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## Botswana Medicines Regulatory Authority




Approved By: \_\_\_\_\_

**Dr Seima Dijeng**

**Director – Inspection and Enforcement**


\_\_\_\_\_

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

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### Revision status sheet


Page	Changes made	Issue No	Process owner's name	Date

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## I. Preamble

- I.1 The Medicine Regulatory Authority (BoMRA) was established through an Act of parliament; the Medicines and Related Substances Act of 2013. The act provides for the regulation of medicines, medical devices, and cosmetics 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. To achieve this goal, the Authority has undertaken to develop a set of guidelines and procedures to guide the import of medicines for personal consumption.
- I.2 One of the key goals of any country's public health system is to make medicines that are safe, efficacious and of high quality available to its population. Because the amount of merchandise imported into the Botswana in personal shipments is normally small, both in size and value, comprehensive coverage of these imports is normally not justified. These procedures clarify how BoMRA may best protect consumers with a reasonable expenditure of resources. There has always been a market in Botswana for some foreign manufactured products that are not available domestically. For example, individuals sometimes prefer products from their homeland or products labeled in their native language to products available in Botswana.
- I.3 Other individuals seek medical treatments that are not available in this country. Medicine are sometimes brought into the country in response to an externally issued prescriptions to allow continuation of a therapy initiated abroad.
- I.4 With increasing international travel and world trade, we can anticipate that more people will purchase products abroad that may not be approved, may be health frauds or may be otherwise not legal for sale in Botswana. BoMRA may allow entry of shipments when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by BoMRA are subject to refusal, BoMRA may examine the background, risk, and purpose of the product before making a final decision.
- I.5 Although BoMRA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments.
- I.6 Because some countries do not regulate or restrict the exportation of products, people who mail order from these countries may not be afforded the protection of either foreign or Botswana laws. In view of the potential scale of such operations, BoMRA has focused its enforcement resources more on products that are shipped commercially, including small shipments solicited by mail-order promotions, and less on those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from foreign medical facility where a person has undergone treatment. It is therefore critical that requirements are set to ensure that some level of control is placed on the medicines that are imported for personal use.

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1.7 In general there are two categories of medicines imported for personal use:

**1.7.1 Medicines purchased over the internet**

Consumers frequently purchase medicines over the internet for reasons of cost or confidentiality. BoMRA cannot ensure the safety and effectiveness of medicine purchased over the Internet from any source outside the country and therefore strongly discourages this practice in order to safeguard the public.

**1.7.2 Medicines bought from foreign pharmacies**

People who have moved here from a foreign country for vacation, attending university, work, etc; BoMRA understands that individuals visiting the country for the various reasons already stated may need to bring personal medication with them. These medicines may have been lawfully prescribed and dispensed in their originating country. Some of the products may be over the counter medicines at the home country and still not be allowed in Botswana.

**2. Laws, Regulations, Policies and relevant Guidelines**

2.1 These guidelines were developed according to the laws and regulations governing Medicines practices and services. The laws and regulations applied are listed below:


- 2.1.1 Medicines and Related Substances Act (MRSA), 2013
- 2.1.2 Medicines and Related Substances Regulations (MRSR), 2019
- 2.1.3 The Single Convention on Narcotic Drugs, 1961
- 2.1.4 The Convention on Psychotropic Substances, 1971
- 2.1.5 The 1988 Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances
- 2.1.6 WHO Good distribution practices for Medicines TRS **957**, 2010, Annex 5
- 2.1.7 WHO guidelines on import procedures for Medicines No **917**, 2003, Annex 3

**3. Legal considerations**

3.1 All transactions concerning the importation of consignments of medicinal products should be conducted through independent authorised Medicines importers authorized by BoMRA.

3.1.1 Unless otherwise specified, only authorized medicinal products appearing on the medicines register (Blue book and Provisional list) will be permitted to be imported (or exported) into (or out of) the country.

