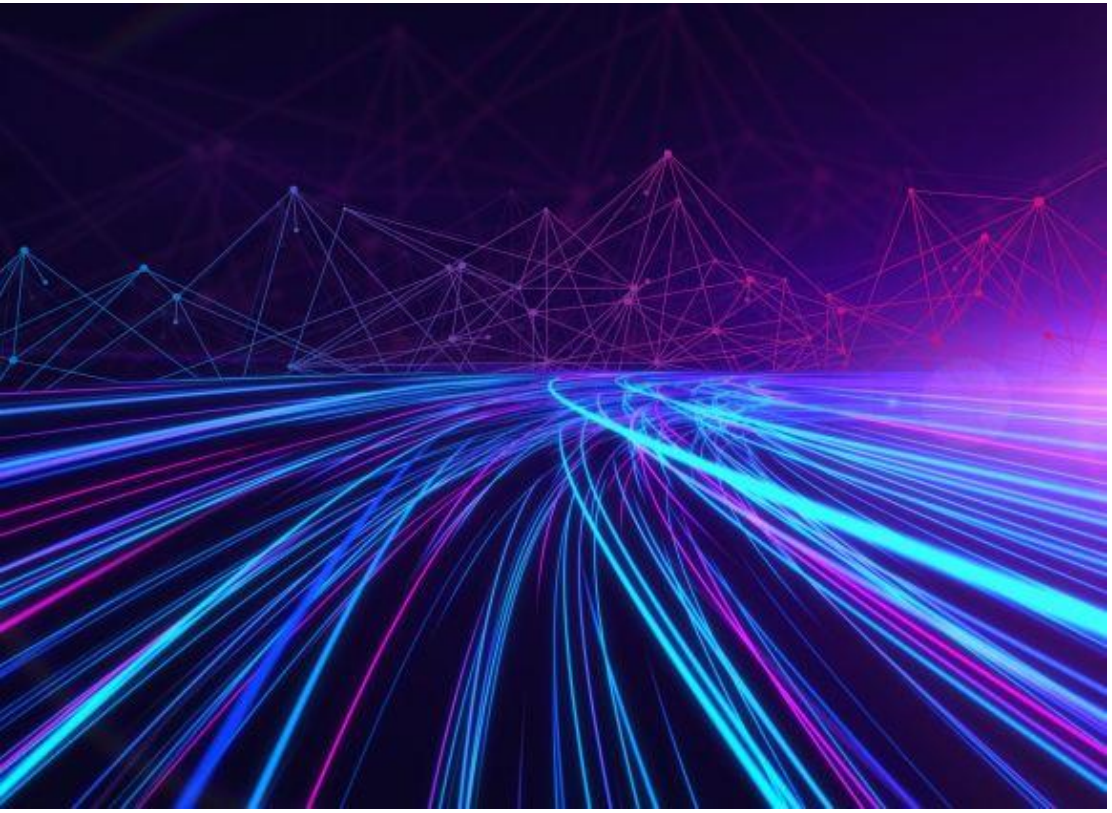
Global Harmonization Working Party
GHWP Towards Medical Device Harmonization



Regulatory Convergence & Reliance

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Why Reliance

- Reliance is a means of improving the **effectiveness and efficiency of regulation** of medical products.
- It allows NRAs to make the **best use of resources, build expertise and capacity, increase the quality of their regulatory decisions, reduce duplication of effort** and, ultimately, promote timely access to safe, effective and quality assured medical products.
- Adoption of reliance measures whenever possible, in a well structured framework underpinned by national or regional policies and strategies, will allow regulators to **focus their resources on activities that contribute to public health that cannot be undertaken by others**.

> *"Reliance represents a 'smarter' form of regulatory oversight, based on constructive regional and international collaboration, that will facilitate and promote convergence and the use of common* international standards and guidelines, resulting in more predictable, faster approval to improve access to quality-assured medical products for patients worldwide."
> – WHO Good Reliance Practices

Source: Annex 10 of the Fifty-fifth report of WHO Expert Committee on Specifications for Pharmaceutical Preparations: (TRS 1033), 25 March 2021

Potential Barriers for Reliance

- Lack of political will
- Lack of accessible information and confidentiality of information
- Lack of common language in documentation
- Differences in national regulatory requirements and evidentiary standards
- Lack of alignment on classification and product change management
- Lack of acceptance of foreign clinical data and real world evidence
- Different level of competencies
- Internal HA resistance and insufficient knowledge of the reference authority

Source: *Annex 10 of the Fifty-fifth report of WHO Expert Committee on Specifications for Pharmaceutical Preparations: (TRS 1033), 25 March 2021*

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Potential Enablers for Reliance

