

# Good Reliance Practices

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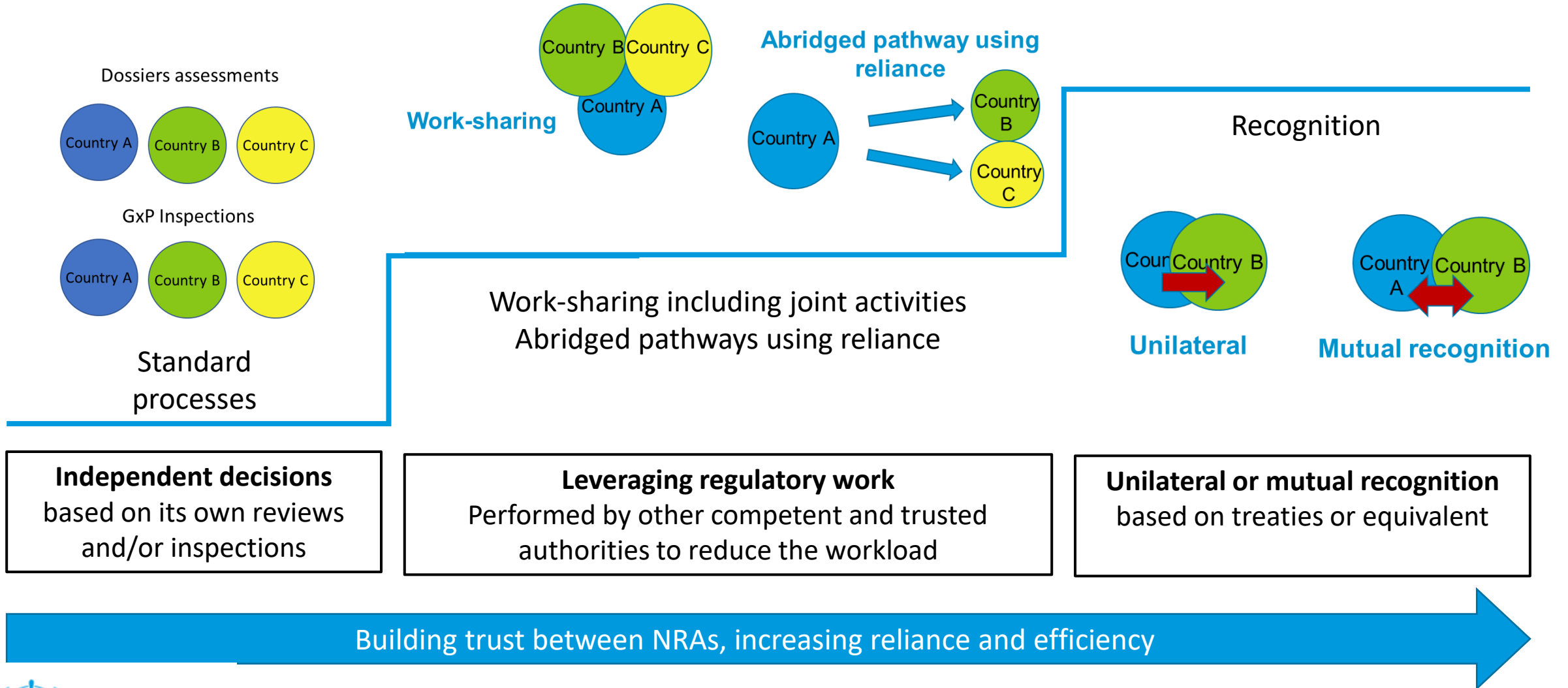
# Access to essential medical products – Reliance approach



- Good health is impossible without access to medical products
- Reliance is an **essential tool for efficiency of the global regulatory oversight** of medical products.
- NRAs rely on the work of trusted institutions to enhance their own regulatory decision
- To improve regulatory efficiency, ensure faster access to quality-assured medical products and reduce duplication of efforts
- Importance of **international cooperation** to ensure the safety, quality and efficacy or performance of locally used medical products

*Each national regulatory authority (NRA) retains ultimate accountability and decision-making power.*

# Key concepts of reliance and examples



# Risk-based approach: NRA strategy

Each NRA should define its **own strategy** for an **appropriate risk-based approach** to reliance

