Botswana Medicines Regulatory Authority

Approved By:

Richard Leepo
Manager – Enforcement

4th March 2024
Date of Approval (DD/MM//YY)

Contents

Revision status sheet

Page	Changes made	Issue No	Process owner's (Title)	Reviewer's name	Date
8	Define unwanted medicine	1.0	Director Licensing and Enforcement	B. Setlhalefi	11/11/2021
16	11.2 (L) Added unwanted medicines	1.0	Director Licensing and Enforcement	B. Setlhalefi	11/11/2021
5	Replaced provisional list with Veterinary Medicinal Products	2.0	Director Licensing and Enforcement	B. Setlhalefi	24/08/2022
6	Added Investigational Medicinal Products to preamble	3.0	Manager Inspection & Licensing	B. Setlhalefi	16/02/2023
6	Added "except Investigational Medicine Products which are directly imported by the Contract Research Organisation (CRO)" under legal considerations	3.0	Manager Inspection & Licensing	B. Setlhalefi	16/02/2023
7	Added (g) under legal considerations	3.0	Manager Inspection & Licensing	B. Setlhalefi	16/02/2023
7	Added definition for Authorized person	3.0	Manager Inspection & Licensing	B. Setlhalefi	16/02/2023
8 and 9	Added definition for IMP, precursor chemicals and responsible person	3.0	Manager Inspection & Licensing	B. Setlhalefi	16/02/2023
8 & 9	Reviewed definitions for narcotic medicines and psychotropic substances	3.0	Manager Inspection & Licensing	B. Setlhalefi	16/02/2023

9	Added Abbreviations for CRO and IMP	3.0	Manager Inspection & Licensing	B. Setlhalefi	16/02/2023
10	Added (f) to expand the purpose and reviewed section 8	3.0	Manager Inspection & Licensing	B. Setlhalefi	16/02/2023
11-12	Procedure for import/export reviewed to include: export, exempted products, IMP's, designation of applicants and number of products per permit	3.0	Manager Inspection & Licensing	B. Setlhalefi	16/02/2023
12-13	10.6 for controlled substances Reviewed to include: exempted products, motivational letter, and limit for products per permit	3.0	Manager Inspection & Licensing	B. Setlhalefi	16/02/2023
15	10.2.9 Acknowledgement after importation, 10.3 Precusor chemicals	3.0	Manager Inspection & Licensing	B. Setlhalefi	16/02/2023
23	Addition of clause 16.2, to address Transit permit timelines	4.0	Manager, Enforcement	B. Setlhalefi	07/02/2024

1. Preamble

The Botswana 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 and export of medicines and Investigational Medicinal Products (IMP's).

2. Laws, Regulations, Policies and relevant Guidelines

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

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

3. Legal considerations

All transactions concerning the importation of consignments of medicinal products should be conducted through independent authorized Medicines importers authorized by BoMRA, except Investigational Medicine Products which are directly imported by the Contract Research Organisation (CRO).

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

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

c) Medicines and their documentation shall not be manipulated or tempered with while being transported to the country.

d) An application for the issue of an import or export permit shall be made by an authorized importer to BoMRA on a prescribed form (attached as Annex 1).

e) An applicant for an import permit must be registered with BoMRA as an importer of medicines.

f) In case of donations, the importer must have a donation certificate and ensure that the product is registered or exempted from registration prior to seeking import authorization. The donated Medicines products must be fit for human consumption, safe and of good quality and not prohibited in the country of origin.

g) For investigational Medicinal products the importer should have an approval letter from the Authority.

h) No importation or exportation of medicines shall be done by post.

i) The period of validity of the import and export permits shall be determined by BoMRA and it shall not exceed **six (6) months**.

4. Definitions

For the purpose of these guidelines the following terms shall be defined as follows:

4.1 **BOMRA**: means Botswana Medicines Regulatory Authority

4.2 **Authority**: means Botswana Medicines Regulatory Authority established under section 3 of MRSA 2013.

4.3 **Authorised importer:** means an individual or company or similar legal entity granted permission to import a medicine into Botswana by BoMRA.

4.4 **Authorised exporter:** means an individual or company or similar legal entity granted permission to export a medicine out of Botswana by BoMRA.

4.5 **Authorized person:** means any person given the responsibility for ensuring the medicines requirements are in compliance with the law and regulations in force in Botswana.

4.6 **Controlled substances:** means prohibited substance or medicine listed in schedule 1A, 1B, 1C, 1D or a precursor chemical.

