Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

Approved By:

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Revision status sheet

Page	Changes made	Issue No.	Process owner's name	Initiated By (Name)	Reviewed By (Name)	Date
11	Under caption 4.1, new definitions added include:- Importation fee, Advance Account, Non – advance, importation clients, Tax Invoice, Credit Note and Quotation	1.0	Zukiswa Raditladi	Richard Leepo	Richard Leepo	11/09/2025
12	Under caption 6 (previously caption 5) Scope to read *"…organization that intends to export, import or transit…"*	1.0	Zukiswa Raditladi	Richard Leepo	Richard Leepo	11/09/2025
13	Caption 8 heading changed to read *"Requirements for importation of medical devices".*	1.0	Zukiswa Raditladi	Richard Leepo	Richard Leepo	11/09/2025
13	Under caption 8.2 (previously caption 8.11) The amended number (b) reads *"Purchase Order or Proforma Invoice"* The Purchase order or *"Proforma Invoice"* shall state for each medical device to be imported, the following: The amended (i) reads	1.0	Zukiswa Raditladi	Richard Leepo	Richard Leepo	11/09/2025

	"Date;"					
13	Under caption 8.2 (previously 8.11) The amended (c) reads "Proof of payment for permit application fee and importation fee.	1.0	Zukiswa Raditladi	Richard Leepo	Richard Leepo	11/09/2025
13	Under caption 8.2:- Numbering changed to levels 8.2.1 and 8.2.1.1 to 8.2.1.4	1.0	Zukiswa Raditladi	Richard Leepo	Richard Leepo	11/09/2025
14	Last paragraph under 8.2 removed.	1.0	Zukiswa Raditladi	Richard Leepo	Richard Leepo	11/09/2025
14	Caption 8.2.2(iv) amended to read "*All permits issued by the Authority shall be valid for four (4) months*".		Zukiswa Raditladi	Richard Leepo	Richard Leepo	11/09/2025
16	Under caption 8.6 Payment of importation fees. Old content replaced with new. The numbering was also amended.	1.0	Zukiswa Raditladi	Richard Leepo	Richard Leepo	11/09/2025
19	Caption 9 heading changed to read *"Requirements for Exporting of Medical Devices"*.	1.0	Zukiswa Raditladi	Richard Leepo	Richard Leepo	11/09/2025
20	Under caption 10.1 Ports of entry "*Kazungula Border Post*" replaced with "*Kazungula One Stop Border*".	1.0	Zukiswa Raditladi	Richard Leepo	Richard Leepo	11/09/2025

1. Preamble

The Botswana Medicines 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 to promote human and animal health by providing guarantees for quality, safety and efficacy of medicines and medicinal products throughout the supply chain. All the actions which are related to medical devices such as their import, manufacturing, sale, distribution and export are governed by the Medicines and Related Substances Act of 2013 and the Regulations of 2019.

Medical devices have become an integral part of the health care sector. This increases the demand for better regulatory frameworks to ensure that products entering the market are safe and efficient.

To be legally marketed in Botswana, many medical devices must be reviewed by the Authority which is responsible for protecting the public health by overseeing medical products. To achieve this goal, the Authority has undertaken to develop a set of guidelines and procedures to guide the import and export of medical devices.

2. Laws, Regulations, Policies and relevant Guidelines

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

a. Medicines and Related Substances Act (MRSA), 2013,
b. Medicines and Related Substances Regulations (MRSR), 2019
c. Guidelines – Medical Devices office
d. WHO Good distribution practices for medical devices TRS **957**, 2010, Annex 5
e. WHO guidelines on import procedures for medical devices No **917**, 2003, Annex 3

3. Legal and registration considerations

For the import of medical devices in Botswana, registration of the product and import license is mandatory. Therefore, a person willing to import medical product in Botswana must obtain registration certificate for the products and import license. A person wishing to obtain an import license must make application for registration in the given period as specified in the guidelines for listing of medical devices (BOMRA/ER/MED/P02/G01) under Medical Devices function at Product Evaluation and Registration Department. In case, before the date of notification, devices have not

been imported in the country, import is not allowed. In a certain period, until an application is rejected or approved, those devices which are currently in use are allowed in the market.

