Botswana Medicines Regulatory Authority

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1. Preamble

Botswana Medicine Regulatory Authority (BoMRA) was established through Act of Parliament; the Medicines and Related Substances Act of 2013. The Act provides for the regulation of medicines, medical devices, and cosmetics in Botswana to promote human and animal health by providing guarantees for quality, safety and efficacy of medicines and medicinal products throughout the supply chain. To achieve this goal, the Authority has undertaken to develop a set of guidelines and procedures to guide the distribution of pharmaceutical products.

These guidelines were developed to ensure that quality and integrity of pharmaceutical products is maintained during the different stages of the products' distribution cycle by various companies, institutions. The nature of the risks involved may generally, however, be the same as those in the manufacturing environment, e.g. mix-ups, contamination, and cross-contamination. There are thus aspects in distribution to which the principles of good manufacturing practice (GMP) should be applied. These include, but are not limited to, storage, distribution, transportation, packaging, labelling, documentation, and record keeping practices.

2. Laws, Regulations, Policies and Guidelines Applied

The guide was developed using principles from the following:

Medicines and Related Substances Act, 2013, (MRSA) and Regulations, 2019
WHO Technical Report Series, No. 957, 2010, (GDP)
WHO Technical Report Series No. 986 Annexure 2 (GMP main principles)
Botswana National Health Quality Standards for Hospitals

2.1. Legal Consideration

The conduct of any pharmaceutical operations in Botswana shall be through a license holder authorised by BOMRA. This include procuring, storing, dispensing, etc.
In terms of section 26 of the MRSA, 2013,

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
c. In the case of a dispensary, the person is authorised in writing by the Director of Health Services to dispense.

3. Definitions and Abbreviations

3.1. Definitions

For these guidelines, the following terms shall be defined as follows:
Authority: Means Botswana Medicines Regulatory Authority established under section 3 of MRSA 2013.
Authorised person: means a person recognised by the regulatory authority as having the responsibility for ensuring compliance with applicable laws and regulations for operating a pharmaceutical business
Counterfeit product: means medicine, cosmetic, related substance or a Veterinary Medicinal Products product 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.
Distributor: means any practice whose activities involve the handling, storing, or supplying of medicines for institutional pharmacies or dispensaries.
Educational Institution: means any university, college, technical college, training facility, or any other related institution where a qualification which complies with the requirements of a prescribed qualification contemplated in the Pharmacy Act can be obtained.
Export: means sending out a medicine, medical device or scheduled substance from the country or cause a medicine, medical device, or scheduled substance to be sent out of the country for purposes other than personal use.
Import: means to bring a medicine, medical device or scheduled substance into the country or cause a medicine, medical device, or scheduled substance to be brought into the country for purposes other than personal use.
Institutional Pharmacy: means a pharmacy on or off the premises of the medical facility which provides services only to the patients of the facility and provides a system of distributing medication based upon chart orders from the medical facility.
Good Manufacturing Practice: means part of quality management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use
Manufacture: means all operations involved in the preparation, processing, compounding, formulating, filling, refining, transformation, packaging, repackaging, and labelling of controlled drugs.

Medicine: any substance or mixture combination of substances manufactured, sold, or presented as suitable for use, in:

a. the diagnosis, treatment, alleviation, modification, prevention of diseases, illness, abnormal physical or mental condition or symptoms thereof or

b. restoring, correcting, or modifying any somatic or psychic or organic condition or

c. any substance, to the extent that it complies with (a) or

d. any substance used to manufacture medicine or is sold as a raw material, precursor chemical or intermediate

e. a complementary medicine; or a substance or mixture of substances declared by the Minister of Health, in consultation with the relevant Authority, by notice in the Gazette to be a medicine or a veterinary medicine or a complementary medicine

Pharmaceutical Operation: means any premises or activities which deal in research, manufacturing, marketing, advertising, dispensing, distribution, storage, or handling of medicines, or prohibited substances

Pharmacist: means a person registered as a pharmacist under the Botswana Health Professional Act

Designate: means someone officially given a particular role, in this case; that of a pharmacist.

