP** - Veterinary Medicinal Products

5.14 **VPS** - Veterinary, Paraprofessional

5.15 **VPP-AH** - Veterinary Para-Professional- Animal Health

5.16 **WHO** - World Health Organization

6 Scope

These guidelines shall apply to VMP retailers approved by BOMRA and all persons aspiring to open a VMP retailer.

7 Categories of Veterinary Medicines

7.1 **Schedule 1A medicine**: a medicine which is highly addictive and therefore liable to abuse, subject to strict storage, dispensing, destruction and record-keeping requirements and may be dispensed only on written prescription, which prescription must be kept by the dispensing pharmacist or veterinary surgeon for a minimum of 5 years

7.2 **Schedule 1B medicine** - a medicine which is less liable to abuse than Schedule 1A and which must be kept under locked storage

7.3 **Schedule 1C medicine** - a medicine which is less liable to abuse and does not have strict storage requirements but is subject to normal storage requirements

7.4 **Schedule 1D medicine** - a medicines which are very low preparations of codeine containing products that are exempt from all controlled drug requirements

7.5 **Schedule 2 Veterinary Medicines (POM-V)**- a medicine, not containing narcotic or psychotropic substances which is dispensed under prescription by a registered veterinary surgeon or pharmacist, or by a veterinary surgeon from their own stock to treat animals under their care.

7.6 **Schedule 3 Veterinary Medicine (VPS)** – a veterinary medicine which may be sold without a prescription from a VMP retailer under the supervision of a veterinary surgeon or paraprofessional or under a written prescription from a pharmacy under the supervision of a registered Pharmacist

7.7 **Schedule 4 Veterinary Medicines (GSM)**- a medicine not containing narcotic or psychotropic substances which is sold without prescription in authorized premises. No prescription is required for these medicines. Dispensed by all qualified persons

8 Categories of Immunological Veterinary Medicinal Products (Vaccines)

8.1 **Schedule 2 Vaccines (POM-V)**- As defined in the guidelines for registration of immunological veterinary medicinal products. These vaccines shall be kept in a VMP retailer under the supervision of a registered Veterinary surgeon and Veterinary paraprofessional or in a pharmacy under the supervision of a registered Pharmacist. The Veterinary paraprofessional shall be under the direct supervision of a Veterinary Surgeon as defined in the code of ethics for Veterinary surgeons and veterinary paraprofessionals.

8.2 **Schedule 3 Vaccines (VPS)**– As defined in the guidelines for registration of immunological veterinary medicinal products. These vaccines shall be kept in a VMP retailer under the supervision of a registered Veterinary surgeon and a veterinary paraprofessional or in a pharmacy under the supervision of a registered Pharmacist. The veterinary paraprofessional shall be under the in-direct supervision of a Veterinary Surgeon as defined in the code of ethics for veterinary surgeons and veterinary paraprofessionals.

9 Application for Approval to Operate a VMP Retailer

For approval of license to sell veterinary medicinal products in Botswana as a retailer, the following documents shall be submitted.

9.1 Completed Application form (Licensing of VMP Operations) - (BOMRA/IL-IL-P02-F01

9.2 Copy of expiring license (for renewals and premises undertaking substantial modifications)

9.3 Declaration letter for continuous personal supervision.

a) The declaration form must be completed and signed by the Qualified or Authorised person as specified

9.4 Approved sketch/plan of the premises (for new facilities or approved premises undertaking substantial modifications)

a) The plan should be approved by BOMRA before partitioning and submission of application for licensing

9.5 Proof of payment

a) A prescribed fee of **P750.00** as set out in schedule 5 of the Medicines and Related Substances Regulations, 2019

b) Name of the premises should be provided as reference

9.6 Certified copy of identity card or passport of the Qualified person

9.7 Copy of the Veterinary Surgeons Council registration certificate and and letter of good standing not older than three (3) months

9.8 Copy of the BHPC certificate and Blue card (for Pharmacists)

10 Processing of the Applications

10.1 Applications shall be completed by qualified persons who reside in Botswana

10.2 Applications should be scanned and emailed to inspections@bomra.co.bw and copied to finance@bomra.co.bw.

10.3 Applications are to be accompanied by a valid proof of payment.

10.4 Hand delivered applications should be submitted at BoMRA, plot 112, International Finance Park, Gaborone**.** The applicant should verify proof of payment with the BoMRA Accounts office before submitting the application documents.

10.5 An application not accompanied by supporting documents shall be rejected. The applicant shall receive a rejection highlighting reasons for rejection.

11 Minimum Requirements for VMP Retailers

11.1 Organization and Management

11.1.1 Corporate Structure

a) The premises should be licensed in accordance with the trade act

b) Premises shall be operated under the continuous personal supervision of an Authorised/Qualified person.

c) The Qualified person's certificates and registration certificates from BVSC or BHPC should be displayed conspicuously in the premises.

d) The Qualified person's name should be displayed conspicuously at the dispensary.