The main requirements for import or export control of medical devices are usually identification of a local representative (registered manufacturer or distributor with BoMRA license), market authorisation certificate from the country of origin, import/export license from BoMRA or import license from the competent authority in the import country and registration of the product. These requirements are fully detailed below. To accomplish this, it is necessary to fulfil the essential principles, classify the product, apply Good Manufacturing Practice and risk management, follow the labelling requirements and establish a documented post market and market surveillance system.

All transactions concerning the import/export of consignments of medicinal devices should be conducted through independent license holder authorized by BoMRA.

a. Unless otherwise specified, only authorized medical devices appearing on the medical devices register (Provisional list) will be permitted to be imported (or exported) into (or out of) the country.
b. All importers of medical devices must import through the authorized PoE (MRSA 2013, Section 36)
c. Medical devices 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 authorised importer to BoMRA on a prescribed form (attached as Annex 1).
e. 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 products must be fit for its purpose, safe and of good quality and not prohibited in the country of origin.
f. No importation or exportation of medical devices shall be done by post.

4 Definitions and Abbreviations

4.1 Definitions

For the purpose of this guideline, the following definitions shall apply:

4.1.1 Advance Account – A credit account held by BoMRA on behalf of a customer for payment of future services.

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

4.1.3 Authorised exporter- an individual or company or similar legal entity granted permission to export a medical device out of Botswana by BoMRA.

4.1.4 Authorised importer- an individual or company or similar legal entity granted permission to import a medical device into Botswana by BoMRA.

4.1.5 Applicant- any person or institution or company that applies formally to get market authorization for medical device in partner states.

4.1.6 Counterfeit product- a medical device that is fraudulently mislabelled with respect to identity and/or source.

4.1.7 Credit Note – A document that indicate a return of funds in the event of damaged or defective products

4.1.8 Distributor- any practice whose activities involve the handling, storing or supplying of medical devices.

4.1.9 Donation- an act or instance of presenting medical devices to recipients in emergency or as a part of development aid in none-emergency situations.

4.1.10 Donor- a governmental or non-governmental organization or individual who voluntarily donates medical devices as a donation.

4.1.11 Export- 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.

4.1.12 Import- 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.

4.1.13 Importation fee – Fees charged and collected on the importation of medical devices and in-vitro devices.

4.1.14 Manufacturer- any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

4.1.15 Medical device- any instrument, apparatus, laboratory equipment and reagents, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, which is intended by manufacturer to be used, alone or in combination for human beings or other animals for one more of the specific purpose(s) of;

a) diagnosis, prevention, monitoring, treatment or alleviation of diseases or compensation for an injury,
b) investigation, replacement, modification or support or the anatomy or of a physiological process,
c) supporting or sustaining life,
d) control of conception,
e) disinfection of medical devices,
f) providing information for medical or diagnostic purposes by means of in vitro examination or specimens derived from the human body or other animal; and
g) does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

4.1.16 Non-advance importation clients – Clients who do not hold advance accounts with BoMRA

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

4.1.18 Permit- any kind of authorisation given to an importer or exporter.

4.1.19 Product licence (Registration Certificate)- an official document issued by the competent Medicine Regulatory Authority for the purpose of marketing or free distribution of a product

4.1.20 Registration- any statutory system of approval required at national level as a precondition for introducing a medical device on the market

4.1.21 Registered, licensed, authorised- these words are used in these guidelines as if they are interchangeable

4.1.22 Tax Invoice – A document used to record a transaction between a buyer and a seller, showing the sales details including the quantity, price of goods or services, applicable taxes and the total amount due.

4.1.23 Quotation – A document that a seller provides to a buyer to offer an estimate of costs of goods and services.

4.2 Abbreviations

The following abbreviations shall apply:

4.2.1 BOMRA- Botswana Medicines Regulatory Authority
4.2.2 IMDRF- International Medical Device Regulators Forum
4.2.3 SRA- Stringent Regulatory Authorities
4.2.4 WHO- World Health Organisation

5. Purpose

This guideline has been developed to:

a. provides guidance for importers and exporters of general medical devices and in vitro diagnostics pursuant to legal requirements.
b. Outlines the responsibilities of the stakeholders involved in the import and export of medical devices.
c. Identifies the persons who can import or export medical devices into or out of Botswana.
d. States the ports through which medical devices can be imported/exported into or out of Botswana.
e. Defines the minimum requirements for a complete application for import or export permit for medical devices.

