27th GHWP Annual Meeting in Nov 2023
Shanghai, China
27 – 30 November 2023

Harmonization efforts and regulatory system strengthening in medical devices regulation

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Revised WHO Global Model Regulatory Framework (GMRF) for medical devices

Chapter 4 - Definition, classification, essential principles, and conformity assessment of medical devices

Chapter 5 - Enabling conditions for effective regulation of medical devices incl. IVDs

Chapter 6 - Establishing a stepwise approach to regulating medical devices

Chapter 7 - Regulatory pathways

Chapter 8 - Additional topics

Chapter 9 - Implementation

Dissemination workshops planned in Q4/2023

[WHO Expert Committee on Biological Standardization: seventy-sixth report (WHO Technical Report Series, No. 1045)]

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Key elements

- Companion diagnostics: expanded and added in section 6.
- Good regulatory practice: *concept more explicit throughout the GMRF*
- Good reliance practice: moved from Chapter 4; *more explicit throughout the GMRF*
- Local production: policy, national strategy to support local manufacturers and no double standards with foreign manufacturers.
- Regulatory testing: no routine testing pre-market. Keep lot verification – *risk-based approach*.
- Regulatory pathway
  - ✓ *according to the 4 risk classes – routinely*
  - ✓ *reliance*
  - ✓ *emergency*
  - ✓ *donation*
  - ✓ *combination and border line products*
- Implementation
  - ✓ *stakeholders' engagement*
  - ✓ *development of a roadmap*
  - ✓ *capacity building*

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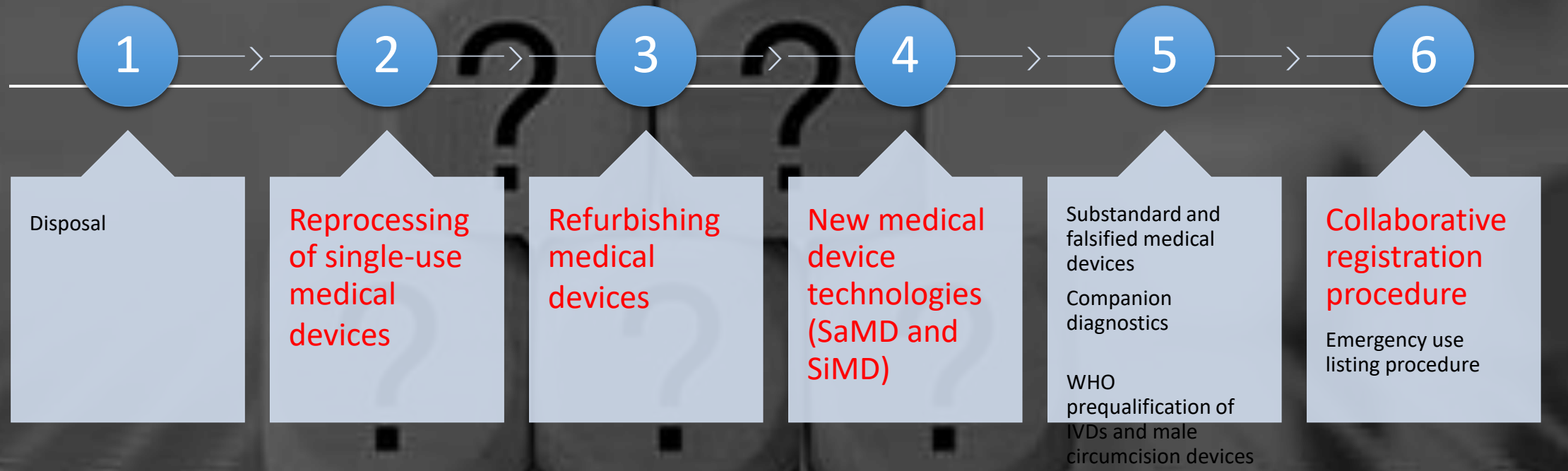
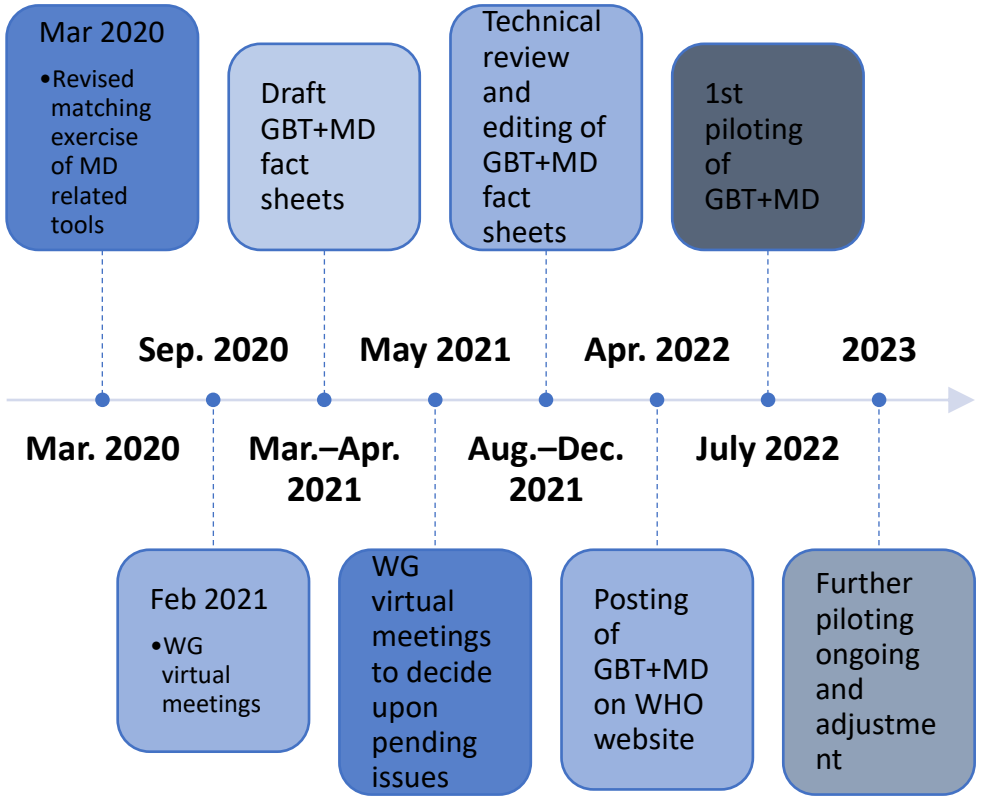
Additional topics



Global Benchmarking Tool (GBT plus medical devices)

- GBT represents the primary means by which the WHO objectively evaluates regulatory systems (*Resolution WHA 67.20*)
- GBT (medicines & Vaccines) introduced in 2016 and revised in 2018
- GBT replaces all tools previously used by WHO, representing the first truly 'global' tool
- Nov. 2019: GBT+Blood (whole blood, blood components and plasma derived blood products)
- **April 2022: draft GBT+Medical Devices including IVDs integrated into the GBT (link)**



www.who.int/medicines

Thank you for your attention!

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