4.7 **Counterfeit product:** means a medicine, cosmetic, related substance or a Medicines product that is fraudulently mislabelled with respect to identity and/or source. Both branded and generic products can be counterfeited, and counterfeit products may include products with correct ingredients, with the wrong ingredients, without active ingredients, with insufficient quantity of active ingredients or with fake packaging.

4.8 **Distributor:** means any practice whose activities involve the handling, storing or supplying of medicines for wholesale to pharmacies or dispensary.

4.9 **Export:** means sending out a medicine, medical device or scheduled substance from Botswana or cause a medicine, medical device or scheduled substance to be sent out of the country for purposes other than personal use.

4.10 Investigational Medicinal Product: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

4.11 Import: means to bring a medicine, medical device or scheduled substance into Botswana or cause a medicine, medical device or scheduled substance to be brought into the country for purposes other than personal use.

4.12 Manufacture: means all operations involved in the preparation, processing, compounding, formulating, filling, refining, transformation, packaging, repackaging and labelling of controlled drugs;

4.13 Medicine: any substance or mixture combination of substances manufactured, sold or presented as suitable for use, in:

a) the diagnosis, treatment, alleviation, modification, prevention of diseases, illness, abnormal physical or mental condition or symptoms thereof or

b) restoring, correcting or modifying any somatic or psychic or organic condition or

c) any substance, to the extent that it complies with (a) or

d) any substance used to manufacture medicine or is sold as a raw material, precursor chemical or intermediate

e) a complementary medicine; or a substance or mixture of substances declared by the Minister of Health, in consultation with the relevant Authority, by notice in the Gazette to be a medicine or a veterinary medicine or a complementary medicine

4.14 National Regulatory Authority (NRA), Competent authorities: are used interchangeably to describe the national agency responsible for the registration of, and other regulatory activities concerning, Medicines.

4.15 Narcotic Medicine: any substance listed in Schedules I and II and IV of the UN convention on narcotic drugs, 1961.

4.16 Port of entry means any place designated as such in terms of section 13 of MRSA, 2013.

4.16 Permit means any kind of authorisation given to an importer or exporter.

4.17 Veterinary Medicinal Product: means any medicine intended for veterinary use, presented in its finished dosage form, that is subject to control by medicines legislation.

4.18 Prescribed Drug or Medicine: a medicine that is ordinarily prescribed by an authorised prescriber, authorised by the relevant regulatory authority in Botswana.

4.19 Precursor Chemical: any substance listed under tables I and II of the UN Convention against Illicit traffic in Narcotic drugs and psychotropic substances, 1988.

4.20 Market authorization (Registration Certificate): an official document issued by the competent Medicine Regulatory Authority for the purpose of marketing or free distribution of a product

4.21 Psychotropic substance: any substance listed in Schedules I, II, III or IV of the UN convention on psychotropic substances, 1971.

4.22 Registration: any statutory system of approval required at national level as a precondition for introducing a Medicines product on the market

4.23 Registered, licensed, authorised: these words are used in these guidelines as if they are interchangeable

4.24 Responsible person: a person registered with the relevant professional body to undertake work or practice within a specific technical field**.**

4.25 Unwanted medicine - means a medicine which has expired, is substandard, banned, or is a counterfeit or any unusable medicine.

5. Abbreviations

For the purpose of these guidelines, the following abbreviations shall apply:

5.1 BOMRA - Botswana Medicines Regulatory Authority

5.2 CRO – Contract Research Organisation

5.3 HFD - Habit Forming Drugs

5.4 IMP – Investigational Medicine Products

5.5 WHO - World Health Organisation

5.6 VMP - Veterinary medicinal products

5.7 SMPC – Summary of Product Characteristics

5.8 PO – Purchase Order

6. Purpose

These guidelines are meant to:

a) Outline the responsibilities of the stakeholders involved in the import and export of medicines.

b) Identify the persons who can import or export medicines into or out of Botswana.

c) State the ports through which medicines can be imported/exported into or out of Botswana.

d) Define the minimum requirements for a complete application for a medicine import or export permit.

e) Outline the process of consignment verification and clearance.

f) Provides guidance to suppliers of Investigational Medicinal Products (IMPs), sponsors, contract research organizations (CROs), investigators and other relevant members of the research team on the regulatory requirements relating to the import and export of IMPs.

