Good Regulatory Practices, Good Reliance Practices and the Global Model Regulatory Framework

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Workshop on Good Regulatory Practices and its implementation in the Medical Devices sector

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Access to medical products – a global challenge

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Good health is impossible without access to medical products

Universal Health Coverage depends on the availability of quality assured affordable health technologies in sufficient quantities

Reasons for limited/insufficient access are numerous

✓Inadequate regulatory capacity and lack of collaboration and work sharing in regulation of medical products between countries

- **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.

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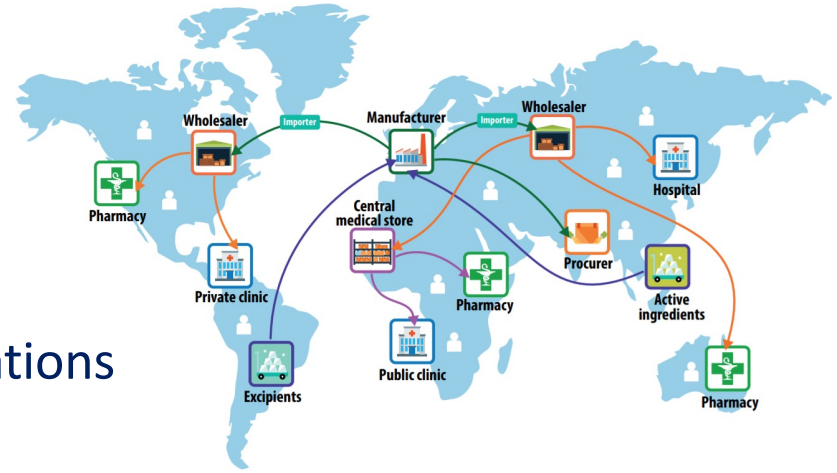
Evolving Science and Regulatory Challenges

- Globalization of markets
- Sophistication of health technologies
- Rapid evolution of regulatory science
- Increasing complexity of supply chains
- Transparency and growing public expectations
- Lack of global regulatory resources



Importance of international cooperation to **ensure the safety, quality and efficacy/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

Benefits of regulatory harmonization

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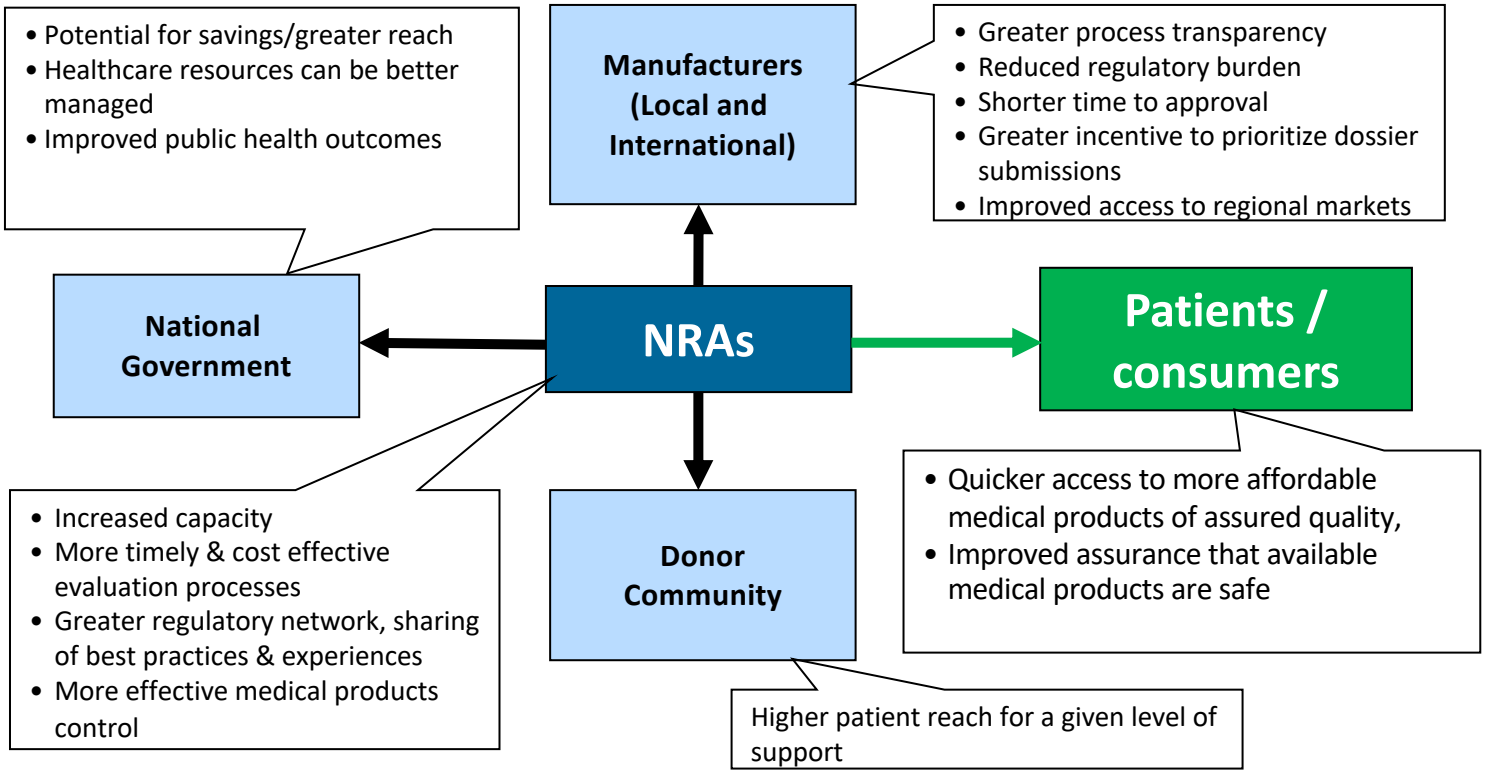

