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Function: Inspection and Licensing	Document No: BOMRA/IL/IL/P01/G04
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Botswana Medicines Regulatory Authority



Approved
By:


Dr Seima Dijeng
Director – Inspections
and Licensing

Date of Approval
(DD/MM//YY)

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1. Preamble

The Medicine Regulatory Authority (BoMRA) was established through an 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. In order to achieve this goal, the Authority has undertaken to develop a set of guidelines and procedures to guide the distribution of complimentary and schedule 4 pharmaceutical products.

In order to protect public health, licensing activities are of outstanding importance and fundamental together with inspection activities to guarantee the Quality, Safety and Efficacy of medical products of high quality are used within the country.

These guidelines were developed to ensure that the quality and integrity of pharmaceutical products is maintained during the different stages of the distribution cycle. They set out appropriate steps to assist in fulfilling the responsibilities involved in the different aspects of the distribution process within the supply chain and to avoid the introduction of counterfeits into the marketplace through the distribution chain. This covers all parties involved in trade and distribution of complimentary and schedule 4 pharmaceutical products, distributors as well as other parties such logistics, traders, transport companies and distribution agents.

2. Scope

These guidelines are intended for those involved in the storage, transportation and distribution of schedule 4 and complementary medicines and they shall apply equally to products for human and for veterinary use which may be provided to any person without a prescription. This includes dealers approved by Ministry of Trade (Council) to sell schedule 4 and complementary medicines; and all parties aspiring to deal with these products.


The document does not specifically cover GMP aspects of finished products in bulk, distribution of labels or packaging, as these aspects are covered by other guidelines.

3. Purpose

The purpose of these guidelines is:

- To ensure that stakeholders involved in the distribution of pharmaceutical products are well informed to ensure compliance to distribution protocols set by the organisation.
- to provide a method of assessing eligibility and the process of lawfully operating pharmaceutical distribution outlets

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- To outline requirements for operating pharmaceutical business under complementary and schedule 4 medicines
- To determine the minimum requirements for handling schedule 4 and complementary medicines

4. Laws, Regulations, Policies and Guidelines Applied


These guidelines were developed using principles from the following;

- Medicines and Related Substances Act, 2013, and Regulations, 2019
- WHO Good distribution practices for Pharmaceutical Products, TRS 957 2010, Annexure 5
- BoMRA Guidelines on Good Distribution Practices of Pharmaceutical Products.

4.1. Legal Consideration

The importation and exportation of Medicines in Botswana shall be through a licensed wholesaler authorised by BOMRA.

1. In terms of 26 (1) of the MRSA, 2013, 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 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.
2. No person shall import, export, distribute or sell medicines except in accordance with a license issued for the import, export, distribution or sale of medicines. (Sec 28 (1) of the MRSA, 2013).
3. A person who wishes to import, export, distribute or sell medicines shall apply to the authority, in the prescribed form accompanied by such fee as may be prescribed and such information as the authority may require (Sec 28 (2) of the MRSA, 2013).
4. The person referred to in subsection (2) shall be resident in Botswana (Sec 28 (3) of the MRSA, 2013).
5. The import, export, distribution or sale of medicines in terms of this section shall be under the continuous supervisory control of a pharmacist, or veterinary surgeon (Sec 28 (4) of the MRSA, 2013).

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6. A person authorised in terms of this act to import, export, distribute, or sell medicines shall not import, export, distribute, sell, or keep in storage contrary to such conditions as may be prescribed, any medicine after the date of expiry indicated on the package of the medicine (*Sec 28 (4) of the MRSA, 2013*).

5. Definitions and Abbreviations

5.1. Definitions

The definitions given below of some of the terms used in this document take into account the terminology of current regulations and recommendations.

- 5.1.1 Authority:** Means Botswana Medicines Regulatory Authority established under section 3 of MRSA 2013.
- 5.1.2 Authorised importer** means an individual or company or similar legal entity granted permission to import a medicine into Botswana by BoMRA.
- 5.1.3 Authorised exporter** means an individual or company or similar legal entity granted permission to export a medicine out of Botswana by BoMRA.
- 5.1.4 Counterfeit product:** means a 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.
- 5.1.5 Distribution:** means any practice whose activities involve the handling, storing, selling or supplying of medicines for wholesale to pharmacies or dispensary.
- 5.1.6 Distributor:** means a company or similar legal entity granted permission to import, export, handle, store or supply medicines to pharmacies, dispensary or individuals.
- 5.1.7 Export:** means sending out a medicine, medical device or scheduled substance from the Botswana or cause a medicine, medical device or scheduled substance to be sent out of the country for purposes other than personal use.
- 5.1.8 Import:** means to bring a medicine, medical device or scheduled substance into the Botswana or cause a medicine, medical device or scheduled substance to be brought into the country for purposes other than personal use.
- 5.1.9 Manufacture** means all operations involved in the preparation, processing, compounding, formulating, filling, refining, transformation, packaging, repackaging and labelling of controlled drugs.
- 5.1.10 Medicine:** means