7. Scope

7.1 This document provides guidance on import/export controls to be applied at ports of entry including verification procedures associated with the handling of consignments of Medicines and related substances. The safety, efficacy, and quality of Medicines can be highly compromised by lack of adequate controls for importation and exportation. These guidelines are therefore intended to make sure that importation of Medicines is carried out within a framework of sound import/export controls and to guide inspectors and partner agencies who perform routine evaluation of consignments at ports of entries.

7.2 That said, the guidelines and associated checklist for inspection of medicinal products will assist authorised officers at ports of entries in the verification and processing of Medicines intended for import into Botswana. Import permits shall be issued to companies and other authorised entities strictly based on the requirements of the set standards.

8. Categories of Authorised importers of Medicines and raw materials

Importers of Medicines shall fall under the following categories:

a) Pharmaceutical wholesalers

b) Pharmaceutical Manufacturers

c) Authorised Researchers

d) Other authorized entities the Authority may permit

9. Requirements for importers

i. All pharmaceutical products to be imported must be registered by BoMRA unless given special approval by the Authority.

ii. All importation of Medicines must be done by importers whose premises are dully licensed by BoMRA.

iii. The importation of all consignments of medicinal products should be channeled through the designated ports of entry and will be cleared by BURS (customs) and Ministry of Health (Port health) in consultation with BoMRA.

10. Procedure for Import/Export of Medicines

10.1 Processing of permits to Import/Export Medicines

10.1.1 Application for permits to import medicines other than HFD's shall only be made by authorised importers using the:

10.1.1.1 Application for Permit to Import Medicines (*BOMRA/IL/IE/P02/F01*) or Application for Export permit of Medicines (BoMRA/IL/IE/P03/F01)

10.1.1.2 Purchase order

The purchase order shall state for each medicine to be imported, the following:

i. Purchase order number and date
ii. Name of the supplier
iii. Name of the manufacturer
iv. Trade or proprietary name
v. The International Non-Proprietary name (generic name) of the product and its strength
vi. The product registration number issued by BoMRA
vii. The quantity to be imported for each drug, its unit value, total value
viii. Signature and stamp of the importer.

10.1.1.3 Proof of payment.

10.1.1.4 For export permit applications, Import permit from the importing country should be provided (where applicable).

10.1.1.5 Application for unregistered medicines should additionally be accompanied by supporting documentation which includes exemption letter or screening letter for samples imported for registration purposes.

10.1.1.6 Application for IMP's should additionally be accompanied by clinical trial approval letter specifying the investigational products to be used.

10.1.2 Importers shall submit soft copy of the PO and application form. The soft copy of the PO and application form shall be sent by email to impex@bomra.co.bw, and copied to finance email finance@bomra.co.bw ..

10.1.3 Authorized persons are expected to submit the names and emails of all officers designated to submit applications on their behalf for authentication purposes.

10.1.4 All soft copies of the application form shall be in Microsoft word format and no application shall be accepted in PDF format..

10.1.5 BoMRA finance office shall provide confirmation of payment to Import and Export control office.

10.1.6 Upon receiving confirmation of payment, BOMRA import/export officer shall:

a) Check for completeness of the application form and the PO. If the documentation is incomplete the application shall be rejected using the Rejection Form, *BOMRA/IL/IE/P03/F03*.

b) If the application meets the documentary checks the application will be processed in accordance with *BOMRA/IL/IE/P02 or BOMRA/IL/IE/P03*.

NB: A maximum of fifty (50) products is allowed per application, and all exempted medicines should be applied for separately from registered medicines.

10.1.7 Upon completion of processing the application, the Original permit, shall be sent to the applicant's email.

10.2 Processing of HFD permits

10.2.1 Importation and exportation of controlled substances

i. Botswana is required to comply with the Treaty Obligations as enshrined in United Nations International Narcotics Control Board's (INCB) 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances and the 1988 Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

ii. Controlled substances are imported for medicinal and scientific purposes only.

10.2.2 Application for permits to import/ export controlled substances shall only be made by responsible person using either Application for permit to Import or export Habit Forming Medicines and/or Psychotropic Substances, (*BOMRA/IL/IE/P01/F01* or *BOMRA/IL/IE/P04/F01*) accompanied by an PO and proof of payment.

10.2.3 Importers shall submit email application to impexhfd@bomra.co.bw copied to finance.. All soft copies of the application shall be in Microsoft word format and no application shall be accepted in PDF format. All hard copies (Original) will be submitted to BoMRA during collection of the processed permits.

