WHO updates on regulatory harmonization efforts

28th GHWP Annual Meeting

KLCC, Kuala Lumpur, Malaysia, 11-12 December 2024

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World Health Organization

Mandated under Resolution WHA 67.20 in 2014

- Recognized the importance of strong regulatory systems to a well-functioning healthcare system

WHO supports Member States in building and sustaining effective regulatory oversight of medical products through its regulatory systems strengthening (RSS) programme

Objectives of the RSS programme

- *Build capacity in Member States consistent with good regulatory practices*
- *Promote regulatory cooperation, convergence and transparency through networking, work-sharing and* ***reliance***

Ultimate goal

- ***Promote access to quality assured medical products (medicines, vaccines, medical devices,***

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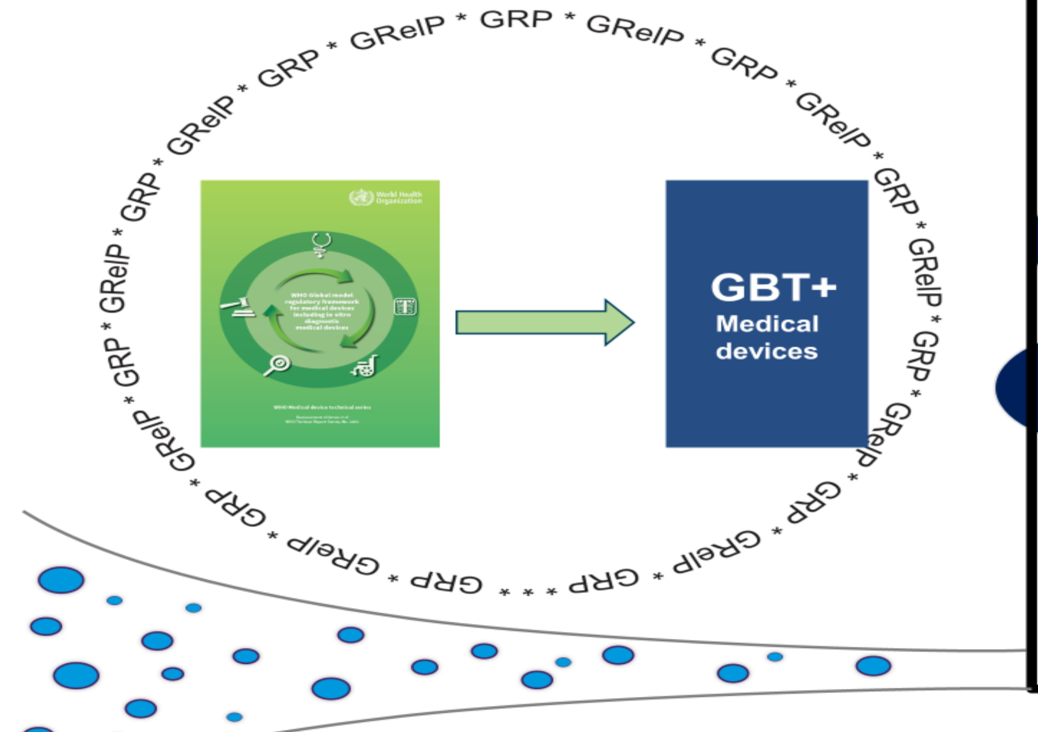
WHO Global Model Regulatory Framework (GMRF), 2023