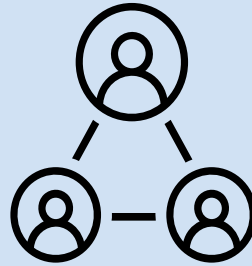
Not one size fits all



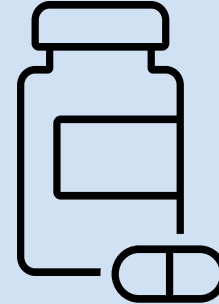
NRA Reliance strategy



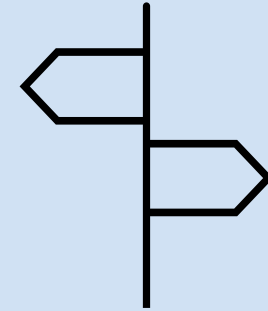
Public health needs and priorities



Level of resources and expertise available



Type and source of products evaluated



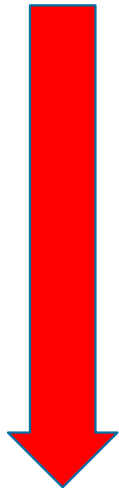
Opportunities for reliance

# WHO Good Reliance Practices – Barriers and enablers

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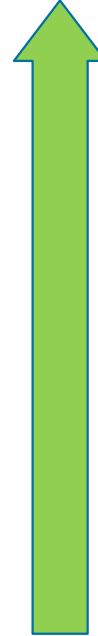
## BARRIERS

- Lack of political will
- Lack of accessible information and confidentiality of information
- Other considerations: language, differences in country-specific regulatory requirements, lack of regulatory alignment of product risk-classifications



## ENABLERS

- Trust
- Convergence and harmonization
- Information-sharing and dialogue among regulators
- Economic or legal integration
- Engagement of stakeholders