11.1.2 Personnel and Training

a) Personnel handling and supervising the dispensing of veterinary medicinal products should be registered and qualified as follows,

i. Veterinary Surgeons

ii. Pharmacists

iii. Veterinary Paraprofessionals registered under the Veterinary Para-Professional Animal Health (VPP-AH) category.

b) The Qualified person shall communicate all post licensure notifications to the Authority.

c) When it is compulsory that the Qualified person be absent from the premises e.g. when sick, the following options may be adopted:

i. The services of a duly registered person may be engaged.

ii. The dispensary shall be closed and locked until the services of a registered person are obtained.

d) Any change in the Qualified person shall be communicated to the authority in writing within 30 days by management.

e) The qualified person shall also submit a letter of resignation before assuming responsibility anywhere else.

f) There should be written job descriptions for all employees involved in the sale of medicines which clearly define their roles and responsibilities.

g) Training of personnel involved in retailing activities should be based on written standard operating procedures (SOPs).

11.2 Premises

11.2.1 Layout

a) The structure of the building should be permanent with a fixed physical address and shall meet building codes.

b) The surfaces of the floor, walls, cabinets, shelves, and counters shall be made of impervious materials to ensure easy cleaning.

c) The dispensary shall be dry, well lit, temperature controlled and of sufficient dimensions to allow the products to be kept in a logical manner

d) Adequate space should be provided in the dispensary to ensure an efficient flow of work.

e) Precautions must be taken to prevent unauthorized persons from entering the dispensary.

11.2.2 Sanitation

a) The premises and its surroundings shall always be kept clean.

b) The premises shall be free from pests. Pest control measures shall be in place and implemented.

c) Covered waste-bin(s) shall always be available in the premises.

d) A hand washing basin with running water shall be provided in the premises for washing hands.

e) The toilet facilities should be well designed, clean and not used for excess medicine storage.

f) Smoking, drinking and eating shall not be allowed in the premises and corresponding signs shall be displayed conspicuously.

11.2.3 Security and Fire Protection

a) Premises should be subjected to appropriate safety and security measures to prevent unauthorised entry.

b) The premises shall be equipped with an effective and suitable fire protection system which shall be regularly serviced.

11.3 General Medicine Storage

11.3.1 Dispensary

a) Medicines shall be stored in the dispensary and segregated from other products.

b) Prescription-only medicines shall be separated from non-prescription medicines and stored appropriately to prevent unauthorized access

c) Medicines shall be protected from adverse weather conditions (i.e. direct sunlight, dust and moisture).

d) All medicines shall be stored in accordance with the manufacturer's recommendations.

e) Temperature control and continuous temperature monitoring devices should be available, in use and records under regular review

f) Temperature monitoring devices should be calibrated at defined intervals and in accordance with the manufacturer's instructions.

g) The temperature in the dispensary should range between 15-25°C (WHO GSP, TRS 908, Annex 9).

h) All expired, damaged and recalled medicines shall be segregated from other stocks and stored in a place labelled accordingly.

i) Expired, damaged and recalled medicines shall not be sold to customers.

11.3.2 Storage of Thermolabile Medicines

a) VMP retailers dealing in thermolabile medicines should have procedures in place to confirm at receiving that cold chain was maintained during transportation and records retained.

b) A refrigerator for storage of thermo-labile medicines shall be installed in the dispensary and shall not be used for any other purposes.

c) All thermolabile medicines shall be stored in the refrigerator.

d) Temperature in the refrigerator shall be maintained between 2 and 8°c and must not be frozen. A continuous temperature monitoring device shall be used to monitor the temperature and records retained.

11.4 Sale of Veterinary Medicinal Products and Vaccines

The following medicine categories may be sold at a VMP retailer.

11.4.1 Schedule 1A, 1B, 1C and 1D

a) Dispensing of the above schedules shall be by an authorised dispenser against a written prescription from a registered Veterinary Surgeon.

b) Validity of prescriptions shall be in accordance with section 40 of the MRSA, 2013

11.4.2 Schedule 2 Veterinary Medicines and Vaccines (POM-V)

a) Dispensing of schedule 2 medicines and vaccines shall be by an authorised dispenser through a written prescription from a registered Veterinary Surgeon or an authorised paraprofessional in accordance with section 39 (2) of the MRSA, 2013. An authorised dispenser shall not supply against a prescription that may not be genuine.

b) Validity of prescriptions shall be in accordance with section 40 of the MRSA, 2013 and section 37 (1) of the MRSR 2019.

c) Prescription records shall be retained in accordance with clause 11.7.2 (a) of these guidelines.

