IMDRF International Medical Device Regulators Forum | 26th Session

Scene Setting: Different paths to developing a regulatory system for medical devices

Perspective from the WHO

Hiiti Sillo

Unit Head, Regulation and Safety

Regulation and Prequalification Department , World Health Organization

WHO regulatory strengthening activities

Mandated under Resolution WHA 67.20 on regulatory systems strengthening for medical products adopted in 2014

Strong regulatory systems - critical component of a well-functioning healthcare delivery

WHO Regulatory Systems Strengthening Programme supports Member States in reaching and sustaining effective and efficient regulatory oversight of medical products

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***

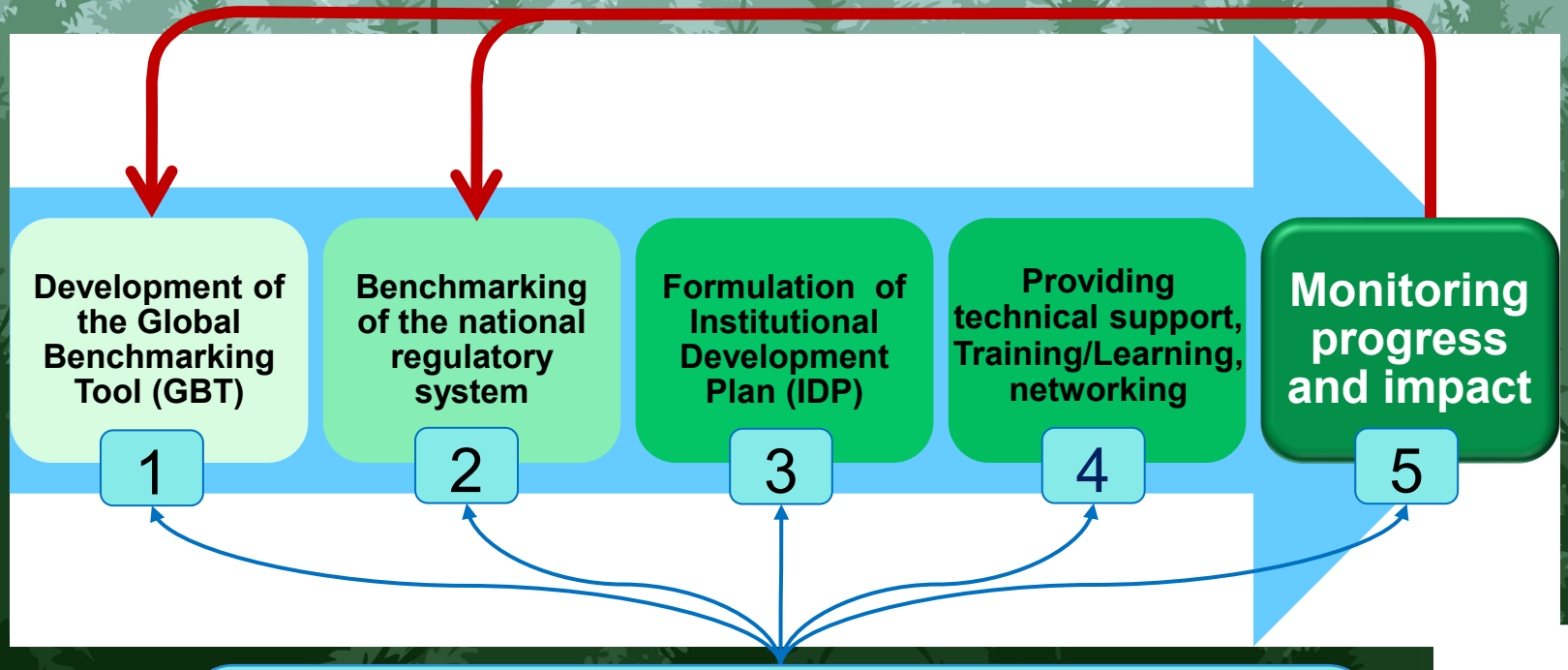
Overview of WHO regulatory strengthening activities