Shaping the future of medical devices regulation

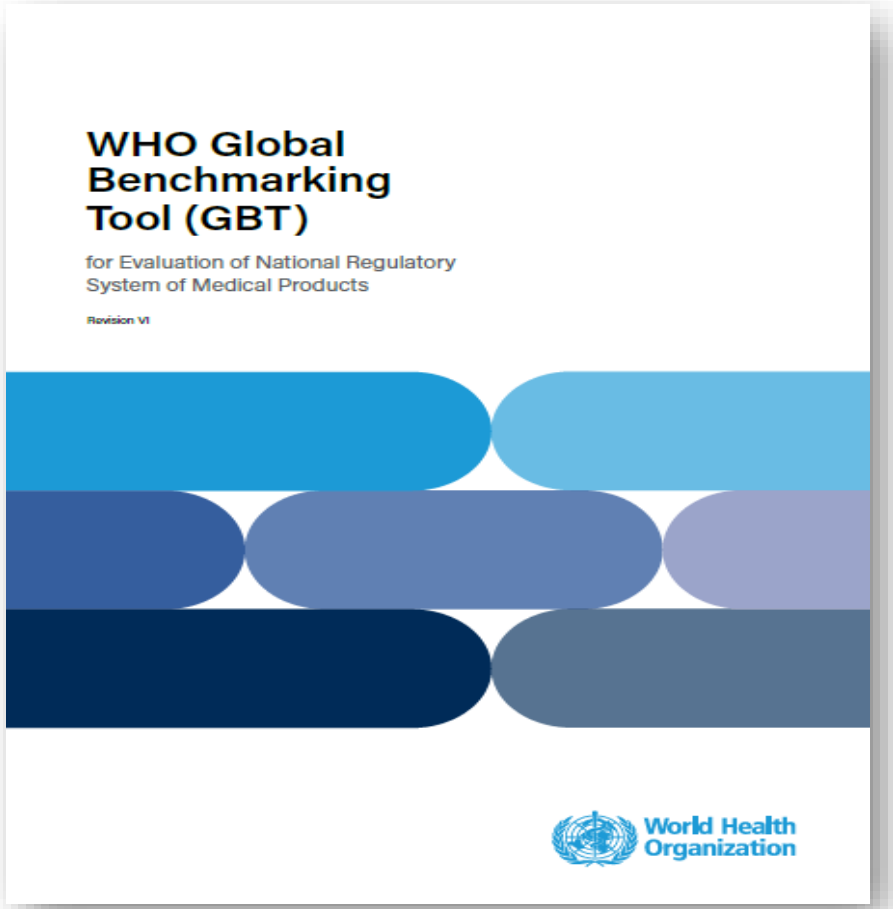
New Table of contents



- GMRF https://www.who.int/publications/i/item/9789241512350
- GBT+ https://www.who.int/tools/global-benchmarking-tools/evaluation-of-national-regulatory-systems-of-medical-devices-in-vitro-diagnostics
- GRP https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf
- GRelP https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf

WHO Global Benchmarking Tool (GBT)

primary means by which the WHO objectively evaluates regulatory systems for medical products



Link: https://apps.who.int/iris/handle/10665/341243

Blood (Nov 2019)

- **Medical Devices**
  - ✓ Revision 1 (Apr 2022)
  - ✓ Revision II (Dec 2024)

Link: https://www.who.int/tools/global-benchmarking-tools

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75 HEALTH FOR ALL

GBT+ MD Version 2 published in December 2024

[WHO Global Benchmarking Tool plus Medical Devices (GBT + Medical devices) for evaluation of National Regulatory system of medical products]

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WHO Global Benchmarking Tool plus Medical Devices (GBT + Medical devices) for evaluation of National Regulatory system of medical products

Revision VI+MD version 2

3 December 2024 | Technical document

Download (5.7 MB)

Overview

The Global Benchmarking Tool Plus Medical Devices (GBT+MD) is an extension of the World Health Organization's GBT framework, designed to support the evaluation and strengthening of regulatory systems for medical devices. While sharing common regulatory principles with other medical products such as medicines, vaccines, and blood products, regulating medical devices presents unique challenges and opportunities that the GBT+MD addresses explicitly.

The WHO Global Benchmarking Tool Plus Medical Devices (GBT+MD) Revision VI+MD version 2, published in December 2024, is the latest release of the GBT for benchmarking medical devices' national regulatory systems. This release comprises six (6) regulatory functions under the overarching framework of the national regulatory system (RS). Additionally, the GBT+MD includes a detailed glossary and fact sheet to provide clarity on key terms and definitions.

Currently, the GBT+MD is available in English. Work is underway to translate the GBT+MD into other official languages of the United Nations (UN).

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Support| global and regional harmonization initiatives

- **Global**
  - International Medical Device Regulators Forum (IMDRF)
- **Regional**
  1. Africa Medical Devices Forum (AMDF)
     - Including Medical Devices Assessment Technical Committee
  2. Asia Pacific Economic Coo-peration (APEC)
  3. Global Harmonization Working Party (GHWP)
  4. Pan American Network of Drug Regulatory Harmonization (PANDRH)
  5. South East Asia Regulatory Network (SEARN)

Promoting | Regulatory work-sharing and reliance

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Reliance in facilitating national regulatory decisions

- Provided there is evidence of product's quality, safety and performance

- Implemented through WHO Collaborative Registration Procedure (CRP)
  - ✓ **Scope:** medicines, vaccines, in-vitro diagnostics (IVDs) & vector control products
  - ✓ 35 regulatory authorities signed to CRP IVDs, launched in 2020
    - 59 products registered through CRP with average time of **52 days** (target 90 days!)