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- a. Any substance or mixture combination of substances manufactured, sold or presented as suitable for use, in:
 - i. the diagnosis, treatment, alleviation, modification, prevention of diseases, illness, abnormal physical or mental condition or symptoms thereof or
 - ii. restoring, correcting or modifying any somatic or psychic or organic condition or
- b. A substance or mixture of substances used to manufacture medicine or is sold as a raw material, precursor chemical or intermediate;
- c. Any labelled preparation in pharmaceutical dosage form that contains as active ingredients, one or more substances of natural origin that are derived from plants or animals;
- d. Herbal tea, or homeopathic, ayurvedic, or other, that contains as active ingredients, substances of natural origin and may be derived from any part of plants or animals in a pharmaceutical dosage form;
- e. Vitamins or minerals prepared in a pharmaceutical dosage form.

5.11 Calibration: The set of operations which establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring, recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established. Including the maximum permissible error or uncertainty of measurement;


5.12 Forwarding agent: A person or entity engaged in providing, either directly or indirectly, any service concerned with clearing and forwarding operations in any manner to any other person and this includes a consignment agent.

5.13 Good distribution practices: That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products.

5.14 Good storage practices: That part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof.

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

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

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5.17 Schedule 4 Medicine: means a medicine which may be sold over the counter by any licensed trader.

5.18 Complementary Medicine – means a labelled substance or mixture of substances manufactured, sold or represented for use as adjuvants to conventional therapy in:

- a. the mitigation or prevention of or abnormal physical states;
- b. restoring, correcting or modifying physical, mental or organic functions in human and animals as determined by the Authority.
- c. and originate from plant, mineral, animal (including microorganisms), homeopathic preparations, nutritional substances in accepted pharmaceutical dosage forms, a combination of the above or any other such preparations as may be approved by the Authority.

5.2. Abbreviations

5.2.1 BOMRA: means Botswana Medicines Regulatory Authority

5.2.2 TRS means Technical Report Reason

5.2.3 WHO means World Health Organization.


6. Requirements for operators

6.1. Application for premise licence

- 6.1.1 BoMRA will license business owners who wish to handle (import, store and distribute) Schedule 4 and complementary medicines. These include retailers and distributors of these products.
- 6.1.2 All interested parties shall refer to Ministry of trade and investment, District Council who are responsible for licensing the business operations (Trade Licenses) after licensing from BoMRA.
- 6.1.3 Licensing shall be done in accordance with guidelines for operating a complimentary and schedule 4 premises.

6.2. Application requirements and procedure

- 6.2.1 Applications for prospective pharmaceutical operations licence and license renewal shall be by he authorised person and be addressed to the Chief Executive Officer, BOMRA.
- 6.2.2 The applicant shall submit filled form 8 (annexure 1), Checklist, (Annexure 2) which shall be checked by the officer in charge, stamped and applicant given a copy, declaration form (Annexure 3)
- 6.2.3 The applicant shall also submit the following

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- a. A detailed sketch plan of the premises to be approved by the Authority (New Operations)
 - b. Name and qualification of the authorised person
 - c. Certified copy of identity card or passport
 - d. Two references (New Operation)
 - e. Proof of payment (use facility name as reference)
 - f. Completed application checklist; *BOMRA/IL/IL/P01/F04*
- 6.2.4 The applicant shall submit sketch plan of premises to BOMRA for approval, before making structural changes to the warehouse.
- 6.2.5 All applications must be submitted to BOMRA at plot 145, International Finance Park or emailed to inspections@bomra.co.bw

6.3. Processing of application


- 6.3.1 Upon receiving the application as specified above, BOMRA will assess it to verify whether the requirements have been fulfilled.
- 6.3.2 If the application meets the prescribed requirements, the authority will proceed to carry out an inspection of the pharmaceutical operations.
- 6.3.3 An application will be rejected if it does not meet the minimum requirements for pharmaceutical operations. The applicant shall receive an inspection report outlining reasons for not awarding a license.
- 6.3.4 New operations shall be inspected within ten (10) working days after the submission of an application, the applicant shall be notified of date and time prior to inspection.
- 6.3.5 License renewal shall be inspected within twenty-one (21) working days after date of application.
- 6.3.6 Application for renewal of existing license shall be submitted three (3) months prior to license expiry.

6.4 Application for registration of complementary medicines

- 6.4.1 Applications for registration of complementary medicines are conducted by BoMRA, Department of Product Evaluation and Registration under Complementary Medicines and Cosmetics Unit.
- 6.4.2 The Document No: BOMRA/ER/CM/P03/G01; Guidelines on Application for Registration of Complementary Medicines in Botswana exists to guide applicants in registering all complementary medicines.

