# Scene Setting: What is reliance and why is it important?

*A perspective from WHO*

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# WHO Regulatory Strengthening Activities

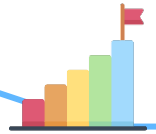
## Mandated under Resolution WHA 67.20 in 2014

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

**WHO supports Member States in reaching and sustaining effective regulatory oversight of medical products through the 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***

# 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 (March 2021)

## 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 (March 2021)

# Reliance at the core of a more efficient use of global resources

**Many countries have limited regulatory capacities**
But still need to facilitate access to quality-assured medical products

Reliance to promote better use of limited resources and to strengthen global regulatory oversight

**Apply a risk-based approach,** avoid duplication where possible, full range of reliance options (work sharing, abridged pathways, etc.)

**Implementation**
Voluntary participation, change mindset, start small, learning by doing, harmonization facilitator but not pre-requisite

**WHO Listed Authorities**
Transparent, evidence-based system to define trusted authorities

# WHO guideline on Good Reliance Practices: key concepts

**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.

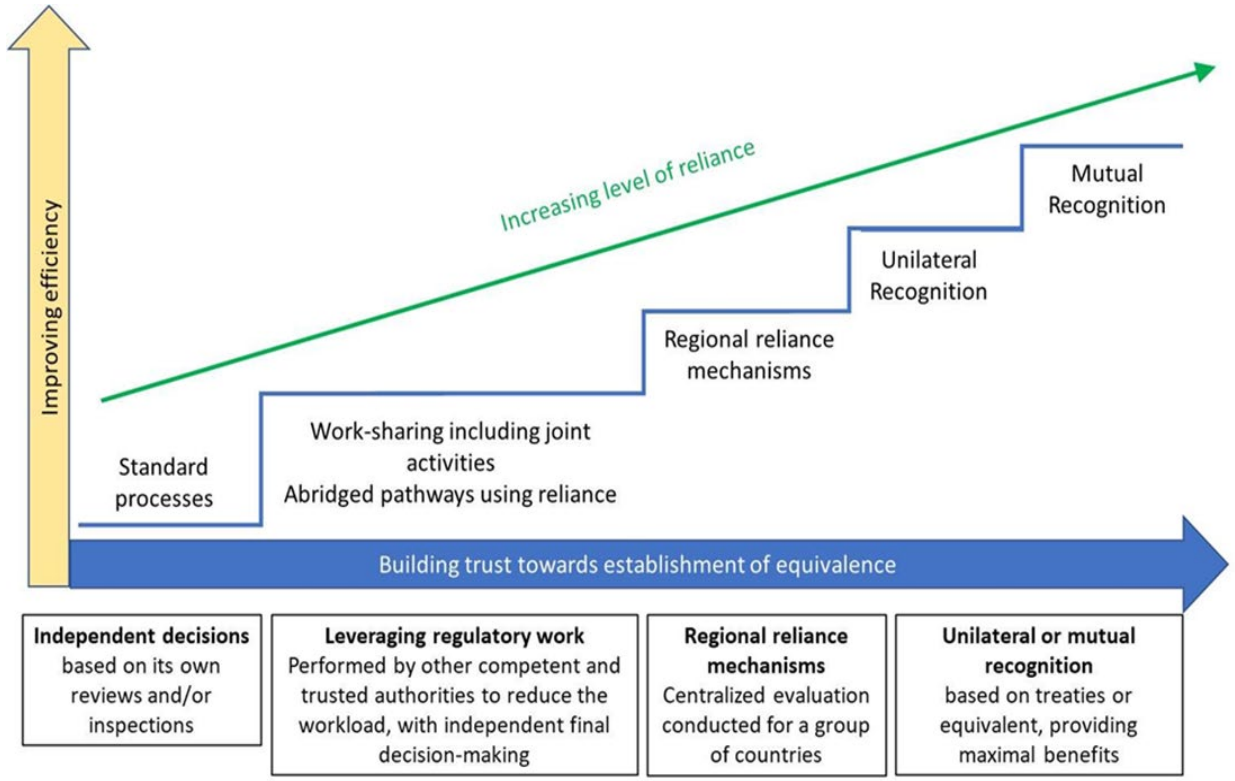
**Life cycle approach**: to apply across the full life cycle of medical products and all regulatory functions (e.g. important for vigilance and post-authorization activities).