3.2. Abbreviations

BOMRA means Botswana Medicines Regulatory Authority
BHPC means Botswana Health Professional Council
GMP means Good Manufacturing Practices
GDP means Good Distribution Practices
TRS means Technical Report Series
WHO means World Health Organization

4. Scope

These guidelines were developed to assist all institutions involved in dispensing of pharmaceutical products to patients. The guidelines are applicable to all pharmacies authorized to operate as institutional pharmacies institutional, both public and private.

They outline:

a. Responsibilities of the stakeholders involved in the distribution or sale of pharmaceutical products
b. Requirements for successful application and licensing of an institutional pharmacy.
c. Documentation necessary to maintain in the operation of an institutional pharmacy.

5. Requirements for operating a Pharmaceutical Operation

5.1. Application requirements and procedure

5.1.1 Applications for prospective pharmaceutical operations licence and license renewal shall be made by the authorised person (pharmacist or designate) and sent to the Chief Executive Officer, BoMRA.

5.1.2 Government owned facilities are exempted from paying the application fee.

5.1.3 All applications must be submitted to BoMRA at plot 112, International Finance Park, Gaborone by hand delivery, or email: inspections@bomra.co.bw.

5.1.4 The applicant shall submit the following.

a) A completed application form (Form 8)
b) A certified copy of the authorised person's registration certificate issued by BHPC
c) A certified copy of a valid Blue card of the authorised person
d) Certified copy of identity card or passport of the authorised person
e) Two references of the authorised person (New Operations)
f) A completed declaration of continuous supervision form
g) Proof of payment verified by the Accounts Office (facility name used as reference).

5.1.5 The applicants are advised to submit a detailed sketch plan of new premises to BoMRA for approval before partitioning.

5.1.6 Application for renewal of existing license shall be submitted three (3) months prior to license expiry.

5.1.7 Application for variation of licence shall be sent to BoMRA using the same application form in subsection (a) above.

5.2. Processing of application

5.2.1 Upon receipt as specified above, the application shall be assessed to verify whether the requirements have been fulfilled.

5.2.2 If the application meets all the prescribed requirements, the application checklist shall be verified by the receiving officer, stamped and applicant given a copy. The original documents will be filled accordingly.

5.2.3 An application will be rejected, and all documents sent back to the applicant if it does not meet the requirements specified above. The applicant shall receive a rejection form highlighting reasons for rejection of application.

5.2.4 BoMRA shall communicate via email or telephone to new operations within ten (10) working days after the submission of an application to schedule an inspection of the applied premises.

BoMRA will not send communication for facilities pending renewal of license. Inspection of these facilities shall be unannounced and conducted as per the annual inspection schedule.

5.2.5 The applicant shall address all pending issues highlighted on the rejection form within 10 working days and send back to the officer dealing with the application as a follow up. Beyond 10 days; the whole application shall be rendered void, prompting the applicant to start the whole process again.

6. Organization and management

6.1 The organization (hospital or clinic), to which the institution pharmacy belongs, must be licensed by the Ministry of Health Inspectorate.

6.2 There must be an organogram or organizational chart clearly indicating authority, responsibility, and interrelations of all personnel within the company structure.

6.3 The operations shall be conducted under the continuous personal supervision of a registered pharmacist/designate with an up to date (BHPC) registration (Blue Card).

6.4 There should be an appointed person at each dispensing point with defined authority and responsibility for implementation and maintenance of a quality system.

6.5 The responsibilities placed on the above-mentioned personnel should not be so extensive as to present any risk to product quality.

6.6 Copies of all relevant licenses and BHPC certificates of authorised person(s) shall be displayed conspicuously at the dispensary. All originals shall be made available to inspectors uponrequest.

6.7 The authorized person's name, qualifications and BHPC certificates shall be displayed conspicuously over the main entrance.

7. Personnel, training, and health

7.1. Whereby the facility has more than one (1) pharmacist, their BHPC certificates and Blue Cards shall be shared with the Authority.

7.2. All personnel in the pharmacy operations must have written employment contracts or job descriptions specific to their daily activities and these job descriptions shall be readily available.