6.5 License Variation

- 6.5.1 An application shall be made by the responsible pharmacist or veterinary surgeon to the authority requesting the authority to make changes to the license issued.

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6.6 Post- licensure notifications

- 6.6.1 An application shall be made by the responsible pharmacist or veterinary surgeon to inform the authority of any post licensure notifications.


7 Requirements for operating (General Considerations)

7.1 Personnel

- 7.1.1 Authorized personnel shall bear the responsibility of ensuring that medical products and health technologies are correctly handled, stored and distributed. Such personnel should have the relevant education, training, experience and/or combination of these elements that will allow them to effectively discharge this responsibility.
- 7.1.2 Procedures and job descriptions for employees and other persons having access to the products must be designed and administered to minimize the possibility of drugs coming into unauthorized possession.
- 7.1.3 All personnel involved in the distribution activities must be trained on pharmaceutical product security, product identification, detection of counterfeit pharmaceutical products and handling and storage of pharmaceutical products.
- 7.1.4 All members of staff should be trained in, and observe high levels of, personal hygiene and sanitation.

7.2 Premises, warehousing and storage

- 7.2.1 Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of materials and products, e.g. starting and bulk products, products in quarantine, and released, rejected, returned or recalled products.
- 7.2.2 Storage surfaces should be kept clean, with adequate lighting, well dry and maintained within acceptable temperature limit. Temperature shall be controlled, and continuous temperature monitoring devices used to verify the adequacy of temperature control.
- 7.2.3 Medicines should be kept off the floor and suitably spaced to allow cleaning. A written sanitation programme should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas.
- 7.2.4 Measures should be taken to protect products from direct sunlight, rain and extreme weather conditions.
- 7.2.5 Separate areas for quarantine, recalled, expired medicines should be provided and clearly labelled and their access to be restricted to authorised personnel.
- 7.2.6 Pharmaceutical products should be stored and handled in a manner that prevents contamination, mix-ups and cross-contamination.

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- 7.2.7 Premises shall be secured to prevent unauthorised persons from entering medicine storage areas.
- 7.2.8 Fire detection and protection equipment shall be kept inside the premises and should be regularly serviced.
- 7.2.9 There should be a pest control procedure to keep all areas free from pests. There should also be a written programme for pest control. The pest-control agents used should be safe, and there should be no risk of contamination of the materials and pharmaceutical products.
- 7.2.10 Receiving and dispatch areas shall be segregated and clearly labelled. Receiving and dispatch bays should protect materials and products from the weather. Reception areas should be designed and equipped to allow containers of incoming materials and pharmaceutical products to be cleaned, if necessary, before storage.
- 7.2.11 Sufficient space should be provided for receiving and dispatch of goods and Temperature monitoring shall be maintained at each area point.
- 7.2.12 There shall be labels in the warehouse prohibiting unauthorised entry, drinking, smoking, and eating.


7.3 Temperature monitoring

- 7.3.1 All areas where pharmaceutical products are stored shall be equipped with continuous temperature monitoring systems. Records shall be maintained to demonstrate temperature control.
- 7.3.2 Calibration of temperature monitoring devices should be done against a certified, traceable reference standard at least once a year or according to the recommendation of the device manufacturer.
- 7.3.3 Temperature Mapping shall be carried out in all medicine storage areas and records be maintained.

7.4 Power Supply

- 7.4.1 The premises shall have access to uninterrupted power supply
- 7.4.2 An automatic backup generator shall be installed and should be equipped with automatic mains failure start-up and automatic shutdown when power is restored.
- 7.4.3 The generator should be regularly serviced, and record should be maintained to demonstrate compliance.

7.5 Supplier authenticity

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- 7.5.1 All pharmaceutical products must be purchased from reliable sources; therefore, it shall be the responsibility of the wholesaler to establish the authenticity of each supplier.
- 7.5.2 Importation or exportation of pharmaceutical products must be through a valid BoMRA permit.
- 7.5.3 The wholesaler must have a process in place that verifies the following:
- a. The name of the entity ordering.
 - b. The entity licence/authorisation number from relevant authority.
 - c. Any other relevant documentation
 - d. That the delivery address on the account and invoice matches the physical delivery address displayed on the licence.


7.6 Complaints

- 7.6.1 There shall be a system in place to ensure that the complaint, the response received from the original product manufacturer/supplier, or the results of the investigation of the complaint, are shared with all the relevant parties.

