Botswana Medicines Regulatory Authority

Approved By: _____ 15-04-2026

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Date of Approval (DD/MM/YYYY)

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Revision status sheet

Page	Changes made	Issue No	Process Owner (Title)	Initiated By (Name)	Reviewed By (Name)	Date
13	Changed clause 8.2.2from "The temperature of the pharmacy should range between (+15 °C and +25°C) ±2°C, to 'the temperature of the pharmacy should range between (+15 °C and +30°C) ±0.5°C. ' this is to align with conditions of registration and Botswana temperature zoning classification.	3.0	Manager – Inspections and Licensing	Maikaego N Moreri	Tshegofatso Chilume	19/02/2026
13	Added: Clause 8.2.3 Temperature monitoring devices should be calibrated at defined intervals and in accordance with the manufacturer's instructions	3.0	Manager – Inspections and Licensing	Maikaego N. Moreri	Tshegofatso Chilume	19/02/2026
Header	Title Change: Name change from Guidelines for Operating a Community Pharmacy to Guideline for Operating a Standalone Pharmacy.	2.0	Manager – Inspections and Licensing	Maikaego N. Moreri	Tshegofatso Chilume	19/02/2026
16	Addition of clause 11 provision for Release of customer information	1.0	Manager – Inspections and Licensing	Tshetsana Senau	Tshetsana Senau	13/12/2021

1. Preamble

The Medicines Regulatory Authority (BoMRA) was established through an Act of parliament; the Medicines and Related Substances Act of 2025. The act provides for the regulation of medicines, medical devices, and cosmetics 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. To achieve this goal, the Authority has undertaken to develop a set of guidelines and procedures to guide the handling of medicines throughout the supply chain.

This document provides guidance on what is required to acquire a license for operating a pharmaceutical retailer by BoMRA. It is a requirement to comply with the guidelines set in accordance with the Medicines and Related Substances Act and Regulations thereto. All stakeholders involved in the supply chain shall ensure the safe handling of medicines so that their quality is maintained until the end user.

2. Laws, Regulations, Policies and Guidelines Applied

These guidelines were developed using principles from the following:

a. Medicines and Related Substances Act, 2025, (MRSA)
b. Medicines and Related Substances Regulations, 2019
c. WHO Technical Report Series, No 1025, 2020, Annex 7

2.1 Legal Considerations

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 the purpose of these guidelines the following terms shall be defined as follows:

3.1.1 **Standalone Pharmacy** – means premises, labelled as such, licensed by the Medicines Regulatory Authority for the storing, dispensing, and selling of medical products, and which is under the continuous control and supervision of a registered pharmacist.

3.1.3 **Dispensary** - dispensary" means any premises in which an authorised dispenser stores, handles, and dispenses medicine listed under Schedule 1, 2 or 3.

3.2 Abbreviations

For the purposes of this Guideline, the following abbreviations shall apply:

3.2.1 **BHPC –** Botswana Health Practitioners Council
3.2.2 **BRIMS** - BoMRA Regulatory Information Management System
3.2.2 **GSDP -** Good Storage and Distribution Practice
3.2.3 **PPL -** Private Practice License
3.2.4 **SOP** – Standard Operating Procedure

4 Scope

4.1 These guidelines were developed to assist all Standalone pharmacies involved in the sale, dispensing or storage of medical products.

4.2 The guidelines are applicable to all pharmacies wishing to operate as Standalone Pharmacies, both government owned and privately owned facilities. These guidelines are meant to:

a. Outline the responsibilities of the stakeholders involved in the sale of medical products.
b. Outline the requirements for successful application and licensing of a standalone pharmacy.
c. Outline the documentation necessary to maintain the operation of a standalone pharmacy.

5. Guidelines for Operating a Standalone Pharmacy

5.1 Submission requirements

Application requirements and procedure

5.1.1 Applications for prospective pharmaceutical operations licence and license renewal shall be submitted by a registered Pharmacist 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 pharmacy.

5.1.5 The sketch plan must clearly indicate the:

a) layout of pharmacy and its dimensions,
b) medical products storage areas,
c) shelving areas,
d) locations of storage areas for expired, quarantined, recalled and returned products,
e) location of temperature controlling units,
f) location of the refrigerator/cold rooms,
g) location of Controlled Substances Cabinet,
h) location of toilets and wash basins.
i) 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 clicks "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 Botswana Health Professionals Council.
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
g. A certified copy of a valid private practice licence for the pharmacist or a permission to employ another pharmacist letter.

