Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

Approved		10-04-2026
By:	**Ms. Zukiswa Raditladi** **Director – Licensing and Enforcement**	**Date of Approval (DD/MM/YYYY)**

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Revision status sheet

Page	Changes made	Issue No	Process owner's (Title)	Initiated By (Name)	Reviewed By (Name)	Date
	Added Section 6 Suspension and Withdrawal	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	09/04/2026
	Added 8.5.2 At minimum the records demonstrating temperature control shall be retained in the wholesaler for a period not less than (6) months.	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	09/04/2026
	Added Section 8.7 Controlled Substances	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	09/04/2026
10	Include "continues to operate under the Medicines and Related Substances Act of 2025" in the Preamble	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
10	Updated "WHO Technical Report Series, No. 957, 2010 Annex 5" to "WHO Technical Report Series, No. 1025, Annex 7" in Pages 6 and 21	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
11	Aligned "Legal Considerations" and "Definitions" Sections as they are in MRSA, 2025	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
All pages	Updated "Medicines and Related Substances Act, 2013, (MRSA)" to	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026

	"Medicines and Related Substances Act, 2025, (MRSA)"					
16	Included sketch plan process in Clauses 5.1.2 to 5.1.5 for pre-licensing	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
14	Included BRIMS Application process in Clauses 5.1.5 to 5.1.11	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
14	Added "5.1.11 Applications are sent to the Finance Department for payment verification before application screening by receiving officer."	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
16	Updated Post Licensure Notification to include 5.5.2 – 5.5.3	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
15	"Inspection is required for granting or re-granting a license or approval of a substantial modification" has been moved to Clause 5.3.1	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
13	Addition of 4.1 to 4.3 Clauses under Scope	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
14	Replaced "after date of application" with "successful application	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026

	submission" at Clause 5.2.5					
All	Replaced "distributor" to "wholesaler"	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
22	Replaced "Counterfeit product" to "Substandard and Falsified product"	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
14	Added "5.2.6 Expedited applications paid with the prescribed fees for P10 000.00 for each scope of operations shall be inspected within five (5) working days from date of successful application submission"	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
15	Expanded on 'License Variation' Section by adding Clauses 5.4.1 to 5.4.7	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
17	Expanded on 'Post Licensure notifications' Section by adding Clauses 5.5.1 to 5.5.3	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
17	Added "…made of impervious washable material" to clause 8.1.5	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
18	Replaced "automatic backup	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026

	generator" to "automatic power backup"					
23	Added "16.2g) Facility Compliance status" and Removed 'Premises contact details (email, telephone line) under Release of Customer Information	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
19	Added "The temperature monitoring device shall make temperature records with a minimum recording frequency of six (6) times per hour for each sensor" at Clauses 8.54 and 8.6.3	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
19	Added "8.6.6 Refrigerator , cold room and freezers should be serviced regularly and records should be maintained."	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
17	Replaced "habit-forming drugs"/ "HFD" with "Controlled Substances"	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
21	Added "…segregation of products" to Clause 9.4.3.10	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026

23	Added Section 15. Sampling and Evidence Collection During Inspection	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
24	Update the Reference Section and added "iii. Veterinary Surgeons Act, 2008 and v. WHO Temperature Mapping of Storage Areas (Technical Report S 961 Annex 9 Supplement 8)"	3.0	Manager Inspections and Licensing	Tsitsi Kema	Maikaego N. Moreri	13/03/2026
7	Added, "subtitle 5.3 Inspection"	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	31/03/2021
7	Added, "5.3.1 The inspection shall be carried out by BoMRA inspectors who shall identify themselves by show of BoMRA inspector identity cards."	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	31/03/2021
7	Added, "5.3.2 The aim of the inspection is to assess premises compliance to these BoMRA Good distribution practises guidelines, Act, Regulations and any other applicable legislation.	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	31/03/2021
7	Added, "5.3.3 The inspection report shall be shared with the inspected facility within 10 working	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	31/03/2021

