PUBLIC NOTICE

REGISTRATION ROADMAP FOR CLASS A AND NOTIFIABLE MEDICAL DEVICES, INCLUDING IN VITRO DIAGNOSTICS, ESTABLISHMENT LICENSING, AND COMPLIANCE DEADLINES

Date : 30th September 2026

The Botswana Medicines Regulatory Authority (BoMRA) wishes to inform all relevant stakeholders of the implementation of regulatory requirements for medical devices, including in vitro diagnostics (IVDs), under the Medical Device Regulatory Roadmap.

The roadmap supports Botswana's progressive strengthening of medical device regulation in line with internationally recognized regulatory principles. The framework aims to protect patients, healthcare professionals, and the public while facilitating access to safe, quality-assured medical devices.

1. Class A Notification Registration

BoMRA is issuing a call for notification registration for the following products:

- Class A medical devices, including Class A IVDs;
- Veterinary-use-only medical devices, including IVDs; and
- Class A dental medical devices and applicable dental consumables.

Classification and Regulatory Pathway: Before submitting an application, stakeholders must verify the applicable product risk classification and confirm the correct regulatory pathway.

Implementation Timeline: Voluntary Transition Phase

During this period:

- Notification registration will be voluntary from **1 October 2026 – 31 March 2027.**
- The applicable application fee will be USD 185 or the equivalent amount in Botswana Pula.
- Fully locally manufactured devices will qualify for a 50% fee reduction, resulting in an applicable fee of USD 92.50 or the equivalent amount in Botswana Pula.
- Partially locally manufactured devices will qualify for a 25% fee reduction, resulting in an applicable fee of USD 138.75 or the equivalent amount in Botswana Pula.

Importation and Transitional Facilitation of dental devices and veterinary devices

- **Import controls and permit requirements are waived for the veterinary-use-only medical devices, dental medical devices and their consumables from the date of this notice until the end of the transition period on 31 March 2027. During this period, no permits will be required for these product lines to support a seamless transition.**

- **Mandatory Compliance Period: Effective 1 April 2027**
- Notification registration for the specified Class A medical devices will become mandatory from 1 April 2027.
- Applicable import controls and regulatory compliance requirements will be enforced in accordance with the relevant legislation and BoMRA procedures from 1 April 2027.

2. Licensing of Medical Device Establishments and Manufacturers

- **Scope:** All establishments involved in the manufacture, importation, exportation, wholesale, distribution, or supply of medical devices must comply with the applicable establishment registration and licensing requirements.
- **Implementation Timelines:**
  - Voluntary Establishment Licensing: 1 October 2026 – 31 March 2027
  - Mandatory Establishment Licensing: 1 April 2027 – 31 March 2028

- **Local Manufacturers**
  For local manufacturers, establishment licensing is a prerequisite for notification registration of locally manufactured medical devices, subject to applicable regulatory requirements.

3. Existing Registration Requirements, Annual Retentions, and Maintenance of the Medical Devices Register

- **Class B, C, and D Medical Devices:** Registration for Class B, C, and D medical devices remains ongoing in line with the previously published roadmap. Stakeholders with unregistered products in these classes are urged to submit applications immediately.
- **Annual Retentions and Register Maintenance:** Stakeholders with registered and listed medical devices are reminded to ensure timely payment of annual retention fees as stipulated. Devices that are not duly retained within the prescribed deadlines will be suspended or removed from the BoMRA Register of Medical Devices, resulting in the revocation of market authorization and import eligibility.

Contact and Submission Details

Applications for facility licensing and product notification registration must be submitted through the BoMRA Regulatory Information Management System (BRIMS) portal: https://brims.bomra.co.bw/

For further inquiries, please contact the Medical Devices Unit at **medicaldevices.services@bomra.co.bw** or call **+267 373 1720.**

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