WHO Good Reliance Practices throughout the life cycle to facilitate access to quality-assured medical products globally

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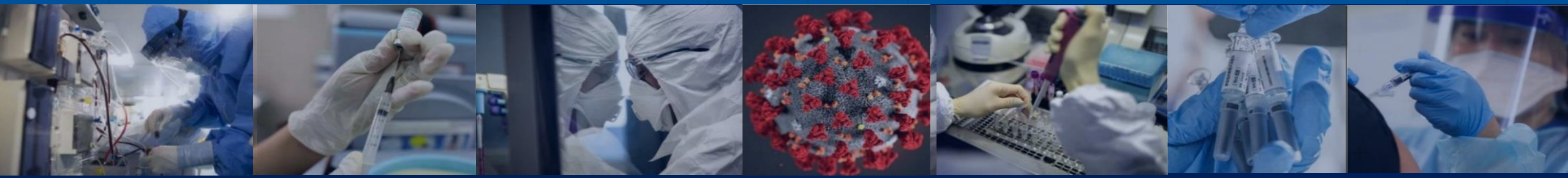

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Long-standing use of reliance to strengthen regulatory oversight

Long history of improving efficiency through reliance e.g. Certificate of Pharmaceutical Products Scheme

"Regulate through reliance" as the hallmark of a **modern** and **efficient regulatory authority**.

Increasing role of reliance

Promoting **"informed" reliance**

COVID-19 response as a strong accelerator for the use of reliance

- "Game-changer" for regulators
- Highest level of collaboration, work sharing and unilateral reliance
- "Must have" versus "nice to have" requirements
- Alignment of requirements/convergence
- Acceleration of decisions
- Stronger regulatory decisions

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Outline

- Reliance for an efficient global regulatory oversight
- Reliance throughout the lifecycle
- Recent examples in post-authorization changes (PAC)
- Take-home messages and best practices

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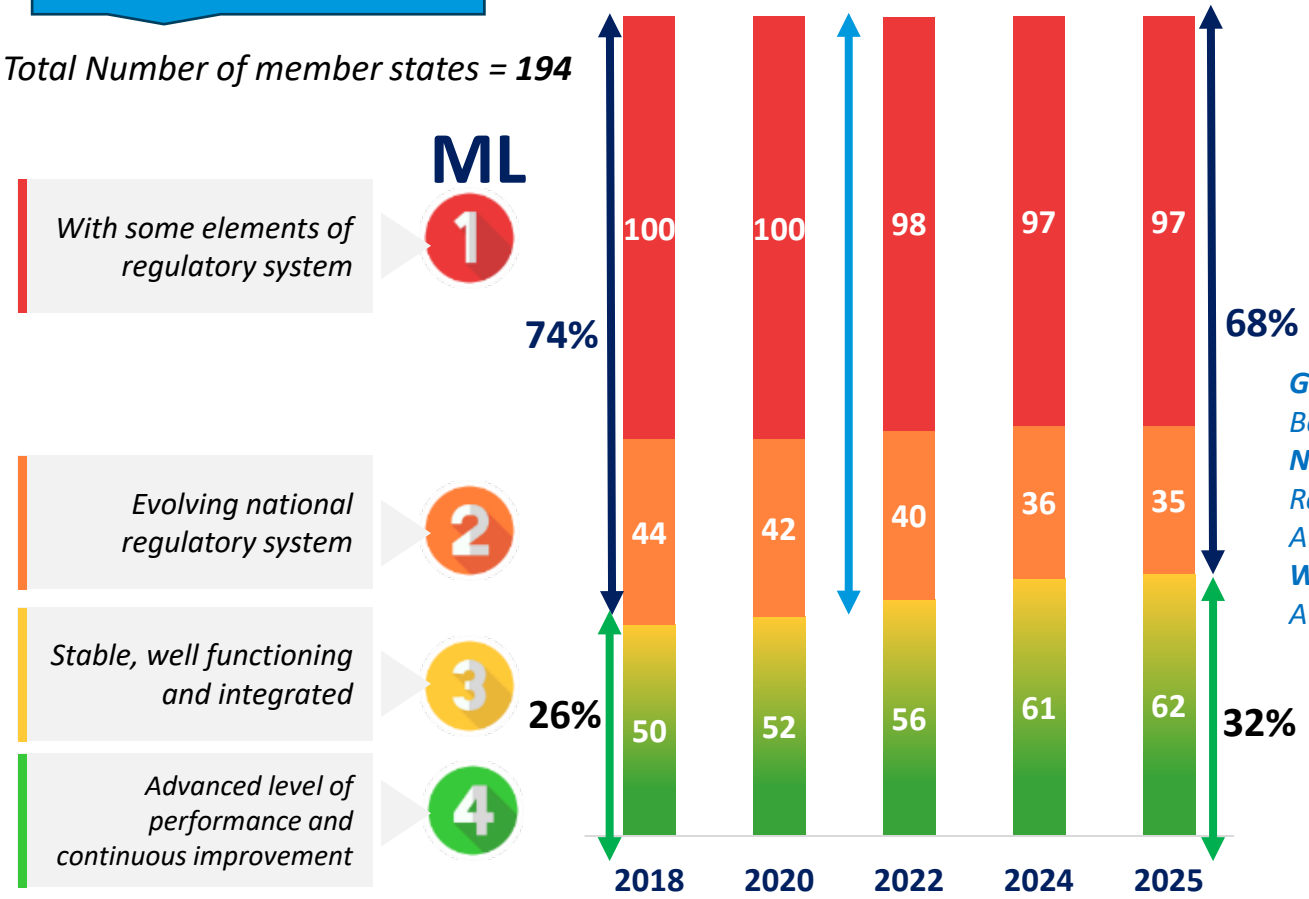
Global status of national regulatory systems

