



SAMED Regulatory Forum

Botswana Update

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Botswana Medicines Regulatory Authority

Function: Medical device listing

Department: Product Evaluation and Registration

Listing

Mandate of Botswana Medicines Regulatory Authority (BOMRA)

- To regulate medicines, medical devices and cosmetics, to promote human and animal health

Reason for listing of medical devices

- To identify medical devices including IVDs that are in circulation in Botswana. Listing medical devices is for purposes of identification and will form a provisional register for medical devices allowed in or out of Botswana.

Listing

Who was required to list medical devices

- Entities or individuals who manufacture/ distribute/ sell/ import & export/ have inventories of medical devices in Botswana.
- All facilities (District Health Management Teams, Hospitals, Laboratories, Central Medical Stores, Pharmacies, veterinary and human clinics etc.) were required to list medical devices and IVDs in their inventory.
- Deadline 31st March 2021.

Listing

Must one have a representative that is based in Botswana to list one's medical devices

- No, and international manufacturers / authorized representatives are allowed to list and export devices to customers
- even if they are not based in Botswana

Listing

Were data sheets, brochures, CE certificates, info on registration in other countries needed

- Not in this exercise, just filled in
- Relevant Form
- Excel sheet
- Signed and dated DoC by Manufacturer
- Artwork of labelling

Classifications

- Based on IMDRF
- Class A, B, C, D

Listing

Will there be a certificate issued after approval of the listing

- There will be an acknowledgement after receiving the documents and a register (database) shall be published after the exercise is complete.
- Due 31st March 2022

Exemption From Registration Of Medical Devices When Importing covid-19 related medical devices & IVDs

- Application for exemption in this instance is mandatory


Exemption

Guideline for Application for Exemption from Registration of Medical Devices

- BOMRA/ER/MED/P01/G01
- Effective date: 08/04/2021
- Applicable to only to Covid-19 related medical devices.

Excludes:

- Rapid Covid-19 antibody test kit and
- All combination products i.e., medical devices with active pharmaceutical ingredients

 Botswana Medicines Regulatory Authority	Page 6 of 9
	Document type: Guideline
Function: Exemptions	Title: Guideline for Application for Exemption from Registration of Medical Devices
Department: Product Evaluation and Registration	Document No: BOMRA/ER/MED/P01/G01
	Issue No: 4.0
	Effective date: 08/04/2021

Exemption

Requirements for Exemption from Registration of Medical Devices

- Application Form & Proof of payment of application fee **BWP 350**
- A copy of a manufacturing license and/or ISO 13485 certificate or Business license
- A copy or proof of the Marketing Authorization and/or Free Sale Certificate issued by the relevant SRA
- CE certificate issued by European notified bodies and/or
- in the case of WHO Prequalification-accepted products, a copy of a final acceptance letter. For Rapid Covid-19 antigen test kit WHO Emergency Use Listing is required
- Clear Pictures/Photographs of a sample with manufacturer's instruction for use of the device.
- Valid for **6 Months**

Exemption cont.


Additional requirements for Exemption from Registration for IVDs

- Clinical Evaluation Report (CER)
- Regular updates to CER
- Declaration of conformity
- WHO Emergency Use Listing for Rapid Cod-19 antigen test kits

Listing of Medical Devices & IVDs

- **Guideline for Listing of Medical Devices**

- BOMRA/ER/MED/P02/G01
- Effective Date: 21/12/2020
- Only applicable to listing of Medical devices. This guideline excludes:
 - ❑ All combination products i.e. medical devices with active pharmaceutical ingredients

 Botswana Medicines Regulatory Authority	Page 1 of 5
	Document type: Guideline
Function: Medical device listing	Title: Guideline for Listing of Medical Devices
Department: Product Evaluation and Registration	Document No: BOMRA/ER/MED/P02/G01
	Issue No: 1.0
	Effective date: 21/12/2020

Listing of Medical Devices & IVDs

Requirements for Listing of Medical Device(s)

- Filled Form for Listing of Medical device(s). Manufacturer or Authorized representative - **Form 1** for listing of medical devices along with Annexure I of Listing of Medical Devices
- Stakeholders other than Manufacturer or Authorized representative shall use **Form 2** for listing of medical devices along with Annexure I of Listing of Medical Devices
- Copy of labeling and Declaration of conformity by the manufacturer
- Filled form and relevant documents emailed to **rmu@bomra.co.bw** and **medicaldevices.services@bomra.co.bw**.