1. Capacity building using Global Benchmarking Tool (GBT) and other guidelines/tools
2. Promoting regulatory convergence, harmonization, work-sharing and networking
3. Promoting regulatory reliance through facilitated regulatory approval pathways, such as WHO Collaborative Registration Procedure (CRP)
4. Prevention, detection and response to substandard and falsified (SF) medical products
5. Strengthening pharmacovigilance systems to respond to adverse reactions/events

6. Strengthening national control laboratories (Medicines & Vaccines)

WHO Five-Step Capacity Building Model for NRAs

Resolution WHA 67.20 on Regulatory Systems Strengthening (2014)



- Stable, well functioning and integrated regulatory system
- Eligibility for vaccine PQ
- WHO listed authorities (WLA)

Coalition of Interested Parties (CIP) Network

WHO network for regulatory systems strengthening to enhance access to safe, effective and quality medical products

30 partners (26 members and 4 observers)

+

- Blood (Nov 2019)
- Medical Devices (Apr 2022)

WHO Global Benchmarking Tool (GBT) rev VI

WHO GBT webpage

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Key guidance tools for regulators of medical products

Good regulatory practices (GRP)

Set of principles and practices applied to the development, implementation and review of regulatory instruments in order to achieve a public health policy objectives in the most efficient way

Addressing responses to **common gaps in regulatory practices** identified during benchmarking of national regulatory systems

Relevant to all regulators, irrespective of resources, maturity or regulatory models (national, supranational and multiple institutions)

Annex 11: Good regulatory practices in the regulation of medical products

Good reliance practices (GRelP)

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

Importance of **international cooperation** to ensure the safety, quality and efficacy or performance of locally used medical products

Make best use of available resources and expertise, avoid duplication and concentrate regulatory efforts and resources where most needed

Annex 10: Good reliance practices in the regulation of medical products

Effective regulation of medical devices is dependent on principles of Good Regulatory Practices (WHO GMRF, 2023)

Legality	Consistency	Independence
Impartiality	Proportionality	Flexibility
Clarity	Efficiency	Transparency

Enabling conditions for effective regulation of medical devices including IVDs

Public confidence in medical devices including IVDs requires effective and efficient regulation built upon a sound legal and policy foundation, as well as GRP. The general principles provided in WHO Good regulatory practices in the regulation of medical products *(4)* should be applied when establishing a new – or revising an existing – system for regulating medical devices including IVDs. These principles include:

- legality
- consistency
- independence
- impartiality
- proportionality
- flexibility
- clarity
- efficiency
- transparency
- science based.

