Good Regulatory Practices

World Health Organization

Webinar on Good Regulatory Practices and Medical Device Regulation,

COVID-19 Medical Device Regulatory Convergence Project (Indonesia)

June 15 2022

Key Themes of WHO's 13th General Programme of Work 2019-2023

Mission

Promote Health - Keep the World Safe - Serve the Vulnerable

Strategic Priorities

Health Coverage:	1 billion more people with health coverage
Health Emergencies:	1 billion more people made safer
Health Priorities:	1 billion lives improved

Medicines and other Health products (MPH)
Dr. Mariângela SIMÃO, Assistant Director General

Outline

- Good Regulatory Practices Principles
- Good Reliance Practices Principles
- WHO Regulatory System Strengthening activities
- Global Model Regulatory Framework for medical devices including IVDs

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Good Regulatory Practices Principles

https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf

WHO Good Regulatory Practices

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Purpose

- Present the **high-level principles** of Good Regulatory Practices.
- Principles to serve as **benchmarks**.
- Guide Member States in **<u>prioritizing</u>** their regulatory activities according to: resources, national goals, public health policies, medical products policies and the medical product environment

Scope

- **Relevant to all regulators**, irrespective of resources, maturity or regulatory models; equally applicable to supranational (e.g. regional), national and subnational regulatory systems.
- **Related audience**: institutions and policy-makers, regulatory networks, regulated parties

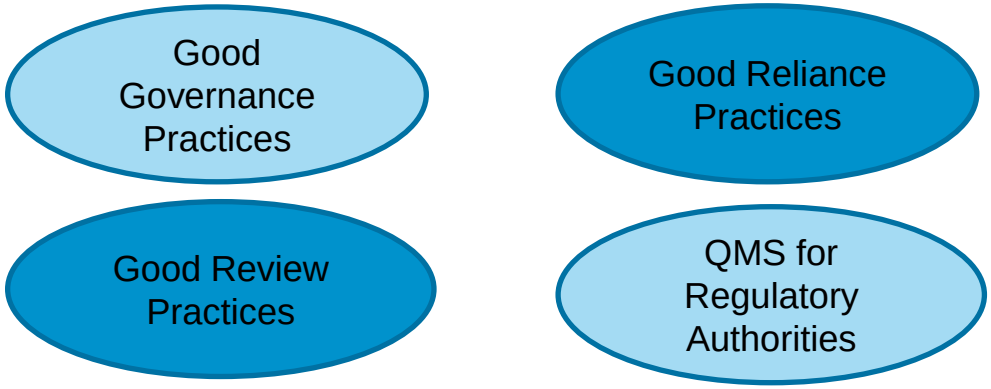
WHO Good regulatory practices in the regulation of medical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-fifth report. Technical Report Series, No. 1033, Annex 11; 2021. Link: https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

WHO Good Regulatory Practices

Objectives:

- Ensure sound and effective regulation of medical products.
- Higher-quality regulation, better regulatory decision-making and compliance.
- More efficient regulatory systems and better public health outcomes.
- Up to date regulatory systems.
- Promote trust among regulatory authorities and other stakeholders.
- Facilitate international cooperation.

Complemented by:



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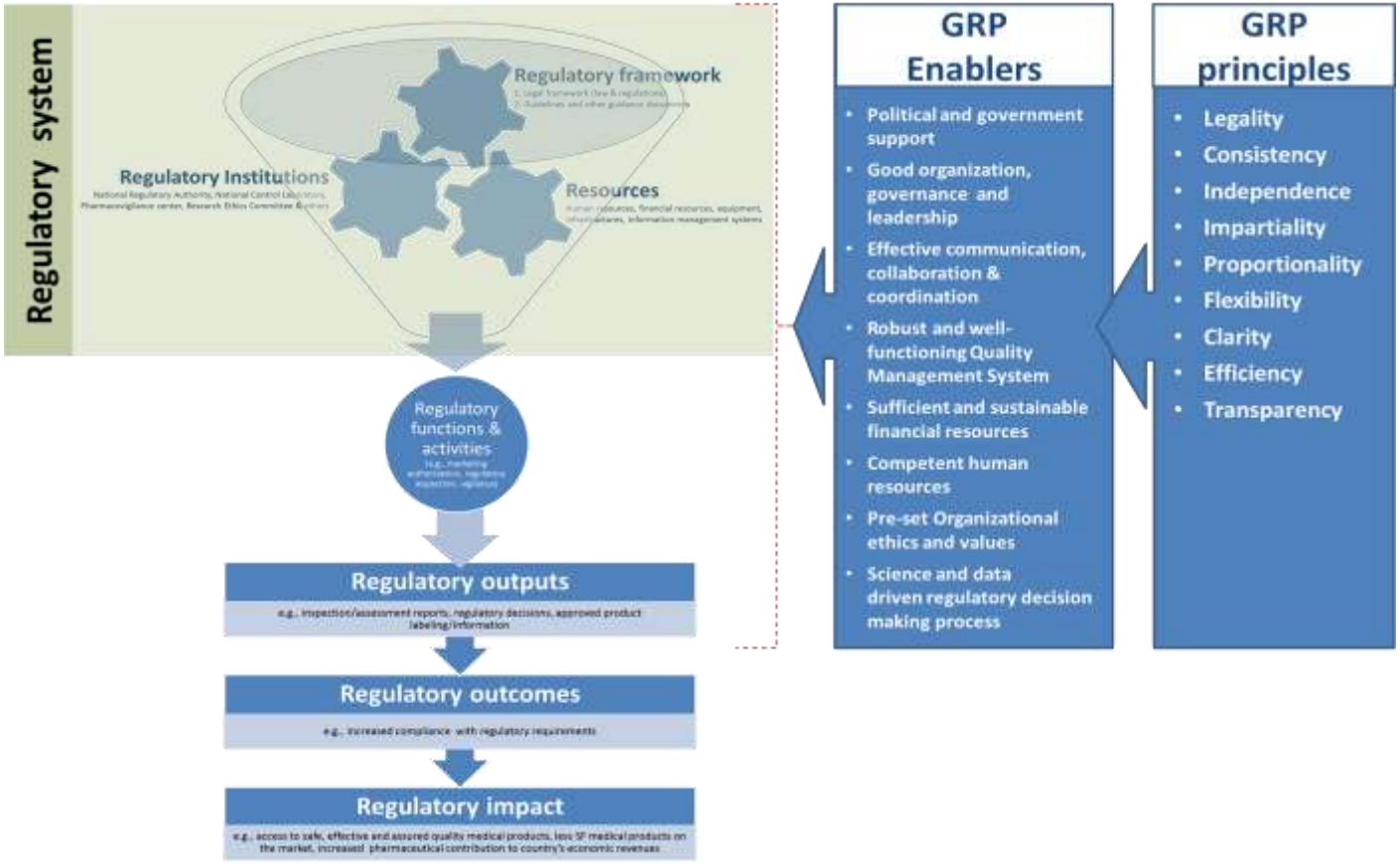
Nine high-level principles

Legality	Consistency	Independence
Impartiality	Proportionality	Flexibility
Clarity	Efficiency	Transparency

Good Regulatory Practices Summary



Principles and enablers of Good Regulatory Practices (GRP) and Components of the regulatory system

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Good Reliance Practices Principles

https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf

Principles of Reliance

International cooperation essential to ensure the safety, quality and efficacy/performance of locally used medical products.
No regulatory authorities even the best resourced one can do it alone.

Make best use of available resources and expertise, avoid duplication and concentrate regulatory efforts and resources where most needed.
Promote a more efficient approach to regulatory oversight, thereby improving access to quality-assured, effective and safe medical products over the entire life-cycle.

The act whereby the regulatory authority in one jurisdiction takes into account and give significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision. Various forms of reliance approaches.

The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions, assessments and information of others.