	days from the date of inspection.					
7	Added, "5.3.4 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	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	31/03/2021
7	Added, "5.3.5 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 recorded in the recommended template for Addressing Deficiencies and submitted to BoMRA.	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	31/03/2021
7	Added, "5.3.6 Failure to address the deficiencies shall result in license withdrawal and in case of new application shall result in termination of licensing process after 30 working	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	31/03/2021

	days from the date of inspection.					
8	Added "5.4 A license can only be varied if it is left with more than three months of validity."	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	17/11/2021
8	Added, clause 5.4.1 and 5.4.2 to explain License variation that require prior inspection and those that do not. Added,	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	17/11/2021
11	Added, "8.1.13. All different sections of the Distributor shall be clearly labelled using waterproof and durable material."	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	31/03/2021
11	Added, "8.6.2 Medicines requiring cold storage temperature shall be kept between 2-8°C."	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	31/03/2021
11	Added, "8.7 and records maintained"	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	31/03/2021
14	Added, "9.2.8 There shall be a referencing system in place that promptly provides link of the dispatched medicines to the original suppliers to enable traceability of pharmaceutical products in the supply chain."	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	31/03/2021

15	"8.5.2 The storage temperature shall range between 15-25˚C ±3 or according to the manufacturer's recommendation."	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	17/11/2021
19	Insert Sec 15. Release of client information	1.0	Manager Inspections and Licensing	Gaone Matlhare	Gaone Matlhare	14/12/2021

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 wholesale guidelines 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 Products, wholesale pharmacies as well as other parties such as 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, 2025, (MRSA)
b. Medicines and Related Substances Regulations, 2019
c. WHO Technical Report Series, No. 1025, Annex 7

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. Prescribed 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 **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 **BOMRA** – Botswana Medicines Regulatory Authority

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

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

3.1.6 **Falsified product** – any regulated product with a false representation of

a) its identity including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients
b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder or
c) its history, including the records and documents relating to the distribution channels used

3.1.7 **Distribution** – the division and movement of regulated products

a) from the premises of the manufacturer of such products
b) from another central point to the end user or
c) to an intermediate point by means of various transport methods, via various storage health establishments

3.1.8 **Medical product** – medicine, complementary medicine, vaccines, in-vitro diagnostics and medical devices

3.1.9 **Medicine** – means

a) any substance, mixture combination of substances manufactured, sold or presented as suitable for use, in:
   i) the diagnosis, treatment, alleviation, modification, prevention of diseases, illness, abnormal physical or mental condition or symptoms thereof or
   ii) restoring, correcting, or modifying any somatic or psychic or organic condition or

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

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

d) Any labelled preparation in pharmaceutical dosage form that contains as active ingredients, one or more substances of natural origin that are derived from plants or animals

e) Homeopathic, ayurvedic, or other, medicine that contains, as active ingredients, substances of natural origin and may be derived from any part of plants or animals in a pharmaceutical dosage forms.

f) Vitamins and minerals prepared in a pharmaceutical dosage form or

g) Any premix

3.1.10 **Substandard medical product** – a medical product which fails to meet wither its quality standards or its specifications, or both, as approved by the Authority in the marketing authorisation

3.1.11 **Pharmacist** – a person registered as a pharmacist under the Botswana Health Professional Act

3.1.12 **Prescription** – a formal written instruction from an authorised health professional to dispense a medical product or a combination of medicines for the treatment of a person or animal specified in the direction

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

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

3.1.15 **Veterinary Surgeon** – a person registered as a veterinary surgeon under the Veterinary Surgeon's act

3.2 Abbreviations

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

3.2.1 **BoMRA**- Botswana Medicines Regulatory Authority

3.2.2 **BRIMS**- BoMRA Regulatory Information Management System

3.2.3 **MRSA** – Medicines and Related Substances Act

3.2.4 **SOP**-Standard Operating Procedure

3.2.5 **TRS-** Technical Report Series
3.2.6 **WHO-** World Health Organization

4. Scope

4.1. These guidelines were developed to assist all facilities involved in importation and exportation of medical products.