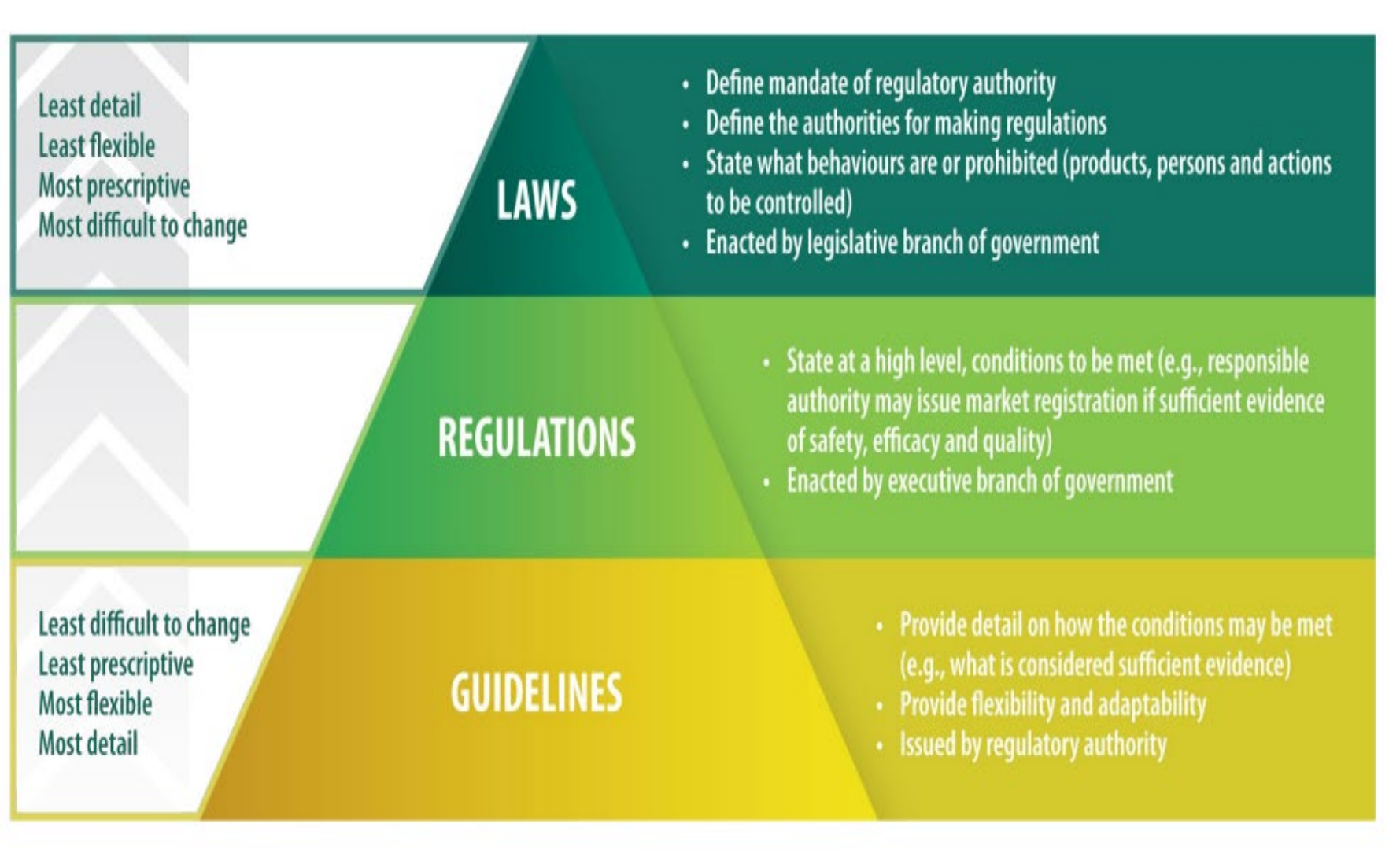
5.1 Legal requirements

Medical device regulations must have a sound basis in law. There is no single approach to the legal foundation of a regulatory framework as this will depend upon the national constitution and existing general national legal and administrative systems within the country. A generalized architecture of such a framework is shown in Fig. 5.1.

In all cases, the law should define the products within its scope and identify the entities subject to regulation. It should create a general requirement that only medical devices including IVDs that are safe, perform as intended and are of appropriate

