Botswana Medicines Regulatory Authority

Approved By:

Ms. Zukiswa Raditladi
Director – Licensing and Enforcement

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Contents

Revision status sheet

Page	Changes made	Issue No	Process Owner (Title)	Initiated By (Name)	Reviewed By (Name)	Date
All pages	Added clauses 5.4 sampling and evidence collection during inspections, 5.5, License variation 5,6, post licensure notifications 5.7, variation of License – change of personnel, 6.0 suspension and withdrawal, 8.2 Temperature control, Cold Chain and Transportation, 8.3, controlled Substances, 11, Returned Rejected expired and Recalled products, 12, Substandard and falsified products,	3.0	Manager – inspections and Licensing	Maikaego N. Moreri	Tshegofatso Chilume	17/04/2026
Page 6	Removed the following definitions Authority, Authorized person, Counterfeit product, Distributor, Educational Institution, Export, Import, Good Manufacturing Practice, Manufacture, Medicine, Pharmaceutical Operation, Pharmacist, Designate.	3.0	Manager – inspections and Licensing	Maikaego N. Moreri	Tshegofatso Chilume	17/04/2026
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Page 5,6 and 14	Name from Institutional to within group practice	2.0	Manager – inspections and Licensing	Maikaego N. Moreri	Tshegofatso Chilume	15/07/25
Page 6	Removed; 5.1.1 Government owned facilities are exempted from paying the application fee.	2.0	Manager – inspections and Licensing	Maikaego N. Moreri	Tshegofatso Chilume	15/07/25
Page 6	Added: 5.1.2 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. 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 e. Fill up the required details and upload details	2.0	Manager – inspections and Licensing	Maikaego N. Moreri	Tshegofatso Chilume	15/07/25
Page 6	Removed: 5.2.2 stamped and applicant given a copy. The original documents will be filled accordingly.	2.0	Manager – inspections and Licensing	Maikaego N. Moreri	Tshegofatso Chilume	15/07/25

Page 7 and 8	Added: 5.3 Inspection	2.0	Manager – inspections and Licensing	Maikaego N. Moreri	Tshegofatso Chilume	15/07/25

1. Preamble

The Botswana Medicine Regulatory Authority (BoMRA) was established through an Act of parliament; the Medicines and Related Substances Act of 2013 and continues to operate under the Medicines and Related Substances Act of 2025. The Act provides for the regulation of the sale, distribution, importation, exportation, manufacturing and dispensing of medical products and related substances and matters incidental thereto in Botswana in order 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 distributions of Medical Products.

The purpose of this guideline is to ensure that the quality, safety, and integrity of medical products are consistently maintained throughout all stages of handling within pharmacies operating under a group practice setting, including hospitals and clinics. This guideline applies to all activities related to the procurement, storage, dispensing, internal distribution, and disposal of medical products within such facilities. It is intended to ensure compliance with applicable regulatory requirements and adherence to Good Pharmacy Practice (GPP) and relevant quality standards.

2. Laws, Regulations, Policies and Guidelines Applied

The guideline was developed using principles from the following:

i. Medicines and Related Substances Act, 2025, (MRSA) and Regulations, 2019
ii. WHO Technical Report Series, No. 1025, 2020, Annex 7,
iii. WHO Technical Report Series No. 986 Annexure 2 (GMP main principles)
iv. Botswana National Health Quality Standards for Hospitals, Vol 1-3
v. Botswana Health professions act, 2001
vi. Public health Act, Chapter 63:01

2.1. Legal Consideration

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

1. *A person shall not manufacture, sell, supply, export, import, distribute, dispense or store a regulated product unless he or she is authorised or licensed by the Authority in accordance with good manufacturing practises and international quality standards. (Sec 58 (1) of the MRSA, 2025).*

2. *A person who wishes to apply for an authorisation or license under subsection (1) shall apply to the Authority in such form and manner and upon payment of such a fee as prescribed (Sec 58 (2) of the MRSA, 2025*

3. *Where the Authority is satisfied that an application meets the prescribed requirements, the Authority shall issue an authorisation or license in the form and manner as prescribed (Sec 58 (3) of the MRSA, 2025*