10.2.4 Application for exempted medicines should additionally be accompanied by supporting documentation which includes exemption letter and summary of product characteristics (SMPC) or the product leaflet.

10.2.5 Applications for substances imported for scientific purpose should be accompanied by a motivational letter for the substance.

NB: A maximum of three substances is allowed per application.

10.2.6 BOMRA Finance shall provide a confirmation of payment to Import and Export control office.

10.2.7 Upon receiving confirmation of payment, BOMRA import/export officer shall:

a) Check for completeness of the application form and the PO (date, name, signature of authorised personnel). If the application is incomplete the application shall not be received.

b) If the application meets the documentary checks the application will be processed in accordance with *BOMRA/IL/IE/P01 or BOMRA/IL/IE/P04*.

10.2.8 Upon completion of processing, the Original permit and approved purchase order shall be given to the importer.

10.2.9 The duplicate permit will be retained with the application form as office records.

10.2.8 Calculation of base Quantity for controlled substances

I. Confirm from MIMS the type of salt used, then apply the corresponding INCB conversion factor to obtain the correct base quantity.

II. Calculating base quantity shall be done using the following formulae:

a) Parenteral:

Total volume of consignment (ml)	X	Strength (mg/ml)	=	Total quantity of salt in consignment (mg)

Then

Total quantity of salt in consignment	X	Conversion factor	=	Base quantity in mg

Note: all pure salts use conversion factor 1 (one)

b) Oral Solids

Total quantity of capsules/ tablets	X	Strength of each capsule/tablet (mg)	=	Total quantity of salt in capsules/ tablets

Then

Total quantity of salt	X	Conversion factor	=	Base quantity in mg

Note: All final base quantities shall be converted and recorded in Kilograms (kg)

iii. The finale base quantity should be included in the application form under column for quantity and presentation of the drug substance.

10.3 Acknowledgements after importation

10.3.1 Upon receipt of the products, the applicant shall submit a completed Acknowledgement Form together with export permit within 7 days of receipt of consignment.

10.3.2 If the Acknowledgement Form is not received from importing company, a reminder letter may be sent to the company asking them to acknowledge receipt.

10.4 Processing of precursor chemical permits (Non-medicinal)

10.4.1 First time applicants for permit to import precursor chemicals shall submit the following attachments:

a) Trading license and company certificate of incorporation
b) Declaration letter of appointment of qualified person (chemist or related lab sciences)
c) Certified copy of qualification certificates of the qualified person.

NB: This submission is not applicable to BoMRA licensed importers.10.4.2 Application for permits to import/ export precursor chemicals shall only be done using either Application for permit to Import or export Habit Forming Medicines and/or Psychotropic Substances, (*BOMRA/IL/IE/P01/F01* or *BOMRA/IL/IE/P04/F01*) accompanied by an invoice and proof of payment.

10.4.2 Importers shall submit both hard and soft copy of the PO, proof of payment and application form. The soft copies shall be sent by email application to impexhfd@bomra.co.bw copied to finance email prior to submission of hard copy. All soft copies of the application shall be in Microsoft word format and no application shall be accepted in PDF format. All hard copies (Original) will be submitted to BoMRA during collection of the processed permit

10.4.3 Precursor chemical applications for non-medicinal use should additionally be accompanied by declaration letter for intended use.

10.4.4 The applicant should state in addition, the quantity of the substance in Kilograms as well as presentation form (liquid or crystals etc.) in the application form.

10.4.5 Acknowledgements after importation section 10.2.9 still applies.

NB: All applicable precursor chemicals are listed in the "Red List" https://www.incb.org/documents/PRECURSORS/RED_LIST/2023/RedList_20th_edition_E.pd

10.5 Processing of applications

10.5.1 Upon receiving the application as specified above, BoMRA will assess it to verify whether the requirements have been fulfilled.

10.5.2 If the application meets the prescribed requirements and the applicant has paid the fees as stipulated in the Fees Regulations in force, and the Authority will issue an import permit as set out in the Annex III of these guidelines.

10.5.3 An application will be rejected if it does not meet any of the importation requirements. An applicant will be given a rejection form (Annex II) stating clearly reason(s) for rejection. Once an application is rejected the applicant will have to reapply for the next permit.

10.5.4 All applications will be processed within **two (2) working days** with exception of special requests which may take longer period.