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Good Regulatory Practices Principles

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 **prioritizing** 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

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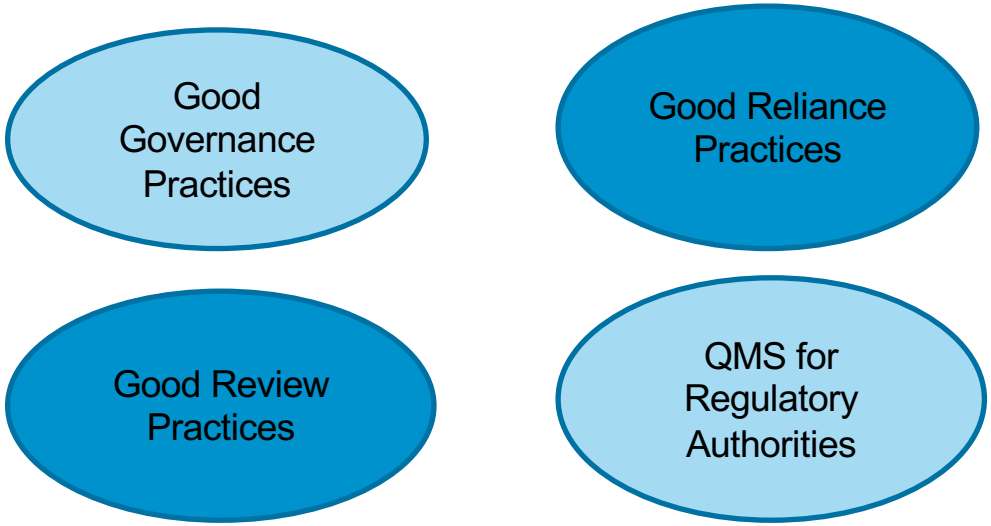
Objectives:

- 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:



Good Regulatory Practices Summary

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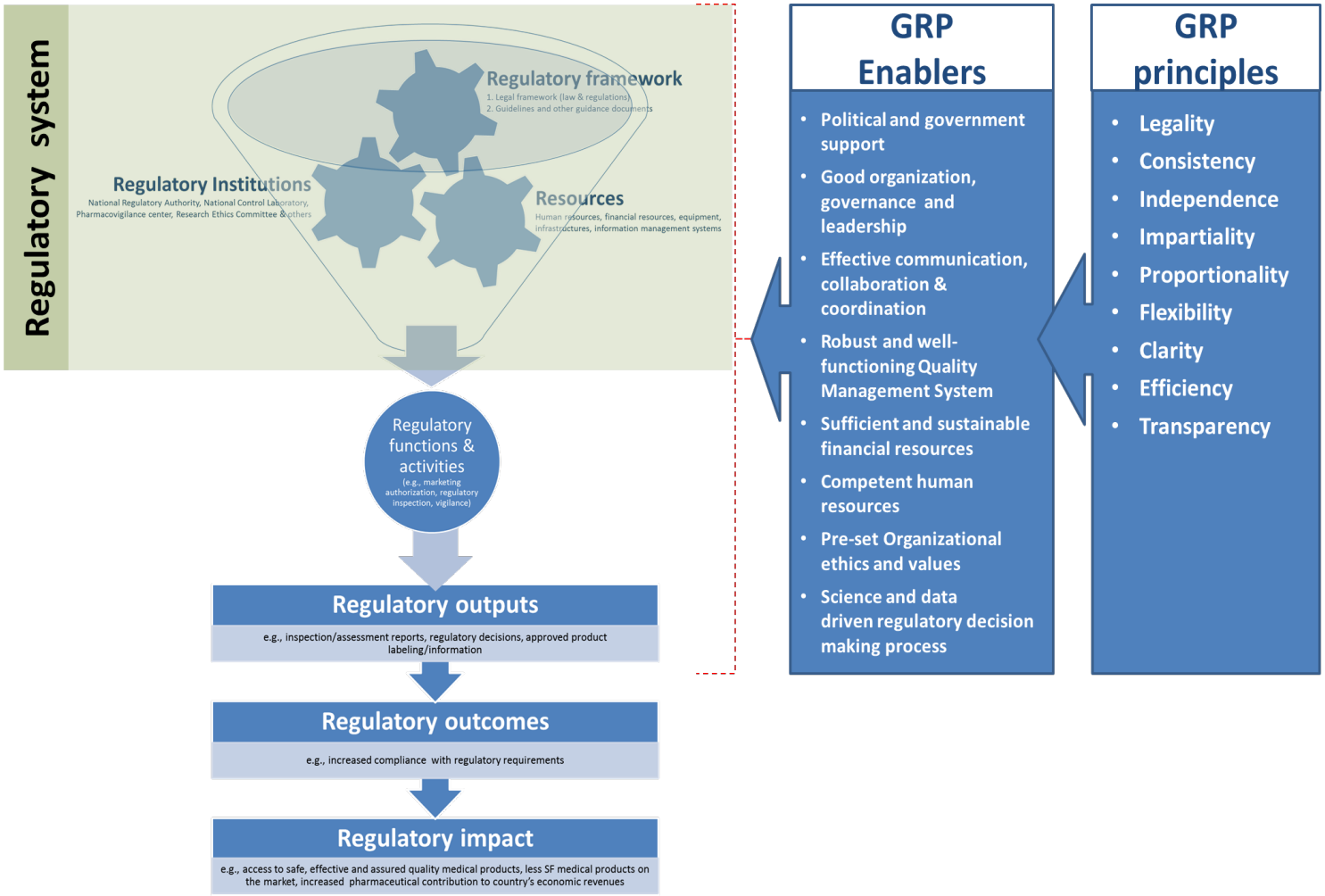

Principles and enablers of Good Regulatory Practices (GRP) and Components of the regulatory system

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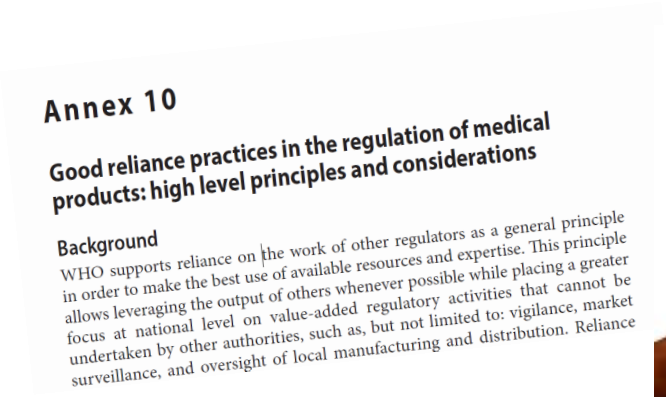
Good Reliance Practices Principles

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

WHO Good Reliance Practices



Annex 10

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

Background

WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to: vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance

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.