7.3. All personnel involved in distribution activities should be trained in the requirements of GDP (Good Distribution Practices) and be capable of meeting these requirements.

7.4. All training, either initial or continuing must be assessable and a record or documented evidence of assessment be kept for all personnel

7.5. There should be suitably trained and adequate personnel at each dispensing point.

7.6. All personnel shall undergo medical examinations prior to employment and those involved in handling hazardous drugs shall undergo periodic medical exams.

7.7. Personnel dealing with special categories of products such as cytotoxic, infectious, or sensitizing should be given specific training and shall be assessed periodically

and record of assessment be maintained. Precautious measures should be taken to prevent exposure to pregnant and women of child-bearing age.

8. Premises and facilities

8.1 Layout

8.1.1 Premises shall be secured with burglar bars at door and windows and security personnel engaged to prevent or provide evidence of unauthorised entry.

8.1.2 There shall also be no unauthorised entry into the dispensary, preparation rooms and other storage areas. Signs restricting access should be displayed.

8.1.3 The design and layout of the pharmacy must permit a logical flow of work, and ensure effective cleaning and maintenance and must minimise the risk of errors, cross-contamination and anything else which would have an adverse effect on the quality of products.

8.1.4 The design of the premises must protect products from direct sunlight, rain, and extreme weather conditions.

8.1.5 Receiving and dispatch areas shall be segregated and clearly labelled as such. These areas must also protect products from extreme weather conditions.

8.1.6 Design of entrances, dispensing counters and doorways must permit ease of access for disabled persons.

8.1.7 Segregated areas shall be available for storage of flammable and explosive substances, highly toxic substances, and radioactive substances (where applicable).

8.1.8 Sufficient waiting area shall be provided, and it shall not be too close to the dispensing area.

8.2 General

8.2.1 There should be designated areas for rejected, returned, or recalled products. These areas must be clearly marked, and their access restricted to authorized personnel. The products and areas concerned should be appropriately identified.

8.2.2 Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of products, fluids, vaccines, bulk products, and non-drugs.

8.2.3 Good storage practices should be applicable where pharmaceutical products are stored throughout the distribution process.

8.2.4 Surfaces should be kept clean, dry, and maintained within acceptable temperature limit. Good housekeeping such as cleaning, sanitation and inspection shall be carried out as scheduled.

8.2.5 Materials and pharmaceutical products should be kept off the floor and suitably spaced to allow cleaning and inspection

8.2.6 Pharmaceutical products should be stored and handled in a manner that prevents contamination, mix-ups, and cross-contamination.

8.2.7 Premises should be free of pests and records shall be maintained to demonstrate the effectiveness of pest control program.

8.2.8 A system should be in place to ensure that pharmaceutical products due to expire first are sold and/or distributed first (FEFO). Where no expiry dates exist for the products, the FIFO principle should be applied

8.2.9 There should be sufficient lighting, ventilation, temperature control and monitoring in all storage areas. The optimal temperature range should be 15±2°C to 25±2°C.

8.2.10 There should be working computer with a dispensing system/program installed, telephone and/or fax.

8.2.11 Smoking, eating, and drinking shall be prohibited in all the storage areas and the signs shall be displayed.

8.3 Specific Storage

Storage conditions for pharmaceutical products should follow the manufacturers specification detailed on product labels.

8.3.1 Cold Chain

8.3.1.1 Refrigeration (fridges, freezers, and cold room) should be capable of maintaining the required temperature ranges and should be serviced as per the maintenance schedule. Service records shall be availed to inspectors.

8.3.1.2 Refrigeration equipment should be equipped with continuous temperature monitoring devices which shall be calibrated against certified, traceable reference standard at least annually. And such record of calibration shall be availed to inspectors.

8.3.1.3 Records for temperature monitoring should be availed at time of inspection to demonstrate temperature control.

8.3.1.4 Refrigerators should have an alert system to indicate when temperatures are out of range. Accepted cold chain temperature ranges between 2°C and 8°C.

8.3.1.5 All cold chain keeping equipment should be fitted with lockable doors or lids, or access control system, to prevent unauthorized access

8.3.1.6 The effectiveness of cold chain maintenance should be demonstrated and assured at all stages to preserve the integrity of thermolabile medicines.