Listing of Medical Devices & IVDs Form 1



- This form should be submitted along with the relevant documents.
- The form and attachments should be emailed to medicaldevices.services@bomra.co.bw and rmu@bomra.co.bw

S/N	Title	To be completed by the stakeholder
1.	Manufacturer / Authorized Representative	
	I.1. Name	Stakeholder's Name.
	I.2. Physical address	Full physical address
	I.3. Phone number	
	I.4. Email address	
2.	Manufacturer of the Product (Please fill in Annexure I)	
3.	Details of the Product (Please fill in Annexure I)	
4.	Declaration by Stakeholder	
	I, the undersigned, certify that all the information above and in the labelling & declaration of conformity concerning an application for listing of the medical device listed below is correct and true.	
	Name of Contact Person	Click or tap here to enter text.
	Position in company	Click or tap here to enter text.
	Date:	Click or tap to enter a date.
	Signature (Initials / Digital)	

Listing of Medical Devices & IVDs Form 2



- This form should be submitted along with the relevant **documents**.
- The form and attachments should be emailed to medicaldevices.services@bomra.co.bw and rmu@bomra.co.bw

S/N	Title	To be completed by the stakeholder
1.	Local Representative/Importer/Distributor/Agent/Facility	
	I.1. Name	Stakeholder's Name.
	I.2. Physical address	Full physical address
	I.3. Phone number	
	I.4. Email address	
2.	Manufacturer of the Product (Please fill in Annexure I)	
3.	Details of the Product (Please fill in Annexure I)	
4.	Declaration by Stakeholder	
	I, the undersigned, certify that all the information above is correct and true.	
	Name of Contact Person	Click or tap here to enter text.
	Position in company	Click or tap here to enter text.
	Date:	Click or tap to enter a date.
	Signature (Initials / Digital)	

Listing of Medical Devices & IVDs Annexure I

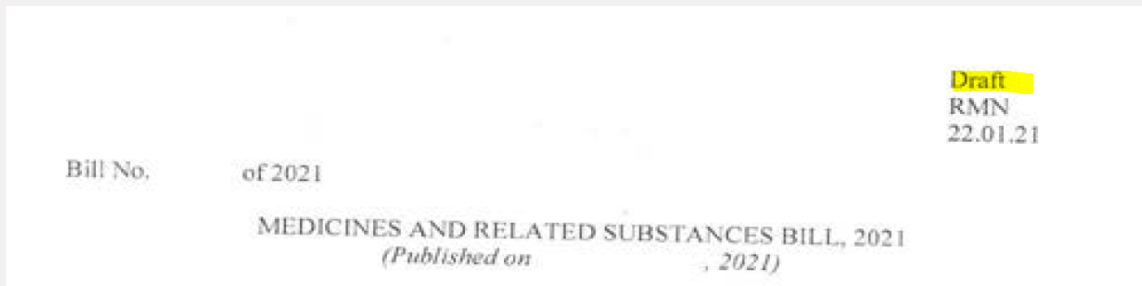
– Excel Sheet

- Product Name
- Brand Name/ Trade Name
- Model Name /Number
- Software Version (If Applicable)
- Device Intended Use
- Product Category (IVD/ Medical Device)
- Device Risk Classification (A,B,C,D)
- Life Span/Shelf Life/ Use period
- Name of Manufacturer
- Physical and Postal Address of Manufacturer
- Email, Fax and Phone number of Manufacturer
- Manufacturing Site Details
- Report any quality, efficacy or safety issue with the device

Current Status with the Listings

- They have had some stakeholder engagement meetings which showed clear intention to work together with Industry
- The review of the Listings is still in process and on-going
- Stakeholders will be notified once completed
- We can anticipate call ups for registrations in the (near?) future

Medicines and Related Substances Bill, 2021



2. The object of this Bill is repeal and re-enact, with amendments, the Medicines and Related Substances Act (Cap. 63:04) to adequately address shortfalls identified in the existing Act. The said shortfalls reduced the Botswana Medicine Regulatory Authority's (Authority) ability to effectively regulate medicines and related substances. Notably, the re-enactment will align the Medicines and Related Substances Act with the model law that the African Union developed for harmonisation of African medical regulation. The African Union model law strengthens regulation across the continent, eases market access and encourages direct foreign investment. Further, the re-enactment introduces enhanced controls to meet the high standards of veterinary medicine regulation, which impacts Botswana's ability to access the export market for products such as beef and other meat products. The re-enactment will also allow for the incorporation of the 2018 enactment (Act No. 39 of 2018), which deleted Part IX on controlled substances.

Medicines and Related Substances Bill, 2021

– PART IX

A Bill
– entitled –

An Act to provide for the establishment of the Botswana Medicines Regulatory Authority whose main objective is to regulate the sale, distribution, importation, exportation, manufacture and dispensing of medicines and related substances; and matters incidental thereto.

Date of Assent:

Date of commencement:

ENACTED by the Parliament of Botswana.

PART IX – *Classification of Medicines and Control of Certain Classes of Medical Products*

49. Classification and description of human medicines
50. Classification and description of veterinary medicines
51. Classification and description of medical devices
52. Classification of in-vitro diagnostic devices
53. Classification of complementary medicine
54. Classification of cosmetics