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 portal.

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.***

5.3 Inspection and Licensing of Establishment

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 good storage and distribution Practices, the Act, Regulations, Good Pharmacy Practice, 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. License renewal or spot 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 inspector 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 responsible Pharmacist 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 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 Pharmacy, 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, 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 sale; 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 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.

5.7.4 Any Change with the responsible Pharmacist shall be communicated to the Authority within 30 Days. The Pharmacy may not be under the continuous supervision of locum pharmacist or a pharmacist without a Private Practice License for a period exceeding thirty (30) Days.

6 Suspension and Withdrawal

6.1 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).

6.2 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***

6.3 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.

6.4 Prior to suspension or withdrawal, the Authority shall notify the licence holder in writing of:
   a. the decision and the grounds upon which it is based.
   b. the corrective actions required to restore compliance; and
   c. 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).

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

6.6 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.

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

6.8 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.

6.9 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.

6.10 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.

7 Personnel and management

7.1 All Pharmacy operations shall be conducted under the continuous supervision of a registered Pharmacist operating within their respective scope of practice as defined by the relevant professional regulatory body.

7.2 All personnel involved in pharmacy activities shall be suitably trained and assessed on the requirements of Good Storage and Distribution Practices, prior to undertaking their duties. Training shall be delivered through documented Standard Operating Procedures (SOPs), and records of training and competency assessments shall be maintained for all personnel.

7.3 All personnel engaged in pharmacy operations shall have a current employment contract and a written job description specific to their role, activities, and responsibilities within the facility.

7.4 All personnel involved in pharmacy activities shall receive initial and continuing training on:
   a. medicinal product security and chain of custody.
   b. product identification and verification.
   c. detection, handling, and reporting of substandard and falsified medicinal products; and applicable regulatory and reporting obligations under the Act and these Guidelines.

7.5 Records of all such training shall be maintained and made available to the Authority upon request.

8. Premises

8.1 Premises — General Requirements

8.1.1 For Pre Licensing, BHPC registration certificates shall be conspicuously displayed at all times for public view in the premises, and the name/s of the pharmacist/s responsible shall be prominently displayed at the facility entrance.

8.1.2 For License renewal, valid trade licence, BoMRA licence, Private Practice license, and registration certificates shall be conspicuously displayed at all times for public view in the premises, and the name/s of the pharmacist/s responsible shall be prominently displayed at the facility entrance.

8.1.3 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 pharmacy.

8.1.4 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.

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

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. Equipment service records shall be maintained.

8.1.9 The area of the section to be used as dispensary (excluding the shelving space) shall not be less than Six (6) square metres for one (1) Pharmacist working there, with additional two (2) square metres for each additional pharmacist (Sufficient space should be provided in the dispensary to ensure an efficient flow of work and effective communication and supervision) (these are guidance values).

8.1.10 A suitable door with minimum height of 900mm shall be used to separate the dispensing area from the other areas. The door shall be lockable to render the dispensary inaccessible in the absence of a Pharmacist.

8.1.11 The dispensary shelves should be designed such that they discourage members of the public from reading the labels of prescription drugs.

8.1.12 A waiting area shall be provided and labelled as such. The area shall be at least two (2) meters away from the dispensing space/ dispensary to allow for privacy.

8.1.13 A room for confidential counselling shall be provided. Its dimensions shall be at least three-square meters and be able to accommodate two chairs and a table. It should be made of solid material, and adjacent to the dispensing area.

8.1.14 A sink with adequate supply of hot and cold running water shall be provided within the dispensing area for washing hands, apparatus, etc. (some detergent and a means of drying hands, except cloths, should be provided).

8.1.15 A pharmacy shall be equipped with a dispensing bench, the top of which shall be covered with smooth washable and impervious material like stainless steel, laminated material, plastic, melamine, Formica etc.

8.1.16 There should be sufficient security measures in place in the pharmacy.

8.1.17 Schedule1, 2 and 3 medicines shall always be stored in the dispensary, whereas schedule 4 can be stored in the front shop (if any).

8.1.18 Schedule 2 medicines shall be stored in a way that patients cannot read their labels.

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 responsible Pharmacist.

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.

8.3.4 The pharmacy shall maintain a register (electronic or physical records) of all codeine-containing products and routinely review the records to identify and monitor for potential misuse or abuse.