10.5.5 All Applications must be submitted at least **21 days** before the arrival/departure of the consignment to avoid delays in processing import applications.

10.6 Variation of import/export permit

10.6.1 Application shall be submitted in an Application for variation of Permit (*BOMRA/IL/IE/F04*) through impex@bomra.co.bw accompanied by original permit to be varied and corresponding PO together with the proof of payment.

10.6.2 The import/exporter shall be allowed to vary the permit for the following details only

a) Supplier details

b) Product quantity and/or strength

c) Port of entry

d) Product strength

10.6.3 For applications that met all the requirements, the permit shall then be retrieved from the relevant shared folder. The new permit will be generated by editing the required components. The original permit will be retained.

10.6.4 All applications for variation shall be processed within 24 hours.

10.7 Payment of permit fees

10.7.1 Starting from February 2020 BOMRA introduced paid regulatory processes as stipulated in the MRSA, 2013 and the Medicines and Related Substances Regulations of 2019 and other relevant guidelines.

10.7.2 The paid services offered by import export control unit are as follows:

Services	Pula
Application to import/export Narcotics, Psychotropics and precursor chemicals	100
Application to vary an import/export permit of Narcotics, Psychotropics and precursor chemicals	100
Application to import/export all products excluding Narcotics, Psychotropics and precursor chemicals	50
Application to vary import/export permits for all products excluding Narcotics, Psychotropics and precursor chemicals	50
Application for transit permit	100
Importation fee for wholesale exempted products	0.25% of the value of the consignment
Importation fee for all other products	0.15% of the value of the consignment

10.8 Payment of importation fees

10.8.1 Upon receipt of consignment, the applicant shall submit the invoice from supplier to the Admin officer for paid services.

10.8.2 The application will be accompanied by a BURS stamped permit and BURS declaration form,

10.8.3 Admin officer shall generate a sales order (import fee quotation).

10.8.4 Applicant will proceed to pay at Finance using the sales order provided.

10.8.5 The applicant will also remit through impex@bomra.co.bw records of all imported products in excel format within 14 days of receipt of the consignment..

10.8.6 For a subsequent permit the applicant shall provide import/export office with proof of payment of importation fees prior to getting a new permit.

11. Clearing of consignments

11.1 Ports of entry

The importation of all consignments of medicines should be done through the designated ports of entry, which are:

a) Sir Seretse Khama International Airport

b) Tlokweng Border Post

c) Ramatlabama Border Post

d) Kazungula Ferry Border Post

e) Pioneer Border post

f) Mamuno border post

g) Ramokgwebana Border post

h) Philip Matante International Airport

Note: *No importations through ordinary or registered post shall be sanctioned.*

11.2 Verification/Inspection of consignments at Ports of entry

a) On arrival at the ports of entry, Medicines will be inspected by BoMRA inspectors to ensure that they comply with the approved specifications and regulations before they are released.

b) On arrival at the ports of entry, Medicines will be inspected by a Customs or Port Health inspector to ensure that they comply with the approved specifications and regulations before they are released.

c) Each consignment must be accompanied by an import permit, an original proforma invoice. Other government agencies may also conduct inspection activities as the rules and regulations apply. Such agencies may include Botswana Police or other authorized agents.

d) In case of controlled drugs, the consignment shall be accompanied by an import permit for habit forming drugs and/or psychotropic substances and a corresponding export permit from the exporting Regulatory Authority.

e) During the process of inspection and release of the consignment, the inspector may sample medicines for further investigations.

f) A visual and physical examination should be routinely undertaken by the customs authorities. Where possible, this is done in collaboration with an inspector or enforcement officer of BoMRA. The size of the consignment should be checked against invoices, and attention should be given to the nature and conditions of the packaging and labelling.

g) The external package will be compared with a standard where this is possible

h) All imported Medicines should adhere to the following labelling requirements:

I. The information printed on labels must be indelible, engraved or embossed on a primary and secondary container;

II. The immediate outer packaging of the Medicines should be clearly labelled in **English language**;

III. The trade or brand name where appropriate shall be stated;

IV. The International Non-Proprietary Name (INN, Generic name) shall be clearly stated;

V. Quantities of active ingredients in the given formulation/API;

VI. Date of manufacture and expiry;

VII. Batch or Lot number;

VIII. Storage conditions;

IX. Name and address of manufacturer;

X. Registration number of the product issued by BoMRA in both outer and inner package of the product(s) where applicable;