- WHO CRP annual meetings, a unique platform for advocacy and addressing challenges
  - ✓ 12-14 Nov 2024, Jakarta, Indonesia

- Useful tools for implementing CRP for medical products
  - ✓ WHO guidelines on CRP for IVDs, TRS 1030, 2021 (Annex 4)
  - ✓ WHO Good Practices of NRAs in implementing CRP for medical products
    - **Revised to include IVDs - to be published in 2025**

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Prequalification of IVDs: 2024 highlights

- **PQDx scope expansion**
  - ✓In-vitro diagnostic medical devices for monitoring of blood glucose in capillary blood; and
  - ✓Haemoglobin A1c point of care analysers for professional use
- **Publication of PQ TSS for TB LAM tests with PQ scope expansion in Q1 2025**
  - ✓First prequalification listing of a TB NAT assay
- **Revised changes guidance implementation from January 2025**
  - ✓ Strengthened risk-based approach and reliance
- **Public consultation on a PQDx process shift concluded**
  - ✓implementation of a streamlined process in Q2 2025
- **Full implementation of assessment sessions, including PQ dossiers and change requests**

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Emergency Use Listing: 2024 highlights

- **COVID-19**
  - ✓SARS-CoV-2 NAT and Ag RDTs transitioned from EUL to PQ

- **MPXV**
  - ✓14 Aug 2024: the WHO DG declared that the outbreak of mpox (clade I) constitutes a PHEIC
  - ✓28 Aug 2024: manufacturers of IVDs for the detection of MPXV nucleic acid are invited to submit an EOI for assessment of candidate IVDs under the EUL procedure
  - ✓EOI received from 66 manufacturers of 81 products - 8 dossiers received and 3 products listed

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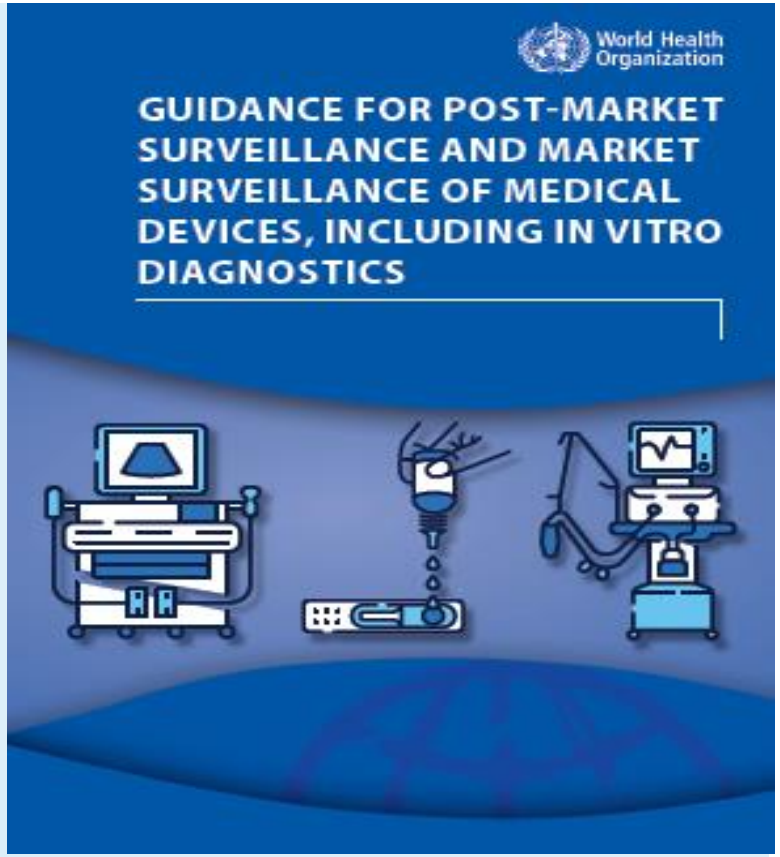
Guidance on post-market & market surveillance