Key concepts of reliance

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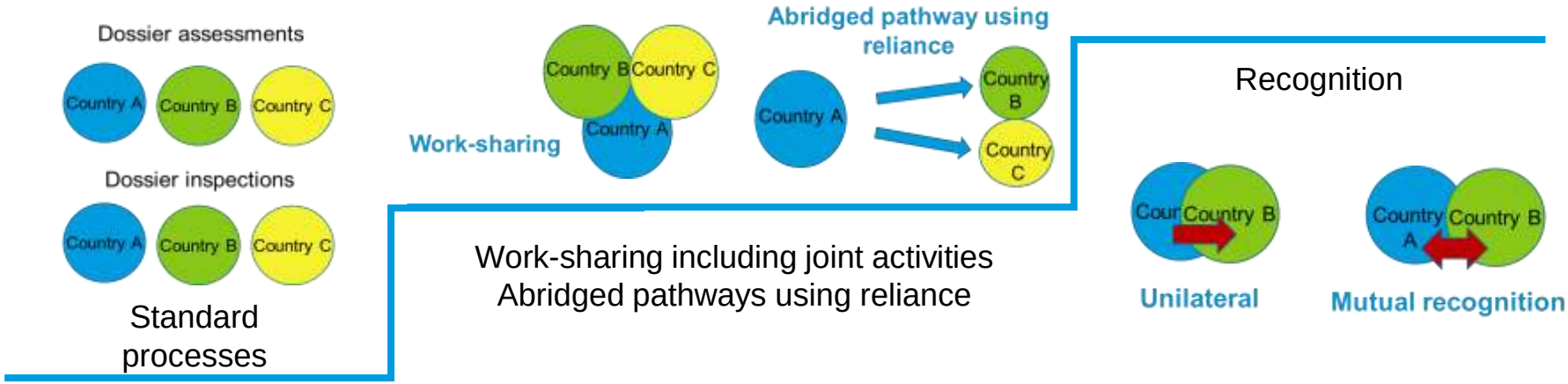

Independent decisions based on its own reviews and/or inspections	**Leveraging regulatory work** Performed by other competent and trusted authorities to reduce the workload	**Unilateral or mutual recognition** based on treaties or equivalent

Building trust between NRAs, increasing reliance and efficiency

WHO Good Reliance Practices – Key concepts

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Recognition (vs. reliance): more formalized approach to reliance, i.e. recognizes the decisions of another regulatory authority, system or institution, with no additional assessment. Usually requires formal and binding legal provisions.

Unilateral vs. mutual: unilaterally/without reciprocity or mutual recognition based on binding mutual agreements or treaties.

Life cycle approach: to apply across the full life cycle of medical products and all regulatory functions (e.g. important for vigilance and post-authorization activities).

Risk-based approach: NRA to define own strategy (e.g. based on type and source of products evaluated, level of resources and expertise available, public health needs and priorities of the country, and opportunities for reliance) .

Regional reliance mechanisms: assessment for medical products can be conducted centrally based on a regional regulatory system for a group of countries (binding or not).

WHO Good Reliance Practices – General considerations

- Reliance anchored in a national regulatory authority strategy
- Cultural change
- Flexibility in approach: “one size doesn’t fit all”
- Investment of resources and time in implementing reliance
- “Sameness” of the product in different jurisdictions
- The role of industry
- Reliance in case of a public health emergency

“Sameness” of a product

“**two products have identical essential characteristics**”

- **All relevant aspects** medical devices and in vitro diagnostics to be considered.
- **Essential role of the manufacturer** to confirm the sameness of a product and to provide the same documentation to different NRAs.
  - ✓ the same regulatory version;
  - ✓ the same product code(s);
  - ✓ the same site of manufacture and quality management system;
- Except for additional country-specific information submitted for review (stability, local label etc.).
- Post-approval changes and vigilance reliance activities as long as the sameness is maintained.