Legality: Sound basis in laws, regulations and guidelines

Legality



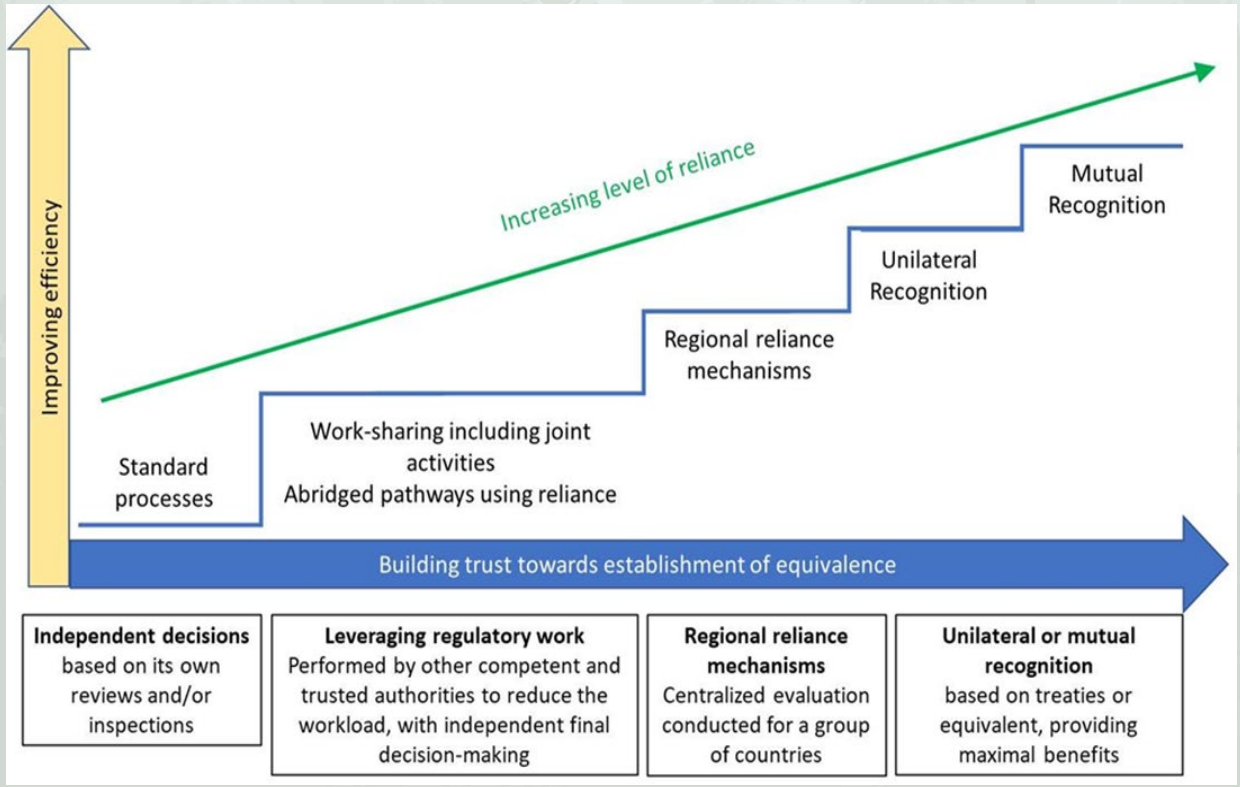
Enablers for effective regulation of medical devices …Good Regulatory Practices (WHO GMRF, 2023)