4. *The Authority may cancel, suspend, withdraw, revoke, vary or renew an authorisation or license and the provisions of section 40 and 41 shall apply with necessary modifications (Sec 58 (4) of the MRSA, 2025*

5. *The Authority shall-*

    a. *Carry out necessary inspections to verify compliance with prescribed requirements and standards of good practice.*
    b. *Keep and maintain a register of all authorised, licensed, suspended, withdrawn, revoked, varied, cancelled and other change of the premises; if satisfied that the prescribed requirement standards of good practise have not been met;*
    c. *Prescribe a form of the register and make it accessible to the public; and*
    d. *for good and sufficient reasons refuse to license or cancel a license for premises which have become unsuitable for purposes for which it is licensed (Sec 58 (7) of the MRSA, 2025*

6. *A person who contravenes this section commits an offence and is liable to a fine not exceeding P100 000 or to imprisonment for a term not exceeding three years, or to both (Sec 58 (8) of the MRSA, 2025.*
7. *A person shall not import, export, manufacture for sale, sell, store, distribute or supply any regulated product which is substandard or falsified Sec 62 (4) of the MRSA, 2025.*

8. *The Authority shall ensure that all premises are inspected to assess compliance to set guidelines.*

3. Definitions and Abbreviations

3.1. Definitions

For these guidelines, the following terms shall be defined as follows:

3.1.1 **Applicant –** a company or entity registered in terms of the CIPA Act and operating in Botswana.

3.1.2 **Authority –** Botswana Medicines Regulatory Authority

3.1.3 **Controlled substances –** means a prohibited substance or medicine listed in Schedules 1A, 1B, 1C, 1D or a precursor chemical.

3.1.4 **Dispenser –** a pharmacist, veterinary surgeon or person authorised to dispense medical products by his or her professional body

3.1.5 **Regulated product –** medical products, blood and blood products, traditional medicines, food and related substances

3.1.6 **The Act –** Medicines and related substances act, 2025

3.1.7 **Within group Pharmacy -** 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.

3.2. Abbreviations

For the purpose of this guideline, following abbreviations shall apply:

3.2.1 **BoMRA** - Botswana Medicines Regulatory Authority
3.2.2 **BHPC** - Botswana Health Professional Council
3.2.3 **GMP** - Good Manufacturing Practices
3.2.4 **GDP** - Good Distribution Practices
3.2.5 **MRSA** – Medicines and Related Substances Act
3.2.6 **MRSR** – Medicines and related Substances Regulations
3.2.7 **TRS -** Technical Report Series
3.2.8 **WHO** - World Health Organization

4. Scope

4.1 The scope of this guideline covers all personnel and functional units involved in the management and use of medical products within a group practice. This includes, but is not limited to, Pharmacists, pharmacy support staff, prescribers, nursing staff, and administrative personnel, as well as any contracted service providers involved in storage, transportation, or handling of medical products within the facility.

4.2 The guideline further applies to all categories of medical products managed within the group practice, including prescription medicines, over-the-counter products, controlled substances, and other regulated health products. These guidelines were developed to assist all facilities involved in dispensing of regulated products to patients. The guidelines are applicable to all pharmacies authorised to operate as within group pharmacies, both government owned and privately owned facilities.

4.3 These guidelines are meant outline:

a. Responsibilities of the stakeholders involved in the distribution or sale of regulated products
b. Requirements for successful application and licensing of a within group pharmacy.
c. Documentation necessary to maintain in the operation of a within group 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 submitted by a Registered Pharmacist; or a person authorised to dispense Medical Products and be addressed to the Chief Executive Officer of BoMRA.

5.1.2 For new facilities, a detailed sketch plan of the premises must be submitted to the Authority for approval prior to sending an application.

5.1.3 The detailed sketch plan must be submitted to *inspections@bomra.co.bw*

5.1.4 The applicant is advised to submit the sketch plan of the premises before making structural changes to the facility.

