Joint IMDRF/Industry Workshop on Reliance

A Regional approach to reliance

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Content

- PANDRH snapshot
- Regional and global reliance principles and practices
- Our mandates: Regulatory System Strengthening
- Regional experiences
- Moving reliance and convergence forward

Pan American Network for Drug Regulatory Harmonization

C Conference

Pharmaceutical regulation of **medicines produced by chemical synthesis** and certain biologicals (vaccines and biotechnology products)

Strategic Development Plan 2014 - 2020

Revision of PANDRH scope to address priorities related to the development of health regulatory systems for medicines, biologicals, and **medical devices**

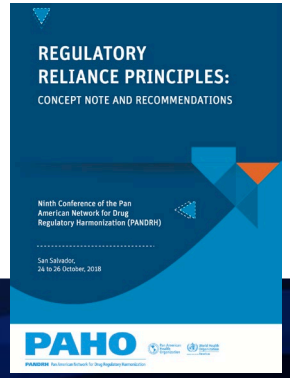
I	II	III	IV	V	VI	VII	VIII	IX	X
'97	'99	'02	'05	'08	'11	'13	'16	'18	'21

'00 — CD42.R11 **Harmonization**

'10 — CD50.R9 **Strenghtening of NRA**

New operational model

'22 — CSP30.R12 **Strenghtening of RS**



NRA: National Regulatory Authority / **RS:** Regulatory System

Reliance principles adopted at the Regional level

Sovereignty | Transparency | Consistency | Legal Basis | Competency

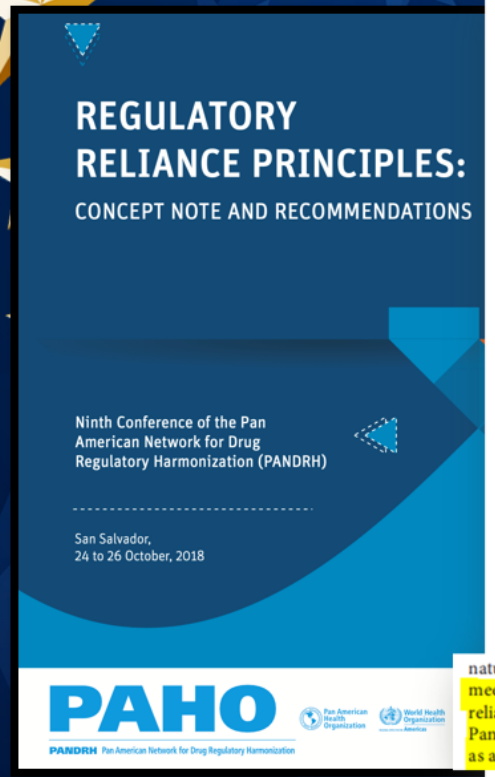
The document outlines **key examples** and **principles** for the **practice of regulatory reliance**.

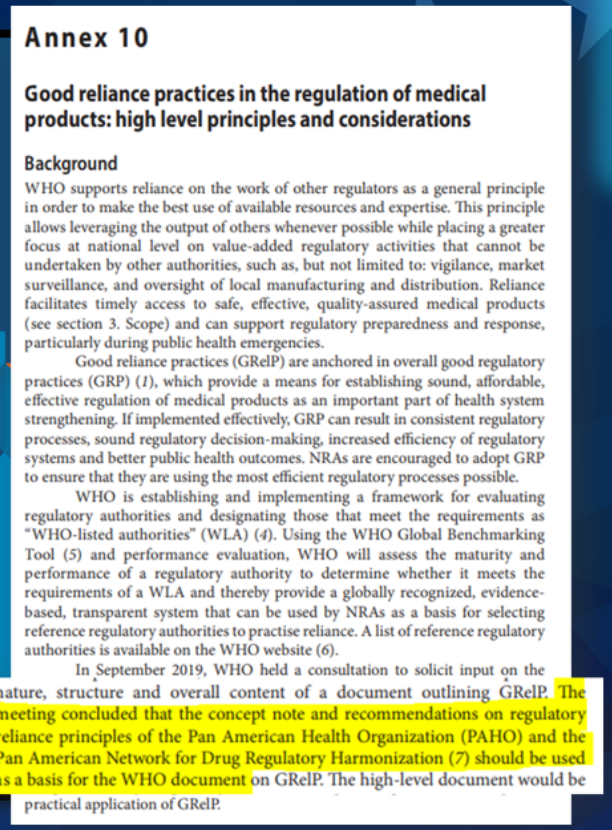
Recommendations

- Inclusion of reliance-related provisions and language in legal documents, where appropriate, for registry, inspection, laboratory testing, among others.
- Encourage Member States to use reliance to increase efficiency.
- Request PAHO and its Member States monitor and evaluate the impact of regulatory reliance across the Region.

Reliance principles adopted at the Regional level

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 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 to ensure that they are using the most efficient regulatory processes possible.

WHO is establishing and implementing a framework for evaluating regulatory authorities and designating those that meet the requirements as "WHO-listed authorities" (WLA) (*4*). Using the WHO Global Benchmarking Tool (*5*) and performance evaluation, WHO will assess the maturity and performance of a regulatory authority to determine whether it meets the requirements of a WLA and thereby provide a globally recognized, evidence-based, transparent system that can be used by NRAs as a basis for selecting reference regulatory authorities to practise reliance. A list of reference regulatory authorities is available on the WHO website (*6*).

In September 2019, WHO held a consultation to solicit input on the nature, structure and overall content of a document outlining GRelP. The meeting concluded that the concept note and recommendations on regulatory reliance principles of the Pan American Health Organization (PAHO) and the Pan American Network for Drug Regulatory Harmonization (*7*) should be used as a basis for the WHO document on GRelP. The high-level document would be practical application of GRelP.