Adopted by WHO Expert Committee on Specification for Pharmaceutical Products in October 2020, published in March 2021
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

- Importance of **international cooperation** to ensure the safety, quality and efficacy/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

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).

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

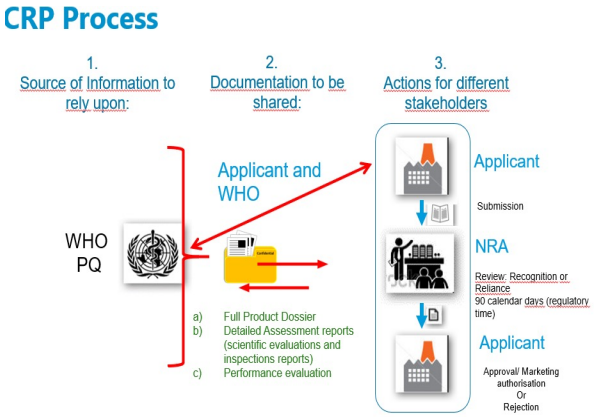
- Abridged pathways for the approval of medical devices with approval from other regulatory authorities.

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

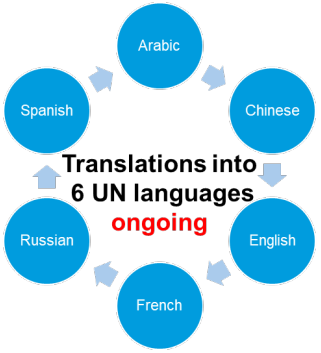
Medical Device Single Audit Program (MDSAP), developed under the International Medical Device Regulators Forum (IMDRF): regulatory authorities of Australia, Brazil, Canada, Japan and the USA have pooled their resources into a robust system of oversight by third party auditing organizations, which, in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

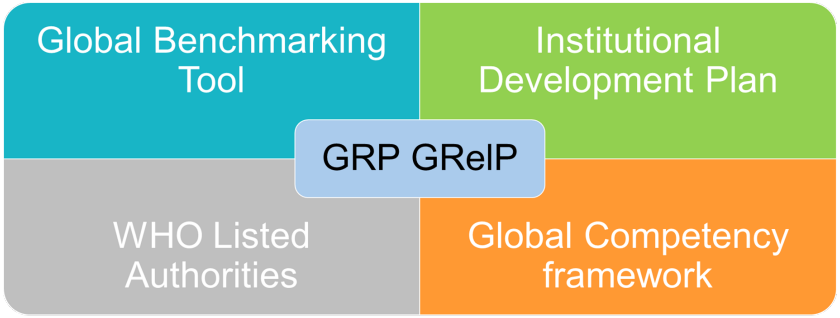
WHO GRP GRelP WHO Implementation Plan

1- Dissemination and translations

We encourage participants to share and advocate for these documents widely!
https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf

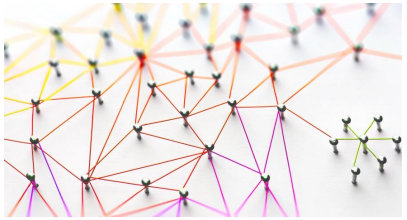


2- Integration with RSS and other WHO activities



WHO GRP GRelP WHO Implementation Plan….

3- Communication, collaboration and support to multi-stakeholders initiatives



- GRP and GRelP presented to numerous external fora.
- WHO supportive of all initiatives promoting reliance and GRP. Thanks to all organizations that have reached out!