3.1.2 All importers of Medicines must import through the authorized PoE (see MRSA 2013, Section 36)


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- 3.1.3 An applicant for an import permit must be registered with BoMRA as an importer of medicines.
- 3.1.4 No importation or exportation of medicines shall be done by post/mail. Registered Courier services will be allowed to bring in medicines on behalf of clients.
- 3.1.5 The Authority may, in such special circumstances as it considers appropriate
- a) exempt, in writing, any medicine or cosmetic from the requirements of subsection (1); or
  - b) by order published in the *Gazette*, declare any medicine or cosmetic to be a banned medicine or cosmetic, in which case the medicine or cosmetic shall not be registered or if already registered, such registration shall be cancelled.
- 3.1.6 Medicine in relation to which an exemption may be made in terms of Section 3 subsection (3) may include;
- a) medicine which has not been registered but was prescribed outside Botswana for a patient's personal use;
- 3.1.7 A medical practitioner may apply in form 4 upon payment of an application fee set out in schedule 5 to the authority to exempt the registration of medicines from outside Botswana, for his or her patients personal use. MRSA Regulation 2019 Sec 6 (1).
- 3.1.8 Subject to subregulation (1) application shall comply with the guidelines and shall be signed by an importing pharmacist residing in Botswana (MRSA Regulation 2019 Sec 6(2)).
- 3.1.9 The authority may, after having considered the application and the supporting documents, grant the exemption. (MRSA Regulation 2019 Sec 6 (3)). This will be done in accordance with Application for Medicine Registration Exemption (BOMRA/ER/EX/P02/G01).
- 3.1.10 A person who imports medicines from outside Botswana for personal use shall not import more than one month's supply of medicines MRSA Regulation 2019 Sec 7 (1).
- 3.1.11 Subject to subregulation(1), where a person brings more than one month supply, but less than three months supply, he or she shall produce upon request by a competent authority, certified copy of the prescription from a medical practitioner MRSA Regulation 2019 Sec 7 (2)
- 3.1.12 Subject to regulation 6 a person shall apply to the authority in writing for an exemption from registration for any subsequent supplies of the imported medicines (MRSA Regulation 2019 Sec 7 (3)). This will be done in accordance with Application for Medicine Registration Exemption (BOMRA/ER/EX/P02/G01).

#### 4. Purpose

- 4.1 The purpose of this guidelines is to provide requirements for the importation for personal-use of BoMRA-regulated products.

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4.2 This guidelines is subject to future amendments by the Director of Licensing and Enforcement, on the prevailing operational requirements by the authority.

## 5. Scope

5.1 This guidelines covers importation of medicines for personal use by persons entering the country or those using courier service due to inability to travel personally. It is applicable only where the conventional route of importation of medicines through a licensed importer is not possible.

## 6. Definitions and Abbreviations

### 6.1 Definitions

6.1.1 **Personal consumption-** means medicines not for further sale or distribution but meant for person use. Most of these products may be brought in person or through baggage or shipped by courier.

6.1.2 **Visitor** – means any person who is not a citizen or permanent resident of Botswana arriving in Botswana

### 6.2 Abbreviations

6.2.1 **BOMRA** - Botswana Medicines Regulatory Authority

6.2.2 **BURS** - Botswana Unified Revenue Services

6.2.3 **CEO** - Chief Executive Officer

6.2.4 **MRSA** – Medicines and Related Substances Act, 2013

6.2.5 **MRSR** - Medicines and Related Substances Regulations, 2019


## 7. Criteria for Importation of Medicines for Personal Use

### 7.1 Requirements for importation of medicines for personal use

7.1.1 Under the personal use importation, medicines can be imported by persons carrying own products. Where this is not possible an appointed representative or courier may bring products on behalf of the patient. In all cases the medicines are to be accompanied by a Doctor's prescription. This provision also applies to medicines not registered in Botswana.

7.1.2 Because safety and quality cannot be guaranteed, medicines including complementary medicines and herbal preparations should not be ordered over the Internet unless the meet the following conditions:

- a) You have been authorized to import such products by BoMRA.
- b) Are licensed by BoMRA as an importer.

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c) The medicine is registered in Botswana or exempted from registration.