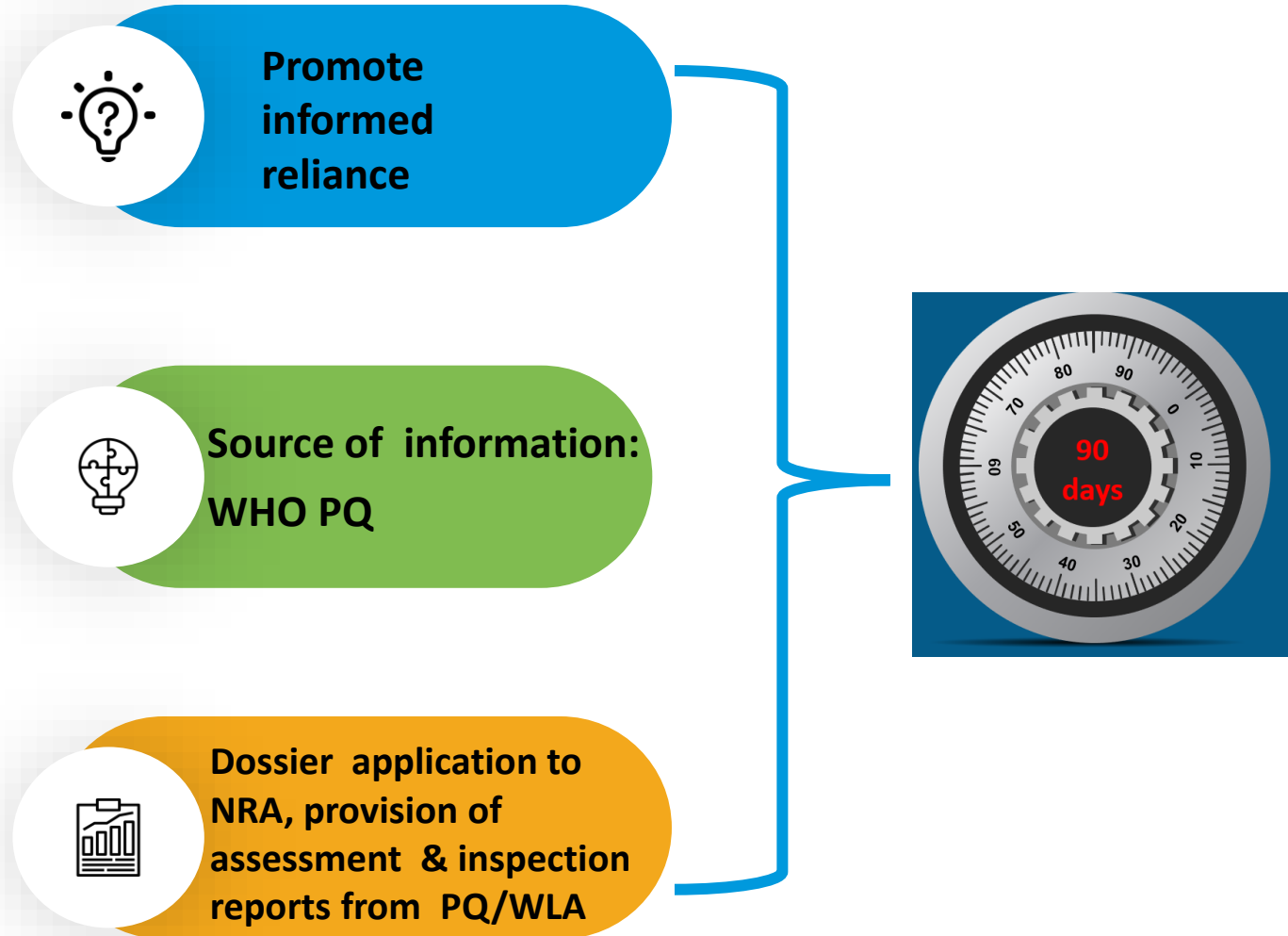


# Example of Reliance, WHO Collaborative Registration Procedure - Overview

- ✓ Accelerate national registration of WHO-prequalified or stringently assessed medical products by leveraging prior evaluations.
- ✓ Same principles for life cycle

## Process:

- ✓ WHO shares assessment reports with participating NRAs.
- ✓ NRAs conduct an abridged review based on WHO evaluations.
- ✓ Faster decision-making while maintaining national regulatory oversight.
- ✓ Product sameness: Quality Information Summary validated by WHO/SRA

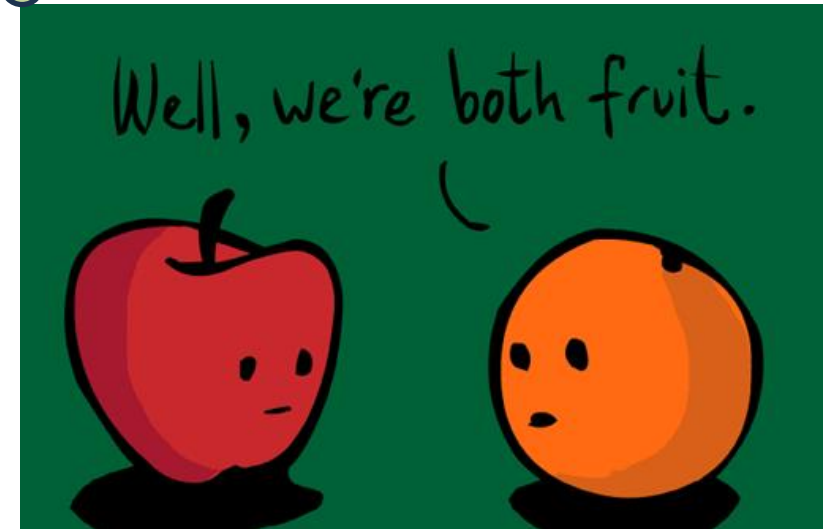


# “Sameness” of a product

- **Results of supporting studies of safety and performance, indications and conditions of use** should be the same.
- **Essential role of the manufacturer** to confirm the sameness of a product and to provide the same documentation to different NRAs.
- Except for additional country-specific information submitted for review (stability, label and labelling information etc.).
- Post-approval changes effectively communicated as long as the sameness is maintained.



“Two products have identical essential characteristics”



# WHO support to reliance implementation

- Development of tools to support NRAs implementation of reliance
- Provides training sessions, workshops, and webinars to strengthen the regulatory capacity of the NRAs
- Technical assistance to countries to enhance understanding and application of reliance principles
- Facilitate regulatory networks: Regional joint assessments/ harmonization networks (ASEAN, AMRH etc)
- WHO collaborative Registration Procedures
- Offers guidance and reliance frameworks during health emergencies such as WHO EUL for medical products





# WHO Good Reliance Practices: Source of information on reliance

## 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



Short eLearning Module of main principles and examples of reliance launched in October 2022  
<https://openwho.org/courses/good-reliance-practices>