(as of March 2026)

Why using reliance?

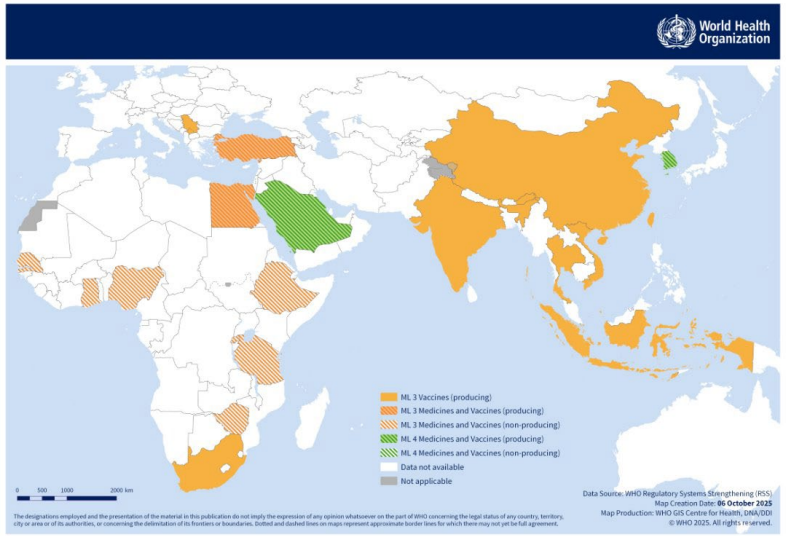
*Total Number of member states = **194***



ML: *(regulatory system) maturity level*

***GBT:** Global Benchmarking Tool,*
***NRA:** National Regulatory Authority,*
***WLA:** WHO Listed Authority*

NRAs benchmarked as ML3/ML4 using GBT



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

WHO Good regulatory practices, 2021

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

WHO Good reliance practices, 2021

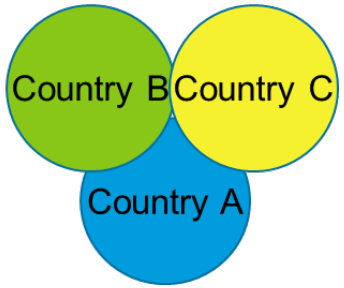
- **62 WHO member states (32%) have well-functioning regulatory systems**
  - ✓ **11 more NRAs achieved ML 3 or ML 4 since 2018 (22% growth)**
- **132 member states (68%) with NRAs still at ML 1 & ML 2**

Source: WHO RSS database, March 2026

Reliance's many shapes and forms

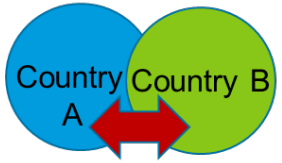
"The act whereby the regulatory authority in one jurisdiction **takes into account and gives significant weight** to **assessments performed by another regulatory authority or trusted institution**, or to any other authoritative information, **in reaching its own decision**. The relying authority remains **independent, responsible and accountable** for the decisions taken, even when it relies on the decisions, assessments and information of others."