5.1.5 The sketch plan must clearly indicate the:

a) layout of pharmacy and its dimensions,
b) location of segregated areas for receiving and dispatch of medical products,
c) medical products storage areas,
d) shelving areas,
e) locations of storage areas for expired, quarantined, recalled and returned products,
f) location of temperature controlling units,
g) location of the refrigerator/cold rooms,
h) location of Controlled Substances Cabinet,
i) location of power back up supply,
j) location of toilets and wash basins.
k) and any other requirement.

5.1.6 Post approval of the sketch plan and completion of the pharmacy construction as per the approved sketch plan, the applicant shall submit the application for pre-licensing through the BRIMS Portal https://brims.bomra.co.bw/

5.1.7 An application for renewal shall be submitted through the BRIMS Portal https://brims.bomra.co.bw/ **three (3) months** before the expiration of the current BoMRA License.

5.1.8 Applications shall be submitted with the prescribed fees for each scope of operation i.e. Human Medicines or Medical Devices.

5.1.9 **Here is a step-by-step guide to submit an application on BRIMS:**

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-licensing"
e. Fill up the required details and upload details

5.1.10 The applicant shall submit the following documents on BRIMS Portal https://brims.bomra.co.bw/

a. A certified copy of the pharmacist's registration certificate issued by a professional body.
b. A certified copy of a valid blue card (Permission to practise ID)
c. Copy of the Expiring BoMRA License (Renewals)
d. An approved sketch plan of the premises (new facilities)
e. Proof of payment (use facility name as reference) or pay online on BRIMS

f. Certified copy of identity card or passport

5.1.11 Confirmation of application submission must be emailed to BoMRA at inspections@bomra.co.bw with the TRC (Tracking Number) number of as the subject the email.

5.1.12 **Note:** Applications are sent to the Finance Department for payment verification before application screening by receiving officer on the BRIMS system.

5.1.13 An application is considered successfully submitted only upon successful payment verification and successful screening by the receiving officer on the BRIMS system.

5.2. Processing of application

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

5.2.2 If the application meets the prescribed requirements, the Authority will proceed to carry out an inspection of the pharmaceutical operations.

5.2.3 An application is considered successfully submitted only upon successful payment verification and successful screening by the receiving officer on the BRIMS portal.

5.2.4 An application will be rejected if it does not meet the minimum application requirements. The applicant shall receive communication outlining reasons for an unsatisfactory application submission.

5.2.5 New operations and license renewal shall be inspected, as per Customer service standards ***BOMRA/CEO/PR/P08/A01*** after the submission of a successful application, the applicant shall be notified of date and time prior to inspection.

5.2.6 Expedited applications paid with the prescribed fees for each scope of operations, timelines for inspection shall be conducted as per Customer service standards ***BOMRA/CEO/PR/P08/A01*** from date of successful application submission.

5.3 Inspection of operations

5.3.1 Inspection is required prior to the granting (pre-licensing) or re-granting (Renewal) of a licence, or upon approval of a substantial modification(variation) to an existing licence.

5.3.2 Inspections shall be conducted by authorised BoMRA inspectors, who shall identify themselves by presenting valid BoMRA Inspector identity cards upon arrival.

5.3.3 The purpose of the inspection is to assess compliance of the premises with these good storage and distribution Practices Guidelines, the Act, Regulations, and any other applicable legislation.

5.3.4 The inspection report shall be issued to the inspected facility within **ten (10)** working days of the inspection date.

5.3.5 Deficiencies identified during inspection shall be categorised as minor, major, or critical, based on the potential impact on product quality, safety, and efficacy, risk to the patient, and likelihood of recurrence.

5.3.6 The categorisation of deficiency, as per Guideline for Classification of GxP Deficiencies- ***BOMRA/IL/IL/P01/G08*** shall inform the facility's Compliance Risk Score, which may determine the frequency and type of subsequent regulatory oversight, including physical inspections, risk assessments, or desk-based abridged assessments.

5.3.7 Where deficiencies are identified, the inspected facility shall, upon receipt of the inspection report, submit a Corrective and Preventive Action (CAPA) plan addressing all findings within the timeframe specified by the Authority.

