Medical Device Regulatory Convergence Project (MDRC)
Good Regulatory Practices & Technical Competencies
South African Health Products Regulatory Authority (SAPHRA) & Regulated Sector

WHO Good Reliance Practices (GRelP)

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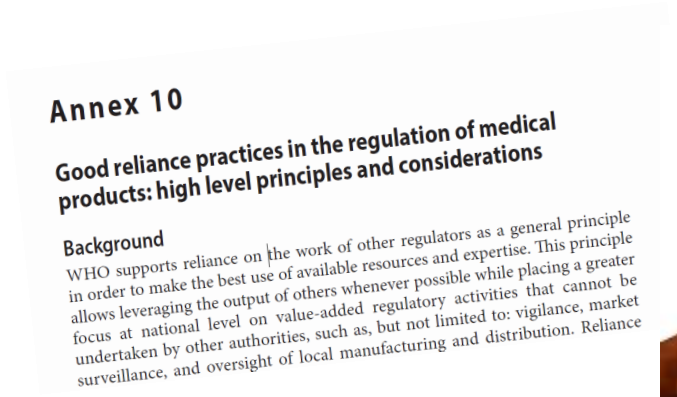
WHO Good Reliance Practices



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.

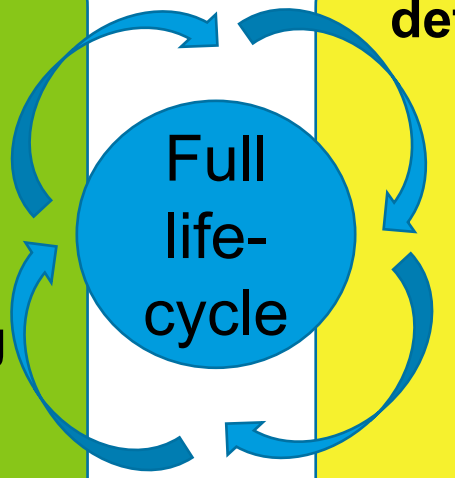
Adopted by WHO Expert Committee on Specification for Pharmaceutical Products in October 2020, published in March 2021
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

- 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 - Scope

Regulatory oversight of medical products:

- medicines,
- vaccines,
- blood and blood products
- medical devices (including in vitro diagnostics).

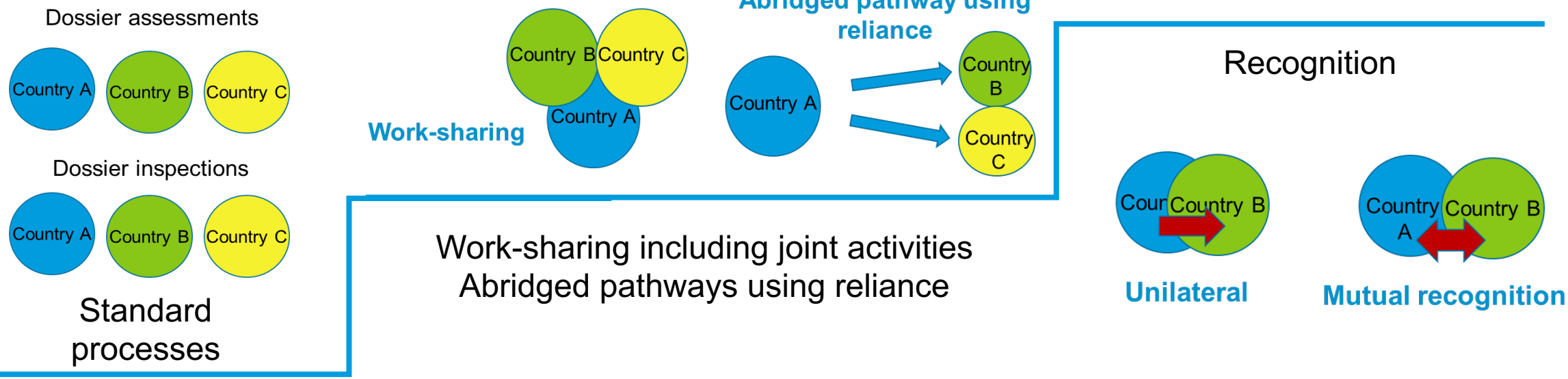


Addressing all regulatory functions as defined in the Global Benchmarking Tool :

- registration and marketing authorization,
- vigilance,
- market surveillance and control,
- licensing establishments,
- regulatory inspection,
- laboratory testing,
- clinical trials oversight,
- NRA lot release.