4.2. The guidelines are applicable to all wholesalers authorized to operate as Human or Veterinary Medicines Wholesaler, both government owned and privately owned facilities. These guidelines are meant to:

a. Outline the responsibilities of the stakeholders involved in the distribution or sale of medical products
b. Outline the requirements for successful application and licensing of a pharmaceutical wholesaler.
c. Outline the documentation necessary to maintain the operation of a pharmaceutical wholesale.

4.3 These wholesalers should carry out importation and exportation of medical products as per the Guidelines for Import or Export of Medicines ***BOMRA-IL-IE-P02-G01***

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; Veterinary Surgeon 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* The area of the premises shall not be less than 100m^2 (guidance value).

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

5.1.5 The sketch plan must clearly indicate the:

a) layout of warehouse 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 warehouse 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 Veterinary Medicines.

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. In the case of a veterinary surgeon, written proof of registration by the Botswana Veterinary 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

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 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 wholesaler 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 or veterinary surgeon 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 or veterinary surgeon;
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 or veterinary surgeon is employed at the licensed wholesale 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 wholesale 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.

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 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 distribution operations shall be conducted under the continuous supervision of a registered pharmacist or veterinary surgeon, operating within their respective scope of practice as defined by the relevant professional regulatory body.

7.2 All personnel involved in distribution activities shall be suitably trained and assessed on the requirements of these Good Storage and Distribution Practice (GSDP) Guidelines 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. The facility shall ensure adequate staffing levels are maintained at all stages of distribution activities.

7.3 All personnel engaged in distribution 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 distribution 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, Warehousing and Storage

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 responsible pharmacist/s or veterinary surgeon/s 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 distributor 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 wholesaler 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 or veterinary surgeon.

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.

9. 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 human and veterinary medicinal 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 Customer Verification

9.2.1 The wholesaler shall verify the following prior to processing any order or delivery:

a. Name and licence or authorisation number of the ordering entity, as issued by BoMRA.
b. validity of the entity licence; and
c. that the delivery address on the account and invoice corresponds to the physical address on the licence

9.3 Standard Operating Procedures

9.3.1 The authorised person shall be responsible for the compilation, review, approval, and update of all SOPs. Current copies shall be maintained at the point of use for easy retrieval. As a minimum, SOPs shall be in place for the following:

a. SOP preparation, review, and control
b. Temperature control, monitoring, and mapping
c. Security of stored medicinal products
d. Receiving of stock and supplier/customer verification
e. Handling, storage, and segregation of medicinal products
f. Returned, rejected, recalled, and expired medicinal products
g. Destruction of unsaleable or unusable stock
h. Product and customer complaints
i. Packaging and dispatch of goods
j. Cleaning of premises and pest control
k. Controlled substances handling
l. Identification and handling of substandard and falsified products
m. Health, personal hygiene, safety, and environmental protection, including spill management
n. Staff training on SOPs
o. Operation and maintenance of vehicles and equipment
p. Retention of records

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 References

16.1 The wholesaler shall be in possession of the following references:

For Both Human and Veterinary Wholesalers

a. Medicines and Related Substance Act, 2025
b. Medicines and Related Substances Regulations, 2019
c. WHO Good Storage and Distribution Practices (Technical Report Series. No 1025, Annex 7)
d. WHO Temperature Mapping of Storage Areas (Technical Report Series. No 961 Annex 9 Supplement 8)
e. Access to list of Human medicines and related substances registered in Botswana (Bluebook) (Human Medicines Wholesaler)

16.2 Additional reference requirements for Veterinary Medical Products Wholesaler.

a. Veterinary Surgeons Act, 2008
b. Access to list of allowed Veterinary medicinal products.