5.3.8 Applicants demonstrating compliance with the prescribed minimum requirements shall be issued a licence.

5.3.9 Where critical non-conformances have been identified, the Authority may require a confirmatory re-inspection prior to licence issuance to verify on-site that all critical findings have been adequately addressed. Applicable inspection fees shall apply.

5.3.10 Where critical non-conformances are identified at a licensed facility and pose an immediate or significant risk to public health, product quality, safety, or efficacy, the Authority may, without prejudice to any other regulatory action:

a. suspend the licence with immediate effect, pending satisfactory resolution of the identified non-conformances and completion of a confirmatory re-inspection; or

b. withdraw the licence where the facility has failed to adequately address critical non-conformances within the period stipulated by the Authority, demonstrates a pattern of repeated non-compliance, or where continued operation presents an unacceptable risk to public health.

5.3.11 The Authority shall notify the licence holder in writing of any suspension or withdrawal, stating the grounds for the regulatory action, the conditions for reinstatement where applicable, and the right of the licence holder to appeal the decision in accordance with the Act.

5.3.12 In addition to suspension or withdrawal, the Authority may impose regulatory enforcement charges in accordance with the Act and applicable Regulations where non-compliance has been established. Such charges shall be commensurate with the nature, severity, and duration of the non-compliance and shall not preclude any further civil or criminal proceedings as provided for under the Act.

5.4 Sampling and Evidence Collection during inspections

5.4.1 Authorised BoMRA officials shall have the authority to collect samples or any physical, documentary, or digital evidence necessary to determine compliance with the Medicines and Related Substances Act, 2025 and its Regulations. Such collection may be conducted during:

a. routine or for-cause inspections;

b. investigations relating to complaints, product quality issues, or suspected substandard or falsified medicines;

c. verification of product authenticity, labelling, or packaging integrity; or

d. inspections related to the importation, distribution, or sale of medicines and related substances.

5.4.2 Where sampling is conducted, the BoMRA Sample Collection Form shall be completed and signed by both the nspector and the responsible representative of the establishment. A copy shall be issued to the establishment at the time of collection.

5.4.3 All samples and evidence shall be handled in accordance with the Authority's sampling procedures to ensure integrity, traceability, and security from collection through to analysis. Collected samples or evidence may be retained, analysed, or submitted to designated laboratories for confirmatory testing, risk assessment, or enforcement purposes.

5.4.4 The owner, licence holder, or representative of the inspected pharmacy shall facilitate access, provide requested documentation, and allow the secure collection of samples or evidence as directed by the inspecting officer. Failure to cooperate shall constitute a breach of licence conditions and may result in regulatory enforcement action.

5.5 License Variation

5.5.1 An application for variation of a licence shall be submitted by the authorised person to the Authority requesting the approved changes to the existing licence.

5.5.2 Where a licence has less than three (3) months remaining validity, a variation application shall not be accepted. In such cases, the applicant shall instead submit a renewal application.

5.5.3 Variations shall be classified as either minor or major, as follows:

a. **Minor variation** — a change that has no significant effect on the safety, efficacy, quality of medicinal products, regulatory risk profile, or scope of licensed activities; or

b. **Major variation** — a change that has a significant effect on the safety, efficacy, or quality of medicinal products, or that materially affects the regulatory risk profile, scope, or nature of licensed activities.

5.5.4 Minor variations include, but are not limited to:

a. administrative changes, including change of business name or contact details;

b. replacement of key personnel with equivalently qualified individuals; or

c. minor premises layout changes that do not affect storage conditions, product flow, or compliance status.

5.5.5 Major variations include, but are not limited to:

a. change of premises location or significant structural modification of licensed premises;

b. change of ownership;

c. change or extension of the scope of licensed activities or product categories handled;
d. introduction of new systems or technologies with potential regulatory impact; or
e. any other change that increases regulatory risk or requires inspection or on-site verification by the Authority.

