PUBLIC NOTICE

07 SEPTEMBER 2023

CALL FOR VOLUNTARY PRIORITY BASED REGISTRATION OF MEDICAL DEVICES INCLUDING IVDS

As mandated by the Medicines and Related Substances Act of 2013, Botswana Medicines Regulatory Authority (BoMRA) is calling on applicants to register their medical devices including In Vitro Diagnostics (IVDs) with the Authority as a step towards availing safe, quality and effective medical devices to Botswana.

Applicants are strongly encouraged to familiarize themselves with the criteria and requirements outlined in the **Registration Guideline** and other relevant guidance documents published on the BoMRA website before submitting their applications.

Voluntary registration will commence on **1st October 2023** and continue for the following 6 months until **31st March 2024.** Note that this is a transition period aimed at preparing applicants for mandatory registration, which shall commence on **1st April 2024**. Voluntary registration will be subjected to the current Registration Fees and the stipulated timelines.

This voluntary registration will be as per the priority list mentioned below. However the priority list will be updated periodically as and when necessary.

The priority list is given below;
In Vitro Diagnostic Medical Devices Prequalified by WHO: HIV; Malaria; Hepatitis A; Hepatitis B; HPV; G6PD; Cholera; Syphilis; Tuberculosis NAT; etc. The link to the In Vitro Diagnostic Medical Devices Prequalified by WHO is as follows: https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists

Locally Manufactured Medical Devices: Medical masks; medical gloves; medical gowns; Viral Transport Media; Vacuum blood collecting tubes; etc.

High Risk Medical Devices and Medical Devices of Importance:

- Medical implants;
  - Heart Implants (Cardiac Stents, Cardiac Pacemakers, Implantable Defibrillators, Implantable Cardiac Recorders)
  - Central Nervous System Implants (Neuro Implants, Spine Implants)
- Contraceptive Devices (Condoms and their Lubricants);
- Pregnancy test kits

For any enquiries kindly contact: medicaldevices.services@bomra.co.bw

Registration Guidelines and other relevant guidance documents can be accessed on the BoMRA website using the following link: https://www.bomra.co.bw/medical-devices/

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BOMRA MEDICINES REGULATORY AUTHORITY
Promoting access to safe medicines