IMDRF International Medical Device Regulators Forum

Update from the World Health Organization

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Overview

Regulatory system strengthening activities

WHO Global Model Regulatory Framework for medical devices

Technical support and reliance

Global Benchmarking Tool (GBT)

Prequalification of IVDs

Transition from EUL to PQ

Prequalification dossier assessments and inspections

Upcoming changes to PQDx

New documents

World health assembly resolutions and decisions

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

- **GMRF officially published in May 2023 following major revision**
  - **Chapter 1.** Introduction
  - **Chapter 2.** Definition, classification, essential principles, and conformity assessment of medical devices
  - **Chapter 3.** Enabling conditions for effective regulation of medical devices including IVDs
  - **Chapter 4.** Establishing a stepwise approach to regulating medical devices
  - **Chapter 5.** Regulatory pathways *New*
  - **Chapter 6.** Additional topics
  - **Chapter 7.** Implementation *New*

https://www.who.int/publications/m/item/who-global-model-regulatory-framework-for-medical-devices-including-in-vitro-diagnostic-medical-devices--annex-3 .

Dissemination workshops planned in Q4/2023

Regulatory pathways – key elements

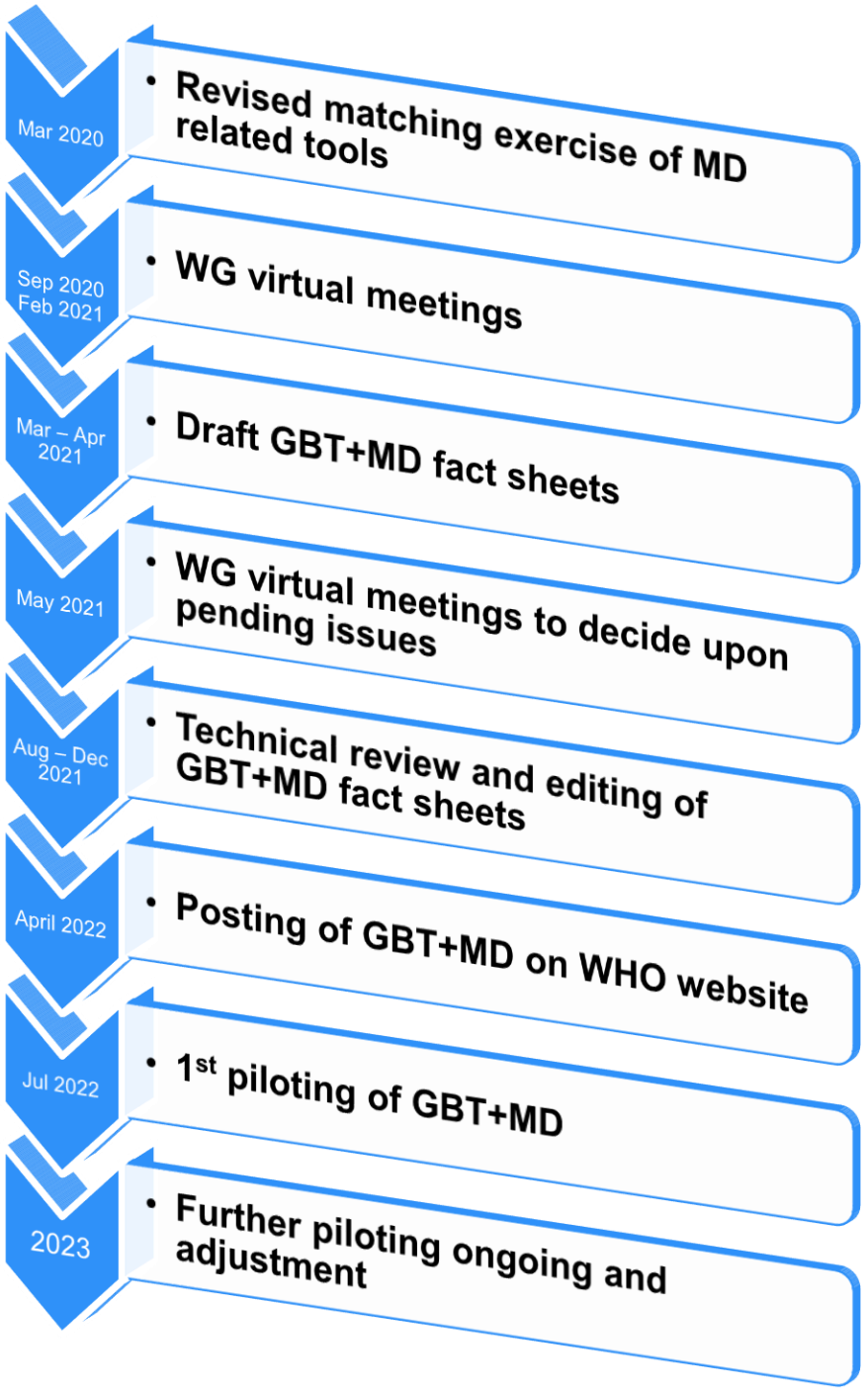
- Pathways defined for
  1. premarket conformity assessment of medical devices according to risk class
  2. premarket conformity assessment of medical devices based on reliance
  3. emergency use authorization or derogation
  4. borderline products
  5. combination products
  6. donated medical devices