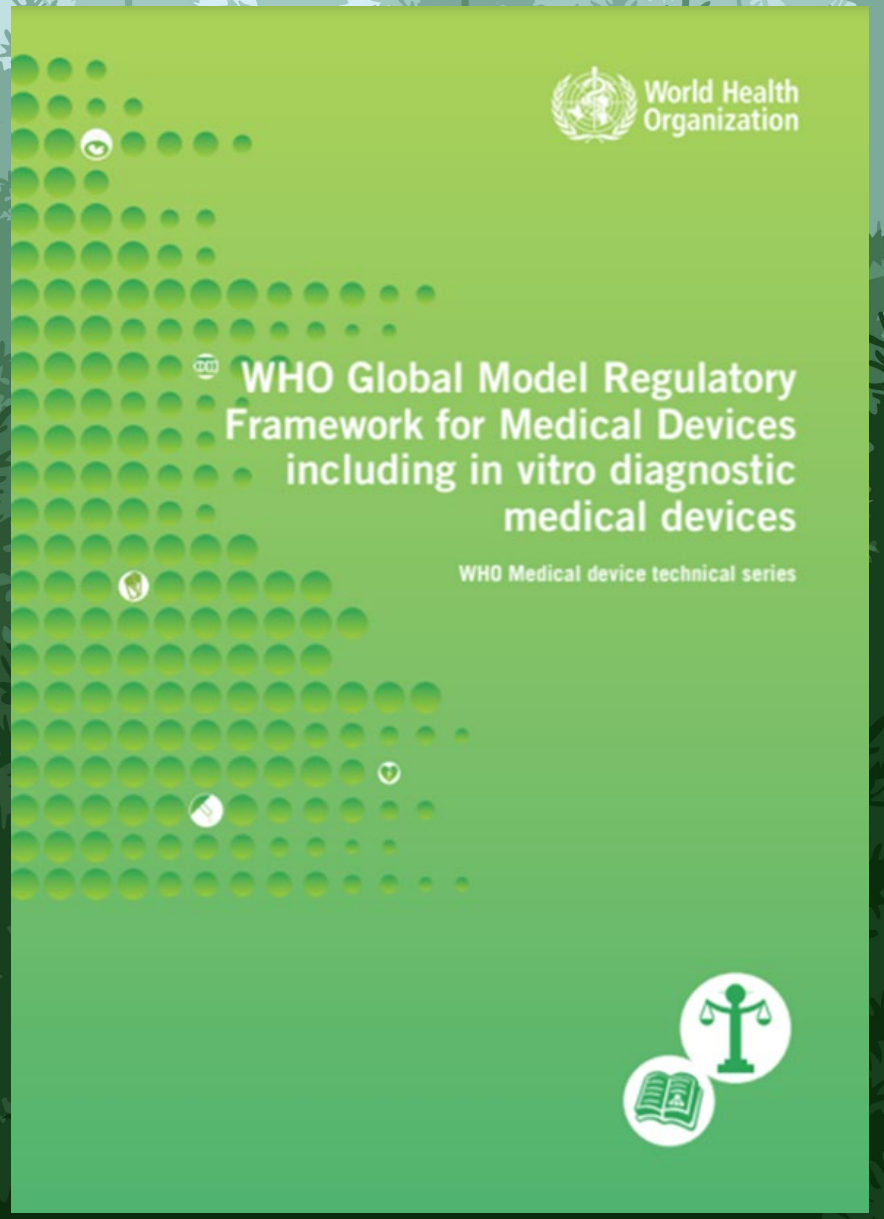
Enablers

- Political and government-wide support
- Effective organization and good governance supported with leadership
- Inter-and-intra-organizational communication, collaboration and coordination
- A robust and well-functioning QMS
- Sufficient and sustainable financial resources
- Competent human resources
- Pre-set organizational ethics and values
- Science- and data-driven decision-making process

Reliance is central to efficient regulation of medical devices

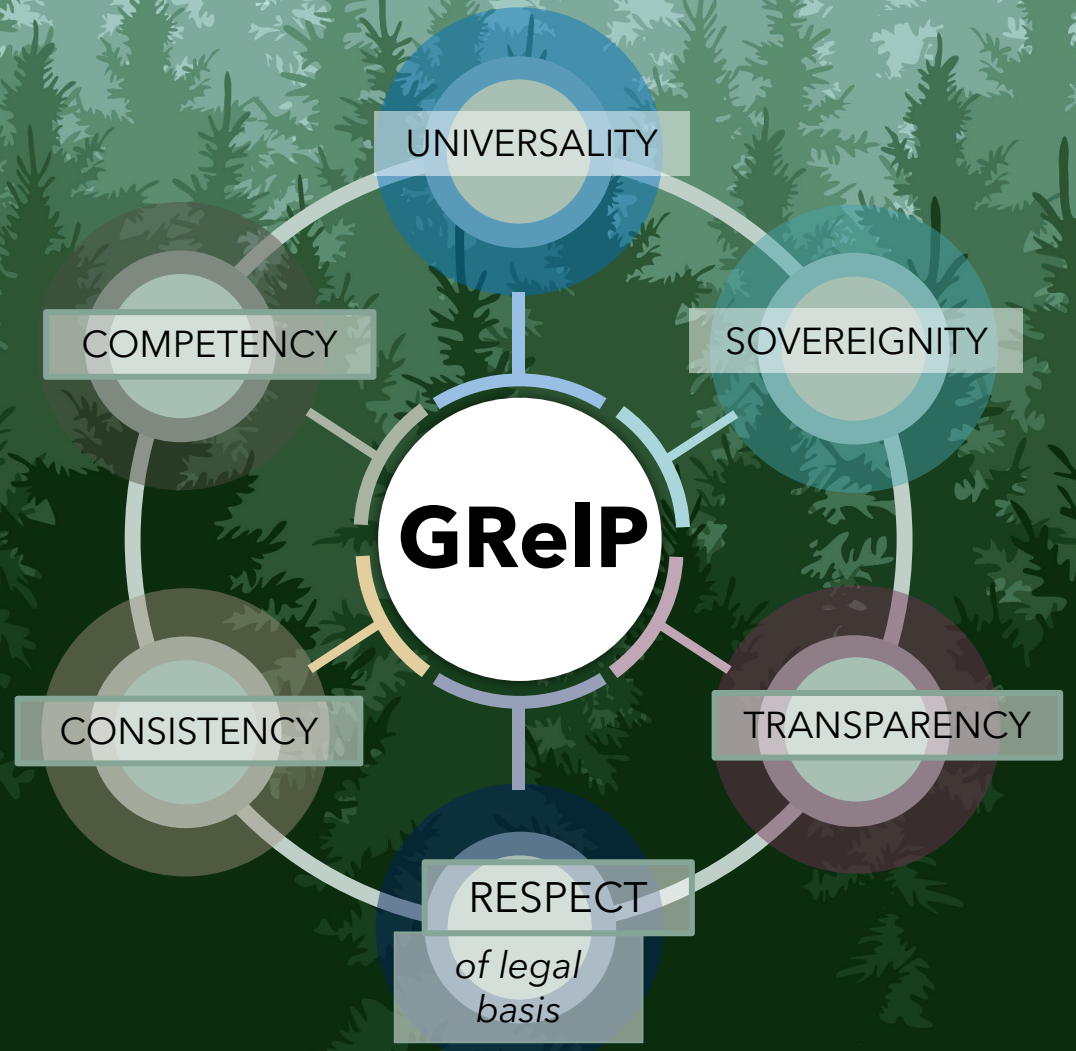
Chapter 3 (section 3.9) Good reliance practices: more explicit throughout the GMRF in all regulatory functions/processes