11.4.3 Schedule 3 Veterinary Medicines and Vaccines (VPS)

a) Dispensing of schedule 3 veterinary medicines and vaccines shall be by a registered Veterinary Paraprofessional as defined in the category authorised to dispense by the BVSC or a veterinary surgeon and a paraprofessional authorised in accordance with section 26 of the MRSA, 2013.

b) A registered pharmacist shall only dispense schedule 3 veterinary medicines and vaccines under a prescription from a registered Veterinary surgeon or an authorized paraprofessional in accordance with section 39 (2) of the MRSA, 2013.

11.4.4 Schedule 4 Veterinary Medicines (GSM)

a) Dispensing of schedule 4 veterinary medicines shall be without a prescription by a qualified person from a VMP retailer, pharmacy or licensed trader

Registered Pharmacists shall dispense schedules 1A,1B,1C,1D, 2 (POM-V) and 3 (VPS) veterinary medicines only under a prescription from an authorised prescriber.

11.5 Counterfeit Veterinary Medicines

A dispenser of veterinary medicines shall have in place, risk management plans to prevent circulation of counterfeit medicines. The plans shall include the following measures:

11.5.1 to prevent the sale and use of counterfeit veterinary medicinal products.

11.5.2 to address counterfeit veterinary medicinal products once detected on the market, and to regularly review risk management plans.

11.6 Storage and sale of Medicated feeds

11.6.1 All medicated feeds shall be stored in accordance with the manufacture's recommendations

11.6.2 Medicated feeds shall be stored separately from non-medicated feeds to prevent cross-contamination

11.6.3 Dispensing of medicated feeds shall be by an authorised dispenser supplied with a written prescription from an authorised prescriber

11.6.4 Medicated feeds shall not be used in animals for the purpose of promoting growth nor to increase yield.

11.6.5 Medicated feeds containing prohibited substances shall not be sold to customers.

11.7 Documentation

Written procedures and instructions should detail all activities relating to the sale or distribution of veterinary medicinal products. The instructions or procedures should be written in clear and unambiguous language and be readily available.

11.7.1 Standard Operating Procedures (SOPs)

The following SOPs should be available and implemented in the premises:

a) Good personal hygiene

   i. The procedure should cover the hygiene and clothing of personnel working in the premises

b) Cleaning of premises

   i. The procedure should detail the frequency of cleaning (floors, shelves), medicine spillages and detergents to be used.

c) Receipt and storage of medicines

   i. Procedure should cover the checking and recording of the following: batch numbers, expiry dates, supplier, quantity received and product integrity.

   ii. The procedure should also cover requirements of clause 11.3 of these guidelines.

d) Dispensing

   i. The procedure should cover the instructions given to the customer at the time of purchase. These instructions should include but not limited to the following: Dosage, Administration, target species, Indications for use, contra-indications, storage, withdrawal periods, proper disposal of un-used or expired products and highlight the risk of antimicrobial resistance and the need for responsible and prudent use.

e) Cold chain management (where thermolabile medicines are kept)

   i. The procedure should detail actions taken to address requirements of clause 11.3.2 of these guidelines.

f) Returned, rejected and expired medicines

   i. The procedure should detail the steps taken when the customer returns the pharmaceutical product. Where any doubt arises over the quality of a pharmaceutical product, it should not be considered suitable for reissue or resale. All returned, rejected and expired products shall be quarantined and records retained.

g) Handling product complaints

i. A complaint about the quality of the product or its packaging shall be returned to the supplier.

ii. The procedure should also detail the checking of similar batches against the complaint.

iii. Product quality problems or suspected counterfeit products should be documented, and the information shared with the Authority.

h) Product Recall

i. The procedure should detail the steps taken after a recall is initiated by the supplier or manufacturer.

ii. All customers to which the pharmaceutical products may have been distributed should be informed promptly and reasons given for the recall.

iii. Recalled medicines should be segregated from other pharmaceutical products.

i) Supplier Approval

i. VMP retailers should only acquire medicines from distributors licensed by the Authority. The supplier list should be updated as necessary and records retained.

j) Pest control.

i. The procedure should detail action taken to address clause 11.2.2(b) of the guidelines

k) Adverse drug reaction reporting

i. The procedure should detail the steps taken in the investigation and reporting of the adverse reactions to the Authority

11.7.2 Records

The following records shall be kept at the premises:

a) Prescription records must be kept by the authorised dispenser for minimum of five (5) years

b) Invoices detailing name of product, batch number, quantity and shelf life

c) Temperature records (records for 5 days prior to inspection shall be made available at the time of inspection (new premises) while historical records should be provided for routine/renewal inspections).

d) Expired/damaged medicines destruction certificates

e) Staff training records on SOPs

11.7.3 Reference Material

The qualified person should have access to the following minimum reference materials:

a) Medicines and Related Substances Act, 2013

b) Medicines and Related Substances Regulations, 2019

c) Veterinary surgeons act, 2008

d) Diseases of Animals act

e) Agrochemicals Act

f) Veterinary Medicines Register

g) MIMS Index of Veterinary Specialities (IVS)/IVS Desk Reference (IDR)

h) Relevant EU directives as advised by DVS from time to time. EU directives can be accessed online- https://eur-lex.europa.eu

12 Inspection and Licensing of Pharmaceutical Operations

12.1 All premises shall be inspected to assess compliance to the set guidelines before granting or re-granting a license or approval of a substantial modification.

