Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

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1 Preamble

1.1 The Medicine Regulatory Authority (BoMRA) was established through 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 pharmaceutical products.

1.2 The purpose of this wholesale guideline is to ensure that the quality and integrity of medical products is maintained during the different stages of the distribution cycle. This covers all parties involved in the trade and distribution of Medical Devices and Invitro Diagnostics including brokers, suppliers, distributors, logistics providers, traders, transport companies and forwarding agents and their employees.

2. Laws, Regulations, Policies and Guidelines Applied

These guidelines were developed using principles from the following;

a. Medicines and Related Substances Act, 2013, (MRSA)
b. Medicines and Related Substances Regulations, 2019
c. WHO Technical Report Series, No. 1025, 2020 Annex 7
d. ISO 13485 Medical Devices – Quality Management Systems – Regulatory Requirements.

2.1 Legal Consideration

The importation of Medicines (medical devices) in Botswana shall be through a licensed wholesaler authorised by BOMRA.

a. 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).
b. 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).
c. The person referred to in subsection (2) shall be resident in Botswana (Sec 28 (3) of the MRSA, 2013).
d. 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).
e. 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).

f. The authority shall ensure that all premises are inspected to assess compliance to set guidelines
The importation and importation of Medicines in Botswana shall be through a licensed.

3. Definitions and Abbreviations

3.1 Definitions

The following terms shall be defined as follows:

3.1.1 **BoMRA** - means Botswana Medicines Regulatory Authority.

3.1.2 **Authorised Person (AP) –** Person given the responsibility for ensuring medical products requirements are in compliance with the laws and regulations in force in Botswana. AP is responsible for overseeing supply chain of medical devices. These entails procurement or importation, storage and distribution to retailers and end users.
The responsibilities also include:

a. to ensure that the provisions of the licence are observed
b. to ensure that adequate records are maintained
c. to ensure that all personnel are trained
d. ensure full and prompt cooperation with product licence holders in the event of recalls
e. to be the liaison person with the regulatory authority on issues of licensing and compliance.

NB. An Authorised person may also be a Qualified Person registered with a professional body to undertake work or practise within a specific technical field or area meeting the minimum requirements guidelines.

3.1.3 **Authority –** means Botswana Medicines Regulatory Authority established under section 3 of MRSA 2013.

3.1.4 **Authorised importer –** means an individual or company or similar legal entity granted permission to import a medicine into Botswana by BoMRA.

3.1.5 **Authorised exporter –** means an individual or company or similar legal entity granted permission to export a medicine out of Botswana by BoMRA.

3.1.6 **Counterfeit product –** means a medicine, medical device, cosmetic, related substance or a 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.

3.1.7 **Distributor -** means any practice whose activities involve the handling, storing or supplying of medical devices for sale to medical health centres and or medical products distributors.

3.1.8 **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.

3.1.9 **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.

3.1.10 **In Vitro diagnostic Device (IVD)**

Means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimen derived from the human or animal solely or principally to provide information for diagnostic, monitoring or compatibility purposes which includes but not limited to – reagents used for IVD purposes, calibrators, control chemicals, specimen receptacles, software and related instruments or apparatus or other articles and are used for diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction and determination of physiological status.

Note 1: An accessory is not considered to be a medical device. However, where an accessory is intended specifically by its manufacturer to be used together with the 'parent' medical device to enable the medical device to achieve its intended purpose, it should be subject to the same procedures and guidance as apply to the medical device itself.

Note 2: The definition of a device for in vitro examination includes, for example, reagents, calibrators, sample collection devices, control materials, and related materials.

3.1.11 **Manufacture –** means all operations involved in the preparation, processing, compounding, formulating, filling, refining, transformation, packaging, repackaging and labelling of controlled drugs.

3.1.12 **Medicine: -** as defined by the MRSA; including any substance, mixture combination of substances manufactured, sold or presented as suitable for use, in:

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

-restoring, correcting or modifying any somatic or psychic or organic condition or

-any controlled substance, to the extent that it complies with (a) or

-any substance or mixture of substances used to manufacture medicine or is sold as a raw material, precursor chemical or intermediate

-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 complementary medicine or medicine.

