Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

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1 Purpose

This guideline is intended to facilitate access to essential veterinary medicinal products, in cases where there are no registered alternatives, or available formulations are not practically administrable in the intended animal. It also assists local professionals when preparing to submit the applications for authorization to import and/or use of compounded veterinary medicinal products (VMPs) in animals in Botswana.

2 Scope

This guideline is only applicable to applications for authorization to import and/or use compounded veterinary medicinal products in Botswana.

3 Definitions and abbreviations

3.1 Definitions

The following definitions shall apply;

3.1.1 **BOV/BV** – a unique identifier for every product registered or listed into the market of Botswana. It is assigned to approval number of the product by BoMRA, depending on the approval pathway; whether actual registration post scientific assessment of a dossier or listing respectively.

3.1.2 **Compounding** – in the context of **extemporaneous medicines** refers to the practice of preparing, mixing, assembling, packaging, or labeling medications tailored specifically to the needs of a patient, typically done at the point of care, such as in a pharmacy or veterinary clinic/hospital.

3.1.3 **Exemption process** - a process that allows certain medications to be sold or used in the market of Botswana without undergoing the full registration process with BoMRA. This process facilitates access to essential urgently needed medicines or medicines intended for uses like research or clinical trials.

3.1.4 **Master Formula –** a document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a manufactured product as well as the processing instructions, including the in-process controls.

3.1.5 **Pharmacopeia** - a legally binding collection of standards and quality specifications for medicines used in a country or region.

3.2 Abbreviations

The following abbreviations shall apply;

3.2.1 BoMRA – Botswana Medicines Regulatory Authority

3.2.2 CoPP – Certificate of Pharmaceutical Product

3.2.3 DCA – Drug Control Authority

3.2.4 ISO – International Organization for Standardization

3.2.5 MRSA – Medicines and Related Substances Act, 2013

3.2.6 RMU – Records Management Unit

3.2.7 HEPA – High Efficiency Particulate Air

3.2.8 SOP – Standard Operating Procedure

4. General Requirements

4.1 Introduction

In accordance with the provisions set out in the Medicines and Related Substances Act (MRSA), and its regulations, no person shall import, export, manufacture, distribute, sell, promote, advertise, store, or dispense, any compounded medicine, unless it is authorized by the Authority.

4.2 Objective

This guideline is intended to streamline the process for authorization of compounded veterinary medicinal products by BoMRA.

4.3 General Principles

The content of this guideline should be read in conjunction with the MRSA and its regulations. Applicants are encouraged to refer to the following documents for further guidance on regulatory matters relating to the manufacture or compounding as well as the use of compounded products:

a) USP Chapter 795 Pharmaceutical Compounding — Nonsterile Preparations,

b) USP Chapter 797 Pharmaceutical Compounding — Sterile Preparations,

c) Any other relevant standards

Key aspects of compounding extemporaneous medicines

1. **Personalization**:
   Medicines are customized according to a patient or group of animals' specific therapeutic needs—dosage, strength, dosage form, route of administration, or ingredient composition.

2. **Preparation on Demand**:
   The medicine is prepared as needed, rather than in advance, to address unique clinical requirements that commercially available products cannot fulfill.

3. **Customization of Dosage Forms**:
   Examples include:

   a. Liquids for patients unable to swallow tablets

   b. Creams or ointments for dermatological conditions

   c. Suspensions for pediatric or geriatric patients

   d. Adjusted dosages for unique patient groups, such as game animals.

4. **Specialized Ingredients**:
   Allows inclusion or exclusion of specific ingredients to avoid allergens, preservatives, or dyes, accommodating patient sensitivities or allergies.

5. **Compliance with Professional Standards**:
   Extemporaneous compounding must adhere to established international standards, such as:

   a. USP Chapter 795 Pharmaceutical Compounding — Nonsterile Preparations,
   b. USP Chapter 797 Pharmaceutical Compounding — Sterile Preparations,
   c. Any other relevant standards

6. **Limited Shelf-Life**:
   Extemporaneously compounded medicines generally have shorter shelf-life due to the absence of stability studies.

7. **Safety and Quality Assurance**:
   Facilities conducting compounding must maintain strict hygiene, proper documentation, and thorough record-keeping to ensure patient safety, medication efficacy, and regulatory compliance.