7.1.3 Individuals can legally import medicines for personal use under the Personal Use Importation as per MRSA/MRSR subject to the following conditions:


- a) If the medicine is prescription-only, it must be accompanied by a valid prescription or written authority from a consulting health practitioner. A copy of the prescription or written authority must be enclosed with the medicine where the Medicine is brought into the country via a courier service.
- b) Controlled substance (Schedule 1) cannot be imported for personal use as per International Narcotics Control Board requirements. Controlled substances can only be brought into the country when a returning resident or visitor arrives with them in Botswana. However, this should always be accompanied by a prescription or letter of authorisation from a registered practitioner in the country of origin.
- c) Personal use import is allowed for up to three month's supply (for medicines, at the maximum dose recommended by the manufacturer) with a prescription.
- d) Imported medicines must be kept in their packaging with all dispensing labels intact.
- e) The imported products should not contain prohibited substances restricted under Botswana laws. For example products such as cannabis are legalised in other countries but are listed as prohibited substances in Botswana.

## 7.2 Requirements for importation of different scheduled medicines


	<b>Schedule</b>	<b>Requirements</b>
I	Prescription Medicine	<p>Under Section 23(4) of the MRSA importation of Schedule 1 and 2 medicine is restricted to a manufacturer or a wholesale. Note that medicine imported by practitioners for treating patients are not considered to be personal importations but rather commercial importation for sale as per Sec 28 of MRSA and these are only imported through licensed distributors.</p> <p><b>Visitors:</b> Foreign nationals may bring, in person or by shipment; into Botswana, a maximum of three month's supply of medicinal products based on the directions for use of a prescription medicine. If the visitor is staying longer than three months, they must seek prescription from a local health practitioner for locally available alternatives unless the medicine sought is not available in the country in which case the patient may import the medicine through the exemption route. MRSA 6(1).</p> <p>When a prescription medicine is couriered to a Visitor, the</p>

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		<p>medicine should be accompanied by documentation indicating that the medicine is destined to the Visitor and/or the Visitor should be prepared to provide documentation/written evidence (stamped passport, student/work visa, letter from an employer/university, copy of prescription, etc) that they are a Visitor to Botswana when requested.</p> <p>The medicine must be shipped/carried in one of the following:</p> <ul style="list-style-type: none"> <li>• Hospital or pharmacy dispensed packaging;</li> <li>• Original retail packaging; or</li> <li>• have the original label affixed to it which clearly indicates what the health product is and what it contains.</li> </ul> <p><b>Botswana Resident:</b> Importations of prescription medicine by Botswana residents are not permitted by mail. So as not to interrupt a course of treatment, BoMRA may permit Botswana returning from abroad single course of treatment or a three months supply based on the directions for use of a prescription medicine.</p> <p>Will individuals taking medication be expected to declare at the entry ports should they be carrying prescription meds?</p>
2	Schedule 3 and 4 medicines.	<p>Individuals are permitted to import a single course of treatment or a three month's supply based on the directions for use, whichever is less, of schedule 3 and 4 medicine.</p> <p>The medicine must be for the individual's own personal use or for the use of a person for whom they are representing.</p> <p>The medicine must be shipped/carried in one of the following:</p> <ul style="list-style-type: none"> <li>• Hospital or pharmacy dispensed packaging;</li> <li>• Original retail packaging; or</li> <li>• have the original label affixed to it which clearly indicates what the health product is and what it contains.</li> </ul> <p>A person shall apply to the authority in writing for an exemption from registration for any subsequent supplies of the imported medicines. MRSA Regulation 2019 Sec 7 (3).</p>
3	Complementary medicines	<p>Individuals are permitted to import a single course of treatment or three months' supply based on the directions for use, whichever is less, of the complementary medicine.</p> <p>The complementary medicines must be for the individual's own</p>

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		<p>personal use or for the use of a person for whom they are representing.</p> <p>The complementary medicines must be shipped/carried in one of the following:</p> <ul style="list-style-type: none"> <li>• Original retail packaging; or</li> <li>• have the original label affixed to it which clearly indicates what the health product is and what it contains.</li> </ul> <p>A person shall apply to the authority in writing for an exemption from registration for any subsequent supplies of the imported medicines. MRSA Regulation 2019 Sec 7 (3).</p>
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## 8. Penalties

- 8.1 Any person that contravenes the requirements within this guidelines may have their products seized and destroyed and be liable to a fine and/or prosecution.

## 9. Review of the Guideline

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