3.1.13 Medical device: Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

a. Intended by the manufacturer to be used, alone or in combination, for humans or animals for;
b. diagnosis, prevention, monitoring, treatment or alleviation of disease
c. diagnosis, monitoring, treatment, alleviation of or compensation for an injury investigation, replacement, modification or support of the anatomy or of a Physiological process supporting or sustaining life control of conception disinfection of medical devices; or providing information for medical or diagnostic purpose by means of in vitro examination of specimens derived from the human body and.
d. which do not achieve its primary intended action in or on human or animal body by pharmacological, immunological or metabolic means but which may be assisted in its intended function by such means

3.1.14 Qualified Person – Person registered with a professional body to undertake work or practise within a specific technical field or area meeting the minimum requirements guidelines.

NB. In this guideline, the Qualified person is also referred to as the Authorised person.

3.2 Abbreviations

The following abbreviations shall apply:

3.2.1 **CAPA** - Corrective Action and Preventative Action
3.2.2 **TRS** - Technical Report Series
3.2.3 **WHO** - World Health Organization

4. Classification of Medical Devices

4.1 Medical devices are grouped into risk classes according to their potential harm to the patient or user, the following are classes of medical devices-

a. **Class A** – Low Risk
b. **Class B** – Low Moderate Risk.
c. **Class C** – Moderate-high Risk
d. **Class D** – High Risk

4.2 Classification Scheme for In-Vitro Diagnostic Devices

a. **Class D** – High Individual Risk and High Public Health risk
b. **Class C** – Moderate public health risk, but high individual risk
c. **Class B** – Low public health risk and/ or moderate individual risk
d. **Class A** – Low individual risk and low public health risk

For in depth information on classification links below. are accessible on the BoMRA website.
Medical Devices
https://www.bomra.co.bw/download/114/adopted-guidelines/32271/principles-medical-devices-classification.pdf
IVD's
https://www.bomra.co.bw/download/114/adopted-guidelines/32269/priciple-ivd-classification.pdf

5. Regulatory Scope

These guidelines are meant to:

a. Outline the responsibilities of the stakeholders involved in the distribution or sale of medical devices.
b. Outline the requirements for successful application and licensing of a Medical Device distributor/ Retailer.
c. Outline the documentation necessary to maintain in the operation of a Medical Device distributor/retailer.

6. Requirements for operating a medical device distributor

Inspection is required for granting or re-granting a license or approval of a substantial modification.

6.1 Application requirements and procedure

6.1.1 The applicant is advised to submit sketch plan of premises to BoMRA for pre-approval, before construction or partitioning the warehouse. The sketch plan should be submitted at inspections@bomra.co.bw

6.1.2 Applications for prospective medical device distributor licence and license renewal shall be made by the authorised person.

6.1.3 Applications are submitted through our Brims Portal https://brims.bomra.co.bw/ Kindly use the hyperlink to create an account if you haven't already and access the Dashboard to navigate to the Inspections & Licensing Module.

6.1.4 Here is a **step-by-step guidance:**

a. On the Home Page click Facility Inspections & Licensing
b. On the Dashboard, click Inspections & Licensing on the left panel
c. Click the Premises Certificates and Licenses drop down
d. Click the blue shaded Facility renewal/Pre- Licencing.
e. Fill up the required details and upload details

6.1.5 All completed applications must be emailed to BoMRA at inspections@bomra.co.bw with the TRC (Tracking Number) number as the subject line.

6.1.6 The applicant shall attach the following on the BRIMS Portal:

a. A completed application form (Form 8)
b. A certified copy of the authorised person's registration certificate issued by relevant certifying body, where applicable.

c. Certified copy of identity card or passport of the authorised person.
d. Two references of the authorised person (New Operations).
e. A completed declaration of continuous supervision form.
f. Proof of payment verified by the Accounts Office (facility name used as reference).
g. Completed application checklist.