7.7 Handling Returned, Recalled and Rejected products

- 7.7.1 All business owners shall be accountable for handling rejected and recalled medicines and shall ensure that counterfeit products are not introduced during this process. Where any doubt arises over the quality of a pharmaceutical product, it should not be considered suitable for reissue or reuse.
- 7.7.2 Returned products should be appropriately identified and handled in accordance with a procedure which involves segregation of such pharmaceutical products quarantined in a designated area.
- 7.7.3 The storage conditions of returned products should be maintained during storage and transit until such time as a decision has been made regarding the product in question.
- 7.7.4 Provision should be made for the appropriate and safe transport of returned and recalled products in accordance with the relevant storage and other requirements.
- 7.7.5 Destruction of pharmaceutical products should be done in accordance with the prescribed national regulations.
- 7.7.6 Records of all returned, rejected and/or destroyed pharmaceutical products should be kept for a predetermined period.

7.8 Substandard and Falsified products


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- 7.8.1 Sale and distribution of a suspected counterfeit pharmaceutical products should be suspended, and the national regulatory authority notified immediately.
- 7.8.2 Counterfeit products found in the distribution chain should be kept apart from other pharmaceutical products.
- 7.8.3 Counterfeit products should be clearly labelled as not for sale and marketing authorization holder should be notified.
- 7.8.4 Proper recall procedures must be followed for all confirmed counterfeit products and measures should be taken to ensure correct handling and such decisions recorded.

8 Documentation

8.1 General


- 8.1.1 Written instructions and records which document all activities relating to the distribution of pharmaceutical products, including all applicable receipts and issues (invoices) should be available.
- 8.1.2 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.
- 8.1.3 The title and purpose of each document should be clearly stated. The contents of documents should be clear and unambiguous.
- 8.1.4 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.
- 8.1.5 The distributor must establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.
- 8.1.6 Documents or Records that are kept in electronic form shall have backups to prevent accidental data loss. Data and record media should be durable
- 8.1.7 Systems, procedures and methodology used to record and store data should be periodically reviewed for effectiveness and updated as necessary.
- 8.1.8 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, with a designated person(s) responsible for recalls
- 8.1.9 The wholesaler shall keep records of purchase and sales of pharmaceutical products in the form of invoices that will reflect the following.
 - a. The date and transaction of every sale
 - b. The name of the medicine

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- c. The name and address of every purchaser or supplier
- d. The quantities sold or bought
- e. The batch numbers.

8.2 Written instructions and records

- 8.2.1 Written instructions and records should be available which document all activities in the storage areas including the handling of expired stock. These should adequately describe the storage procedures and define the route of materials and pharmaceutical products and information through the organization in the event of a product recall being required.
- 8.2.2 Records should be kept for each delivery. They should include the description of the goods, quality, quantity, supplier, supplier's batch number, the date of receipt, assigned batch number and the expiry date.
- 8.2.3 Records must be retained in the facility for a minimum period of 3 years.
- 8.2.4 For easy retrieval, copies of all SOPs must be present at the point of use.
- 8.2.5 The following SOPs should (as a minimum requirement) be in place in a wholesale pharmacy:
 1. Procedure for creating and reviewing SOP's (SOP for SOP's)
 2. procedure for temperature control and monitoring
 3. Procedure for security of stored pharmaceuticals
 4. Procedure for destruction of unsaleable or unusable stocks
 5. Procedure for retention of the records.
 6. Procedure for recall of pharmaceutical products
 7. Procedure for cleaning of premises
 8. Procedure for dispatch of goods
 9. Procedure for Handling and Storage of Goods
 10. Returned, rejected and expired medicines;
 11. Procedure for handling product complaints
 12. Procedure for recalled medicines
 13. Procedure for health, personal hygiene, safety and environmental protection
 14. Procedure for elimination of pest, insects, rodents and others.
 15. Procedure for handling spilled substances.
 16. Procedure for checking of supplier and client authenticity
 17. Procedure for receiving stock.
 18. Procedure for training of staff.
 19. Procedure for operation and maintenance of vehicles and equipment
 20. Procedure for identification and handling of counterfeit products
 21. SOP for vendor qualification

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9 Reference Materials

9.1 The wholesale shall be in possession of the following references

- i. Medicines and Related Substance Act 2013
- ii. Medicines and Related Substances Regulations, 2019
- iii. WHO Good Distribution Practices: WHO Technical Report Series, No. 961, 2011, Annex 9
- iv. Guide to good storage practices for pharmaceuticals: WHO Technical Report Series, No. 908, 2003, Annex 9.
- v. List of medicines allowed in Botswana (Updated Bluebook)

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

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12. Annexures

Application for licensing of pharmaceutical premises

13. References

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2. Medicines and Related Substances Regulations, 2019
3. WHO Good Distribution Practices: WHO Technical Report Series, No. 961, 2011, Annex 9
4. Guide to good storage practices for pharmaceuticals: WHO Technical Report Series, No. 908, 2003, Annex 9.