Botswana Medicines Regulatory Authority

Approved By: _____ _____

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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 2013 [No. 8 of 2013] 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.

4. Definitions and Abbreviations

4.1 Definitions

None

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, 2013.

4.2.5 **MRSAR** - Medicines and Related Substances Regulations, 2019.

4.2.6 **PoE** – Port of Entry.

5. Verification of consignments at Ports of entry

5.1 It is proposed that all imports 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 Border
vi. Sir Seretse Khama International Airport

6. Roles for the key players

6.1 BOMRA:

i. Shall authorise importation or exportation of any pharmaceutical product prior to purchase and shipment of any such consignment
ii. Perform physical examination and clearing consignments of medicine at selected ports of entry on a random basis
iii. Identify Points of Entry to be designated for import of regulated products
iv. Shall reconcile all importation/ exportation data generated during PoE checks done by BURS and Port Health

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

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

6.2 BURS

i. Provide facilities for temporary storage of quarantined 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*

6.3 Handling of detained/quarantine medicines by BURs and Port Health Officials:

i. BURS will be the first point of contact for imported medicines.

ii. Upon identifying the consignment as medicines and related substances, BURS will forward the same to Port Health for document verification and inspections. Samples may be collected during this inspection.

iii. Pharmaceutical consignments that have passed inspections will be forwarded to BURS for final processes before release to customers

iv. Products that do not meet the documentary requirements will be quarantined in the custody of BURS.

v. All quarantined products will be documented, and all this information submitted to BOMRA for resolution

NB: detained products will be handled in accordance with Guidelines for Handling of quarantine/detained or confiscated goods.

7. Collection of importation fees

7.1 In accordance with MRSA regulations 2019 26(7) a person authorised to import medicines shall pay a fee as set out in the regulations in line with prescribed guidelines.

7.2 The fees shall be paid through BURS facilitation in line with the Memorandum of Agreement between BOMRA and BURS. The procedure will be guided by the SOP for Verification of Medicines and related substances at designated ports.

7.3 To assist BURS to differentiate the different fees they collect for different entities BOMRA has proposed for the BOMRA importation fees to be identified by 'BOMRA invoice fee' or 'BOMRA import consignment fee'.

7.4 To facilitate this collection of fees BOMRA initiated permit numbers that will help BURS with differentiating the different medicines that attract different rates.

7.5 Permits are generated using the ***Import permit for medicines, medical products or cosmetics form 11 BOMRA-IL-IE-P02-F05, Permission to Import Veterinary Medicinal Products*** template ***BOMRA-IL-IE-P02-F04, and or Transit permit for medicines and cosmetics*** template ***BOMRA-IL-IE-P02-F08, and*** **Import Permit for Habit Forming Medicines and/or Psychotropic Substances** template **BOMRA/IL/IE/P01/F02**

7.6 Numbering of permits shall be in the form: IE/YYYY/MM/I(VMP/HM/TRA/WE/HFD)XXXX where:

a) YYYY is the current year,

b) MM is the current month,

c) I for imports, and followed by, either;

d) VMP for Veterinary Medicinal Products, or

e) HM for Human Medicines, or

f) TRA for transit permits,

g) HFD for habit forming drugs,

h) WE for Wholesale Exemptions, and;

i) XXXX is a number starting with 0001.

7.7 Permits shall attract different rates as listed below:

Medicine	**Medicines consignment fee**	**Permit numbering**
Importation fee for **wholesale exempted products**	0.25% of the value of the consignment	1. IE/YYYY/MM/IWEXXXX E.g. **Permit No: IE/2020/10/IWE2800**
Importation fee for **all other products**	0.15% of the value of the consignment	1. IE/YYYY/MM/IVMPXXXX **E.g. Permit No: IE/2020/10/IVMP2800** 2. IE/YYYY/MM/IHMXXXX **E.g. Permit No: IE/2020/10/IHM2800** 3. IE/YYYY/MM/TRAXXXX **E.g. Permit No: IE/2020/10/TRA2800**

		4. IE/YYYY/MM/HFD/XXXX **E.g. Permit No: IE/2020/10/HFD2800**

7.8 Imports invoice fee rates shall trigger the following rates:

7.9 A 0.25% rate for all permits with a **WE** in their permit numbers

7.10 All other permit numbers will trigger 0.15% rate, except permits with a **TRA** in their numbers which shall not be liable to payment of fees as they are transit permits.

8 Review of the guidelines

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