Botswana Medicines Regulatory Authority

Approved By: _____ _____

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Table of Contents

1. Preamble 4
2. Purpose 4
3. Scope 4
4. Definitions and Abbreviations 5
5. Seizure or confiscation of medicines and related substances 5
6. Detained goods 6
7. Custody and safe keeping 6
8. Turnover of seized medicines and submission of report 7
9. Transfer of confiscated goods 7
10. Roles and Responsibilities 8

Revision status sheet

Page	Changes made	Issue No	Process owner's name	Date
5	Define unwanted medicines	1.0	Director Licensing and Enforcement	11/11/2021
6	Introduce basis for seizure	1.0	Director Licensing and Enforcement	11/11/2021
4	Include IVD in regulated products	1.0	Director Licensing and Enforcement	11/11/2021

1. Preamble

1.1 The Department of Inspections and Licensing through the Import/Export Office is responsible for inspection and enforcement of all legal requirements for distribution of medicinal products and medical devices. The main activities are ports of entry verification, on-site inspections of compliance of suppliers with good distribution practices (GDP) and undertake product quality surveillance and random product sampling to ensure compliance to Botswana registration protocols.

1.2 The following products are subject to inspection and compliance verification at ports of entry;

a) Human medicinal products, including both active pharmaceutical ingredient (API) and finished pharmaceutical products (FPP),
b) Biologics, including vaccines, blood, and blood products**,**
c) Veterinary products and
d) Medical devices and In-Vitro Diagnostics

1.3 The Unit, in conjunction with the Enforcement Unit investigates suspected breaches of the Medicines and related substances Act, 2013 and Regulations, 2019. The Team conduct inspections countrywide and follow-up cases reported at ports of entry to control counterfeit products, illegal pharmaceutical operations, importation without permit, wholesale, retail dealings and dispensing without licence. BOMRA collaborates with Ministry of Health and Wellness (Port Health) and BURS who conduct oversight inspection and verification of medical products at designated ports of entry and refer to BOMRA on decisions taken.

2. Purpose

2.1 The guideline aims to strengthen PoE processes to;

i. Establish a mandatory procedure for the detention/destruction of infringing medical products without the need for a legal action.

ii. Address the challenges arising from increasing use of postal or courier traffic for movement of medical goods as a result of the increase in online sales of medicines.

iii. Establish processes for accepting, storing, controlling, releasing, and destroying prohibited and restricted medical products that have been seized, detained, or abandoned.

3. Scope

3.1 The guideline applies to:

i. Imported goods that were cargo reported and are goods found in a customs place such as borders and airports that have not been entered in the time required.

ii. Imported goods found at distributors, manufacturers or retailers.

iii. These guidelines are applicable to products confiscated in accordance with non-compliances as stipulated in MRSA 2013, Guidelines on Import/Export, Guidelines on

Good Distribution Practices of Pharmaceutical Products, Guidelines for Operating a Community Pharmacy, Guidelines for Operating a Veterinary Medicinal Products Retailer, Guidelines on handling imports for personal consumption and Guidelines on handling pharmaceutical donation.

4. Definitions and Abbreviations

4.1 Definitions

4.1.1 **Unwanted medicine** - means a medicine which has expired, is substandard, banned, or is a counterfeit.

4.2 Abbreviations

The following abbreviations shall apply:

4.2.1 **BOMRA** - Botswana Medicines Regulatory Authority

4.2.2 **BURS** - Botswana Unified Revenue Services

4.2.3 **PoE** – Port of Entry

5. Seizure or confiscation of medicines and related substances

Medicines that are considered to not have met import requirements shall be rejected entry. This medicines are classified as unwanted medicines and treated in accordance with section 37 of MRSA 2013.

The inspecting team (BOMRA or Port Health) having initial custody and control of medicines shall immediately, after the seizure and confiscation, make a physical inventory **BOMRA/IL/IE/P05-G01/F01**, inspection and seizure form **BOMRA/IL/IE/P05/F03** and, photograph the same in the presence of:

5.1.1 The person from whom such items were confiscated and/or seized or his/her representative or legal counsel.

5.1.2 A representative from BURS, who shall be required to sign copies of the inventory BOMRA/IL/IE/P05-G01/F01 and inspection and seizure form BOMRA/IL/IE/P04/F03 report covering the medicines and who shall be given a copy thereof.

5.2 When goods are seized, they are itemised, and then:

5.2.1 Small seizures are placed into sealed bags (up to 15kgs in weight) for deposit with BOMRA.

5.2.2 Large seizures are counted and secured within a vehicle and then transported to BOMRA.

5.2.3 Large seizures can consist of full shipping containers of seized material. These are counted by BURS unless BOMRA have taken responsibility for the operation or the goods are seized inland by BOMRA teams.

5.3 The physical inventory BOMRA/IL/IE/P05-G01/F01, inspection and seizure form BOMRA/IL/IE/P05/F03 and photograph shall be completed at the place where the search is

served; or at the nearest police, as long as the integrity and the evidentiary value of the seized items are properly preserved by the inspection team, shall not render void or invalid such seizure of and custody over the said items.