6. Scope

The document applies to any person, institution and organization that intends to export, import or transit medical device(s) for the purpose of selling, research or donation of medical devices in Botswana. It applies to general medical devices and in vitro diagnostics.

Other objectives include control of unwanted medical devices as well as minimizing accumulation of non- functional medical devices but also to alleviate problems associated with donation by promoting good medical devices donation practice.

7 Categories of importers of medical devices including in vitro diagnostics:

Importers of Medical Devices shall fall under the following categories:

a. Medical Devices Manufacturers
b. Medical Devices wholesalers
c. Authorised Researchers or Clinical Trial Investigators
d. Individuals (medical purposes only)
e. Other authorized entities the Authority may permit

8 Requirements for importation and exportation of medical devices.

8.1 Requirements for importers or exporters

i. All medical devices including diagnostics to be imported or exported must be registered by BoMRA unless given special approval by the Authority.

ii. All importation/exportation of medical devices must be done by importers whose premises are dully licensed by BoMRA.

iii. The importation or exportation of all consignments of medical devices should be channelled through the designated ports of entry and will be cleared by Botswana Unified Revenue Services (BURS) (customs) and Ministry of Health (Port health Services) in consultation with BoMRA.

8.2 Procedure for importation of Medical devices

8.2.1 Application for permits to import medical devices shall only be made by authorised importers using the:
8.2.1.1 Application for Permit to Import Medical Devices - **BOMRA/IL/IE/P02/G03/F01**
8.2.1.2 Purchase Order or Proforma Invoice.

The Purchase order or Proforma Invoice shall state for each medical device to be imported, the following:

a. Date;
b. Name and address of the supplier;
c. Name and address of the importer;
d. Name and address of the manufacturer;
e. Country of origin;
f. Clear description of items including brand and common names as declared in information of medical devices including in vitro diagnostics submitted to the Authority;
g. The quantity, pack size, unit value, total value in convertible currency;
h. Batch or Lot number;
i. Manufacturing and expiry date;
j. Mode of shipment (sea, air, road);
k. Point of entry;
l. Signature and stamp of the supplier and/or manufacturer responsible for exporting the products; and
m. Application form which shall be signed by the importer.

8.2.1.3 Proof of payment for permit application fee and importation fee.

8.2.1.4 Importers shall submit copy of either Purchase Order (PO) or Proforma Invoice (PFI) and completed application form. Upon receiving proof of payment for fees, BOMRA import/export officer shall:

a. Check for completeness of the application form and the accompanying PO or PFI (date, name, signature of authorised personnel). If the PO or PFI is incomplete the application shall be rejected using the Rejection Form – ***BOMRA/IL/IE/P02/G03/F02.***
b. If the application meets the documentary checks the application will be processed in accordance with **BOMRA/IL/IE/P02/G03/F03**.

8.2.2 Processing of applications

i. Upon receiving the application as specified above, BoMRA designated officer will assess it to verify whether the requirements have been fulfilled.
ii. 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.
i. An application will be rejected if it does not meet any of the importation requirements. An applicant will be given a Rejection Form - **BOMRA/IL/IE/P02/G03/F02** (Annex II)

stating clearly reason(s) for rejection. Once an application is rejected the applicant will have to reapply for the next permit.

ii. All applications will be processed within **two (2) working days** with exception of application for importation of products which have not been registered and donations which may take longer to process.

iii. All permits issued by the Authority shall be valid for four (4) months. The permit shall not be transferable and will be issued to cover only one shipment for ease of traceability.

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

8.3 Special Importation Requirements

8.3.1 Importation of medical devices with no market authorization

An application for importation of such medical devices should be accompanied by a letter stating reasons for the importation. An import permit will be issued if the following criteria are fulfilled:

a) Medical device has been approved by **IMDRF** or SRA member countries or Prequalified by WHO or in the WHO Emergency Use Listing;
b) Evidence that a medical device is in circulation in the manufacturer's country of origin (Free Sales Certificate);
c) Declaration of Conformity to Essential Principles of Safety and Performance by the manufacturer;
d) CE Certificate except for "class A" medical devices; and
e) Evidence of insurance against consequences of the use of a class D medical device (country policy insurance).