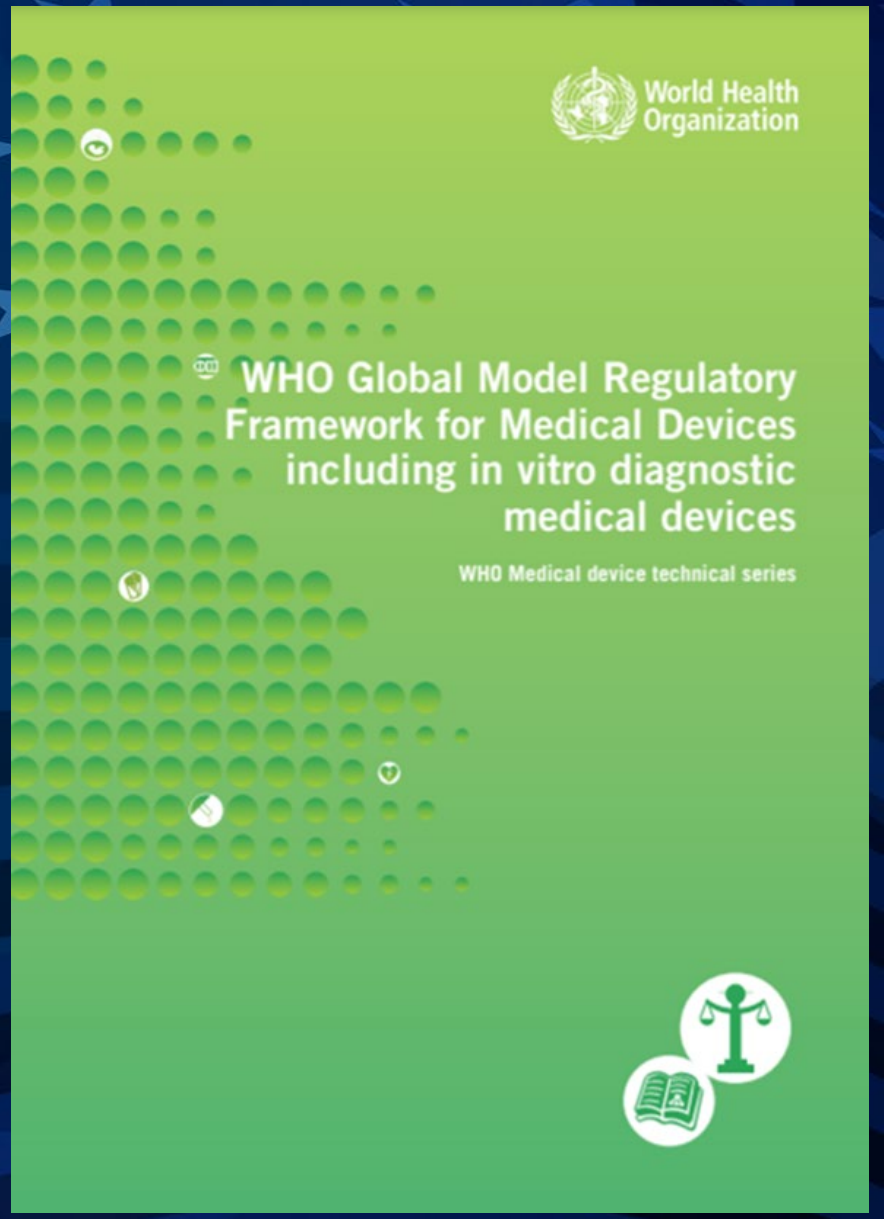
**Risk-based approach:** NRA to define own strategy (e.g. based on type and source of products evaluated, level of resources and expertise available, public health needs and priorities of the country, and opportunities for reliance) .