5.4 The first copy of the Inventory should be given by the seizing officer to the owner of the goods or his/her authorized representative, if available; otherwise the copy should be kept in the file. The goods together with the Duplicate & Triplicate copies of the Inventory should be forwarded weekly to BOMRA. The confiscating officer shall give receipt on both the Duplicate and Triplicate copies of the Inventory and return the duplicate copy to the seizing officer for keeping in the seizure file after stamping by receiving officer.

5.5 The medicines shall be properly marked for identification, weighed where possible or counted, sealed, packed and labelled by the inspection team.

5.6 Where any substance is found in packages or containers of similar size and/or weight and bearing identical markings, the seizing officer shall cause all such packages or containers to be classified, numbered, and separated into lots ready for weighing, counting, sampling, sealing and labelling.

5.7 Where it is physically possible to count and weigh the seizure as a complete entity, the seizing officer shall cause it to be counted and weighed. Where it is not physically possible to count or weigh the seizure as a complete entity, that seizing officer shall cause its count or gross weight or net weight to be estimated.

6. Detained goods

6.1 Where products are detained by Port/health and/or BURS for further information from BOMRA, a sample product is sent to BOMRA together with a detention certificate. This will be assessed by Regulatory officers for compliance with requirements.

6.2 Products that meet requirements are released through writing a letter of product release.

6.3 Where products registrability status cannot be determined, the products will be submitted to registration department for assistance using an inspection referral form **BOMRA/IL/IE/P05-G01/F02**.

7. Custody and safe keeping

7.1 BOMRA Law and enforcement unit shall have respective control over safekeeping of confiscated substances.

7.2 BOMRA shall store controlled medicines separately from dangerous drugs. Storage facilities must be adequately protected.

7.3 Narcotics and Psychotropics drugs shall first be packaged in plastic heated envelopes, sealed and then be stored in designated heavy-duty steel cabinets.

7.4 Officers must be guided by chemical labels and material safety data sheet (MSDS) to ensure proper storage and safe handling procedures, first aid procedures, proper leak, spill, and disposal techniques, protective equipment, and other safety procedures.

7.5 Prior to storing chemicals products, officers must ensure that they are properly labelled.

7.6 The chemical label should include a minimum of the following:

i. the chemical name of the material

ii. the date received.

iii. hazardous properties such as flammability, reactivity, corrosiveness, toxicity, etc

iv. additional safety information or precautions such as use of protective equipment, etc.; and;

v. additional optional information may include fire fighting equipment or first aid measures.

8. Turnover of seized medicines and submission of report

8.1 Within twenty-four (24) hours upon confiscation/seizure of medicines, the medicine shall be submitted to BOMRA for qualitative and quantitative examination.

8.2 Within the same period, and in conformity with prescribed operational reporting procedures, the seizing officer/team shall also prepare a report of the confiscation/seizure, which include particulars of:

i. the time, place and date of seizure.

ii. the particulars of the person(s) arrested/charged/importing products.

iii. the identity of the seizing officer and all person's present

iv. the circumstances in which seizure took place.

v. a description of the vehicle, vessel, place or person searched and the location where the substance was found.

vi. a description of the substance found.

vii. a description of packaging, seals and other identifying features

viii. a description of quantity, volume and units and the measurement method employed.

ix. all subsequent movements of the substance or chain of custody; and

x. any other matter

9. Transfer of confiscated goods

9.1 When seized / detained goods are transferred from one custodian to another, the Original Inventory and the Re-inventory, if any, shall invariably be handed over along with the goods.

9.2 While conducting stock checks, or during transfer of goods, seals on the packages shall always be compared with the specimens of seals on the corresponding Inventories.

9.3 The specimen of seal on the Inventories shall act as final proof where any tampering of seals is suspected or when discrepancy in the goods is found at the time of opening the packages.

9.4 In cases where the detained / seized goods are physically handed over to a third party or are only partially handed over to BOMRA, Inventory shall be prepared in quadruplicate instead of triplicate and the fourth copy shall be given to such party. Other copies of the Inventories will be dealt with in the usual manner.

9.5 A Register for Handing Over and Taking Over of Confiscated Goods between Port health/BURS and BOMRA - **BOMRA/IL/IE/P05/G01/F03**, shall be filled in triplicate with the original accompanying the goods and duplicate and triplicate left with BURS and Port health, respectively.

10. Roles and Responsibilities

10.1 Importer/Exporter

i. Meet all financial obligations relating to applications, clearing or shipping of consignments, and to storage.

10.2 BURS

i. Provide facilities for temporary storage of quarantined/confiscated products.

ii. Ensure that all pharmaceutical consignments undergo initial clearance approval by Port Health.

iii. Carryout consignment document checks and share authorised invoices with the Authority.

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

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

10.3 Port Health

i. Perform physical examination and clearing consignments of medicine at ports of entry

ii. Shall reconcile all importation/ exportation data generated during PoE checks done with BURS and BOMRA.

iii. Provide facilities for temporary storage of quarantined/confiscated products.

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

v. Shall inform the client of the confiscated goods and the reasons for confiscation