5.5.6 An application for variation shall be submitted through the BoMRA Regulatory Information Management System (BRIMS) portal at https://brims.bomra.co.bw/, accompanied by:

a. the prescribed variation fee, determined according to the classification of the variation as minor or major; and
b. such supporting documentation and information as the Authority may require.

5.5.7 The Authority reserves the right to reclassify a proposed minor variation as a major variation where, upon assessment, the change is determined to carry regulatory, public health, or animal health implications not apparent from the original submission.

5.5.8 A licensee shall not implement any proposed variation prior to receipt of approval from the Authority. Implementation of a variation without prior approval shall constitute a breach of licence conditions and may result in regulatory enforcement action.

5.6 Post- licensure notifications

5.6.1 The licensee shall notify the Authority promptly of any post-licence changes or events, including but not limited to:

a. prolonged absence of the authorised person exceeding thirty (30) days;
b. engagement of a locum Pharmacist
c. temporary or permanent closure of the facility;
d. resignation or departure of the authorised person; or
e. any other change that may affect the compliance status or operational capacity of the licensed facility.

5.6.2 Where more than one Pharmacist is employed at the licensed facility, the authorised person shall notify the Authority accordingly and submit proof of current registration with the relevant professional regulatory body for each such person.

5.6.3 Any change of the authorised person responsible for the licensed facility shall be communicated to the Authority in writing within thirty (30) working days of the change taking effect. The notification shall be accompanied by the credentials and proof of registration of the incoming authorised person.

5.7 Variation of Licence — Change of Personnel

5.7.1 Where a change of the authorised person constitutes a material change to the licence, the licensee shall submit a formal application for variation of licence in accordance with Section 5.5. Such an application shall be required where:

a. the change involves a difference in professional qualification or scope of practice that may affect the categories of products authorised for distribution; or
b. the Authority determines, upon assessment of the notification, that the change warrants formal regulatory review and licence amendment.

5.7.2 The licensee shall ensure that a suitably qualified and registered authorised person is in place and responsible for the facility at all times. Operation of a licensed pharmacy facility without a designated authorised person, beyond the period **permitted (30) thirty calendar days** shall constitute a breach of licence conditions and may result in suspension of the licence.

5.7.3 All notifications required under this section shall be submitted through the BRIMS portal at https://brims.bomra.co.bw/ and shall include such supporting documentation as the Authority may require.

5.8 Suspension and Withdrawal

5.8.1 Where a licence holder fails to meet the required standards and guidelines, the Authority may suspend or withdraw the licence in accordance with the Medicines and Related Substances Regulations (MRSR) 2019, Section 23(1).

5.8.2 The procedure for suspension and/or withdrawal of a licence shall be guided by the facility's applicable Compliance Risk Score profile, as determined in accordance with the Guideline for Classification of GxP Deficiencies ***BOMRA/IL/IL/P01/G08***

5.8.3 The severity and nature of identified non-conformances, including the presence of critical findings posing immediate risk to public or animal health, shall inform the regulatory action taken.

5.8.4 Prior to suspension or withdrawal, the Authority shall notify the licence holder in writing of:

5.8.5 the decision and the grounds upon which it is based.

5.8.6 the corrective actions required to restore compliance; and

5.8.7 the licence holder's right to respond within seven (7) working days of receipt of the notification, in accordance with MRSR 2019, Section 23(2).

5.8.8 Where a licence is suspended, the facility shall cease all licensed operations for the duration of the suspension.

5.8.9 The facility shall remain closed until all identified non-conformances have been satisfactorily addressed and, where required, verified by the Authority through a confirmatory re-inspection. Applicable re-inspection fees shall apply.

5.8.10 Where a licence is withdrawn, the facility shall immediately and permanently cease all licensed operations. no distribution, storage, or handling of medicinal products under the withdrawn licence shall be permitted, in accordance with MRSR 2019, Section 23(4).

5.8.11 A licence holder whose licence has been withdrawn and who wishes to resume operations shall submit a fresh application for a new licence and pay the prescribed application and licence fees as set out in Schedule 5 of the MRSR 2019. Such an application shall be subject to full assessment and inspection by the Authority prior to any licence being granted.