Work-sharing



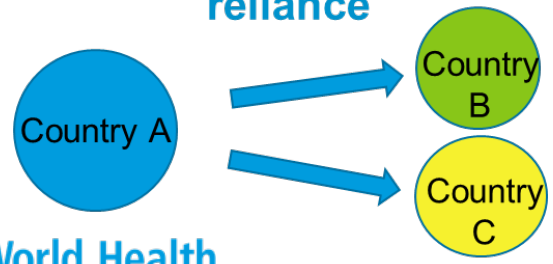
Recognition

Unilateral



Mutual recognition

Abridged pathway using reliance



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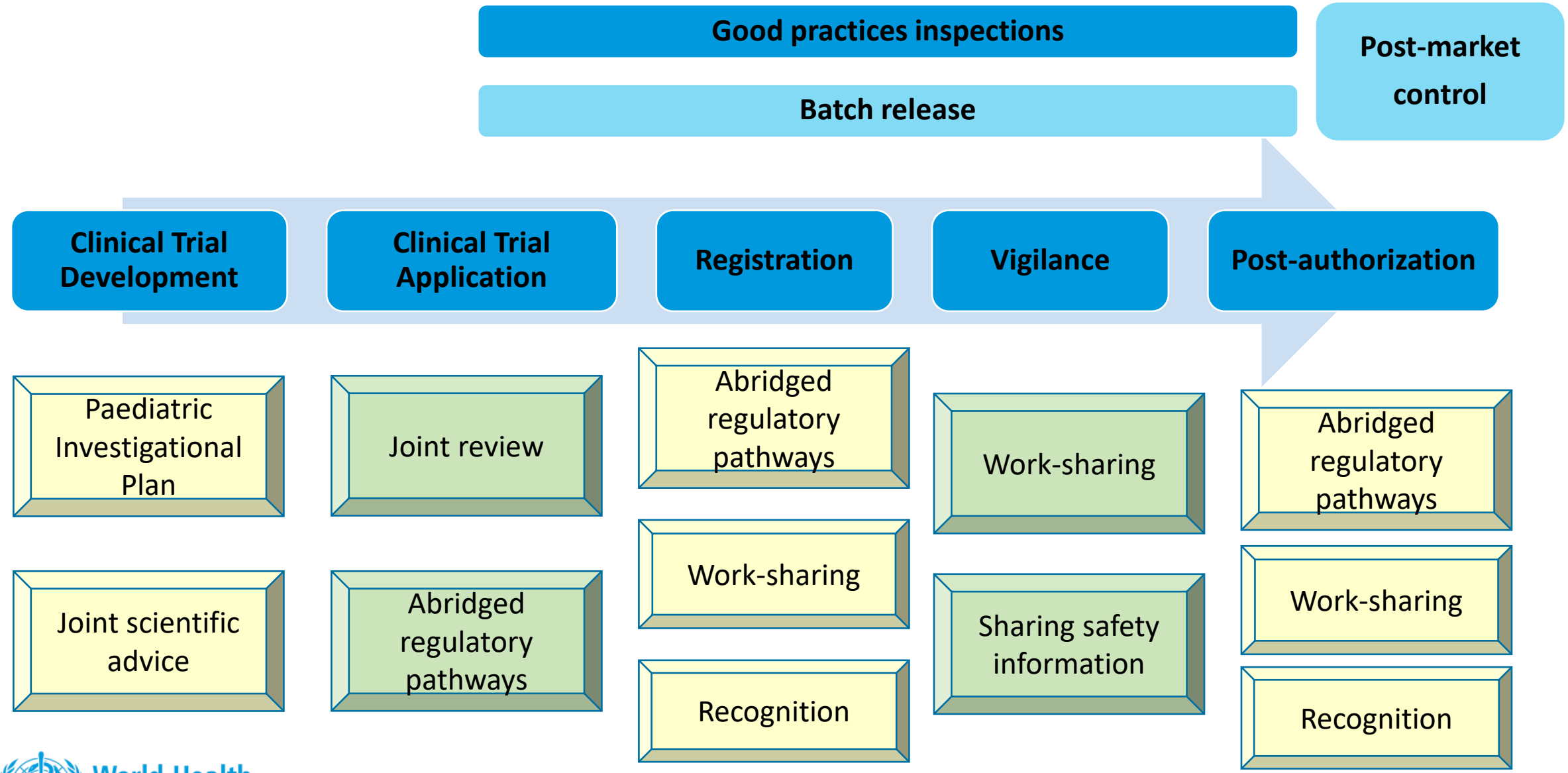
- Sovereignty maintained;
- More efficient use of global regulatory resources;
- Decrease duplication, increase trust and collaboration.

