
Development of the WHO Global Benchmarking Tool

28th GHWP Annual Meeting & GHWP Technical Committee Meeting
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WHO regulatory strengthening activities

Mandate

Resolution WHA
67.20 (2014) on
Regulatory
Systems
Strengthening for
medical products

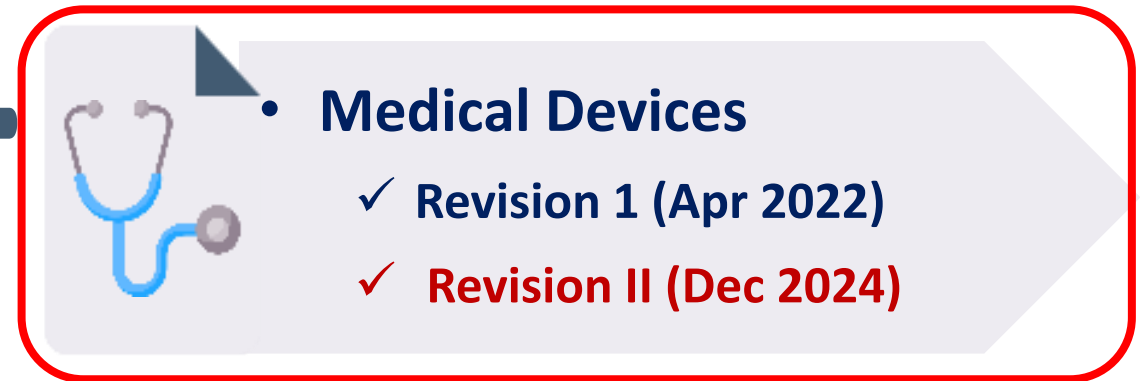
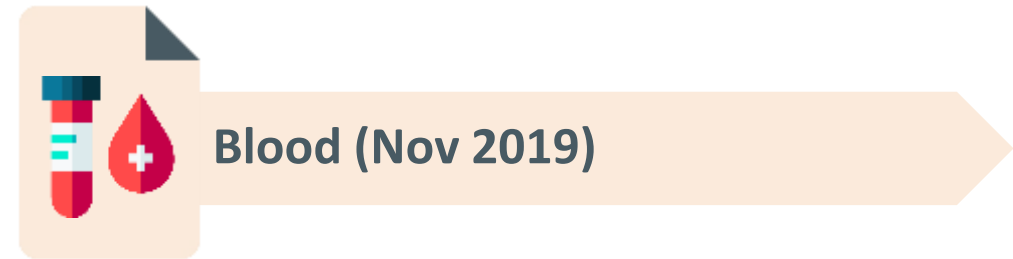
1. Regulatory capacity building using Global Benchmarking Tool
2. Promoting regulatory convergence, harmonization and networking
3. Promoting regulatory reliance through facilitated regulatory approval pathways, such as WHO Collaborative Registration Procedure (CRP)
4. Strengthening national control laboratories (Medicines & Vaccines)
5. Prevention, detection and response to substandard and falsified (SF) medical products
6. Strengthening pharmacovigilance systems to respond to adverse reactions/events

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>



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



World Health Organization



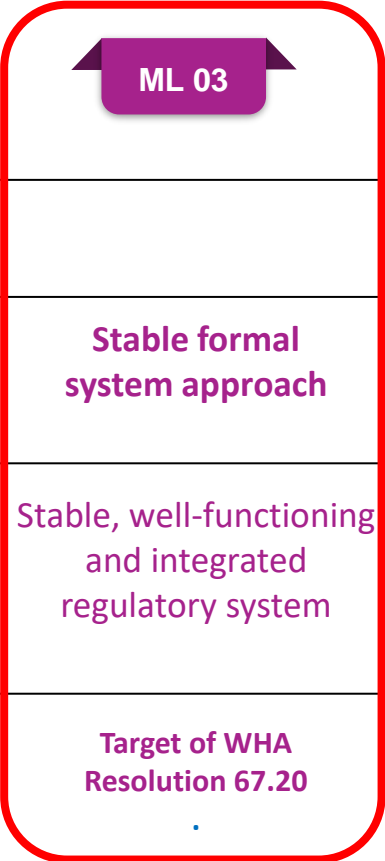
HEALTH FOR ALL

Global Benchmarking Tool: Maturity levels (ML)

- concept of 'maturity level' or ML adapted from ISO 9004
- allows WHO and regulatory authorities to assess the overall 'maturity' of the regulatory system on a scale of 1 to 4
- Higher maturity levels demonstrate effective and efficient regulatory systems