4- Development of curriculum and detailed training material. Introductory online training is available on the link

https://openwho.org/courses/good-reliance-practices

5- Additional guidance and next steps

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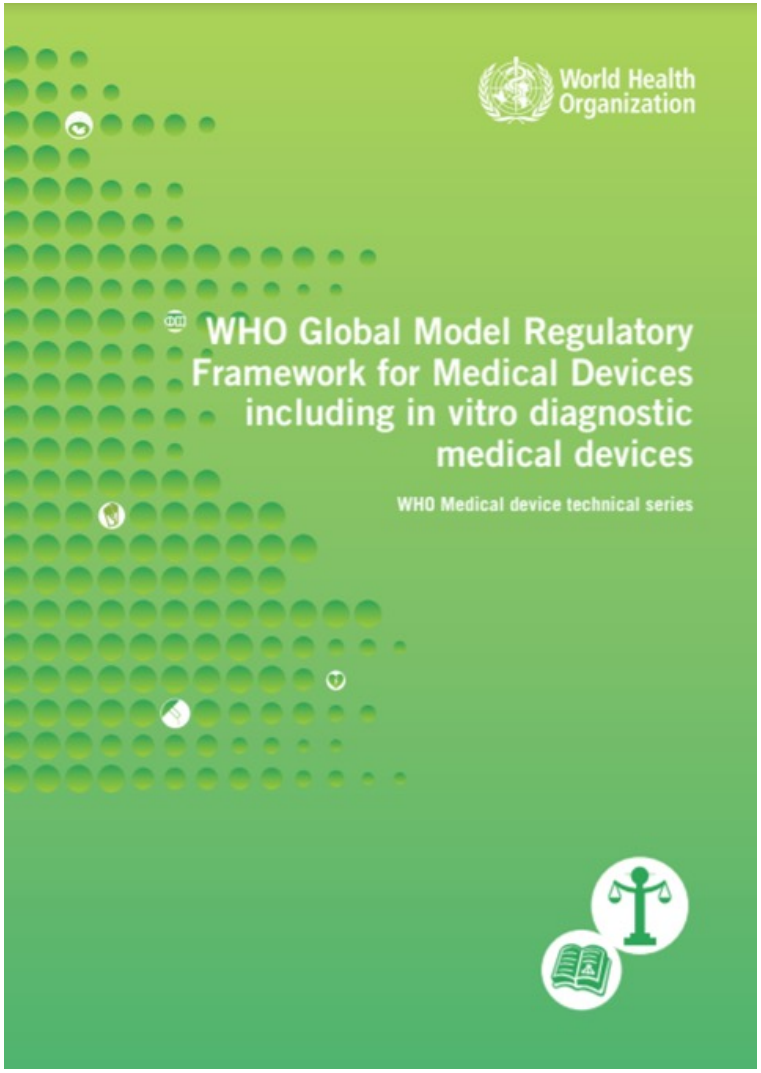
Global Model Regulatory Framework for medical devices including IVDs

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

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

Expanded and new topics (I)

Chapter 2 Definition, classification, essential principles, and conformity assessment of medical devices

- Companion diagnostics: expanded and added in section 6.
- Alignment of medical device definition with the revised IMDRF medical device definition.

Chapter 3 Enabling conditions for effective regulation of medical devices including IVDs

- Good regulatory practice
- Good reliance practice: key concepts and levels of reliance.
- Chapter 4 Establishing a stepwise approach to regulating medical devices
- Local production: policy, national strategy to support local manufacturers and no double standards with foreign manufacturers.
- Regulatory testing: no routine testing pre-market. Keep lot verification.

Expanded and new topics (II)

Chapter 5 Regulatory pathways

- Regulatory pathway according to risk class: routine assessment and renewal.
- Regulatory pathway based on reliance: Regulatory pathway for emergency use authorization or derogation: preparedness and importance of reliance.
- Regulatory pathway for combination products: the need for a single regulatory pathway.
- Regulatory pathway for borderline products.
- Regulatory pathway for donated medical devices.

Expanded and new topics (III)

Chapter 6 Additional topics

- Reprocessing of single-use medical devices: only in dire and exceptional situations.
- Software as a Medical Device (SaMD) and Software in a medical device (SiMD): framework for assessing SaMD.
- Companion diagnostics: framework for specific type of IVD.
- Collaborative Registration Procedure: specific form of work sharing and reliance.
- Emergency use listing: practice of EUL by WHO as an example for WHO Member states.

Chapter 7 Implementation

- Involving stakeholders in the regulatory process: important part of GRP.
- Developing a road map: systematic planning and follow up.
- Regulatory capacity building: important part of GRP.

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Questions