4.4 Inclusion/Exclusion Criteria

4.4.1 Inclusion Criteria

A compounded preparation will only be considered in cases where:

a) There are no registered or listed alternatives, or alternative options based on the cascading principles enshrined in the Code of Ethics for Veterinary Surgeons and Veterinary Paraprofessionals, section 2.12.8.

b) Where there are no suitable formulations from cGMP compliant facilities.

c) The available formulations: dosage form and/or strength are not practically possible for administration in the animal or group of animals at hand e.g., some game animals and compounding is done using registered/unregistered medicines/products/actives.

d) No hazardous/prohibited ingredients are used in the compounded formulations.

e) Compounding is performed by licensed/registered Pharmacists or Veterinarians from a licensed facility complying with established international standards. Reference: USP NF Chapter 797 for sterile products and USP NF Chapter 795 for non-sterile products.

f) There is evidence of sterilization of the products and their components for sterile formulations.

g) For all products, there is evidence of licensing and/or approval to compound medicines issued from the local competent Authority.

h) There is evidence of Authorization to export the compounded medicines.

i) The labeling information is compliant, if the compounded product is intended for export or imported into Botswana.

j) Compounded VMPs are only allowed for companion and game animals.

k) If compounded VMPs are imported, the importer is a licensed importer – a wholesale dealer or a veterinary surgeon licensed by BoMRA.

l) External compounding facilities are liable for inspection by BoMRA for compliance with good compounding practices.

4.4.2 Exclusion Criteria

A compounded preparation will not be considered in cases where:

a) The molecules and/or products are prohibited for use in animals in Botswana in accordance with the SI 50 of 2024, SI 103 of 1987 or any other legal instrument recognized in Botswana.

b) The molecules and/or products are intended for use in food-producing.

c) The molecules and/or products are intended for purposes of growth promotion or performance enhancement.

d) The products are intended for use in animals/patients NOT under the direct care of a registered veterinary surgeon.

e) The molecules and/or products are intended for purposes of import/export for general distribution or stocking for resale.

f) The molecules and/or products compounded were previously rejected, suspended, delisted or cancelled for quality or safety reasons.

4.5 General Requirements for Authorization of Compounded Veterinary Medicinal Products

4.5.1 The applicant should complete the relevant application form on BRIMS, Individual Prescription-based - **BOMRA/ER/VET/P03/F01**.

4.5.2 Compounded VMPs shall only be authorized for use if the product is deemed safe and suitable for the intended animal.

4.5.3 All submitted supporting documents should be written in English language.

4.5.4 The applicant should ensure that all the required, correct information is provided. This includes the following supporting documents:

a) A valid prescription for the compounded product, if it is for a specific patient.

b) Evidence of compliance with established compounding standards.

c) A product label for the compounded product should at the minimum contain;

i. Full name and address of the compounding facility
ii. Generic name of product, dosage form, strength
iii. Indication
iv. Method and route of administration
v. Batch number
vi. Pack size (Quantity)
vii. Compounding date
viii. Expiry Date
ix. Storage instructions e.g. store below 30°C, Protect from light.
x. Any special handling instructions and warnings

5. Validity of Compounded VMP Authorization Letters

5.1 All compounded VMPs authorization Letters are valid for the quantity for which they are approved, and for three (3) months from date of issue.

6. Payments

6.1 The applicable exemption application fees for authorization of compounded VMPs shall be as per the published fee schedule.

7. Handling of authorized compounded VMPs.

7.1 All compounded VMPs should be kept in their original packaging material, and at storage conditions recommended by the compounding facility and in accordance with good storage practices.

7.2 The applicants are required to keep all records in accordance with the legislation.

7.3 The applicants are required to monitor and report to the Authority any quality defects, and adverse events (safety or efficacy related) for all compounded VMPs.

8. Requirements for Good Compounding Practices

Extemporaneous compounding must adhere to established international standards, such as:

a. USP Chapter 795 Pharmaceutical Compounding — Nonsterile Preparations,

b. USP Chapter 797 Pharmaceutical Compounding — Sterile Preparations,

c. Any other relevant standards

8.1 Facilities/Premises

a) Compounding of VMPs should be conducted from licensed facilities/premises that comply with established standards of good compounding practices.

b) Compounding facilities/rooms must be separated from other rooms e.g. dispensary

c) The compounding facility should be designed to allow for;

1. Easy of cleaning and sterilisation where applicable
2. Protection of the integrity and the quality of the compounded product from external forces/factors e.g. light, pressure, water etc.
3. Prevention of mix-ups, contamination and / or cross contamination of products

d) A procedure for sterilizing the facility and equipment used for compounding should be in place.

e) Clean rooms for sterile products must be maintained in accordance with established clean room standards.

8.2 Equipment and Utilities

a) The equipment and utilities should be selected, located, designed, constructed and maintained to suit the operations to be carried out.

b) The installation and use of equipment and utilities should aim to minimize the risk of errors, contamination, cross-contamination, build-up of dust or dirt and, in general, any adverse effect on the quality of products.

c) The equipment used for compounding should be made of suitable materials i.e. non-reactive, non-corrosive material.

d) There should be adequate, suitably sized equipment for use during the compounding of VMPs.

e) All the equipment used in the facility should be maintained in good working order.

f) All measuring equipment should be calibrated routinely, and evidence of calibration of equipment should be maintained in accordance with established procedures.

g) All equipment should be maintained in a cleaned and/or sterilized state, if not in use, in accordance with established procedures. The procedures should be cognizant of the different nature of products: sterile, non-sterile, creams, ointments, etc.,

h) Where applicable, HVAC system can be used to control the particulate air of cleanrooms and anterooms where products are compounded.

i) Where applicable, the WATER system can be used to supply water of suitable / appropriate quality for the compounding of medicinal products. The scale of the system may depend on the production scale/need.

j) Appropriate qualification tests, and requalification should be done. Evidence of such should be maintained in accordance with established procedures.