Technical support and promoting regulatory reliance for IVDs

- **Technical support to countries and regional regulatory networks**
  - **In June 2023, AMRH SC endorsed Specific Considerations for Regulating Maternal, Newborn and Child Health Medical Devices — Market Authorization**
    - Developed by AMDF in collaboration with MSH/MTaPs
    - Dissemination workshop conducted early August 2023
  - **Regional training workshop on assessment of MDs technical planned in Q4 2023**
    - in collaboration with MSH/MTaPs and Tanzania Medicines and Medical Devices Authority (TMDA)
  - **Southeast Asian Regulatory Network (SEARN) WG5 on medical devices**
    - survey on regulatory landscape
    - development of workplan 2023/2024 prioritizing capacity building and reliance
- **Collaborative Registration Procedure (CRP) for IVDs**
  - 17 applications received with 7 national registrations and 10 are under assessment (***only 9 assays registered in 2022)***
  - Advocacy workshops for Francophone countries in Africa, 25-27 Sept 2023 in Cotonou, Benin
  - 11th CRP annual meeting, 12 – 15 Dec, Doha, Qatar

Global Benchmarking Tool (GBT)

- 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)**



GBT + Medical Devices – work in progress

- GBT+MD developed in consultation with regulators from over 20 countries in all 6 WHO regions
  - Including global and regional networks

- First piloted in June/July 2022 in Africa
  - confirmed its value & revealed areas for further improvement

- Further piloting during the week of 18 Sept 2023 in Asia
  - Lessons will help further refine/adjust the tool

- WG meetings Q4 2023 to review learnings from the pilots

WHO Prequalification: Transition of SARS-CoV-2 NAT and Ag RDTs from EUL to PQ

End of the PHEIC triggered:

- No new EUL submissions accepted
- Cancellation of ongoing assessments
- Start of transition phase EUL → PQ

EUL listed IVDs will remain eligible for procurement until Jan 31, 2024, provided that the manufacturer adheres to post-listing obligations

For products transitioning to PQ the EUL listing validity will be maintained until a PQ decision is taken

For products not undergoing PQ assessment, the EUL listing validity will not be extended beyond Jan 31, 2024

To remain eligible for procurement manufacturers of EUL listed IVDs will have until Dec 31, 2023, to apply for PQ assessment

Technical Specifications TSS-20 and TSS-21 have been published

SARS-CoV-2 IVDs (NAT & Ag RDTs) are now eligible for WHO PQ

PQDx IVD product dossier assessments and inspections

WHO PQ has implemented the **ToC format for dossiers** and review reports

A **new assessment model** is being ruled out: assessment sessions

- involvement of SMEs
- support from several IMDRF NRAs
- capacity building for NRAs with growing regulatory capacity

Inspections:

EUL QMS reviews wrapped up as part of EUL PQ transition

18/33 applicants with active applications have MDSAP

Prequalification of IVDs: upcoming changes

Based on the experience with PQ assessments, change requests assessments and pandemic:

1. Change review process under revision: new report template being piloted and new guidance for manufacturers planned
2. Abridged PQ procedure to be amended to further build on collaboration and reliance
3. Expansion of assessment capacity
4. the ePQS Portal will be live by 1 Jan 2024
5. PQDx scope expansion plan to be published soon

Prequalification of IVDs: new documents

Published:

- **TSS 20** - In vitro diagnostic medical devices used for the qualitative detection of SARS-CoV-2 nucleic acid
- **TSS 21** - SARS-CoV-2 antigen rapid diagnostic tests for professional use and self-testing

Coming soon:

- Haemoglobin A1c point of care analysers for professional use
- In-vitro diagnostic medical devices for monitoring of blood glucose in capillary blood
- Haemoglobin PoC analysers

World Health Assembly Resolutions and Decisions

WHA76.5 Increasing access to medical oxygen

…to promote the convergence and harmonization of regulations governing the provision of medical oxygen and access to safe, effective and quality assured medical oxygen sources and devices..

WHA76.3 Strengthening diagnostics capacity

..to leverage international…. collaboration for harmonizing for the regulation, manufacturing and supply of all types of diagnostics

WHA75(25) Standardization of medical devices nomenclature

to integrate available information related to medical devices, including terms, codes and definitions, in MEDEVIS

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Thank you/Questions

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