The high-level document will be complemented in a second step **by an interactive repository of practical examples of reliance and questions and answers documents**

Key concepts of reliance



Independent decisions based on its own reviews and/or inspections	**Leveraging regulatory work** Performed by other competent and trusted authorities to reduce the workload	**Unilateral or mutual recognition** based on treaties or equivalent

Building trust between NRAs, increasing reliance and efficiency

Life Cycle Approach

Risk Based Approach

Regulatory pathways involving reliance

MAIN PRINCIPLES:

- **Sharing information / expertise** (assessment, inspection and testing results or expertise) that serve as basis for authornational decisions – avoiding duplication.
- **Voluntary participation** – reference authorities, participating ities and manufacturers/sponsors

WHO PQ collaborative registration procedure

Vaccines: 2004

- Medicines: Started in 2012
- Diagnostics: Pilot 2019
- Vector control: Pilot 2020

"SRA" collaborative registration procedure

Initiated in 2015

- European Medicines Agency (EMA)
- UK Medicines and Healthcare Products Regulatory Agency (MHRA)
- 20 African NRAs

Regional networks

African Medicines Regulatory Harmonization Project (AMRH)

ASEAN SIAHR Project

WHO Good Reliance Practices – Principles

Universality

Applies to all NRAs irrespective of their levels of maturity or resources

Sovereignty of decision-making

NRAs maintain independence, sovereignty and accountability

Transparency

Key enabler to adopting new, more efficient ways of conducting regulatory operations. NRAs to be transparent about their reliance approaches

Respect of national/regional legal basis

Coherent with national/regional frameworks and policies

Consistency

Established for specific and well-defined categories of products and processes

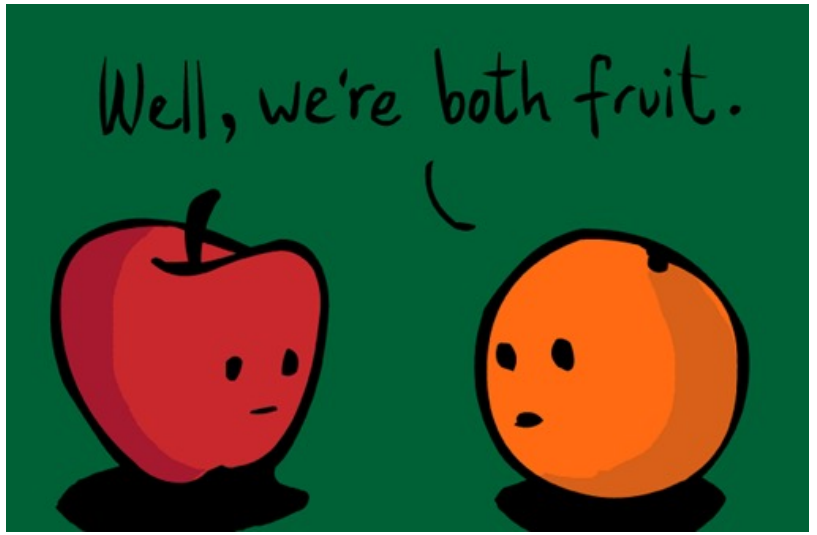
Competency

Build and maintain appropriate competencies and scientific expertise

“Sameness” of a product

“two products have identical essential characteristics”

- **All relevant aspects** of drugs, medical devices and in vitro diagnostics to be considered.
- **Results of supporting studies of safety and performance**, indications and conditions of use should be the same.
- Impact of **potential, justified differences** to **be assessed** by the manufacturer (and the relying NRA) in determining the possibility of using foreign regulatory assessments/decisions.
- **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, local label etc.).
- Post-approval changes and vigilance reliance activities as long as the sameness is maintained.



Examples of Reliance in the Medical Device field –

World Health Organization

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

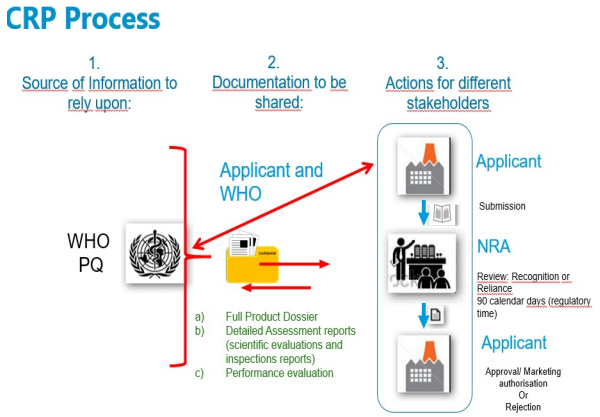
- Abridged pathways for the approval of medical devices with approval from other regulatory authorities.

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

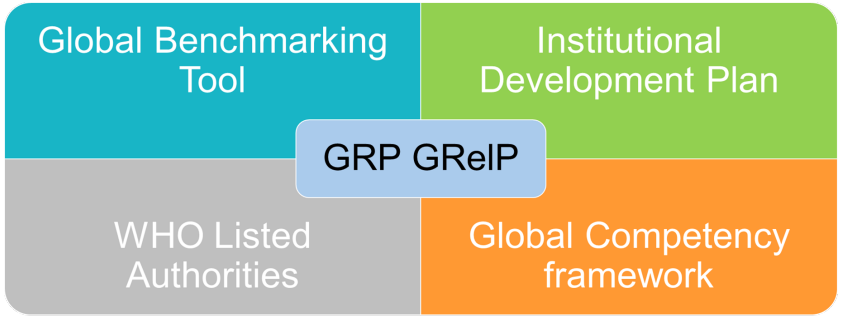
World Health Organization

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



www.who.int/medicines

Thank you for your attention!

World Health Organization