5.8.12 Where the Authority determines that non-compliance poses an immediate and serious risk to public or animal health, the Authority may suspend a licence with immediate effect, without prior notice, and notify the licence holder of the grounds for such action as soon as practicable thereafter. The licence holder shall retain the right to respond and appeal in accordance with the Act and applicable Regulations.

5.8.13 Suspension or withdrawal of a licence shall not preclude the Authority from imposing additional regulatory enforcement measures, including financial penalties or referral for criminal prosecution, where warranted under the Act and applicable Regulations.

6. Organization and management

6.1 The organization (hospital or clinic), to which the 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 upon request.

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

6.8 There should be a Quality Management System in place.

6.9 The operation must have a code of conduct to which all employees adhere to, failing which management must have policies and procedures to address breach of code.

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 GSDP (Good Storage and 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 medical examinations **at least once every two years**, or more frequently if required by risk assessment, regulatory requirements, or observed health concerns.

7.7. Personnel dealing with special categories of products such as cytotoxic, infectious, or sensitizing should be given specific training and shall be assessed at least **once every two years,** or more frequently if required by risk assessment, regulatory requirements, or observed health concerns. Record of assessment shall be maintained.

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

8. Premises and facilities

8.1 Premises — General Requirements

8.1.1 The trade licence, BoMRA licence, and registration certificates shall be conspicuously displayed at the reception or public service point, and the name/s of the pharmacist/s responsible shall be prominently displayed at the facility entrance.

8.1.2 Premises shall be secured against unauthorised entry through appropriate physical access controls. Signage prohibiting unauthorised entry, eating, drinking, and smoking shall be prominently displayed throughout the facility.

8.1.3 All surfaces shall be clean, dry, and constructed of smooth, impervious, and washable materials. Medicinal products shall be stored off the floor, adequately spaced, and handled in a manner that prevents contamination, mix-ups, and cross-contamination.

8.1.4 Products shall be protected from direct sunlight, rain, and extreme weather conditions always.

8.1.5 Receiving and dispatch areas shall be physically segregated, clearly labelled, and of sufficient size to accommodate the orderly receipt and dispatch of goods. Temperature monitoring shall be maintained and recorded in each area.

8.1.6 Dedicated, clearly labelled, and segregated areas shall be provided for quarantined, recalled, expired, rejected, and returned medicinal products. Records for each such area shall be maintained and kept current.

8.1.7 Written cleaning and pest control procedures shall be in place, specifying methods, responsibilities, and frequencies. Records demonstrating the execution and

effectiveness of both programmes shall be maintained and made available to the Authority upon request.

8.1.8 Appropriate fire detection and protection equipment shall be installed throughout the facility, regularly serviced, and supported by a documented fire prevention and control procedure. Regular fire drills shall be conducted and all personnel trained accordingly. Training, drill, and equipment service records shall be maintained.

8.1.9 The premises shall have access to a reliable, uninterrupted power supply. An automatic backup power system with mains failure start-up and automatic shutdown on power restoration shall be installed, regularly serviced, and tested. Service records shall be maintained and made available to the Authority upon request

8.2 Temperature Control, Cold Chain & Transportation

8.2.1 All medicinal product storage areas and refrigeration units shall be equipped with continuous temperature monitoring devices recording at a minimum frequency of six (6) times per hour per sensor. Temperature monitoring records shall be retained for a minimum of six (6) months and made available to the Authority upon request.

8.2.2 Ambient storage areas shall maintain temperatures between 15 – 30°C. Products requiring protection from moisture shall be stored at no more than 60% relative humidity. Cold chain products shall be stored within the following ranges, or in accordance with the manufacturer's recommendations:

a. Refrigerated products: 2 – 8°C
b. Freezer products: -20 ± 5°C
c. Deep freezer products: -70 ± 10°C

8.2.3 All temperature monitoring devices shall be calibrated annually against a certified, traceable reference standard, or as recommended by the device manufacturer. Calibration records shall be maintained.

