FREQUENTLY ASKED QUESTIONS

MEDICAL DEVICES LISTING EXERCISE

1. What is the mandate of Botswana Medicines Regulatory Authority (BOMRA)?

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

2. What is the importance of listing of medical devices?

A 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.

3. Who is required to list medical devices?

A This notice affects entities or individuals who manufacturer/ distribute/ sell/ import & export/ have inventories of medical devices in Botswana.

4. Are Facilities supposed to list their medical devices too?

A Yes, all facilities (District Health Management Teams, Hospitals, Laboratories, Central Medical Stores, Pharmacies, veterinary and human clinics etc.) are required to list medical devices and IVDs in their inventory.

5. What is the definition of medical device – for the purpose of registration.

A **Definition of a Medical device:**
Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article –

a) intended by the manufacturer to be used, alone or in combination, for humans or animals for
i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
iii. investigation, replacement, modification or support of the anatomy or of a physiological process;
iv. supporting or sustaining life;
v. control of conception;
vi. disinfection of medical devices (manufactured for specific medical devices); or
vii. providing information for medical or diagnostic purpose by means of in vitro examination of specimens derived from the human body; and

b) which do not achieve its primary intended action in or on human or animal body by pharmacological, immunological or metabolic means but which may be assisted in its intended function by such means.

BOMRA
MEDICINES REGULATORY AUTHORITY
Promoting access to safe medicines

6. What is the definition of In Vitro Diagnostics (IVD) Device?

A In Vitro Diagnostics (IVD) Device means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimen derived from the human or animal; solely or principally to provide information for diagnostic, monitoring or compatibility purposes which includes but is not limited to – reagents used for IVD purposes, calibrators, control chemicals, specimen receptacles, software and related instruments or apparatus or other articles and are used for the following test purposes; diagnosis; aid to diagnosis; screening; monitoring; predisposition; prognosis; prediction; determination of physiological status.

7. Do we list medical equipment, consumables, reagents, IVDS etc.?

A YES.

8. Do we list spare parts of medical devices ?

A No, they are not considered as medical devices.

9. In case of medical equipment - does each model, accessories and consumables required to be listed?

A YES.

10. Are all big and small medical equipment required to be listed?

A YES, all medical devices from bandages, instruments, implants to all hospital furniture, mortuary equipment, medical & laboratory equipment and IVDS are required to be listed.

11. What about x-ray films, chemicals for wet processing and cassettes?

A YES, they are medical devices and should be listed.

12. Would you need additional information like data sheets, brochures, CE certificates, registration in other countries? Or just to fill the Excel sheet.

A Not in this exercise, for now just fill in the Excel sheets.

13. Do we have to get a representative that is based in Botswana to list medical devices?

A No, you can list from anyhere if you do not have a representative in Botswana.

14. Are international manufacturers / authorized representatives allowed to list and export devices to customers even if they are not based in Botswana?

A YES

15. Where can the guidelines and forms for listing of medical devices be found?

- At the BOMRA website **(www.bomra.co.bw)** under downloads ▸ guidelines & Manuals ▸ Registration ▸ Medical Devices.
- At the BOMRA website **(www.bomra.co.bw)** under downloads ▸ Forms ▸ Medical Devices

16. What is the deadline for listing of medical devices?

A 31st March 2021 and submit to: **medicaldevices.services@bomra.co.bw** and **rmu@bomra.co.bw**

17. Will there be a certificate issued after approval of the listing?

A There shall be an acknowledgement after receiving the documents and the whole register (database) shall be published after the exercise is complete.

18. Do you require amendments to the listing if changes are made to the information over time?

A Yes, we do, and some changes will be captured through future application for registration of medical devices.

19. Please advise on the criteria used for determining risk classification of the device. Have you adapted the IMDRF guidelines for classification?

A Yes classification of risks follows IMDRF guidelines for classification. In annexure I, kindly state how your medical device is classified by the manufacturer.

20. What is the definition of STAKEHOLDER as mentioned in the guideline?

A Stakeholder in this context (refers to Manufacturers/ authorized representative/ local representative/ importer/ distributor/ agent/facility).

21. Where multiple distributors of the same device are used in Botswana. Are they all expected to submit the same list of medical devices?

A YES but If documents are submitted by manufacturer/authorized representative then only manufacturer/authorized representative need to complete this exercise.

22. Question on application for Exemption from Registration of Medical Devices, which medical devices should we apply for exemption from registration?

A All Covid-19 related medical devices & IVDS and their consumables (e.g. covid-19 test kits; covid-19 testing equipment, IVDs including reagents, calibrators, controls, consumables etc; ventilators and its consumables; Oxygen concentrators; monitoring equipment; infusion pumps, PPEs, IF thermometers, medical masks, medical gowns, medical gloves and other medical devices used for covid-19).

23. Where can one find the Guideline and forms for Application for Exemption from Registration of Medical Devices?

- At the BOMRA website **(www.bomra.co.bw)** under downloads ▸ guidelines & Manuals ▸ Registration ▸ Medical Devices.
- At the BOMRA website **(www.bomra.co.bw)** under downloads ▸ Forms ▸ Medical Devices

24. Is It Mandatory To Apply For Exemption From Registration Of Medical Devices When Importing covid-19 related medical devices & IVDs?

A Yes, it is mandatory.

25. Do we need to apply for exemption from registration and importation of non covid-19 related medical devices?

A No, you need to list them as per the listing guidelines and application to registration of those will start once the legal framework is finalised.

26. Covid-19 related medical devices are eligible for the listing exercise or only exemption process are applicable?

A They can apply for both processes.