Product life cycle: examples of reliance



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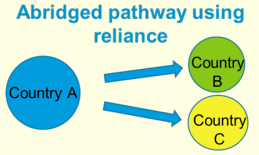
Increasing use of reliance in Post-Authorization Changes (PAC) management

https://icmra.info/drupal/en/strategicinitatives/pqkms

Collaborative assessments and inspections

PAC reliance pilots



- **Principles**: use a reference authority to submit a key supply change variation to a group of countries at the same time
- **Approval time within 6 months** vs. few years
- **Same package** for all regulatory authorities (harmonization & convergence)
- Example European Medicines Agency: 11 initiated/completed pilots, **12-80% reduction in approval time** (31 received to date)
- **77 National Regulatory Authorities** participated to date

International Coalition of Medicines Regulatory Authorities (ICMRA) Pilots

Example for a Post Approval Change Management Protocol for Drug substance and Drug product for an oncology product

- EMA as lead assessor, US FDA participated & PMDA Japan as observer
- Harmonized list of questions
- EMA & US FDA approval on the same day!

Possibility to combine different reliance models (e.g. ICMRA collaborative assessment + unilateral reliance) for global reach

Take home messages and best practices for PAC management

How to collectively better manage the PAC workload?

Initial authorization

Post-authorization changes

- Pragmatic approach, simplification of regulatory frameworks
- Convergence & harmonization
- Efficient tracking systems at National Regulatory Authorities
- Reliance to manage backlog and accelerate approval (different queue for reliance variations)
- Increase transparency of PAC assessment
- Accommodate new concepts for product lifecycle management (e.g. ICH Q12)
- Ensuring product sameness
- Build trust between stakeholders

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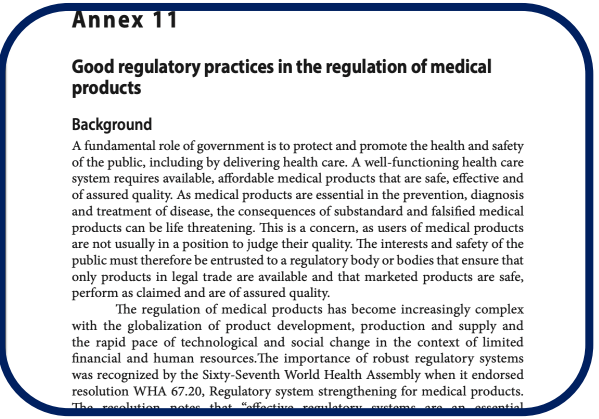
The use of reliance for PAC management should be the new norm

Resources



Annex 11

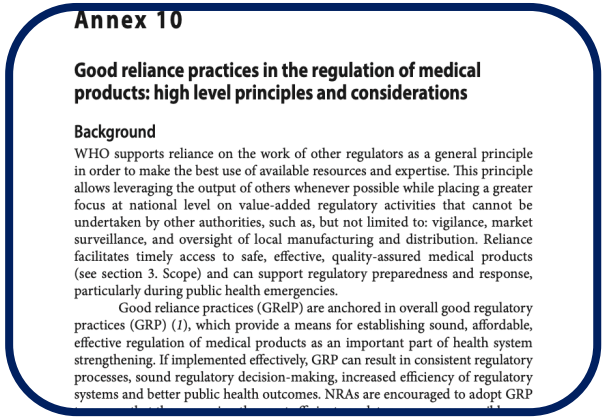
Good regulatory practices in the regulation of medical products

Background

A fundamental role of government is to protect and promote the health and safety of the public, including by delivering health care. A well-functioning health care system requires available, affordable medical products that are safe, effective and of assured quality. As medical products are essential in the prevention, diagnosis and treatment of disease, the consequences of substandard and falsified medical products can be life threatening. This is a concern, as users of medical products are not usually in a position to judge their quality. The interests and safety of the public must therefore be entrusted to a regulatory body or bodies that ensure that only products in legal trade are available and that marketed products are safe, perform as claimed and are of assured quality.

