# Botswana Medicines Regulatory Authority

**Approved By:**

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**Date of Approval (DD/MM//YY)**

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## Revision status sheet

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| 4 | Minister to Ministry of Health and Wellness | 2.0 | Director Licensing and Enforcement | 03/05/2022 |
| 6 | Clause 4.6 on reporting | 2.0 | Director Licensing and Enforcement | 03/05/2022 |
| 7 | Clause 6: added 6.7 Ports of Entry Report Template | 2.0 | Director Licensing and Enforcement | 03/05/2022 |
| 4 | Added definition for clearing agents and removed risk profiling | 3.0 | Director Licensing and Enforcement | 14/10/2022 |
| 5 to 7 | Verification of medicines with a permit and those without a permit | 3.0 | Director Licensing and Enforcement | 14/10/2022 |
| 8 | Added yearly POE verification schedule | 3.0 | Director Licensing and Enforcement | 14/10/2022 |
| 9 | Updated process map | 3.0 | Director Licensing and Enforcement | 28/11/2022 |
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## 1. Purpose

This document describes the process for verification of consignments of medicines and related substances transiting through designated ports of entry/exit.

## 2. Scope

The document is applicable to both human & veterinary medicines and related substances imported, exported & transited through designated ports of entry/exit. This document will implement requirements in accordance with the following supporting documents:

i. MRSA 2013 & MRSA Regulations of 2019
ii. Customs Act number 33 of 2018
iii. BURS & BOMRA Memorandum of Agreement
iv. Import/export control guidelines

## 3. 3. Definitions and Abbreviations

### 3.1 Definitions

For the purpose of this procedure, the following definitions shall apply;

i. **Authorized Inspector:** a person authorized in writing by BOMRA to perform the duties of consignment verification of medicines and related substances at PoE.
ii. **Clearing agents:** Independent companies which have been licensed by BURS to provide customs services to importers and exporters in Botswana.
iii. **Designated Ports:** Ports through which medicines and related substances may be imported, exported, or transited as authorized by the Minister of Health & Wellness

### 3.2 Abbreviations

3.1.1 **BOMRA:** Botswana Medicines Regulatory Authority
3.1.2 **BURS:** Botswana Unified Revenue Service
3.1.3 **PoE:** Port of Entry
3.1.4 **SAD 500:** Single Administrative Document

## 4. Procedure

### 4.1 Submission of declarations

4.1.1 A declaration is lodged electronically through an authorized Clearing agent unless otherwise specified. Required attachments shall include:

i. BOMRA permit: for all BoMRA licensed importers.
ii. Tax/commercial invoice: required for importation fees.
iii. Exemption letter/certificate: for all unregistered products.

iv. Airway bill- applies for consignment cleared at airport.

v. Packing list: provides information about the consignment.

vi. BOMRA Importers/exporters license

vii. Clinical trial authorization letter

## 4.2 Profile selection

4.2.1 Once a declaration is lodged all medicines and related substances will be configured to go through physical inspection (Red) in the Customs Management System (CMS). This will also apply during network outages when manual processes are implemented.

4.2.2 Clearing agent will inform BOMRA of the impending import/export for the purpose of appointing for consignment verification.

## 4.3 Verification of consignments

4.3.1 Documentary checks:

i. An authorized inspector shall confirm that all required documents are availed and valid using a Checklist for Consignment Verification - *BOMRA/IL/IE/P05/F01*.

ii. All document details will be captured in the system, i.e., permit number, license number.

4.3.2 Physical examination

i. This shall be done by authorized inspectors.

ii. Physical examination of consignments will be conducted daily during hours of operation.

### 4.3.3 Verification of medicines on an import permit

i. The authorised inspector shall confirm that the Importer or consignment clearance agent has all the required documents which include BoMRA Import Permit (Human, VMP, *HFD permit),* or HFD export from the exporting country, exemption letter(for unregistered products), Airway bill, Commercial Invoice and/ or Packing List.

ii. All Import permits provided at POE will be recorded on the checklist for consignment verification *(BOMRA/IL/IE/P05/F01).*

iii. During physical inspection the authorized inspector shall then check by random sampling whether the consignments conform to what was authorized in terms of labelling requirements, expiry dates, the authorised quantities in accordance with the checklist for consignment verification. However, for clinical trials, the consignment shall not be opened only the seal and packaging integrity checks and other checks as indicated in the checklist for consignment verification shall be conducted.

iv. The customer shall provide copies of the Import Permit, airway bill and commercial invoice to the Authority for filing and payment of importation fees, which shall be shared with the relevant office for processing.

v. Only the original permit (for HFD permits), original airway bill and commercial invoice shall be cleared. The Inspector shall indicate on each respective product, the quantity imported and the balance thereof remaining on the original permit.

vi. After physical inspection of consignment, the authorised inspector shall stamp the documents to clear consignment or issue conditional release if there are outstanding issues. Conditional release is given to applicants for the following reasons:
   a) Documentary requirements are not fully met by the client.
   b) Authorised inspector is unavailable to clear consignments at PoE.