- **Describes**
  - **Post-market surveillance** activities for manufacturers
  - **Feedback** procedure for users (rather than just complaints)
  - **Market surveillance** activities for regulators
- **Reflects international standards/guidance**
  - ISO/TR 20416:2020 Medical devices — Post-market surveillance for manufacturers
  - IMDRF/AE WG/N43 Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes



https://www.who.int/health-topics/substandard-and-falsified-medical-products

Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics

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WHO Global Surveillance and Monitoring System (GSMS)

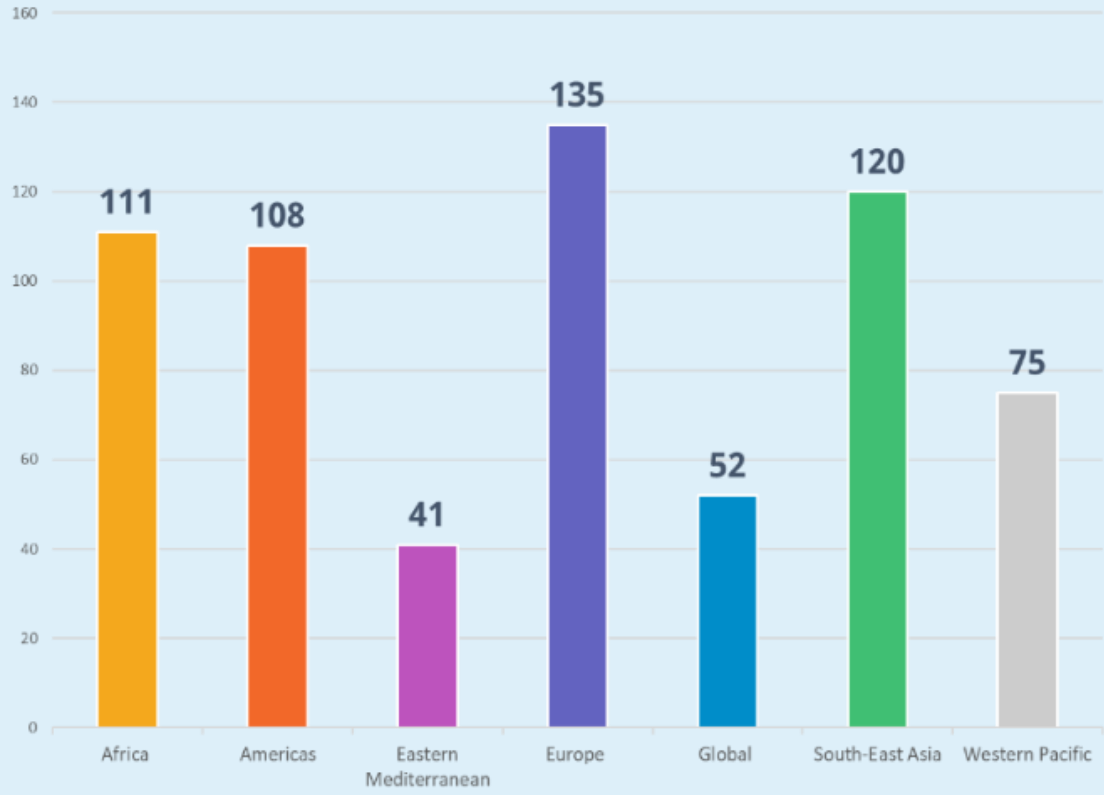
- **WHO Global Surveillance and Monitoring System**

✓ Manufacturers of PQ and EUL IVDs are obliged to report to WHO
✓ WHO's GSMS reporting portal is being re-designed for manufacturers to directly input incidents

- **One-stop searchable shop for IVD safety information**

✓ Planning to automatically collate all field safety notices for IVDs recommended by WHO
  - Using WHO Epidemic Intelligence from Open Sources (EIOS) system

WHO regions where IVD incidents occurred 2014-2024



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… and finally

Rollout of GBT+MD will transform regulatory landscape for medical devices

… along with implementation of the principles of WHO GMRF

Regulatory co-operation, networking, work-sharing and reliance remain a priority for the WHO

Alignment and ***harmonization*** *of 'regulatory harmonization* initiatives' to minimize duplication

Revision of WLA Policy to expand scope to integrate MDs, including IVDs

… building on the lessons from the use of the GBT+MD

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My health,
my right

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THANK YOU