8.3.2 Importation of medical devices for personal use

Applications for importation of class B, C and D medical devices for personal or animal use, should be accompanied by a written recommendation from a registered medical practitioner, dentist, veterinary surgeon or any other authorized practitioner.

8.3.3 Importation of investigational medical devices

Applications for importation of investigational medical device should be made by a clinical trial sponsor or Principal Investigator for a study approved to be conducted in Botswana. Such applications should be accompanied by clinical trial approval letter, ethical board clearance and copy of certificate of clinical trial issued by the Authority.

8.4 Variation of import/export permit

8.4.1 Application shall be submitted in an Application for variation of Permit - **BOMRA/IL/IE/P03/F04** through impex@bomra.co.bw accompanied by original permit to be varied and corresponding PO or PFI together with the proof of payment.

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

a. Supplier details
b. Product quantity
c. Port of entry

8.4.3 For applications that meet 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.

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

8.5 Payment of permit fees

8.5.1 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.

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

Services	Pula
Application to import/export medical devices	50
Application to vary an import/export permit of medical devices	00
Application to for transit permit	100
Importation fee for all other products	0.15% of the value of the consignment

8.6 Payment of importation fees

8.6.1 Automated Importation Fee Billing and Payment For Permit

8.6.1.1 The importer shall upon application for a permit simultaneously submit a proforma invoice or a purchase order related to the permit for calculation of permit and importation fees which will be consolidated into one quotation.

8.6.1.2 The calculation of importation fees will be as follows;

- Total consignment value X 0.15% for all registered products
- Total consignment value X 0.25% for exempted products
- The fees calculated will be translated at a monthly average exchange rate per currency denomination. The exchange rates shall be updated in the BRIMS system on a monthly basis by the Finance team.

8.6.1.3 The importer will proceed to preview the respective quotation which will reflect the permit and importation fee cost items,

8.6.1.4 The importer will review the quote and if satisfied, proceed to accept the quotation and process payment.

8.6.1.5 The Importer can opt to pay the quotation either by Payment Gateway (Visa or Mastercards) or through their Advance Account held with BOMRA as the only payment options available.

8.6.1.6 Non - advance importation clients who do not hold advance accounts with BoMRA shall proceed to request for the payment option through the Finance & Accounts Management unit.

8.6.2 Manual Permit Applications – Calculation & Payment of Permit Application & Importation Fees

8.6.2.1 The importer shall pay both permit & importation fees in advance. The following documents are required for the manual calculation of importation fees;

- Request for service form – including both permit & importation fee service

- Proforma Invoice/ Purchase Order

8.6.2.2 The Administration Officer shall generate a sales quotation for the importation & permit fees based on the proforma invoices or purchase orders submitted.

8.6.2.3 The Applicant will proceed to pay the quotation offline by depositing directly at the bank or through electronic funds transfer.

8.6.2.4 Upon payment of fees, the importer shall submit proof of payment to the Administration Officer for verification, billing and receipting. The importer will then proceed to apply for a permit.

8.6.3 Importation Fees Refunds

8.6.3.1 In the event the importer fails to source all the contents against the permit issued, and the permit expires, the Authority will only refund the importer for the following;

a. Partially supplied permits – When the contents of the approved permit are not 100% fulfilled by the supplier and the permit has reached expiry.
b. Supplier Issued Credit Note – For defective and damaged items received by importers from suppliers.

8.6.4 Requirements for a Refund Claim

8.6.4.1 It is the responsibility of the importer to submit in BRIMS a valid claim for a refund after the permit validity has lapsed. The importer shall upon receipt of the final invoice from the supplier subject to permit expiry, submit the following documents to the Authority through BRIMS to validate their claim. The documents required are as follows;

a. Valid Supplier Tax Invoice bearing the Supplier stamp and BURS customs clearance stamp
b. Stamped BURS customs declaration forms
c. Valid supplier Credit Note bearing the supplier stamp
d. BoMRA approved Permit relevant to the importation fees being claimed

8.6.5 Processing of Refunds

a. The Administration Officer will assess, verify and recommend/oppose the refund claims in BRIMS and submit to the Accountant for approval/rejection.

b. The Accountant shall review the claim for approval or rejection.

c. Upon claim approval, the excess paid on initial importation charged shall be credited to the importer's advance account for future use.

d. Upon claim rejection, a notification will be sent to the importer notifying the grounds for rejection.