The regulation of medical products has become increasingly complex with the globalization of product development, production and supply and the rapid pace of technological and social change in the context of limited financial and human resources.The importance of robust regulatory systems was recognized by the Sixty-Seventh World Health Assembly when it endorsed resolution WHA 67.20, Regulatory system strengthening for medical products. The resolution notes that "effective regulatory systems are an essential

[TRS 1033 - Annex 11: Good regulatory practices in the regulation of medical products]



Annex 10

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

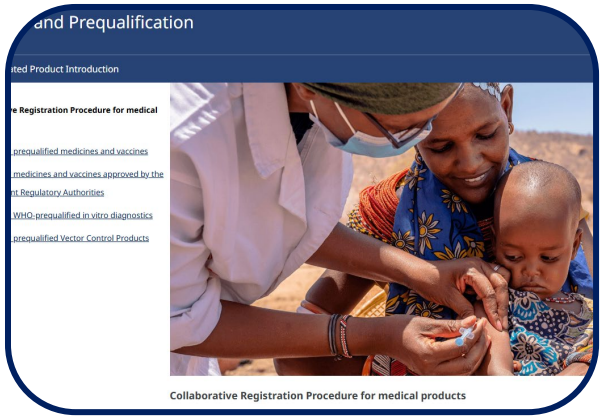
Background

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 facilitates timely access to safe, effective, quality-assured medical products (see section 3. Scope) and can support regulatory preparedness and response, particularly during public health emergencies.

Good reliance practices (GRelP) are anchored in overall good regulatory practices (GRP) (*1*), which provide a means for establishing sound, affordable, effective regulation of medical products as an important part of health system strengthening. If implemented effectively, GRP can result in consistent regulatory processes, sound regulatory decision-making, increased efficiency of regulatory systems and better public health outcomes. NRAs are encouraged to adopt GRP

[TRS 1033 - Annex 10: Good reliance practices in the regulation of medical products: high level principles and considerations]

[GRelP e-Course] (Available in English, French & Spanish)



Collaborative Registration Procedure for medical products

[WHO SAP Webpages]

IPRP

IPRP Questions and Answers document[1] on Reliance
Version dated 30 September 2022

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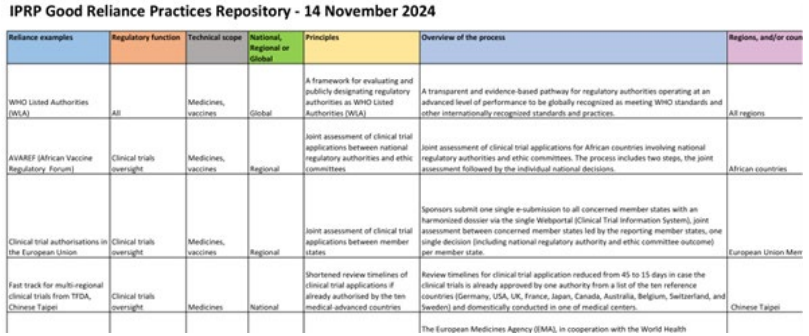

IPRP Good Reliance Practices Repository - 14 November 2024

Reliance examples	Regulatory function	Technical scope	National, Regional or Global	Principles	Overview of the process	Regions, and/or coun
WHO Listed Authorities (WLA)	All	Medicines, vaccines	Global	A framework for evaluating and publicly designating regulatory authorities as WHO Listed Authorities (WLA)	A transparent and evidence-based pathway for regulatory authorities operating at an advanced level of performance to be globally recognized as meeting WHO standards and other internationally recognized standards and practices.	All regions
AVAREF (African Vaccine Regulatory Forum)	Clinical trials oversight	Medicines, vaccines	Regional	Joint assessment of clinical trial applications between national regulatory authorities and ethic committees	Joint assessment of clinical trial applications for African countries involving national regulatory authorities and ethic committees. The process includes two steps, the joint assessment followed by the individual national decisions.	African countries
Clinical trial authorisations in the European Union	Clinical trials oversight	Medicines, vaccines	Regional	Joint assessment of clinical trial applications between member states	Sponsors submit one single e-submission to all concerned member states with an harmonized dossier via the single Webportal (Clinical Trial Information System), joint assessment between concerned member states led by the reporting member states, one single decision (including national regulatory authority and ethic committee outcome) per member state.	European Union Mem
Fast track for multi-regional clinical trials from TFDA, Chinese Taipei	Clinical trials oversight	Medicines	National	Shortened review timelines of clinical trial applications if already authorised by the ten medical-advanced countries	Review timelines for clinical trial application reduced from 45 to 15 days in case the clinical trials is already approved by one authority from a list of the ten reference countries (Germany, USA, UK, France, Japan, Canada, Australia, Belgium, Switzerland, and Sweden) and domestically conducted in one of medical centers.	Chinese Taipei
					The European Medicines Agency (EMA), in cooperation with the World Health	

[International Pharmaceutical Regulators Programme Questions & Answers on Reliance and Repository]

You can provide input/feedback to [IPRPsecretariat@ich.org]

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Questions and additional information

WHO Facilitated Product Introduction Website

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

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Working Together !!!

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