Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

Approved By: _____ 09/04/2026

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Director – Licensing and Enforcement

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Revision status sheet

Page	Changes made	Issue No	Process owner's name	Initiated By (Name)	Reviewed By (Name)	Date
5	Addition of the PH; Port Health abbreviation	1	Ms. Zukiswa Raditladi	B. Setlhalefi	B. Setlhalefi	18/02/2026
5	Amend sentence to read import/export/transit	1	Ms. Zukiswa Raditladi	B. Setlhalefi	B. Setlhalefi	18/02/2026
5	Addition of ports; Phillip Matante International Airport, Ramatlabama Border and Gaborone Container Terminal and correction to Kazungula One Stop Border Post	1	Ms. Zukiswa Raditladi	B. Setlhalefi	B. Setlhalefi	18/02/2026
6	Addition of clause 6.3 that speaks to Port Health responsibilities	1	Ms. Zukiswa Raditladi	B. Setlhalefi	B. Setlhalefi	18/02/2026
7	Removed Clause 7 on Collection of Importation fees. Address in - Guidelines for Import or Export of Medicines - IL-IE-P02-G01	1	Ms. Zukiswa Raditladi	B. Setlhalefi	B. Setlhalefi	18/02/2026
8	Addition of Definitions of Authority and Agency	1	Ms. Zukiswa Raditladi	B. Setlhalefi	B. Setlhalefi	18/02/2026
	Citing of Terms of Reference between BoMRA and Port Health Services dated 13th September 2024.	1	Ms. Zukiswa Raditladi	B. Setlhalefi	B. Setlhalefi	18/02/2026

1. Preamble

1.1 Botswana Medicines Regulatory Authority (BOMRA) is a statutory body established through an Act of Parliament, the Medicines and Related Substances Act of 2025 [No. 5 of 2025] to regulate medicines, cosmetics and medical devices. BOMRA regulates the sale, distribution, importation, exportation, manufacture and dispensing of medicines, related substances as well as cosmetics.

1.2 Since all the regulated products under BoMRA mandate are imported, it is critical to control the importation of the products to ensure only products that have undergone the necessary assessments to ensure safety, quality and efficacy are allowed into the country. To this end BoMRA is responsible for importation control of the products. This however, can only be done with the facilitation of the custodians of borders, which is the Customs Office under the Botswana Unified Revenue Service (BURS) and other entities such as Port Health. In recognising the need for effective utilisation of scarce Government Resources and also appreciating the vastness of our PoEs, it is critical that working relationships with those already at PoEs be established for the control of imports of medicines, medical devices and cosmetics.

1.3 BoMRA proposes a tripartite arrangement where Port Health Officers carry out initial checks on all medicines consignments before clearing them for BURS processes. BoMRA is to carry out random inspections at designated PoEs with greater frequency of these randomised checks carried out at PoEs with the highest volumes of pharmaceutical imports such as Sir Seretse Khama International Airport and Tlokweng. PoE verification shall be done in accordance with Guidelines for import /export of Medicines and SOP for PoE verification.

2. Purpose

2.1 The purpose of this document is to:

i. Define areas of cooperation and role clarity between BoMRA and PoE personnel (BURS and PH officers) to ensure seamless operations at port of entry.

ii. Highlight and describe activities to be undertaken at PoE and clarify who will carry out the activities.

iii. Suggest PoE to be designated for importation of medicines, medical devices and cosmetics.

3. Scope

This guideline is applicable to information related to clearance of import/export of medicines and medical products.

4. Definitions and Abbreviations

4.1 Definitions

1.1.1 Authority - Botswana Medicines Regulatory Authority

1.1.2 Agency – Refers to Botswana Unified Revenue Services, Botswana Medicines Regulatory Authority, Port Health Services- BOMRA-IL-EL-P05-G01

4.2 Abbreviations

The following abbreviation shall apply:

4.2.1 BoMRA - Botswana Medicines Regulatory Authority
4.2.2 BURS - Botswana Unified Revenue Services
4.2.3 CEO - Chief Executive Officer
4.2.4 MRSA - Medicines and Related Substances Act, 2025.
4.2.5 MRSR - Medicines and Related Substances Regulations, 2019.
4.2.6 PoE – Port of Entry.
4.2.7 PH – Port Health Services
4.2.8 CRIA - Clean Report of Inspection and Analysis
4.2.9 NC – Non Conformity

2. Designated Ports of Entry

It is proposed that all imports/exports/transits be done through designated ports of entry, which are proposed as follows:

i. Tlokweng Border
ii. Pioneer Border
iii. Ramokgwebana Border
iv. Mamuno Border
v. Kazungula One Stop Border
vi. Sir Seretse Khama International Airport
vii. Phillip Matante International Airport
viii. Ramatlabama Border

6 Roles for collaborative parties

6.1 BOMRA:

i. Shall authorise importation or exportation of any medical product prior to purchase and shipment of any such consignment

ii. Perform document review, physical inspection and clearing consignments of medical products at ports of entry/exit or an authorized premises on a random basis

iii. Samples may be collected during consignment inspection

iv. Identify Ports of Entry/Exit to be designated for import/export/transit of medical products

v. Shall reconcile all importation/ exportation data generated during PoE checks done by BURS and Port Health

vi. Shall avail document storage and equipment necessary to operationalize the collaborative arrangement

vii. Avail checklists to facilitate checks and data collection as may be required

6.2 BURS

i. BURS will be the first point of contact for medical products at the Port of Entry/Exit.

ii. Provide facilities for temporary storage of quarantined products

iii. Carryout consignment document checks including but not limited to permits issued by the Authority

iv. Retain records as appropriate to enable information reconciliation between the two agencies

v. BURS shall accord high priority for clearing of medical products: medical *products are prone to degradation and some need to be stored under specially controlled temperatures*

vi. BURS to perform seal of commercial consignments of which the Authority will perform verification at the premises of authorized importers. The seal issued by BURS will be addressed to the Authority and therefore seal breaking will be performed by Officer of the Authority.

6.3 PORT HEALTH SERVICES

The terms of reference entered into between Botswana Medicines Regulatory Authority and Port Health Services dated 13th September 2024 shall apply. In line with the ToRs the role of Port Health Services will include but not limited to the following:-

i. Provide facilities for temporary storage of quarantined/seized products
ii. Ensure commercial consignment document checks and undergo physical inspection and the necessary measures are applied
iii. Ensure that Personal consumption of medical products are physically inspected and necessary action on seizure/detention/quarantine and/or release is performed.
iv. Samples may be collected during consignment inspection
v. Retain records as appropriate to enable information reconciliation between the two agencies. Submit data periodically to the Authority.

7 Handling of seized/detained medical products by BURS and Port Health Officials:

i. Products that do not meet the documentary requirements will be detained pending compliance in the custody of BURS and/or Port Health
ii. All detained products will be documented, and all this information submitted to BOMRA for resolution.
iii. Failure to meet compliance requirements for detained products will result in seizure by BURS and/or Port Health. Seized products shall be handed over to the Authority for disposal.

NB: Detained products will be handled in accordance with Guidelines for Handling confiscated goods.

8 Review of the guidelines

The guidelines will be reviewed periodically every two (2) years.