Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

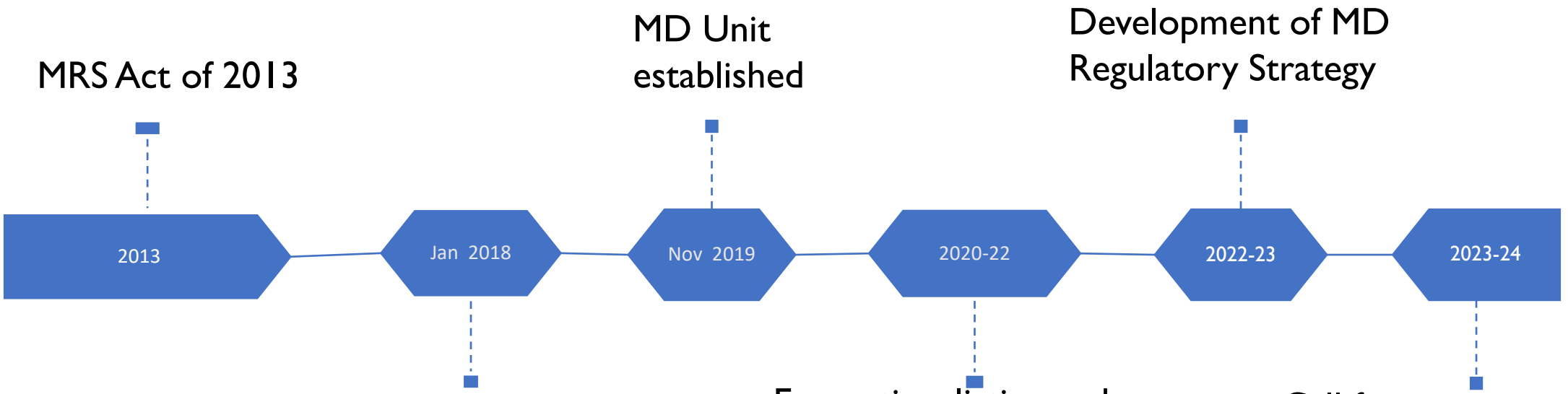
BOMRA MEDICAL DEVICES Regulation Update by BD Mosweu

Presentation Outline

- MD Regulation Roadmap in Botswana
- MD Regulatory Strategy
- Regulatory Convergence
- Work Status Update
- Expectations

28th GHWP Annual Meeting and 28th GHWP TC Meeting, 9th - 12th Dec 2024
Kuala Lumpur, Malaysia

Medical Devices Regulation Roadmap in Botswana



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GHWP

Vision & Mission

Vision: The trusted Authority for excellence in medical products and cosmetics regulation

Mission: We regulate medicines, medical devices and cosmetics to promote human and animal health

Values:

Integrity

Customer Focus

Efficiency

Teamwork

BOMRA has developed a 3-Year MD Regulatory Strategy (2022-2025)

- based on basic level of controls stipulated in the WHO's GMRF for MD including IVDs.
- It emphasizes on the use of basic principles outlined to ensure protection of public health and safety in the use of medical devices.
- Outlines the registration, vigilance and licensing plans for medical devices in a stepwise approach

Called for registration for priority MD

- All SRA and WHO PQ IVDs and compatible analyzers/systems (e.g. HIV, Malaria, Syphilis, TB, HPV, Hepatitis B & C)
- All locally manufactured medical devices including IVDs (medical masks, gowns, gloves, blood collection tubes etc)
- High risk devices of national importance; CNS implants, contraceptives, pregnancy test kits and MNCH related devices

Convergence / Harmonization Activities

BOMRA is a member of IMDRF, AMDF, MDA TC, ARSO, MD SADC TWG.

- Harmonization of Guidelines and standards through IMDRF, AMDF, ARSO.

Developed a reliance and recognition policy for MD to facilitate access of quality, safe and effective MD in Botswana.

- SRA & IMDRF Members
- WHO CRP for PQ IVDs.
- ISO 13485 or MDSAP Certificate
- GMDN and GS1 UDI

Adopted/adapted IMDRF Guidelines, UNFPA Guidelines, WHO Guidelines etc.

Work Status Update

Parameter	Value
Number of listed medical devices Subjected to annual retention fee from (January – March 2025)	154 967
Listed Medical Devices Establishments & number of Local Manufactured licensed	96 & 5 respectively
No. of MD Applications approved for screening/received	65 of 73
No. of Applications registered / received (groups) from April 2024	28/34 (300 group members)
No. of exemptions applications done (valid for 6 months)	1304 (229 through BRIMS) (84% approvals)

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MD TIMELINES

Registration Route	Notification	Class B	Class C	Class D
Screening	Within 3 months	Within 1 month	Within 2 months	Within 2 months
Abridged	NA	Within 4 month	Within 6 months	Within 8 months
Full Evaluation (for local manufacturers)	NA	Within 6 months	Within 8 months	Within 10 months
Full Evaluation (for foreign manufacturer)	NA	Within 8 months	Within 10 months	Within 12 months
Expedited	NA	Within 4 months	Within 6 months	Within 8 months
WHO CRP	Within 3 months			
Query Response	Within 1 Month			
Exemptions	Within 72 Hours			
Major Variations	Within 3 months			
Minor Variations	Within 3 months			
Notification variations	Within 1 Month			

Expectations after joining GHWP as a member

- Access to technical documents from GHWP Members
- Capacity building from being part of the GHWP WG, priority being:
  - WG1 – Premarket submission and CSDT
  - WG2 – Premarket IVDD
  - WG4 – Post Market
  - WG5 – Clinical Evidence for performance and safety
  - Special Trask Group - Common Evaluation Reliance Practice (CERP)
- Networking and learning from other GHWP members
- Build a robust regulatory framework for MD.
- Center of excellence in regulation of MD.
- Training and other capacity building opportunities such as training and twining opportunities with GHWP members
- Reliance and recognition of regulatory decisions and reports from GHWP members

Thank you/Questions

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