Examples of Reliance in the Medical Device field –

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Abridged Regulatory Pathways

- WHO-Collaborative Registration Procedure for in-vitro diagnostics.

https://www.who.int/publications/m/item/collaborative-procedure-between-the-who-and-nra-s-in-the-assessment-and-accelerated-national-registration-of-who-prequalified-ivd-s-annex4

- Abridged pathways for the approval of medical devices with approval from other regulatory authorities.

Example in Australia, https://www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds, Singapore, https://www.hsa.gov.sg/medical-devices/registration/overview#toggle=togglepanel-overseas-reference-regulatory-agencies

- WHO EUL Facilitated Procedure for SARs CoV-2 assays

https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction/eul-facilitated-procedure

- Thai-FDA - Singapore HSA Regulatory Reliance

Reliance system for a group of countries

Medical Device Single Audit Program (MDSAP), developed under the International Medical Device Regulators Forum (IMDRF): regulatory authorities of Australia, Brazil, Canada, Japan and the USA have pooled their resources into a robust system of oversight by third party auditing organizations, which, in turn, audit the quality management systems of medical device manufacturers.

https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap

WHO Regulatory System Strengthening activities

WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products: revision VI

Objectives of the WHO regulatory system strengthening programme

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1

- **Build regulatory capacity** in Member States consistent with good regulatory practices

2

- **Promote regulatory cooperation, convergence and transparency** through networking, work-sharing and **reliance**

- **World Health Assembly Resolution 67.20 in 2014**
  - ✓ recognized the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related United Nations Sustainable Development Goals and Universal Health Coverage.