**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 GMRF for MDs and Reliance

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



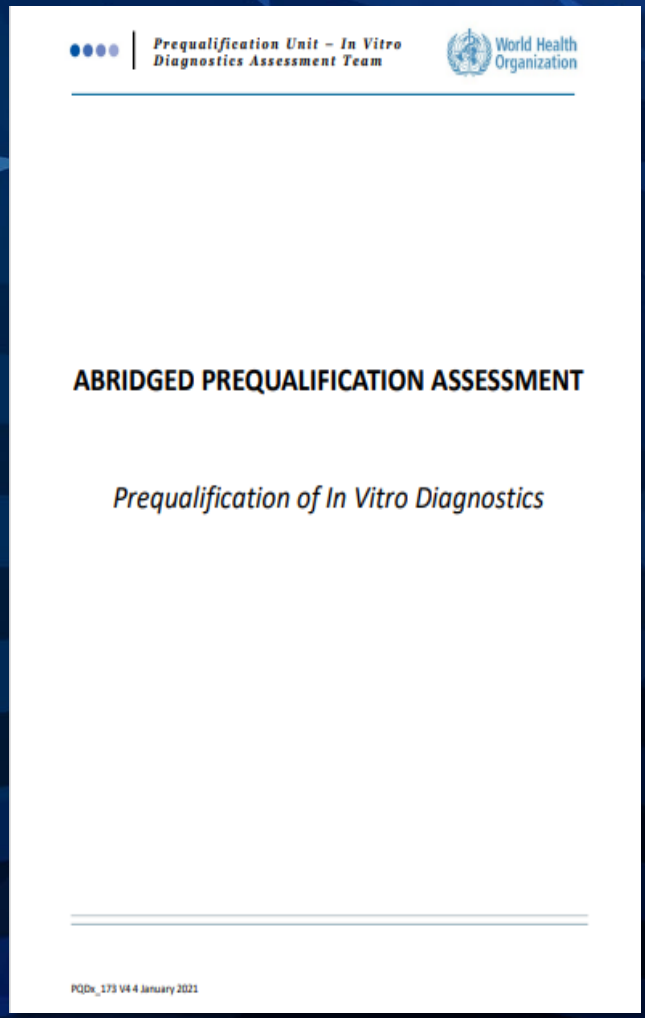
# *WHO Prequalification (PQ)* and Reliance

- **An IVD submitted for PQ may already have received stringent regulatory approval**
  - ✓ A PQ full assessment could entail duplication of effort
  - ✓ In such cases an abridged assessment may be appropriate
    - Aimed at reducing the time taken to assess a product
    - Focusing on aspects where PQ assessment brings added value
- **Prior regulatory approval may provide a level of assurance on product's quality, safety and performance where it is approved**
  - ✓ This may not be the case in other jurisdictions, including LMICs
- **WHO reviews the PSF and supporting documentation to determine**
  - ✓ The product qualifies for an abridged prequalification assessment
  - ✓ If not, will go a full prequalification assessment

# PQ & Reliance: Decision to abridge the assessment

- WHO will compare the **key differences**
  - ✓the stringent regulatory version and the regulatory version submitted for PQ, including:
    - product description; intended use; test procedure; labelling and instructions for use; quality management system; design; manufacturing site; key suppliers; verification/validation studies; and/or lot release criteria

- Provided **no substantial differences** are observed, the product will be eligible for **abridged PQ assessment**


Prequalification Unit – In Vitro Diagnostics Assessment Team

World Health Organization

ABRIDGED PREQUALIFICATION ASSESSMENT

*Prequalification of In Vitro Diagnostics*

PQDx_173 V4.4 January 2021

# PQ & Reliance: Recognized stringent assessments

| Stringent Regulatory Authority (Recognized SRA) | Risk classes undergoing stringent assessment |
|---|---|
| **European Union** | Annex II, List A (IVDD), Class C and Class D (IVDR) |
| **Food and Drug Administration of the United States of America** | Class III |
| **Health Canada** | Class III and Class IV |
| **Therapeutic Goods Administration, Australia** | Class 3 and Class 4 |
| **Ministry of Health, Labour and Welfare, Japan** | Class III |
| **Singapore Health Sciences Authority** | Class C and Class D |

- The abridged assessment procedure is currently under revision, a new version is planned in 2024
- Amendments will include
    1. The recognition of additional assessments
    2. A streamlined procedure with a more limited assessment scope

# Reliance in facilitating national regulatory decisions

- **Facilitating timely approvals of IVDs in countries is one of the roles of the WHO**
  - ✓Provided there is evidence of product's quality, safety and performance
- **Implemented through WHO Collaborative Registration Procedure (CRP**
  - ✓**Scope:** medicines, vaccines, **in-vitro diagnostics** & vector control products
  - ✓CRP IVDs was introduced in 2020
  - ✓**Current status:**
    - 35 regulatory authorities from LIMCs have signed to CRP for IVDs
    - 20 assays received national registrations based on reliance
- **WHO guideline on CRP for IVDs, 2021**
  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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