XI. Enclosed and accompanying literature must be in English

Note: *Spelling errors, low-quality printing and other defects may be signs of a substandard or falsified product.*

The external package should be intact and should not show any signs of damages or infiltrations that may change or can alter the inner content.

i) Falsified products and or other unwanted products which have been imported in contravention of the law will be forfeited and destroyed, or otherwise dealt with in accordance with legal procedures. Such procedures will be defined and appropriately recorded.

j) A consignment suspected of being substandard, falsified or not authorized should be placed in quarantine pending investigations which may include sampling

k) Representatives of the manufacturer of the authentic product, and/or the owner of the trademark, and the consignee should immediately be advised of such action.

l) The inspector should notify BoMRA about confirmed or suspected cases of imported substandard or falsified Medicines or unwanted medicines without delay.

m) On inspection of the consignment the following actions may be taken:

I. An approval for release may be given.

II. A query may arise whereby the consignment may be held at customs warehouse or owner's premises pending further investigation.

III. An outright rejection of the consignment and re-export or destruction at owner's expense may be issued.

11.3 Release or rejection of a consignment

a) **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 all the supporting documents with an official stamp marked "APPROVED FOR RELEASE".

III. In case of partial shipment a consignment will be issued one import permit which can be used in two divided shipments and an inspector will clearly mark in the original permit and proforma invoice that it is "PARTIAL SHIPMENT" and the quantity imported and remaining will be indicated in the proforma invoice and permit.

IV. Consignment can be given a CONDITIONAL RELEASE where the port of entry officer has only verified the document checks for the products and releases the products for further release into the market by BoMRA inspectors.

b) **Conditions for rejection**:

I. Consignments which do not meet importation requirements will be rejected through the rejection form attached - Annex II and the accompanying documents shall be stamped with an official stamp marked "STOP RELEASE".

II. Drugs rejected for quality reasons will be CONDEMNED;

III. Drugs 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 an inspector will issue a Rejection/Detain Form of Medicines consignment(s)

c) **Re export of rejected products**

I. A re-export exercise should be preceded by re-inspection of the rejected consignment to confirm that it is still intact before re-export permit is issued by BoMRA;

II. Re-loading for re-export should be witnessed by Customs officials and Inspector(s) from BoMRA;

III. Copies of re-export documents stamped at the exit port shall be submitted to BoMRA as evidence of completion of re-exportation exercise;

12. Destruction of rejected products

12.1 Destruction of rejected medicines will be done as prescribed in MRSA 2013 regulations and BoMRA will provide technical advice on mode of destruction according to the guidelines of disposal of unfit Medicines.

12.2 Any destruction made under this regulation shall be done pursuant to the Botswana Environmental affairs regulations.

12.3 A Destruction Certificate after completion of the destruction exercise.

13. Sampling of imported products

13.1 Arrangements should be made with the inspector or enforcement officer of BoMRA for the routine physical and chemical sampling and subsequent physical and chemical analysis of exceptionally large and/or valuable consignments and any other consignment that may appear to have deteriorated, or that is damaged or is of doubtful authenticity.

13.2 BoMRA will sample imported Medicines and raw materials for further investigation when deemed necessary. The sample collection form will be used during sampling which will be signed in duplicate by the inspector and consignee and one copy will be issued to the latter.

13.3 Investigation or consultation may take some time before they are concluded, especially where it involves laboratory analysis of the consignment. Where such cases arise, a conditional release may be given to the importer with instruction to store the consignment in approved premises until results of the investigations are out.

13.4 It is important to note that laboratory analysis may take up to two weeks from the time a consignment is sampled to when the results are released. The time mentioned above applies only if the laboratory analysis is to be done at BoMRA Laboratory. Where analysis is to be carried out outside BoMRA Laboratory, a longer period may be required.

14. Responsibilities of stakeholders

14.1 The Authority

I. All applications for permits shall be made to BoMRA.

II. BoMRA shall authorise importation or exportation of any Medicines product prior to purchase and shipment of any such consignment.

III. BoMRA shall sign and seal all permits to be issued.

IV. BoMRA will authorise Officers who shall be responsible for physical examination and clearing consignments of Medicines products at the port of entry.

V. BoMRA will designate points of Entries for regulated products

14.2 The Importer or Exporter

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

II. To ensure that imported medicines meet the Botswana labelling requirements.

III. To apply for the import or export permit and to timeously submit all documentation to the Authority.

IV. Timeously notify the Authority of importation or exportation of any consignment.

V. Keep a record of all permits, and all documents required for and relating to the importation or exportation of medicines and avail such records when requested.