Principles & Enablers for effective reliance (GRelP, 2021 & GMRF, 2023)

principles



Enablers

- TRUST
- CONVERGENCE & HARMONIZATION
- INFO SHARING AND DIALOGUE among regulators
- ECONOMIC OR LEGAL INTEGRATION
- STAKEHOLDERS ENGAGEMENT

enablers

source: *Good reliance practices in the regulation of medical products: high level principles and considerations*

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WHO health products assessment and reliance

- Reliance principles are embedded in WHO assessment processes – PQ and EUL
  - ✓abridged assessments build on reliance on recognized approvals
- WHO is strengthening the implementation of reliance principles across the assessment mechanisms:
  - ✓**EUL:** strengthened reliance on FDA EUA listings and a streamlined assessment pathway for mpox NAT assays
  - ✓**PQ:** a new abridged assessment procedure under development with implementation in 2025
    - MDSAP recognition with no on-site audit (already implemented in 2024)
    - Streamlined product dossier submission implementation in 2025

… and finally

- WHO GMRF is a useful tool for developing a risk-based approach to regulation of medical devices

- GBT+MD will be instrumental in identifying gaps/areas for improvement
  - ✓elaborating institutional development plans (IDPs)

- Buy-in and interest from countries & stakeholders on the use of GBT+MD
  - ✓including asks for the list of ML3/ML4 & future WLAs for MDs by global procurement agencies

- Reliance for better use of limited resources and strengthening global regulatory oversight of medical devices

"No one single agency can do it all alone; reliance is a 21st Century regulatory tool"
Emer Cooke, Executive Director, EMA, DIA Global, June 2024, San Diego, USA

- IMDRF is a unique platform for learning by regulators of medical devices, specifically those from LMICs!

Useful WHO tools and guidelines

1. TRS 1025 - Annex 13: WHO guideline on the implementation of quality management systems for national regulatory authorities
2. Annex 11: Good regulatory practices in the regulation of medical products
3. Annex 10: Good reliance practices in the regulation of medical products
4. WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices, Annex 3
5. Global Benchmarking Tool (GBT)+MD, 2024 (in final stages)

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THANK YOU

For more information, please email: silloh@who.int