For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

Medical Devices Regulatory Updates-Botswana

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Agenda

The MRSA & Regulations

MD Regulation Background in Botswana

MD Regulation Strategy & Roadmap

Challenges

The MRSA & Regulations

"Interpretation: The MRSA. cited as the Medicines and Related Substances Act 2013 came into effect by order published in the Gazette."

The Act gives the Authority powers to regulate the supply chain of medicines, medical devices and cosmetics in Botswana to ensure their quality, safety and efficacy.

ACT further gives powers to make regulations, guidelines, SOPs and Policies
- 1 MRS Regulation of 2019; 11 Procedures: 2 Policies: 13 Guidelines
- ACT undergoing amendment
- followed by regulations, guidelines to align

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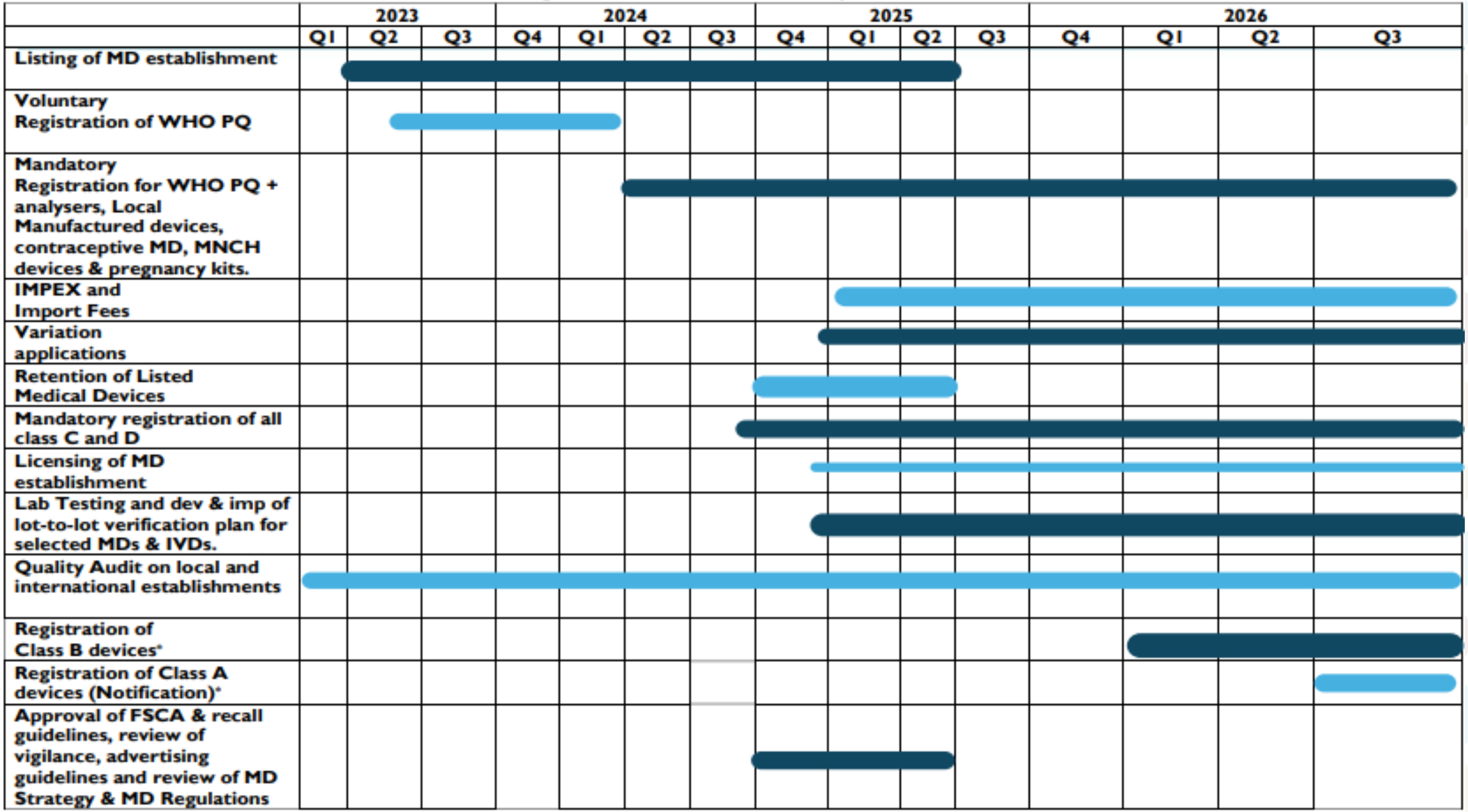
MD Regulation Roadmap



Procurement or Importation of MD

- No medical devices shall be imported to Botswana without approval & import permit from BOMRA.

- Updated medical devices registers available on BRIMS.

- Exemption process to be used for authorization of MD not called for registration.

- Note that once called for registration, exemption process will be used twice only, with the second one used when there is evidence of submission for registration.

Improving quick access to safe, quality and effective MD to Botswana

1. **Combined Registration process**

- BoMRA will be implementing a combined registration process (screening and evaluation) from 1st October 2025.
- Combined registration fee for registration.

2. **Immediate Registration**

- Immediate Registration for selected Class B Medical Devices from SRAs and with ISO 13485 and meeting BOMRA's requirements

3. **Mechanisms for expediting assessment**

- Simplify requirements; workshop technical requirements; encourage expedited applications.

Collaborations, Convergence & Harmonization initiatives

IMDRF (International Medical Devices Regulatory Forum)

GHWP (Global Harmonization Working Party)

AMDF (African Medical Devices Forum) & MDA TC (Medical Devices Assessment Technical Committee)

WHO CRP

ARSO (African Organization for Standardization)

RPI (Radiation Protection Inspectorate), BOBS (Botswana Bureau of Standards) & have MOUs with other NRAs in Africa

ISO 13485 or MDSAP (MD Single Audit Programme) certificates

Align to GMDN, GS1 UDI systems for nomenclature UDI System

Challenges

1. Last minute applications for registration & retention
2. Lack of applications for import permits
3. Goods stuck at the points of entries to Botswana
4. Increase in exemptions applications
5. New users on BRIMS

Still to be done:

1. Import controls for spare parts, consideration registration numbers on selected MD labels
2. Regulation of single use, reprocessing & refurbished MD

Solutions:

1. Targeted MD stakeholder engagements
2. Expedited assessments
3. BRIMS Refreshers

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THANK YOU