8.3 Personnel

a) Compounding should be conducted by a registered Pharmacist/Veterinarian or paraprofessional under the direct supervision of the veterinary surgeon/pharmacist, with adequate knowledge, training and competency to perform compounding duties at the level at which they are involved.

b) The compounding professional should have regular training during their employment for the purpose of keeping up to date with any advancements or changes in compounding.

c) The person responsible for compounding should wear appropriate clean clothing during operations being carried out.

d) The compounding personnel should have a demonstrable knowledge of Good Compounding Practices (GCP).

e) Personnel involved in compounding should conduct regular competency assessments to determine whether they are following established procedures.

f) When compounding sterile products personnel must wear appropriate protective clothing including shoe covers, hair covers, face masks and sterile gloves.

8.4 Documentation/QMS

a) Senior management should assume responsibility for the Quality Management System, as well as the quality of the products compounded and released from their facility.

b) The Quality Management System should encompass the quality policy, organizational structure, procedures, processes, and resources. All parts of the quality management system should be adequately resourced and maintained.

c) All quality-related activities and procedures should be defined and documented manually or electronically.

d) A procedure for control of cross contamination, where multiple products are compounded in the same facility should be available for use by the compounding professional.

e) All compounding documents for every batch produced must be kept on site.

f) SOPs for sterilization of equipment, materials and preparations where applicable should be in place particularly for sterile compounding.

g) For compounding sterile products, a standard operating procedure for aseptic compounding and filling should be in place.

h) At each compounding facility, adequate documentation and records should be maintained.

8.5 Materials

a) Supplies

Supplies (e.g., beakers, utensils, needles, syringes, filters, and tubing sets) should be of suitable composition such that the surfaces that contact components are not reactive or sorptive.

b) Components

Compounding personnel must follow the facility's SOPs, which must address the selection, receipt, evaluation, handling, storage, and documentation of all components, including all ingredients and container closures.

8.6 Procedures

a) All ingredients used must be kept according to their manufacturers specifications observing the chemical compatibility charts if available.

b) For sterile compounding, all compounding procedures must adhere to strict aseptic techniques to maintain sterility.

c) Compounding must never be conducted concurrently with other manufacturing or dispensing activities.

d) Compounding of sterile products must not be conducted in the same space or equipment as non-sterile products unless results for sterilization of the equipment can be proven by microbiological test results.

e) A compounding record should be completed every time a preparation is compounded.

f) Every critical process such as weighing, measuring or mixing has to be verified to ensure that compounded preparation is being prepared consistently according to the expected quality standards.

g) For sterile preparations, evidence of sterilization for the container closure system (packaging) including other applicable components should be available.

h) Media fill studies should be conducted and records maintained for facilities using aseptic compounding methods.

8.7 Quality Assurance / Quality Control

a) A written procedure for conducting quality assurance/ quality control tests in the facility should be in place.

b) A comprehensive quality control program must be in place to monitor and control the compounding processes.

c) All compounding records and final checks should be reviewed for accuracy and conduct in the process.

d) Written procedures such as listing of ingredients, quantities, order of mixing or preparation and detailed description of compounding process should be available including the equipment as well as the container closure system.

e) Operation at each step of weighing and measuring of compounding process should be counter checked by the Responsible Person.

8.8 Complaints/Recalls

a) There must be a procedure for handling complaints and/or recalls for non-compliant or defective compounded product(s).

b) Adequate investigations should be conducted for errors, defects, complaints and other signs indicating quality problems to ensure that appropriate remedial action is taken.

c) When deficiencies about the product are potentially harmful to health, a recall should be initiated immediately and the relevant authority should be informed without delay.

d) Records of complaints and/or recalls should be maintained.

8.9 Self-Inspection

a) There should be written standard operating procedures and programmes for periodic self-inspections, quality audits and supplier audits.

b) The quality assurance system for personnel, premises, equipment, documentation, production, quality control, distribution of the compounded preparation, arrangements for dealing with complaints and outsourced activities, should be examined at regular intervals in order to verify their conformity as described in this Guide.

c) Areas to be covered by self-inspections must include but not be limited to; premises, personnel, equipment, maintenance and calibration, storage conditions of materials and finished products, production and in-process controls, quality control, documentation, change controls and deviations management, complaints and recalls, qualification and validation, cleaning procedures.

d) The outcomes of the self-inspection should be documented, including corrective actions and preventive actions.