vii. On issuing a conditional release, the consignment verification form shall be carbonated and one copy is stamped and given to the importer/ clearing agent. The inspectors shall then make a follow up of all the conditional released consignments to make sure the importers resolve the issues atleast 2 working days after clearance

viii. Once the importer resolves the outstanding issues, the consignment is released and the overall decision is documented on page 3 of the checklist or referred to Enforcement if further investigations are required using Procedure for Referring Non-conformities or Offences to Enforcement Unit *(BoMRA/IL/IL/P12)*.

ix. Any consignment recommended for release shall be sent to BURS for consignment clearence process by BURS

### 4.3.4 Verification of medicines without an import permit

### a. Medicines for personal use

i. These include all prescription medicines or complementary medicines or any products within the BoMRA regulatory scope but not requiring an import permit like cosmetics and medical devices.

ii. All medicines meant for personal use shall be verified using checklist for consignment verification - Personal Consumption *(BOMRA/IL/IE/P05/F02)*.

iii. The Authorised inspector shall ensure that all the required documentation is provided, which include prescription (for prescription medicines only), airwaybill, packing list and invoice.

iv. During physical inspection the authorised inspector shall then check whether the consignments conform to labelling requirements, expiry dates, the prescribed quantities in accordance with the checklist for consignment verification. Imported quantities shall be guided by the prescription if it does not exceed three months supply, and any extra quantities shall be handed to port health for seizure.

v. Any products that do not meet requirements stipulated in 4.3.4 shall be handed to Port Health.

**b. Medical devices clearance**

i. Covid related Medical Devices shall be required to be accompanied with BoMRA exemption letter, Airway bill, Commercial Invoice and/ or Packing List, while all other medical devices will cleared right away.

ii. Any product that does not meet the requirements shall be handed to Port Health for Seizure.

## 4.4 Decisions after inspection

4.4.1 Conditions for release of consignments:

i. All approved consignments will be released by the inspector once satisfied that all importation conditions have been fulfilled.

ii. An Inspector will stamp on the BOMRA permit with an official stamp.

iii. Consignment can be given a Conditional/Provisional Release where the authorised inspector has only verified the document checks for the products and releases the products for further release into the market by BOMRA inspectors.

4.4.2 Conditions for rejection:

i. Consignments which do not meet importation requirements will be released to the custody of Port Health.

ii. Medicines and related substances rejected for quality reasons will be seized by Port Health.

iii. Those rejected because of being unregistered in Botswana or inappropriately labelled, upon application *may* be re-exported to a third country *on special request* and *with special clearance from the Medicines Regulatory Authority* of the country where the consignment is being exported to;

iv. Where the consignment is rejected/detained the inspector will issue an Inspection/Seizure Form - ***BOMRA/IL/IE/P05/F03***. This document shall be copied to BURS.

v. All confiscated products shall be handled in accordance with Guideline for Handling Confiscated Goods ***(BOMRA/IL/IE/P05/G01)***.

## 4.5 Clearing conditions

Clearance of goods shall be according to two categories i.e. commercial and personal use.

### 4.5.1 Commercial

i. These are goods which are mostly for resale or distribution for resale and they will be cleared using the SAD 500 through the services of an authorized Clearing Agent. All commercial imports will be expected to utilize the services of authorized and accredited Clearing Agent.

### 4.5.2 Personal

i. Clearance of all personal consumption consignments shall be done as according to clause 4.3.4 (a) in accordance with the Personal Consumption Guidelines ***(BOMRA/IL/IE/P05/G02)***,

## 5.0 Reporting

5.1 To facilitate implementation of this procedure, BOMRA authorized inspectors and import/export control unit officers shall visit ports of entries and perform consignment verification checks according to the annual Ports of Entry Verification Schedule – ***BOMRA/IL/IE/P05/F05***. The POE verification exercise shall be done atleast 3 times a week between 0900 hours and 1600 hours.

5.2 Any work done at Ports of Entries shall be reported monthly in the Ports of Entry Verification Report Template ***(BOMRA/IL/IE/P05/F04)*.**

5.3 Reports shall be given unique numbers in the following format: XXX/YYYY, where XXX is number starting with 001 and YYYY is the year in which the inspection was conducted. (e.g 001/2022)

## 6.0 Responsibility

6.1 BOMRA authorized inspectors together with BOMRA import/export control unit officers shall be responsible for implementation of this procedure in accordance with the Guideline for facilitation at port of entry ***(BOMRA/IL/IE/P05-G03)*.**

6.2 The Director, Licensing and Enforcement is responsible for overseeing the implementation and review of the procedure.

## 7.0 Records

7.1 Detention records

7.2 Checklist for Consignment Verification - BOMRA/IL/IE/P05/F01

7.3 Checklist for consignment verification-Personal Consumption - BOMRA/IL/IE/P05/F02

7.4 Inspection/Seizure Form - BOMRA/IL/IE/P05/F03

7.5 Ports of Entry Verification Report Template - BOMRA/IL/IE/P05/F04

7.6 Ports of Entry Verification Schedule – BOMRA/IL/IE/P05/F05

## 8.0 Annexure: Process Map