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

6.1.8 Application for variation of licence shall be sent to BoMRA using the same application form (Form 8).

6.2 Processing of application

6.2.1 Upon receiving the application as specified above, BoMRA will assess it to verify whether the requirements have been fulfilled.

6.2.2 If the application meets the prescribed requirements, the authority will proceed to carry out an inspection of the medical device's operation.

6.2.3 An application will be rejected if it does not meet the minimum requirements for medical devices operations.

6.2.4 New operations will 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.

6.2.5 License renewal inspections will be conducted within twenty-one (21) working days after the date of receipt of application.

6.3 Inspection

6.3.1 The inspection shall be carried out by BoMRA inspectors who shall identify themselves prior to commencing the inspection.

6.3.2 The inspection report will be shared with the applicant within 10 working days from the date of inspection.

6.3.3 The inspection report shall categorise the deficiency findings as minor, major and critical based on potential negative effect to quality, safety and efficacy, patient, and the reoccurrence of the deficiency.

6.3.4 The inspected premises shall upon receipt of the Inspection report be required to do a Root Cause Analysis and carry out corrective action and preventive action (CAPA) within 10 working days. The implemented actions shall be submitted via the BRIMS customer portal

6.3.5 Upon receipt of satisfactory response to inspection findings (CAPA) the facility shall be licensed within 10 working days.

6.3.6 Failure to address the deficiencies may result in license withdrawal for licensed facilities or termination of the licensing process for new facilities.

6.4 License Variation

6.4.1 An application for license variation shall be submitted to BoMRA in the following cases;

a) change of Authorised person

6.4.2 The following components of variation shall require prior inspection:

a) Physical address (relocation)-a relocation shall not be applied for as a variation of license but rather as pre-licensing.
b) Licensee
c) Modification of any substantial nature

6.4.3 An application shall be made by the Authorised person to the authority requesting the authority to make changes to the license issued.

6.4.4 A license can only be varied if it is left with more than three months of validity.

6.5 Post- licensure notifications

6.5.1 The Authorized person shall inform the authority of any post licensure notification.

6.5.2 Change of the Authorised person in charge shall be communicated to the Authority within 30 working days.

7. Organization and management

7.1 The facility shall have an organogram or organizational chart clearly indicating authority, responsibility, and interrelations with the company structure

7.2 All employees must be informed or trained on their Job descriptions. Employees must sign their job descriptions as way of acknowledging and understanding of their roles and responsibilities.

8. Personnel

8.1 Operations shall be done under continuous supervision of a Health professional in line with their scope of practise.

8.2 All personnel in the operations must have employment contracts or job descriptions specific to their role/ activities/responsibilities.

8.3 All personnel involved in the distribution activities must receive initial and continuing training on SOP'S relevant to their tasks, role, or responsibilities.

8.4 Initial and continuing training of SOPs for all personnel involved in the distribution activities must be included in a written training programme or plan.

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

8.6 All personnel involved in the distribution activities must be trained on pharmaceutical product security, product identification, detection of counterfeit pharmaceutical products.

8.7 There should be suitably trained and adequate personnel at all stages of the distribution activities.

9. Premises, Warehousing and Storage

9.1 The trade licences, BOMRA license and the registration certificates shall be conspicuously displayed at the reception or service point.

9.2 Good storage practices should be applicable throughout the distribution process. Storage areas should be of sufficient capacity.

9.3 Surfaces should be kept clean, dry and maintained in a good state of repair.

9.4 Medical device products should be kept off the floor and suitably spaced to allow cleaning and inspection and should be stored and handled in a manner that prevents mix-ups and contamination.

9.5 Written procedures for cleaning should be available and shall indicate the frequency of cleaning. All cleaning agents shall be approved by management.

9.6 There should be a pest control procedure to keep all areas free from pests. This includes the receiving and loading areas. Records shall be maintained to demonstrate implementation of the pest control program

9.7 All different sections of the warehouse shall be clearly labelled using waterproof and durable material.

9.8 Receiving and dispatch areas shall be segregated and clearly labelled. Measures should be taken to protect products from direct sunlight, rain and extreme weather conditions.