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>

#### 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 countries involved	Link to publicly available information
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	<a href="#">WHO Listed Authorities (WLA)</a>
AVAREF (African Vaccine Regulatory Forum)	Clinical trials oversight	Medicines, vaccines	Regional	Joint assessment of clinical trial applications between national regulatory authorities and ethics committees	Joint assessment of clinical trial applications for African countries involving national regulatory authorities and ethics committees. The process includes two steps, the joint assessment followed by the individual national decisions.	African countries	<a href="https://www.who.int/health-topics/immunity/overf">https://www.who.int/health-topics/immunity/overf</a> <a href="https://www.who.int/health-topics/immunity/overf/first-review-process">https://www.who.int/health-topics/immunity/overf/first-review-process</a>
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 ethics committee outcome) per member state.	European Union Member States	<a href="https://www.european-council.europa.eu/media/eu-press-room-volume-18_en">https://www.european-council.europa.eu/media/eu-press-room-volume-18_en</a> <a href="https://www.ema.europa.eu/en/press-room/2020/0004/ema-submission-harmonisation-medical-products-clinical-trial-authorisation">https://www.ema.europa.eu/en/press-room/2020/0004/ema-submission-harmonisation-medical-products-clinical-trial-authorisation</a>
Fast track for multi-regional clinical trials from TFD, Chinese Taipei	Clinical trials oversight	Medicines	National	Shortened review timelines of the clinical trial applications if already authorized 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	<a href="https://www.mh.gov.tw/NewsContent.aspx?cid=424841-37051">https://www.mh.gov.tw/NewsContent.aspx?cid=424841-37051</a>
EU-MRAII (Article 58)	Scientific Advice, Marketing Authorisation	Medicines, vaccines	Global	Scientific opinion from the European Medicines Agency for medicinal products to be used outside of the European Union	The European Medicines Agency (EMA), in cooperation with the World Health Organization (WHO), can provide scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU). Target national regulatory authorities are invited to participate in the EMA evaluation. The EMA scientific opinion is then used to facilitate in-country registration. Target national regulatory authorities are also invited to participate in scientific advice procedure.	All regions	<a href="https://www.ema.europa.eu/en/human-regulatory/scientific-advice/marketing-authorisation/medicines/ema-scientific-advice-procedure">https://www.ema.europa.eu/en/human-regulatory/scientific-advice/marketing-authorisation/medicines/ema-scientific-advice-procedure</a>
Swissmedic, Switzerland Marketing Authorisation for Global Health Products	Scientific Advice, Marketing Authorisation	Medicines, vaccines	Regional	Involvement of target National Regulatory Agencies (NRAs) and the WHO in the Swissmedic assessment process	The MAGIP is based on the approach of involving target National Regulatory Agencies (NRAs) and the WHO in the Swissmedic assessment process. Scientific advice to clarify scientific questions in the development phase regarding the planned submission. Marketing authorisation procedure follows the regular Swissmedic marketing authorisation procedure (same time frame, procedure steps and evaluation criteria) with the difference that concerned NRAs and the WHO are involved.	Sub-saharan region of Africa	<a href="https://www.swissmedic.ch/swissmedic/en/press-releases/2022/02/02220201.html">https://www.swissmedic.ch/swissmedic/en/press-releases/2022/02/02220201.html</a> <a href="https://www.who.int/news-room/feature-stories/2022/02/02220201">https://www.who.int/news-room/feature-stories/2022/02/02220201</a>



[Good Reliance Practices Repository Version 1.0 2024 1114.xlsx](#)



*\*Take  
home message*

- Reliance is about making the best use of available resources and expertise and avoiding duplication and concentrate regulatory efforts and resources where most needed;
- No single regulatory body can do everything alone, regardless of its size, maturity – reliance is a 21<sup>st</sup> century regulatory tool;
- Implementing reliance mechanism is not a weakness, but rather a sign of strength and smart way of regulation medical devices;
- WHO good reliance practices guideline (2021) provide principles that could be translated into national regulatory framework to facilitate effective implementation of reliance;
- Choose a regulatory framework that is **least burdensome**, ensuring **timely access** to safe and effective health products, **without compromising public safety**.



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**When a bird builds its nest it uses the feathers of other birds.**

– African Proverb –

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# Thank you

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