8.3.1.7 There should be an appointed person(s) with defined responsibility for implementation and maintenance of the activities of each fridge or cold room.

8.3.1.8 Thermolabile medicines should not be stored with other non-medicinal products, food, cold drinks, and water.

8.3.2 Controlled Substances

8.3.2.1 Schedule 1 medicines shall be kept in bolted locked steel cabinets or rooms with controlled access. Sec 48(2) of regulations 2019

8.3.2.2 The storage area should be clearly labelled as such and should always be locked to ensure security of these products. The key should always be in the custody of the pharmacist or designate.

8.3.2.3 Registers for record keeping should be kept and balanced within 7 days of dispensing.

8.3.3 Fluid and Non-drug storage

8.3.3.1 There should be an appointed person with defined responsibility for all activities on these areas.

8.3.3.2 The area should be secured to prevent unauthorised entry.

8.3.3.3 The place should be free of pests, insects, and rodents. Records of pest control should be maintained.

8.3.3.4 Storage of products should permit effective cleaning. Cleaning records should be availed.

8.3.4 Bulk storage area

8.3.4.1 There should be an appointed person responsible for implementation and maintenance of the activities of this area.

8.3.4.2 There should be a system in place to ensure traceability of inventory. Products should also be stored in a systematic manner, above the floor and not too close to the roof or ceiling.

8.3.4.3 There should be a system in place to track expiries, recalled medicine and link procured products with supplier or manufacturer.

8.3.4.4 The area should be free from leakages, tipping hazards etc.

8.3.4.5 Temperature should be controlled, and continuous temperature monitoring device(s) should be in place and records retained.

8.3.5 Storage areas at the Wards

8.3.5.1 There should be an appointed person responsible for implementation and maintenance of the activities of storage areas at each ward.

8.3.5.2 Storage areas should be free from leakages, tipping hazards etc.

8.3.5.3 Temperature should be controlled, and continuous temperature monitoring device(s) should be in place and records retained.

8.3.5.4 Periodic stock counts/checks shall be conducted and all damaged and expired to be physically separated from normal stock.

8.3.5.5 The place should be organised, access controlled, clean and free from pests (records of cleaning and pest control availed).

8.4 Production Areas [Chemo, Nuclear, TPN, etc]

8.4.1 Where Chemo- or Nuclear therapy and total parental nutrition (TPN) are provided by the institution; there shall be designated areas designed for such.
8.4.2 Measures should be in place to ensure security of personnel, products and equipment and access into each area should be controlled.
8.4.3 There should be an appointed person responsible for implementation and maintenance of the activities in these areas.
8.4.4 Personnel involved in activities in these areas should be trained, assessed and records of assessment should be retained.
8.4.5 There shall be access to wash basins or emergency showers
8.4.6 There should be adequate cleaning of both premises and equipment and cleaning records should be maintained.
8.4.7 Waste management system should be assured across all working areas to enhance correct segregation and disposal of biohazard waste.
8.4.8 There shall be a list of all equipment procured and the list shall be updated once a new equipment has been procured.
8.4.9 Proper gowning should be in place and the choice of personal protective equipment (PPE) should be justified to ensure adequate protection. Adequate instruction in the use of PPE should be provided.
8.4.10 All areas requiring PPE usage should be properly identified by warning signs.
8.4.11 The schematic diagrams of the installation of the safety chambers (BSC) should be available showing the direction of air flow.

8.5 Fire protection and power supply

8.5.1 Fire detection and protection equipment shall be available in the premises and should be regularly serviced.
8.5.2 There shall be signs for fire extinguisher(s) and escape routes within the premises.
8.5.3 A procedure for fire prevention, control and escape should be available. Staff should be trained to carry out regular fire drills. Training records shall be maintained.
8.5.4 The premises shall have access to uninterrupted power supply
8.5.5 An automatic backup generator shall be installed. It should be regularly serviced, and records retained to demonstrate compliance.

9 Documentation

9.1 General

9.1.1 Written work instructions of activities relating to the handling of pharmaceutical products should be available.

9.1.2 The documented information, whether paper or electronic, should be secure, attributable, legible, traceable, permanent, original, accurate and retrievable.