ML 01

ML 02

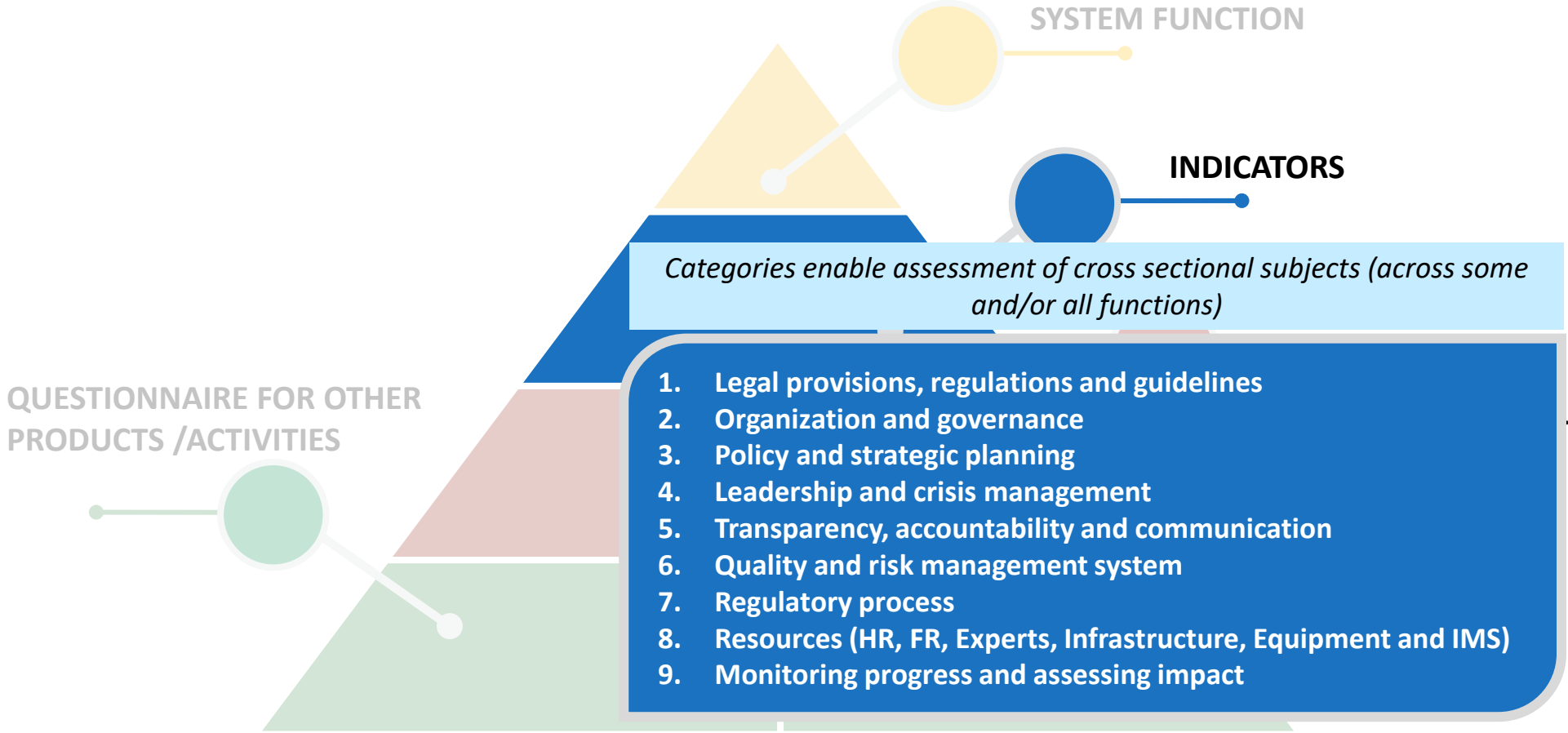


ML 03

ML 04

MLs				
ISO 9004	No formal approach	Reactive approach	Stable formal system approach	Continual improvement emphasized
WHO GBT	Some elements of the regulatory system exist	Evolving national regulatory system that partially performs essential regulatory functions	Stable, well-functioning and integrated regulatory system	Regulatory system operating at an advanced level of performance and continuous improvement
	Can ensure the quality of products if rely on ML3/ML4 regulatory systems		Target of WHA Resolution 67.20	Well-resourced Regulatory systems

Categories of Indicators (cross cutting subjects) of the GBT



WHO Global Benchmarking Tool (GBT)

Strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC (WHA 67.20 in 2014)



used in over 100 countries to evaluate regulatory systems and determine maturity levels



provides structured framework for regulatory system strengthening



helps identify gaps and guide capacity building



Facilitate regional and global regulatory reliance among regulators

Development of GBT+MD: Unification of WHO tools



GBT+ enhanced by incorporating approaches adapted from the existing tools

Development of GBT+MD



Mar 2020

Review and matching of existing tools for medical devices

Sep 2020-Feb 2021

WG meetings to review progress

Mar-Apr 2021

Drafting fact sheets

May 2021

WG meetings to review fact sheets

Consultative process with experts from NRAs and regional & global networks of regulators

Aug – Dec 2021

Technical review and editing of fact sheets (WHO)



Development of GBT+MD (cont...)

April 2022

Revision 1 published

Jul 2022 - Sep 2023

Piloting of the tool

- Kenya (2022)
- Singapore (2023)

Dec 2023 - Feb 2024

Working Group discussions:

- areas of amendment based on the findings from the pilots
- amendments and editing

March - Oct 2024

- Updating the fact sheets based on the outcome of the WG discussions
- Feedback to WG and final consensus building

- Confirmed its value in benchmarking of medical devices regulatory systems in different country settings
- Revealed additional areas for further improvement to align with the updated GMRF and merging of market control and vigilance functions

Nov 2024

Computerization & roll out (Nigeria)

Dec 2024

Official Publication (revision 2)

GBT+ MD Revision II published!

[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).

Benchmarking process



What are the next steps for the GBT+MD

Translate the tool into official UN languages, as appropriate

Support countries in applying GBT +MD along with implementation of the GMRF

Training of regulators on applying the tool in regulatory assessments

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

**My health,
my right**



THANK YOU