VI. Remit Actual quantities of imported medicines and timelines for such importation

VII. Calculate the estimates & assessments of controlled substances, submit to BoMRA on the prescribed form

VIII. Acknowledge receipt of imports, use acknowledgement form, form 17

IX. Submit quarterly report of total imports and exports of controlled substances

14.3 Customs and Port Health Officials

I. All consignments will be cleared by customs in consultation with the inspectorate of BoMRA and cleared consignment documents shall be stamped and signed.

II. Customs and Port Health Officials in collaboration with a Regulatory Officer (RO) from the Authority will carry out physical examination of imported consignments of medicinal products and their documentation.

III. Customs shall check that all consignments of medicines are authorized by BoMRA.

IV. Port officials shall notify the Authority of confirmed or suspected cases of counterfeit products.

15. Importation of Medicines for Personal Use

15.1 Import of human medicines for personal use

a) Importation of medicines for personal use or for use by a member of family will be limited to 90 days' supply.

b) Importation of medicines for personal use should be accompanied by a prescription from a registered medical practitioner, dentist, veterinary surgeon or any other authorized practitioner.

c) Apart from prescription, a letter giving reasons for importation from qualified medical practitioner, dentist, veterinary surgeon or any other authorized practitioner should also be submitted.

d) It must be emphasized that the intent of the 'personal use importation' guidance is to generally permit BoMRA exercise its enforcement discretion for medicines that may not otherwise be available in the country.

NB: All pharmaceutical consignments imported into Botswana shall comply with Botswana requirements and Medicines and related substances act and shall be handled in accordance with Guidelines for importation of medicines for personal consumption *BOMRA/IL/IE/P02/G03*

15.2 Complementary medicines

15.2.1 The terms "complementary medicine" and "alternative medicine" refer to a broad set of health care practices that are not part of that country's own traditional or conventional medicine and are not fully integrated into the dominant health care system. They are used interchangeably with traditional medicine in some countries (WHO 2019).

15.2.2 Medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homoeopathic and certain aromatherapy preparations are referred to as 'complementary medicines' and are regulated as medicines under the Medicines and Related Substances Act (2013). Complementary medicines can either be listed or registered on the Blue book depending on ingredients and claims made for the medicines.

15.2.3 Complementary medicines are nutritional substances in pharmaceutical substances, plant-based medicines, probiotics in a pharmaceutical dosage form

15.2.4 Complementary Products available on international websites are not regulated by the BoMRA. BoMRA advises that consumers do not order medicines, including dietary supplements and herbal preparations, over the Internet unless you know exactly what is in the preparation and have checked the legal requirements for importation and use in Botswana. For more information consumers are advised to contact BoMRA before purchasing such products.

NB: All pharmaceutical consignments imported into Botswana shall comply with Botswana requirements and Medicines and related substances act and shall be handled in accordance with Guidelines for handling imports of schedule 4 and complementary medicines *BOMRA/IL/IE/P02/G04*.

15.3 Importation of Medicines for Companion Pets

a) This is acceptable for individual small animal medicine purposes or companion animals.

b) Importation of medicines for personal use should be accompanied by a prescription from a registered veterinary surgeon or any other authorized practitioner.

15.4 Importation of donated medicines and related substances

To ensure that donations are properly handled, guidelines have been prepared in line with those published by World Health Organization (WHO) and Southern African Development Community (SADC) with some modifications to suit the specific needs of Botswana. These guidelines are directed not only to potential medicine donors, but also to all persons and organizations that may solicit medicine donations and were developed primarily to ensure that all donations meet the express needs of recipients in Botswana. For requirements associated with medicines donations, Guidelines for Handling Pharmaceutical Donations *BOMRA/IL/IE/P02/G02* will apply.

16. Permit for in-transit medicines

A person transporting medicines through Botswana is expected to apply to imports/ exports office for a transit permit of consignment prior to leaving the country of origin through an approved application form, accompanied by export permit from the country of origin, proof of payment and import permit of the country of destination.

16.1 The application should entail:

a) a list of all medicines to be transported,

b) quantities,

c) mode of transport,

d) ports of entry to be used and port of exit

e) the expected date they are to be transit

16.2 All applications will be processed within one (1) working days with exception of special requests which may take longer period.