8.2.4 Temperature mapping shall be conducted in all medicinal product storage areas, including refrigeration equipment and transport vehicles, in accordance with Good Storage and Distribution Practices requirements.

8.2.5 Refrigerators, cold rooms, and freezers shall be dedicated solely to medicinal product storage, equipped with access controls and alert systems to notify personnel of out-of-range temperatures. All cold chain equipment shall be regularly serviced and service records maintained.

8.2.6 Upon receipt of cold chain products, the pharmacy shall verify and document that the required storage temperatures were maintained throughout transportation prior to acceptance of the consignment.

8.2.7 Medicinal products shall be transported under appropriate temperature-controlled conditions, with continuous temperature monitoring at a minimum recording frequency of six (6) times per hour per sensor. Transport vehicle storage areas shall be temperature-mapped prior to use for medicinal product distribution.

8.2.8 Where third-party carriers are used for the transportation of medicinal products, the pharmacy shall have in place written agreements with such carriers specifying and

ensuring compliance with all applicable temperature control, monitoring, and documentation requirements set out in these Guidelines**.**

8.3 Controlled Substances

8.3.1 Controlled substances shall be stored in dedicated storage areas with restricted access or in securely bolted and locked steel cabinets. Access controls or keys shall be held exclusively by the authorised person.

8.3.2 A register entry shall be made within **twenty-four (24) hours** of any importation, exportation, distribution, sale, storage, or supply of a controlled substance. Register balances shall be reconciled within **seven (7) days** of each transaction.

8.3.3 All controlled substance records and registers shall be retained for a minimum period of **five (5) years** and made available to the Authority upon request.

8.4 Fluid and non-drug storage

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

8.4.2 The area should be secured to prevent unauthorised entry.

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

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

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

8.5Bulk storage area

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

8.5.2 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.

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

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

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

8.6Storage areas at the Wards

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

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

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

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

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

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

8.7.1 Where Chemo- or nuclear therapy and total parental nutrition (TPN) are provided by the institution; there shall be designated areas designed for such.

8.7.2 Measures should be in place to ensure security of personnel, products and equipment and access into each area should be controlled.

8.7.3 There should be an appointed person responsible for implementation and maintenance of the activities in these areas.

8.7.4 Personnel involved in activities in these areas should be trained, assessed and records of assessment should be retained.

8.7.5 There shall be access to wash basins or emergency showers.

8.7.6 There should be adequate cleaning of both premises and equipment, and cleaning records should be maintained.

8.7.7 Waste management system should be assured across all working areas to enhance correct segregation and disposal of biohazard waste.

8.7.8 There shall be a list of all equipment procured, and the list shall be updated once a new equipment has been procured.

8.7.9 There shall be a maintenance plan to ensure continual quality assurance of the product and services.

8.7.10 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.

8.7.11 All areas requiring PPE usage should be properly identified by warning signs.

8.7.12 The schematic diagrams of the installation of the safety chambers (BSC) should be available showing the direction of air flow.

8.7.13 A detailed record of compounding including date of preparation, batch number(s) of ingredients, quantities, calculations, expiration date of the ingredients and product, signature of the pharmacist shall be kept in the pharmacy.

8.7.14 All the SOPs applicable to the activities of this area should be available at point of use.

9.0 Documentation

9.1 General

9.1.1 Written instructions and records documenting all distribution activities, including receipts and invoices, shall be maintained at the facility for a minimum of three (3) years and made available to the Authority upon request.

9.1.2 All records, whether paper or electronic, shall be secure, attributable, legible, traceable, permanent, and accurate. Paper records shall be completed in indelible, non-erasable ink on non-temperature-sensitive, non-photosensitive paper. Electronic records shall have backups to prevent accidental data loss.

9.1.3 Permanent records shall be maintained for each stored product, indicating recommended storage conditions and any applicable precautions. Import and export of medicinal products shall be conducted in accordance with BoMRA guidelines on importation and exportation of regulated products.

9.1.4 A document control system shall be established and maintained governing the preparation, review, approval, amendment, and control of all distribution-related documents, covering both internally generated and externally sourced documents. Documents shall be clear, unambiguous, approved, signed, and dated by an authorised person. A referencing system enabling traceability of dispatched medicines to original suppliers shall be in place.