WHO GBT

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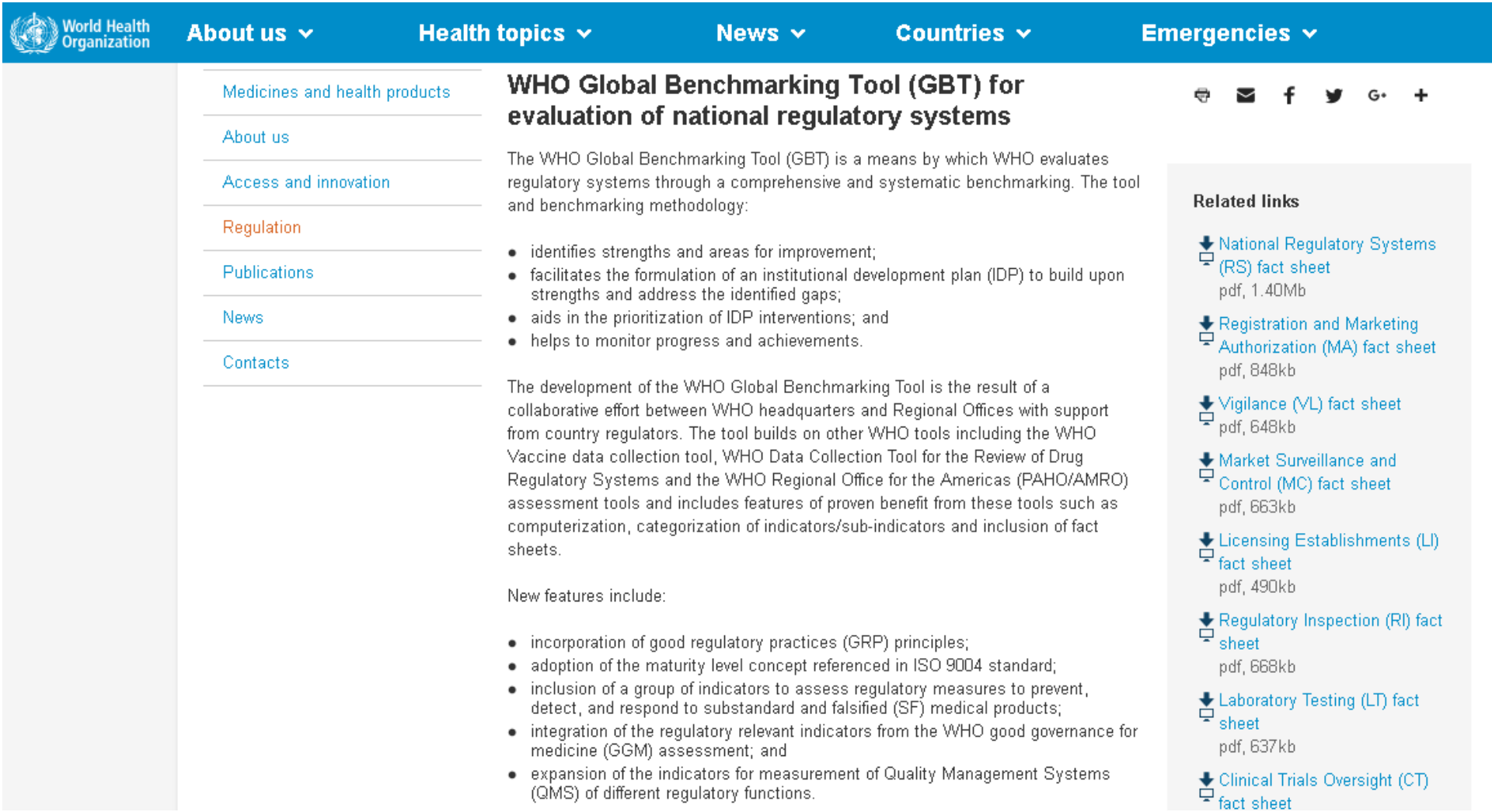
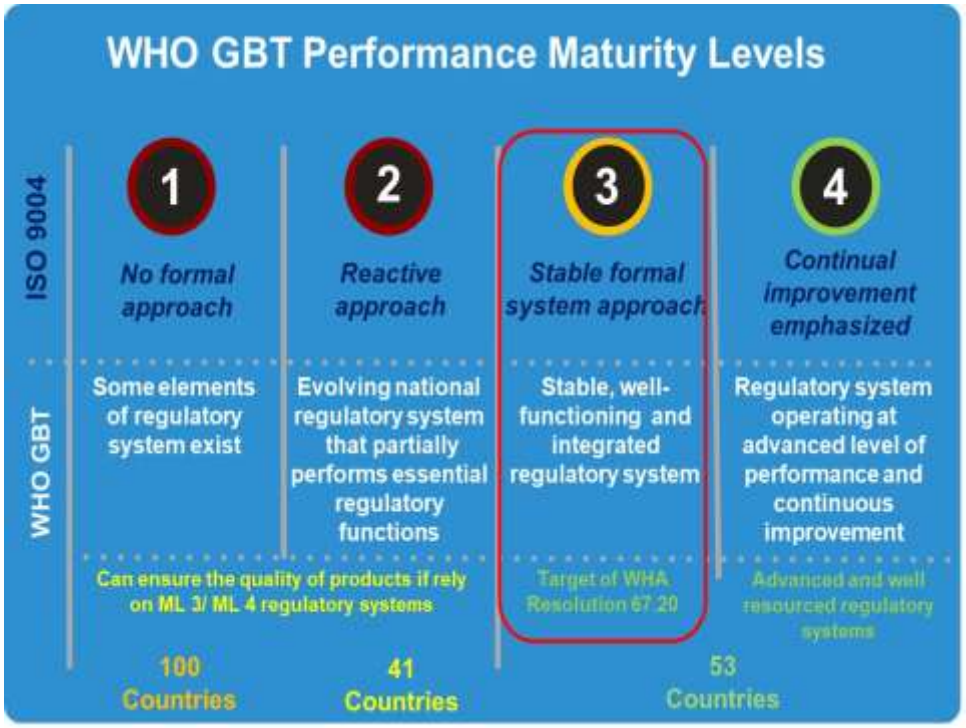


WHO Benchmarking of National Regulatory Authorities (NRAs)