9.9 Sufficient space should be provided for receiving and dispatch of goods.

9.10 There shall be labels in the warehouse prohibiting unauthorised entry.

9.11 Fire Safety

a. Fire detection and protection equipment shall be kept inside the warehouse and should be regularly serviced.

b. A procedure for fire prevention, detection and control should be available. Staff should be trained to carry out regular fire drills. Training records shall be maintained.

c. Smoking shall be prohibited in all areas.

10. Temperature Control in Storage Areas

10.1 Many medical devices require specific storage conditions. The manufacturer's instructions, in the product labelling will explain specific needs for refrigeration, freezing, or controlled room temperature.

10.2 Storage areas where temperature sensitive medical devices are stored shall be equipped with continuous temperature monitoring systems. Records shall be maintained to demonstrate temperature control.

10.3 The storage temperature shall range between 15-25°C or according to the manufacturer's recommendations.

10.4 Storage areas where temperature sensitive medical devices are stored shall be equipped with continuous temperature monitoring systems or devices. Records shall be maintained to demonstrate temperature control.

10.5 Temperature Mapping shall be carried out in all storage areas.

10.6 Refrigeration

10.6.1 Refrigerators, cold rooms and freezers should be capable of maintaining the required temperature limits

10.6.2 Medical devices requiring refrigeration storage temperature shall be kept between 2-8°C.

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

10.6.4 Refrigeration equipment should be equipped with a calibrated continuous temperature monitoring device or system.

10.7 Transport Vehicles

10.7.1 Temperature sensitive medical devices shall be transported in vehicles with Temperature-controlled storage

10.7.2 Temperature monitoring systems or devices shall be used to continuously monitor temperature during medical device transit and records maintained.

10.7.3 Monitoring devices should be calibrated as per the defined frequency and traceable to an international standard.

11. Documentation

11.1. General

11.1.1 Written instructions and records which document all activities relating to the distribution of medical devices, including all applicable receipts and issues (invoices) should be available.

11.1.2 Records shall be kept in the facility for at least 3 years.

11.1.3 The documented information, whether paper or electronic, should be secure, attributable, legible, traceable, permanent, original and accurate (Meet ALCOA ++ principles).

11.1.4 For paper documents or records,

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.

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

11.2. Documentation Systems

11.2.1 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.

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

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

11.2.4 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.

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

11.2.6 Documents or Records that are kept in electronic form shall have backups to prevent accidental data loss. Data and record media should be durable

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

11.2.8 There shall be a referencing system in place that promptly links the dispatched medical device to the original supplier to enable traceability in the supply chain.

11.2.9 There should be a system, which includes a written procedure, to effectively and promptly recall medical devices with known or suspected to be defective or counterfeit.

11.2.10 The distributor shall keep records of purchase and sales of pharmaceutical products in the form of invoices that will reflect;

a) The date and transaction of every sale;

b) The name of the Medical devices;

c) The name and address of every purchaser or supplier;

d) The quantities sold or bought;

e) The batch number;

11.3 Customer verification

The distributor must have a process in place that verifies the following:

a) The name of the entity ordering

b) The entity licence/authorisation number from BOMRA

c) Any other relevant documentation

d) That the delivery address on the account and invoice matches the physical delivery address displayed on the licence

11.4 Standard Operating Procedures

11.4.1 The Health Professional shall be for the compiling, reviewing, updating and authorizing Standard Operating Procedures (SOPs).

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

11.4.3 The following SOPs should (as a minimum requirement) be in place in the distributorship.

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 medical devices
4. Procedure for destruction of unsaleable or unusable stocks
5. Procedure for retention of the records
6. Procedure for recall of medical devices
7. Procedure for cleaning of premises
8. Procedure for packaging and dispatch of goods
9. Procedure for Receiving and Handling and Storage of Goods
10. Returned, rejected and medical devices.
11. Procedure for handling product complaints
12. Procedure for handling recalled medical devices
13. Procedure for elimination of pest, insects, rodents and others.
14. Procedure for checking of supplier and client authenticity
15. Procedure for training of staff.
16. Procedure for segregation of pharmaceutical products
17. Procedure for identification and handling of counterfeit products

12 Complaints

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

13 Returned and Rejected products

13.2 Returned and rejected should be appropriately identified and handled in accordance with a procedure which involves at least the physical segregation of such medical devices in quarantine in a dedicated area; or other equivalent (e.g. electronic) segregation.