9. Documentation and Procedures

9.1 General

9.1.1 Written instructions and records documenting all regulated product activities and transaction, 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.

9.1.4 A document control system shall be established and maintained governing the preparation, review, approval, amendment, and control of all pharmacy-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 All documented procedures and plans shall be reviewed at least once every 2 years.

9.1.8 A pharmacy shall be equipped with the following minimum apparatus and equipment:

a. A suitable number of tablets counters and spatulas
b. A suitable range of graduated glass measuring cylinders, mixing slab or tile and any suitable glassware necessary for the proper carrying out of the dispensing duties of a Pharmacist.
c. A suitable range of containers for the dispensing of tablets, capsules, creams, ointments, and liquids

d. A suitable range of labels for the above-mentioned containers (in iv), The labels shall bear the details of the pharmacy, strength, batch number, expiry date, provision for patient name, directions for use and name of the drug. (the details as per the regulation 8)
e. A digital scale.
f. A suitable range of mortars and pestles of glass or earth-ware material
g. A working dispensing programme and printer.
h. Access to copying facilities
i. Telephonic; fax or email contact.

9.1.9 Continuous temperature monitoring records of 7 days, prior to pre-licensing inspection shall be made available at inspection time.

9.1.10 Schedule 1A 1B and 1C, medicines shall be dispensed only on written prescription, record of the transaction entered into a Controlled Medicines register and a prescription record book.

9.1.11 All records and transactions and all registers shall be maintained and be made available for inspection. Schedule 2, medicines shall be dispensed only on written prescription.

9.1.12 Containers of every medicine dispensed to a patient shall have a label with information listed below where applicable:

a. Name of the Patient.
b. Name of the medicine and strength
c. Dosage instructions
d. Date of dispensing
e. Name or signature of dispenser
f. Name of pharmacy

9.1.13 Containers of pre-packed medicines shall have a label bearing the following information:

a. Name, strength, and quantity of the medicine
b. Batch number
c. Expiry date
d. Name of manufacturer

9.1.14 No medicines should be sold to any person below the age of sixteen (16) without a legal guardian present.

9.1.15 Adequate compounding equipment should be purchased when in-house compounding is to be carried out, and substances prepared in-house shall be kept for a period not exceeding seven (7) days unless stability for that period can be substantiated.

9.1.16 A prescription record book or electronic records shall be kept for all prescription drugs. Copies of prescriptions and invoices whether partially or wholly dispensed shall be kept in the pharmacy for at least 3 years.

9.1.17 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.

9.1.18 The bulk breaking records shall be maintained, and they should include all details of the medicines to allow for traceability to the original container.

9.1.19 Invoices from approved distributors shall be kept for at least three (3) years.

9.1.20 Only registered Medicines or B Listed Medicines (as per Human Medicines Register) and approved Complementary Medicines shall be kept in the pharmacy.

9.1.21 Only registered Medical Devices or Listed Medical Devices (as per Medical Devices Register) shall be kept in the pharmacy.

9.2 Standard Operating Procedures

9.2.1 The following Standard Operating Procedures shall be available:

a. Good personal hygiene
b. Cleaning of premises (floors, shelves, etc.).
c. Receipt, storage and pre-packaging (bulk breaking)
d. Dispensing and follow up of patients
e. Goods requiring special handling (e.g. thermo-labile; cold chain management)
f. Returned, rejected and expired drugs
g. Handling customer and Products complaints
h. Recalled medicines
i. Ensuring supplier's authenticity
j. Elimination of pest, insects, rodents and others
k. Extemporaneous preparations
l. Adverse drug reaction reporting
m. Handling of Controlled Substances
n. Procedure for identifying substandard and falsified products

9.2.2 A training plan for role specific SOPs for personnel shall be availed at pre-licensing, and records shall be maintained.

10 Reference Materials

10.1 A pharmacy shall have access to the following minimum reference books:

a) Access to Medscape on-line.
b) The latest addition of MIMS or BNF, any other compendium or MDR up to 2 years old;
c) A Medical dictionary, not more than 5 years old.
d) Medicines and Related substances Act, 2025, and Medicines and Related Substances Regulation. 2019.
e) Access to the Human Medicines Registers on the BRIMS Portal

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

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. Related Documents

16.1 Declaration form for continuous supervision by a pharmacist; ***BOMRA/IL/IL/F03***
16.2 Application Form 8; ***BOMRA/IL/IL/F02***
16.3 Application submission checklist; ***BOMRA/IL/IL/F04***