The document presents the overarching principles of regulatory reliance in the oversight of medical products and use of reliance to enhance the effectiveness and efficiency of regulatory oversight.

Key messages

- NRA are encouraged to include reliance-related provisions as part of their flexible regulatory pathways.
- Reliance should be considered in all regulatory functions of the life cycle of a medical product, as appropriate.
- Effective implementation of reliance will benefit not only NRA but also patients, health care providers and the industry.
- Reliance is equally relevant for low-resourced and well-resourced NRA.

Reliance for emergency use authorizations in a pandemic

PAHO Pan American Health Organization World Health Organization Americas

Reliance for Emergency Use Authorization of Medicines and Other Health Technologies in a Pandemic (e.g. COVID-19)

Purpose and Context

This document provides guidance to national regulatory authorities (NRAs) and regulatory systems on practical ways to implement reliance for emergency use of medicines and other health technologies in and around a pandemic.[1] Note that countries use different terminologies for emergency use and the Pan American Health Organization (PAHO) will use the term "Emergency Use Authorization" (EUA). For the purposes of this document, medicines and other health technologies are defined to include pharmaceuticals, vaccines, and in Vitro Diagnostics (IVDs).

Countries are encouraged to develop plans for regulatory preparedness and response in a pandemic including related to EUA of medicines and health technologies. This will afford an orderly and legal process to expedite the incorporation of these products into health systems. According to WHO guidance[(1)], **country regulatory frameworks should include laws and/or policies that permit EUA for medicines and other health technologies, a pandemic preparedness plan that acknowledges EUA, technical procedures that use reliance and recognition on trusted/reference authorities for the EUA, and a system to monitor EUA products in the market.** This document focuses on technical procedures for reliance to issue an EUA.

Definitions and Principles of Reliance and Recognition

PAHO's "Regulatory Reliance Principles: Concept Note and Recommendations"[(2)],cites WHO's definition of reliance as "the act whereby the NRA in one jurisdiction may consider and give significant weight to—i.e. totally or partially rely upon—evaluations performed by another NRA or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken even when it relies on the decisions and information of others". PAHO's document goes on to say that recognition is considered a form of reliance. The WHO defines recognition as "the routine acceptance by the NRA in one jurisdiction of the regulatory decision of another NRA or other trusted institution". The use of reliance should incorporate the following principles: a legal basis to carry out reliance; sovereignty in making the decision to use reliance, including the need to document the decision as part of good review practices; transparency in the standards and processes used; consistent application; and staff competencies to implement reliance.

The document provides guidance to NRA and regulatory systems on practical ways to implement reliance for emergency use of medicines and other health technologies in and around a pandemic

Key messages

- Countries are encouraged to develop plans for regulatory preparedness and response in a pandemic including related to EUA of health technologies.
- It is not intended to replace marketing authorization processes under regular circumstances.

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF International Medical Device Regulators Forum

CSP30.R12
Policy to Strengthen National Regulatory Systems for Medicines and Other Health Technologies

OBJECTIVE

- Promote efficient regulatory systems in all Member States, tailored to the needs of their health systems, with a maturity level of 3 or higher in order to ensure the quality, safety, and efficacy of health technologies, in keeping with PAHO/WHO recommendations.
- Where national policies are in place and the context permits, regulatory systems can help foster the production of health technologies that promote equitable access, health and well-being, and economic and social development.

Adopt sustainable State policies to strengthen the governance and stewardship of regulatory systems	Promote the strengthening of regulatory systems to ensure consistent, transparent processes based on regulatory science
Strengthening regulatory harmonization and convergence	Adopt new evaluation systems based on the WHO Global Benchmarking Tool (GBT) and related mechanisms

The policy was **adopted at the 30th Pan American Sanitary Conference** and urges Member States, in keeping with their contexts and needs, to:

i) Promote transparent regulatory decision-making and information exchange among countries as a requirement for convergence, harmonization, and reliance on regulatory decisions from other jurisdictions…

n) … the adoption of practices for reliance on decisions from other jurisdictions to achieve regulatory goals.

Experiences in the use of reliance in the Americas

XI Regional Meeting on Medical Device Regulation

El Salvador, October 2023

Panel: NRA experiences in the use of reliance

Argentina | Brazil | Canada | Colombia | Cuba | Ecuador | El Salvador | USA | Mexico | Peru

KEY OBSERVATIONS

- The adoption of reliance practices by some countries of the Region improved their efficiency and use of resources.
- Reliance is applied under different premarket conditions; while some countries apply reliance on higher risk classes of medical devices, others do the opposite.
- Gaps persist in the transparency of regulatory decisions. Publication of aspects related to decision-making, information exchange and availability of public information are still lacking in the countries of the Region.
- Increasing interest to participate in regional and international initiatives and adopt the use of international guidance and standards.

Moving reliance practices forward

1. Encourage the inclusion of reliance-related provisions and language in legal documents.

2. Promote effective integration of reliance throughout medical devices' lifecycle and across all regulatory functions.

3. Enhance transparency and exchange of information on regulatory decisions.

4. Enhance communication and collaboration with the industry.

5. Promote the application of reliance practices which should be extended to post market activities.

PANDRH – Moving forward

Develop the PANDRH Strategic Development Plan and include **reliance** as a **priority topic**

Support **Medical Devices** regulatory **harmonization** and **convergence** in the Americas

Organize the **XI Pan American Conference on Harmonization of Drug Regulatory Authorities (CPANDH)** in Q3 2024 – Mexico City

Foster the **dialogues** and **cooperation** on regulatory reliance among **NRA** and **stakeholders**

Enhance PANDRH **collaboration** with other **international harmonization** initiatives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