12.2 Inspection of new premises shall be announced while for renewal premises may or may not be announced.

12.3 Compliant new premises will be inspected and licensed within four (4) weeks while renewals will be inspected and licensed within six (6) weeks.

12.4 Expedited license applications will be inspected and licensed within two (2) weeks. Applications for expedited license shall be accompanied by a prescribed fee of P10 000 as set out in schedule 5 of the MRSR, 2019.

12.5 All registered premises are subjected to at least one (1) inspection per year.

12.6 An application for license renewal shall be made at least three (3) months before the expiry of a license. The applicant shall refer to clause 8 of the guidelines for guidance.

13 Post Inspection Compliance

The following process shall apply to premises which do not comply with the set standards and guidelines:

13.1 A final report with non-conformances or deficiencies shall be issued to the applicant, giving them ten (10) working days to address non-conformances.

13.2 Whereby no action plan to address non-conformances has been submitted to the authority within the stipulated time in 13.1, the applicant shall be issued with a notice to annul the application for new applicants or facilities.

13.3 Lack of compliance to 13.1 and 13.2 for new applicants, shall result in the application being declared null and void. The applicant shall submit a new application and pay the prescribed re-inspection fee of P750.00 as per schedule 5 of the regulations.

13.4 A notice for suspension of the licence shall be issued in accordance with clause 15 of the guidelines for license holders who do not comply with clause 13.

14 Variation of License

14.1 A license holder shall apply to the Authority for variation of his or her license (MRSR 2019, sec 22(1))

14.2 The application shall be in the form- Application for Licensing of VMP Operations, accompanied by a fee as set out in schedule 5 of the MRSR, 2019

14.3 The Authority may approve the amendments and where the Authority does not approve, it shall inform the unsuccessful in writing, stating the reasons for the decision. (MRSR 2019, sec 22(3))

15 Suspension or Withdrawal of a License

15.1 Where the license holder does not meet the required standards and guidelines, the authority may suspend or withdraw a license. (MRSR 2019, sec 23(1)).

15.2 In general, the procedure for suspension and/or withdrawal of licence shall be guided by the applicable risk score profile of the facility as defined in the guideline for classification of deficiencies.

15.3 The Authority shall notify the license holder of the decision and may indicate the actions to be taken by the license holder and give the license holder seven days to respond (MRSR 2019, sec 23(2)).

15.4 The facility shall remain closed for the suspension duration of 30 days while action is being taken to address non-conformances.

15.5 Where a license is withdrawn the facility shall cease to operate. (MRSR 2019, sec 23(4)).

15.6 The license holder shall re-apply for a license and pay the prescribed fees as set out in schedule 5 of the MRSR, 2019.

16 Post licensure Notification

16.1 An application shall be made by the responsible pharmacist to inform the authority of any post licensure changes that are instituted in the premises.

17. Release of Customer Information

17.1 BOMRA Inspections and licensing department holds the information relating to customers in strict confidence as the terms and conditions of services provided. Except for information that the customer places in the public domain or when agreed between the Inspectorate and the customer, all other information is considered proprietary information and shall be regarded as confidential.

17.2 The inspection body shall seek authorization and clearance from the Chief Executive Officer, before any customer information is placed in the public domain or shared with a third party.

17.3 The inspection body shall notify the customer in advance, unless prohibited by law, when the inspection body is required, by law or authorized by contractual arrangements, to release confidential customer information.

17.4 Information about the customer obtained from other sources other than the customer (e.g. complainant), shall remain confidential between the inspection body and the customer. Identity of the source can only be shared with the customer if the source has agreed to it in writing.

17.5 The following information about the customer shall be shared through BoMRA public domains

1. Company Name (licensee and business name)
2. License number
3. Business address (physical address)
4. Type of business (authorized activity)
5. Premises contact details (email, telephone line)
6. RP Name
7. License validity

18 Annexure

18.1 Annexure 1 Application for Licensing of VMP Operations (BOMRA/IL-IL-P02-F01 Iss1)

18.2 Annexure 2 Declaration Form (BOMRA/IL-IL-P02-F03 Iss1)