13.3 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.

13.4 Provision should be made for the appropriate and safe transport of rejected medical devices prior to their disposal.

13.5 Destruction should be done in accordance with the prescribed national regulations

13.6 Records of all returned, and rejected medical devices should be kept for a predetermined period.

14 Counterfeit

14.2 No person shall import, export, manufacture, distribute, sell, promote, advertise, store or dispense, any counterfeit products.

14.3 Counterfeit Medical devices found in the distribution chain should be kept apart from other pharmaceutical products.

14.4 Counterfeit Medical devices should be clearly labelled as not for sale and marketing authorization holder should be notified.

14.5 Sale and distribution of a suspected counterfeit medical devices should be suspended, and the national regulatory authority notified immediately

14.6 Confirmation of Medical device being counterfeit, a formal decision should be taken on its disposal, ensuring that it does not re-enter the market and the decision recorded.

15 Contract Activities

15.2 Activities relating to distribution of medical devices which is delegated to another entity should be performed by authorised personnel and in terms of the written contract.

15.3 Compliance to the contract should be mandatory.

15.4 Subcontracting should be acceptable only under stipulated conditions, and the subcontractors should be authorised for that function.

15.5 Auditing of contract acceptor should be done periodically.

16 Self-Inspection

16.2 Self-inspection should be carried out to monitor implementation and compliance with principles of GDP and this should trigger corrective and preventive actions

16.3 Self-inspection should be conducted in an independent, detailed way by a competent person.

16.4 The results of all self-inspection should be recorded. Reports should contain all observations made during inspection and proposals for corrective measures. There should be an effective follow up programme on non-conformities.

17 References

The distributor shall be in possession of the following references

i. Medicines and Related Substance Act 2013

ii. Medicines and Related Substances Regulations, 2019

iii. TRS 1025 - Annex 7: Good storage and distribution practices for medical products

iv. ISO 13485 Medical Devices – Quality Management Systems – Regulatory Requirements.

v. Global Harmonization Task Force-GHTF/SG1/N15:2006 Global Harmonization Task Force-GHTF/SG1/N15:2006

vi. International Medical Device Regulator's Forum- IMDRF/IVDWG/N64FINAL:2021

18 Retailing of Medical Devices

18.1 Retail of medical devices and IVD's shall be subject to the following conditions

i. The medical device or IVD of Class A to D shall be handled by a qualified person.
ii. The medical device or IVD of Class A to B shall be handled by a Authorised person.
iii. The medical Devices or IVD's retailed or to be retailed shall be listed or registered with BoMRA.
iv. An application for Authorization to sell medical device and IVD's shall be approved by BoMRA.
v. Medical devices or IVD's shall be procured from BoMRA Licensed distributors.
vi. Good documentation Practices as outlined in this guideline are practised
vii. Materiovigilance is documented and reported timeously to BoMRA

18.2 Application requirements for a retailer

18.2.1 Applications for prospective Medical Device Distributor license and license renewal shall be by a registered Health Professional or a resident of Botswana

18.2.2 The applicant is advised to submit sketch plan of premises to BoMRA for pre-approval, before construction or partitioning retailer. The sketch plan should be submitted at inspections@bomra.co.bw

18.2.3 The applicant shall also submit the following;

a) A certified copy of the professional registration certificate issued by a professional body (Qualified person)

b) Proof of valid/renewed professional body membership i.e., copy of a valid Blue card or equivalent

c) A detailed sketch plan of the premises approved by the Authority (New Operations).

d) The applicant shall submit filled form 8

e) Proof of payment (use facility name as reference)

f) Completed application checklist

g) Declaration form (Annexure 3)

18.2.4 All applications must be submitted through the BRIMS customer portal.