The onus will be upon the importer to submit, within the system set timelines, necessary consignment documents to allow adjustment to be implemented.

9 Requirements for Exporting of Medical devices

9.1 Application for permits to export medical devices shall only be made by authorised facilities using the:

9.1.1 Application form for Permit to Export Medical Devices - **BOMRA/IL/IE/P03/G03/F01**

9.1.2 Proforma Invoice

The Invoice shall state for each medical device to be imported, the following:

n. Proforma Invoice number and date;
o. Name and address of the supplier;
p. Name and address of the importer;
q. Name and address of the manufacturer;
r. Country of origin;
s. Clear description of items including brand and common names as declared in information of medical devices including in vitro diagnostics submitted to the Authority;
t. The quantity, pack size, unit value, total value in convertible currency;
u. Batch or Lot number;
v. Manufacturing and expiry date;
w. Mode of shipment (sea, air, road);
x. Point of exit;
y. Signature and stamp of the exporter and/or manufacturer responsible for exporting the products.

9.1.3 Proof of payment.

9.1.4 Authorization to import from the importing country.

9.2 Thereafter the application to export medical devices shall be processed as in clauses 9.1.2 to 9.1.7 and clause 9.2 of these requirements. If the application has met all the documentary checks the application will be processed in accordance with **BOMRA/IL/IE/P03/G03/F02.** If some requirements have not been met, a rejection form will be issued using form **BOMRA/IL/IE/P02/G03/F02**

10 Clearing of consignments

10.1 Ports of entry

The importation of all consignments of medical devices 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 One Stop Border
e. Pioneer Border post
f. Mamuno border post
g. Ramokgwebana Border post

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

10.2 Verification/Inspection of consignments at Ports of entry

a. On arrival at the ports of entry, devices will be inspected by BoMRA Inspectors or designate (Customs or Port Health Inspector) to ensure that they comply with the approved specifications and regulations before they are released.

b. Each consignment must be accompanied by an import permit and 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.

c. During the process of inspection and release of the consignment, the Inspector may sample where possible for further investigations.

d. 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 device(s) specifications should be checked against invoices, and attention should be given to the nature and conditions of the packaging and labelling.

e. All imported medical devices should adhere to the following labelling requirements:

i. Name of the device
ii. Name and address of the manufacturer
iii. The identifier of the device, including the identifier of a device that is part of a system, test kit, medical device group
iv. Family or medical device group family *(where applicable)*
v. Batch or lot number
vi. If the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as size, net weight, length, volume or number of units
vii. The words "sterile" if the manufacturer intends to sale the device in a sterile condition
viii. The words "for single use only" if the device is intended for that purpose
ix. the manufacturing and expiry date of the device expressed in month and year (where applicable)
x. unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use
xi. the directions for use, unless directions are not required for the device to be used safely and effectively and any special storage conditions applicable to the device
xii. where a package that contains a device is too small to display all the information in accordance with (a-k) above, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sell.

Labelling information shall be written in a language understood by the users. It can be in English and any other language and shall be expressed in a legible, permanent and prominent manner that can easily be understood by the intended user.

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.

f. Falsified products and or other 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.

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

h. The inspector should notify BoMRA about confirmed or suspected cases of imported substandard or falsified products without delay.

i. On inspection of the consignment the following actions may be taken:

   i. An approval for release of consignment.

   ii. Detain the consignment 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.

10.3 Release or rejection of a consignment

10.3.1 Conditions for release of consignments:

i. All approved consignments will be released by BoMRA 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.

10.3.2 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. Medical devices rejected for quality reasons will be **CONDEMNED;**

iii. Medical devices 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 Medical devices 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 medical devices consignment(s)

10.3.3 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.

