

OPERATING A VETERINARY MEDICINAL PRODUCTS RETAILER



Purpose

The Purpose Of These Guidelines Is:

1. To ensure that business operators are well informed on what should be presented to BOMRA to facilitate the license approval process.
2. To define categories of veterinary medicines and vaccines to be stored and dispensed by VMP retailers
3. To define the minimum requirements for operating a VMP retailer
4. To ensure proper storage and handling of veterinary medicinal products.

Laws, Regulations, Policies and Guidelines Applied

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:

1. Medicines and Related Substances Act, 2013, and Medicines and Related Substances Regulations, 2019
2. Diseases of Animals Act
3. Veterinary Surgeons Act 2008
4. OIE Terrestrial Animal Health Code-28/06/2019 Chapter 6.10
5. WHO Good distribution practices for Pharmaceutical Products TRS 957 2010 Annex 5
6. WHO Good storage practices for pharmaceuticals TRS 908 2003, Annex 9

Legal Considerations

1. In terms of MRSA 26 (1) No person shall practice as a pharmacist or operate a pharmacy or a dispensary on any premises unless:
 - The person has applied for and been issued with a license in respect of the said premises for operating the pharmacy or dispensary.
 - 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.
2. 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).



Scope

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

Requirements for licensing to Operate a VMP Retailer
Minimum Requirements for VMP Retailers

Corporate Structure

The premises should be licensed in accordance with the trade act

Premises shall be operated under the continuous personal supervision of an Authorised/Qualified person duly registered with Botswana Veterinary Council or Botswana Health Professional Council.

Premises

Layout

1. The structure of the building should be permanent with a fixed physical address and shall meet building codes.
2. The surfaces of the floor, walls, cabinets, shelves, and counters shall be made of impervious materials to ensure easy cleaning.
3. Adequate space should be provided in the dispensary to ensure an efficient flow of work.
4. Precautions must be taken to prevent unauthorized persons from entering the dispensary.

General Medicine Storage

Dispensary

1. Medicines shall be stored in the dispensary and segregated from other products.
2. Prescription-only medicines shall be separated from non-prescription medicines and stored appropriately to prevent unauthorized access
3. Medicines shall be protected from adverse weather conditions (i.e. direct sunlight, dust and moisture).
4. All medicines shall be stored in accordance with the manufacturer's recommendations.



5. Temperature control and continuous temperature monitoring devices should be available, in use and records under regular review
6. The temperature in the dispensary should range between 15-25oC (WHO GSP, TRS 908, Annex 9).
7. Temperature monitoring devices should be calibrated at defined intervals and in accordance with the manufacturer's instructions.

Storage of Thermolabile Medicines

1. A refrigerator for storage of thermo-labile medicines shall be installed in the dispensary and shall not be used for any other purposes.
2. All thermolabile medicines shall be stored in the refrigerator.
3. Temperature in the refrigerator shall be maintained between 2 and 8oc.
4. A continuous temperature monitoring device shall be used to monitor the temperature and records retained.

Sale of Veterinary Medicinal Products and Vaccines

1. The following medicine categories may be sold at a VMP retailer.
2. Over the counter veterinary medicines by Veterinary Technician, Veterinary Surgeon or Pharmacist (with a prescription from qualified person)
3. Vaccines to be stored under the supervision of a Veterinary Surgeon or Pharmacist

Storage and sale of Medicated feeds

1. All medicated feeds shall be stored in accordance with the manufacture's recommendations.
2. Medicated feeds shall be stored separately from non-medicated feeds to prevent cross-contamination.
3. Dispensing of medicated feeds shall be by an authorised dispenser supplied with a written prescription from an authorised prescriber.
4. Medicated feeds shall not be used in animals for the purpose of promoting growth nor to increase yield.
5. Medicated feeds containing prohibited substances shall not be sold to customers.

Documentation

Standard Operating Procedures (SOPs)

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



1. Good personal hygiene
2. Cleaning of premises
3. Receipt and storage of medicines
4. Dispensing
5. Cold chain management (where thermolabile medicines are kept)
6. Returned, rejected and expired medicines
7. Handling product complaints
8. Product Recall
9. Supplier Approval
10. Pest control.
11. Adverse drug reaction reporting

Records

The following records shall be kept at the premises:

1. Prescription records must be kept by the authorised dispenser for minimum of five (5) years
2. Invoices detailing name of product, batch number, quantity and shelf life
3. 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).
4. Expired/damaged medicines destruction certificates
5. Staff training records

Reference Material








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

1. Medicines and Related Substances Act, 2013
2. Medicines and Related Substances Regulations, 2019
3. Veterinary surgeons act, 2008
4. Diseases of Animals act
5. Agrochemicals Act
6. Veterinary Medicines Register
7. MIMS Index of Veterinary Specialities (IVS)/IVS Desk Reference (IDR)
8. Relevant EU directives as advised by DVS from time to time. EU directives can be accessed online- <https://eur-lex.europa.eu>





Promoting access to safe medicines

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