- **The current GBT Rev VI covers only medicines, vaccines and blood and blood products**
- **Revision of the tool to integrate medical devices and IVDs indicators into the GBT was initiated end of last year. The work involved WG members:** WHO, Medical devices and IVDs regulators and laboratory experts and other MDs experts who are non regulators.
- **Discussion :** 1 September 2020 to June 2021.
- **Status:** Editorial work and publishing in Q4.
- **Pilot:** Q1 of 2022

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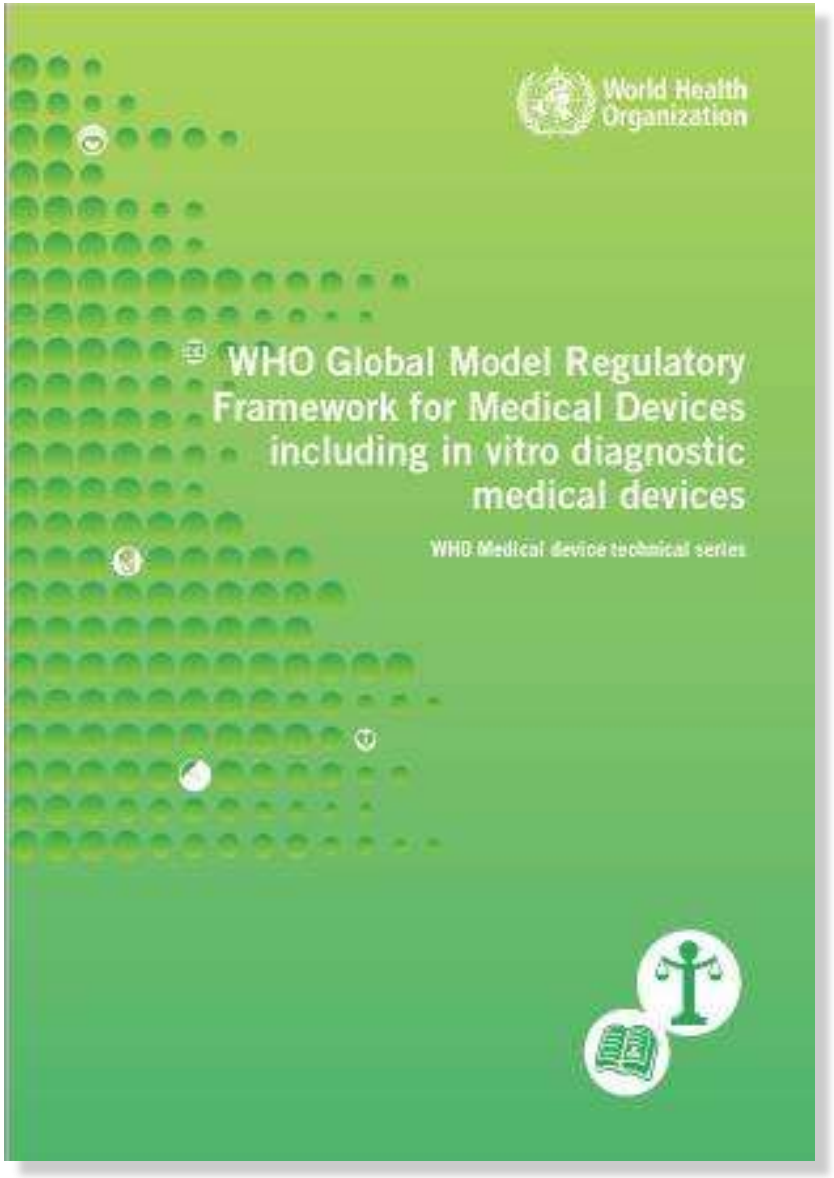
Global Model Regulatory Framework for medical devices including IVDs