10.3.4 Destruction of rejected products

i. Destruction of rejected medical devices 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 medical devices.
ii. Any destruction made under this regulation shall be done pursuant to the Botswana Environmental affairs regulations.
iii. A Destruction Certificate after completion of the destruction exercise.

10.4 Sampling of imported products

10.4.1 Arrangements should be made with BoMRA Inspector or Enforcement Officer for the sampling and subsequent 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.

10.4.2 BoMRA will sample imported medical devices 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.

10.4.3 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.

10.4.4 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.

11 Donated Medical Devices

11.1 Requirements for donated medical devices

It is important for applicants to adhere to the following key donation principles

a) All donations will be in accordance with the recipient's needs and should comply with the existing government health policies, laws, guidelines and administrative arrangements.
b) Maximum benefit to the recipient
c) Donation should comply with applicable standards and there will not be double standards regarding safety and performance of donated items.
d) Prior and effective communication between donor and recipient before products can be donated.

11.2 Application to import donated medical devices

Any person, institution and organization intending to donate medical devices will be required to apply for a certificate to import the products from the Authority prior to shipment of the donated consignment. The following documents shall accompany the application

a) A support letter from the relevant authority from the exporting country which supports such donation (where applicable);
b) A support letter from the importer;
c) Donation certificate from the donor (Affidavit with regards to safety and performance of the donated medical devices); and
d) One original proforma invoice

The Authority will assess if the medical device is compatible with the recipient request

a) Medical devices intended to be donated must be collected as much as possible from known sources for ease of traceability in case of manufacturers Field Safety Corrective Action (FSCA).
b) Donated medical devices should have a shelf life of not less than twelve months.

c) If the medical device is used it must be reconditioned, tested and all essential parts, accessories and working materials included before shipment together with the relevant supporting documents to indicate that the device is in good working condition.

11.3 Donated medical devices shall:

i. Be robust and fully operational as a full system or as a separate subsystem;
ii. Meet or exceed existing safety and performance specifications provided by the manufacturer, international or appropriate national standards;
iii. Include all essential parts, accessories and working materials;
iv. Have its label, user manual and other documents written in English
v. be packed suitable for road, air or sea transport under tropical conditions.
vi. For software operated medical devices, the software shall be either preloaded and/or accompanied by the software package.
vii. For electrical equipment, the electrical needs of the equipment shall be set to the standard voltage of 220V/50Hz to 240V/50Hz and for X-ray emitting equipment that it shall be calibrated and inspected by a qualified Medical Physicist or certification from any approved radiation body
viii. Damaged, outmoded, and redundant medical devices for which spare parts and consumables are no longer available and/or equipment which is no longer supported by the manufacturer shall not be accepted.
ix. The Authority will issue donation import permit when satisfied that all conditions of application have been fulfilled, otherwise, the application will be rejected in writing by stating the reason for rejection. The permit issued for importation of donated medical devices will be valid for six (6) months.

11.4 Verification at the Port of Entry

Donated medical devices shall have port clearance from the Authority and shall be accompanied by the following documentary evidence:

a) Valid import certificate;
b) packing list;
c) proforma invoice,
d) airway bill or bill of lading;
e) certificate of refurbishment for used medical devices (issued by the manufacturer of certified company);
f) certificate of analysis for sterile medical devices;

g) The certificate of refurbishment mentioned under (e) must state the following:
   i. tested, labelled and packed; and replaced or repaired and the repair service that were performed on the medical device and the source of the repair parts and provide an acceptance report for these parts;
   ii. if calibrated it shall state and verify the operation of the medical device performance standard used to calibrate it; and disinfected or decontaminated as appropriate.