9.1.3 For paper documents or records,

i. The ink used shall

a) Be indelible

b) Not be temperature-sensitive or photo sensitive

c) Not be erasable

ii. The Paper used shall not be temperature-sensitive, photosensitive, or easily oxidizable.

9.1.4 There should be permanent records, written or electronic, for each stored product indicating recommended storage conditions and any precautions to be observed.

9.2 Documentation Systems

9.2.1 Procedures should be established and maintained for the preparation, review, approval, use of and control of changes to all documents relating to the distribution processes.

9.2.2 There should be procedures in place for handling of both internally generated documents and those from external sources.

9.2.3 The title and purpose of each document should be clearly stated. The contents of documents should be clear and unambiguous.

9.2.4 All documents should be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and should not be changed without the necessary authorization.

9.2.5 The institution must establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.

9.2.6 Systems, procedures, and methodology used to record, and store data should be periodically reviewed for effectiveness and updated, as necessary.

9.2.7 There should be a system, which includes a written procedure, to effectively and promptly recall pharmaceutical products known or suspected to be defective or counterfeit.

9.2.8 The institution shall keep records of purchase and sales of pharmaceutical products in the form of invoices. Records of procurement shall be kept in the facility for a period of at least 3 years.

9.2.9 Record of receipt should reflect the following.

a) The date of receipt

b) The name of the medicine

c) The name and address of supplier
d) The quantities, strength, and dosage form of medicine
e) The batch number of each product
f) Signature of receiving officer
g) Signature of pharmacist

9.2.10 Other records that should be maintained include:

a. Pest control records
b. Maintenance and service records including calibration records
c. Record of expiries,
d. Record of recalled products
e. Records of ADR reports
f. Temperature records
g. Stock take
h. Cleaning records
i. Training records
j. Incidents reports
k. Destruction certificates

9.3 Standard Operating Procedures

9.3.1 The Authorised person or a designated qualified person should be responsible for the compilation, review, updating and authorisation of Standard Operating Procedures (SOPs).

9.3.2 For easy retrieval, hard copies of all SOPs must be present at the point of use.

9.3.3 The following SOPs should (as a minimum requirement) be in place in an institutional pharmacy:

1. Procedure for creating and reviewing SOP's (SOP for SOP's)
2. procedure for temperature control and monitoring
3. Procedure for cold chain maintenance
4. Procedure for security of stored pharmaceuticals
5. Procedure for destruction of stock
6. Procedure for retention of the records.
7. Procedure for recall of pharmaceutical products
8. Procedure for cleaning of premises
9. Procedure for packaging and dispatch of goods
10. Procedure for handling and storage of goods
11. Procedure for handling returned, rejected, and expired medicines
12. Procedure for handling product complaints
13. Procedure for recalled medicines
14. Procedure for health, personal hygiene, safety, and environmental protection

15. Procedure for elimination of pest, insects, rodents, and others.
16. Procedure for handling spillages.
17. Procedure for handling of habit-forming drugs
18. Procedure for verifying supplier and client authenticity
19. Procedure for procurement of stock
20. Procedure for receiving stock.
21. Procedure for inpatient and ward dispensing
22. Procedure for training of staff.
23. Procedure for handling incidents
24. Procedure for operation and maintenance of vehicles and equipment
25. Procedure for identification and handling of counterfeit products
26. Procedure for fire prevention, detection, and control
27. Procedure for waste management
28. Procedure for ward stock management
29. Procedure for handling high alert medication
30. Procedure for infection control

10. Post licensure Notification

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

11. Release of Customer Information

11.1 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.

11.2 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.

11.3 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.

11.4 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.

11.5 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

12. Reference Materials

12.1 General WHO Good Distribution Practices (Technical Report Series. No 961, 2011 Annex 9)

12.2 PIC/S Guide to Good Distribution Practice for Medicinal Products, June 2014

12.3 Medicines and Related Substance Act 2013

12.4 Medicines and Related Substance Regulations 2019

12.5 Botswana Treatment Guidelines