9.1.5 Electronic data systems shall be periodically reviewed for effectiveness and updated as necessary. A system for the identification, collection, retrieval, storage, maintenance, and disposal of all applicable documentation shall be established and maintained.

9.1.6 Purchase and sales records shall be maintained in the form of invoices capturing: transaction date; product name; batch number; supplier or purchaser name and address; quantities bought or sold; name of receiver or dispatcher; and signature of the authorised person.

9.1.7 A written recall procedure shall be in place, with designated responsible person(s), enabling effective and prompt recall of medicinal products known or suspected to be defective, substandard, or falsified.

9.2 Documentation Systems

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

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

9.2.3 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.

9.2.4 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.

9.2.5 The 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

9.2.6 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 a within group pharmacy:

1. Procedure for creating and reviewing SOP's (SOP for SOPs)
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 and waste management
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 controlled substances
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 falsified and substandard products
26. Procedure for fire prevention, detection, and control
27. Procedure for ward stock management
28. Procedure for handling high-alert medication
29. Procedure for infection control

10. Complaints

10.1 A documented complaints system shall be in place ensuring that complaint details, responses from the original manufacturer, and investigation outcomes are communicated to all relevant parties in a timely manner.

11. Returned, Rejected, Expired and Recalled Products

11.1 Returned, rejected, expired, and recalled medicinal products shall be physically segregated in a dedicated, clearly labelled quarantine area, or by an equivalent electronic segregation system. Required storage conditions shall be maintained throughout segregation and transit pending a disposition decision.

11.2 Any product whose quality is in doubt shall not be considered suitable for reissue or reuse. Disposal of medicinal products shall be carried out in accordance with applicable national regulations, and records of all returned, rejected, destroyed, expired, and recalled products shall be retained for a defined period.

11.3 The authorised person shall be accountable for the return and recall process and shall ensure that unsaleable products are not reintroduced into the supply chain. Appropriate and safe transport arrangements shall be made for returned, recalled, rejected, or expired products in accordance with applicable storage and handling requirements.

12. Substandard and Falsified Products

12.1 No person shall import, export, manufacture, distribute, sell, store, or dispense any substandard or falsified medicinal product. Any such product identified in the distribution chain shall be immediately segregated, clearly labelled as not for sale, and BoMRA notified without delay.

12.2 The marketing authorisation holder shall be notified of any confirmed or suspected substandard or falsified product. Upon confirmation, a formal documented decision shall be made regarding disposal, ensuring the product does not re-enter the market.

13. Contract Activities

13.1 Any distribution activity delegated to a third party shall be performed by authorised personnel under a written contract specifying all applicable requirements.

13.2 Subcontracting shall only be permitted under defined conditions, and subcontractors shall hold appropriate authorisation for the contracted function. Contract acceptors shall be audited periodically to verify compliance.

14. Self-Inspection

14.1 Regular self-inspections shall be conducted by a competent, independent person to monitor compliance with GSDP principles and trigger corrective and preventive actions where required. All self-inspection findings, observations, and proposed corrective measures shall be recorded, and an effective follow-up programme shall be maintained to ensure closure of non-conformities.

15. Release of Customer Information

15.1 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

15.2 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

15.3 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

15.4 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

15.5 The following information about the customer shall be shared through BoMRA public domains

a. Company Name (license and business name)
b. License number
c. Business address (physical address)
d. Type of business (authorized activity)
e. Authorised Person's Name
f. License validity

g. Facility Compliance status

16. Reference Materials

The pharmacy shall be in possession of the following references:

16.1 Medicines and Related Substances Act, 2025
16.2 Medicine and Related Substances Regulations, 2019
16.3 National Health Quality Standards, 2013, (Vol 1- 3)
16.4 A Medical Dictionary (Not more than 5 years old).
16.5 Access to Human Medicines Register on the BRIMS portal.
16.6 The latest edition of MIMS or BNF, any other compendium or MDR up to 2 years old.