11.5 Labelling of the donated medical device

Depending on its nature and type, the label of donated medical device should have the following minimum information:

i. the name of the medical device;
ii. model number or serial number;
iii. manufacturing and expiry date (where applicable);
iv. name and address of the manufacturer;
v. handling and storage requirement(s);
vi. technical direction for use;
vii. an indication, if applicable, that the medical device is intended to be used;
viii. The words "used only for clinical or performance investigations" before being supplied;
ix. for a sterile medical device, the word "Sterile" and where appropriate, description of methods of re-sterilization;
x. if the device is a refurbished, an indication of the device as refurbished device;
xi. if the device is intended for presentation or demonstration purposes only, it must be labelled as "for presentation or demonstration purposes only, not for use on human";
xii. if the device emits radiation for medical purpose, details of its nature, type and where appropriate, the intensity and distribution of the radiation;
xiii. if the device is to be installed with or connected to other medical device or equipment, or with dedicated software, in order to operate as required for its intended use, sufficient details of its characteristics to identify the correct device or equipment to use in order to obtain a safe combination;
xiv. if the device is an in vitro diagnostic medical device it must be labelled as "in vitro diagnostic" or "IVD";

xv. the intended purpose of the medical device, the intended user of the medical device, and the kind of patient on whom the medical device is intended to be used (if this information is not obvious); and

xvi. Any number, letter or symbol, and any letter or number in a symbol, used in the label shall be legible.

xvii. Each donated medical device shall have accompanying user manual having detailed information on handling, installation, operation, maintenance, trouble shooting, precautions and other important information.

xviii. Donated medical devices shall be transported, stored and handled in accordance with acceptable transportation, storage and handling requirements.

xix. Labelling information of the medical device can be provided on the medical device itself, packaging used for the medical device, on an insert supplied with the medical device or in a printed document or using other appropriate media.

xx. At the time of importation, medical devices must have a valid shelf life not less than 65% of the original shelf life where applicable. Considerations can be made during emergencies and when it is evident that the product will be fully consumed within a specific period of time.

11.6 Reporting

The recipient will be required to report relevant information to the Authority including defects, adverse events, problems related to quality and safety and other reportable cases related to the donated equipment.

11.7 Disposal

Donated medical devices shall be disposed-off based on manufacturer`s instructions for safe disposal of the product.

12 Responsibilities of stakeholders

12.1 The Authority

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

ii. BoMRA shall authorise importation or exportation of any medical devices 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 medical devices at the port of entry.

v. BoMRA will designate points of Entries for regulated products

12.2 The Importer or Exporter

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

ii. To ensure that imported medical devices 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 medical devices and avail such records when requested.

vi. Remit actual quantities of imported medical devices and timelines for such importation

vii. Acknowledge receipt of all imports.

12.3 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 medical devices and their documentation.

iii. Customs shall check that all consignments of medical devices are authorized by BoMRA.

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

13 Permit for in-transit medical devices

13.1 A person transporting medical devices 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.

13.2 The application should entail:

a. a list of all medical devices 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

14 Review and Appeal procedures

a) Any applicant who is not satisfied by the decision of the Authority in relation to any application to import or export of medical devices may appeal for review of the decision to the BoMRA Chief Executive Officer (CEO) within a period of 14 days from the date of receipt of the decision.
b) The Authority may review its decision, reject or vary the condition of approval.
c) After reconsideration of the application, if the applicant is not satisfied by the decision of the review, may appeal to higher authorities (depending on individual countries appeal policies and procedures).

15 References

a. WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices https://who.int/medicines/areas/quality_safety/quality_assurance/trs1003_annex4.pdf?ua=1
b. MEDICAL DEVICE REGULATIONS: Global overview and guiding principles: Dregs_Couverture_der (who.int)
c. Guidelines on import procedures for medical products: https://www.who.int/medicines/areas/quality_safety/quality_assurance/WHO_TRS_1019_Annex5.pdf?ua=1

16 ANNEXURES

16.1 Annexure 1 Application for Permit to Import Medical Devices (BOMRA/IL/IE/P02/G03/F01 Issue No. 1.0)

16.2 Annexure 2 Import/Export Rejection Form (BOMRA/IL/IE/P02/G03/F02 Issue No. 1.0)

16.3 Annexure 3 Permission To Import Medical devices (BOMRA/IL/IE/P02/G03/F03 Issue No. 1.0)

16.4 Annexure 4 Application for Permit to Export Medical Devices (BOMRA/IL/IE/P03/G03/F01 Issue No. 1.0)

16.5 Annexure 5 Export Permit for Medical Devices (BOMRA/IL/IE/P03/G03/F02 Issue No. 1.0)