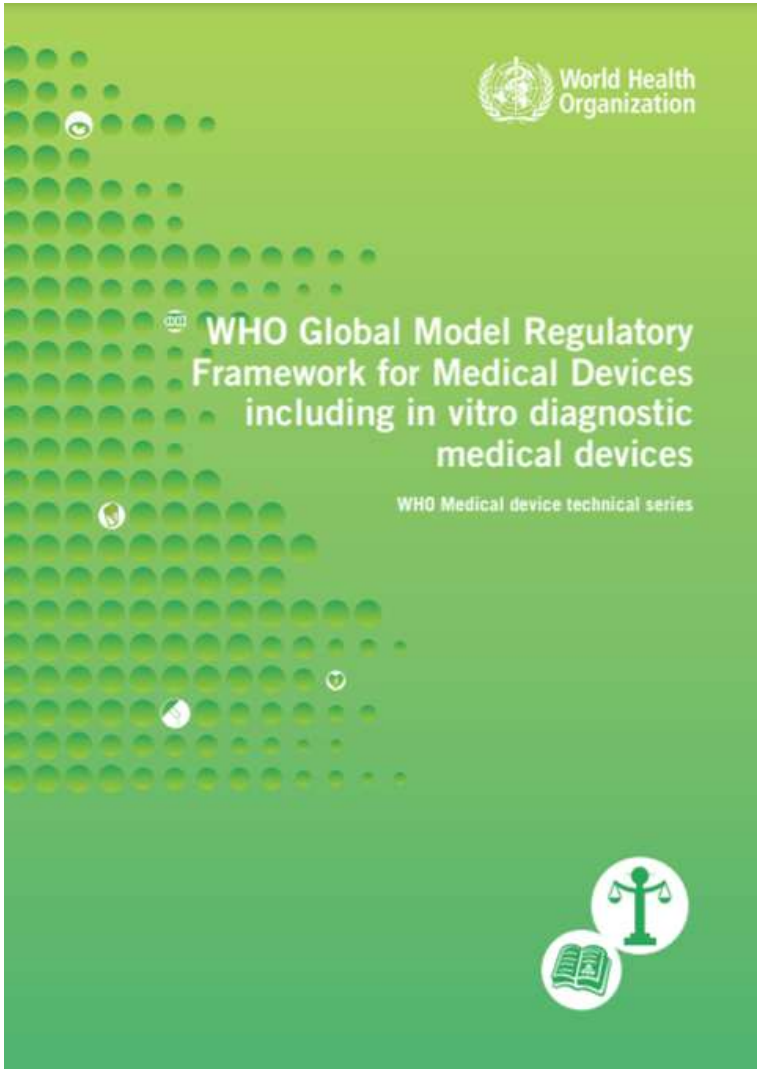
https://apps.who.int/iris/handle/10665/255177

The WHO Global Model Regulatory Framework for Medical Devices including IVDs…. Key points



- ✓ Published by WHO in 2017; on going review
- ✓ Relevant for WHO Member States;
- ✓ Recommends two steps i.e. basic regulatory controls towards an expanded level;
- ✓ Describes the role and responsibilities of a country's NRAs for implementing and enforcing the regulations;
- ✓ Describes circumstances in which a regulatory authority may either: "rely on", or "recognize" the work products from trusted regulatory sources

Why revise and update the GMRF



https://www.who.int/publications/i/item/9789241512350

- ✓ The WHO Global Model was published in 2017, developed in 2015-2016.
- ✓ Rapidly changing field, technologies are advancing in their nature and complexity e.g., AIs, Software as medical devices.
- ✓ Update of guidance such as PMS & MS, GRel, GRP and discussions during integration of MDs indicators into the GBT
- ✓ Experience with implementation including challenges experienced by regulators during the COVID-19 pandemic which clearly demonstrates the importance of safe, reliable, and appropriate quality medical devices including IVDs.
- ✓ Experience in the use of the GMRF teaches that countries would benefit expansively from a more detailed guidance on some topics.

Outline of the revised GMRF

- Introduction
- Definition, classification, essential principles, and conformity assessment of medical devices
- Enabling conditions for effective regulation of medical devices including IVDs
- Establishing a stepwise approach to regulating medical devices
- Regulatory pathways
- Additional topics
- Implementation

Thank you

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