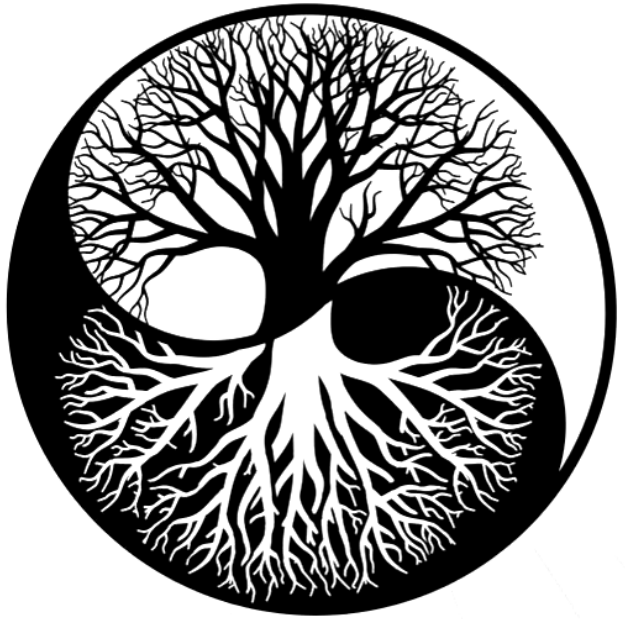
- Trust
- Convergence and harmonization
- Information-sharing and dialogue among regulators
- Economic or legal integration
- Engagement of stakeholders

Source: *Annex 10 of the Fifty-fifth report of WHO Expert Committee on Specifications for Pharmaceutical Preparations: (TRS 1033), 25 March 2021*

The Interplay between Convergence and Reliance

Convergence

A voluntary process whereby the regulatory requirements in different countries or regions become more similar or "aligned" over time. Convergence results from gradual adoption of internationally recognized technical guideline documents, standards and scientific principles, common or similar practices and procedures or the establishment of appropriate domestic regulatory mechanisms that align with shared principles to achieve a common public health goal.



Reliance

The act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessments 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.

Source: *Annex 11 of the Fifty-fifth report of WHO Expert Committee on Specifications for Pharmaceutical Preparations: (TRS 1033), 25 March 2021*

How Does the Interplay Work

- Reliance represents a "smarter" form of regulatory oversight, based on constructive regional and international collaboration, that will facilitate and promote convergence and the use of common international standards and guidelines, resulting in more predictable, faster approval to improve access to quality-assured medical products for patients worldwide.
- Convergence and harmonization of requirements, standards and guidelines are important enablers of regulatory cooperation and reliance.
- However, differences in standards and practices, do NOT prevent one authority from relying on another, particularly when the relying authority has limited capacity and expertise.

Source: *Annex 10 of the Fifty-fifth report of WHO Expert Committee on Specifications for Pharmaceutical Preparations: (TRS 1033), 25 March 2021*

Convergence status: Yes | Partial | No

Opportunities for Convergence

There is better convergence among markets with formal reliance mechanism

Formal reliance existing

A Set of Good Regulatory Practices	Country A	Country B	Country C	Country D	Country E	Country F	Country G
Adoption of IMDRF best practices (e.g. risk classification)	Yes	Partial	Partial	Yes	Yes	Yes	Yes
Common dossier template (e.g. IMDRF RPS, AMDD CSDT)	Yes	No	No	Yes	Yes	Yes	Yes
Acceptance of overseas clinical evidence	Yes	Yes	Yes	Yes	Yes	Yes	Yes
No in-country lot testing	Yes	Partial	Partial	Yes	Yes	Yes	Yes
No country-specific labeling requirements	Partial	No	No	No	Yes	No	No
No prior approval required in country of origin and/or country of manufacturer	Yes	No	Yes	Yes	Yes	Yes	Yes
No re-registration requirements	Partial	No	Yes	No	Yes	No	Yes
No redundant inspections	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Leverage Real World Evidence (RWE)	Yes	Partial	Partial	Yes	Yes	No	No

No formal reliance

A Set of Good Regulatory Practices	Country H	Country I	Country J	Country K	Country L	Country M	Country N
Adoption of IMDRF best practices (e.g. risk classification)	Partial	No	Yes	Yes	Yes	No	Partial
Common dossier template (e.g. IMDRF RPS, AMDD CSDT)	Yes	Partial	Yes	Yes	No	Yes	No
Acceptance of overseas clinical evidence	No	Partial	Partial	No	Yes	Yes	Partial
No in-country lot testing	Partial	Yes	Partial	Yes	Yes	No	Yes
No country-specific labeling requirements	No	No	Yes	Yes	No	No	No
No prior approval required in country of origin and/or country of manufacturer	No	No	Yes	Yes	Yes	Yes	Yes
No re-registration requirements	No	No	No	Partial	No	No	No
No redundant inspections	No	Yes	Yes	Yes	Yes	Yes	No
Leverage Real World Evidence (RWE)	Yes	Partial	No	No	No	No	Partial

Data source: Roche internal analysis of 14 markets for IVD products

Benefits of Implementing Global Convergence and Reliance

- Conserve and **optimize the use of limited regulatory resources**, elevate regulation to one high standard and accelerate access to safe, high-quality, effective, and innovative medical technologies to benefit patients, caregivers, and healthcare providers.
- Facilitate an environment conducive to the **growth of the medical technology sector**, **enhancing innovation** and providing knowledge-based jobs.
- Enhance **global health equity** through the acceleration of global access to safe, effective and innovative medical technologies.

"The future of medical products regulation is in convergence/ harmonization, collaboration, and networking based on reliance and trust."

Source*: GMTA paper on The Need to Advance Global Convergence and Regulatory Reliance to Accelerate Access to Medical Technology.*
Dr. Samvel Azatyan, RCN/REG/RPQ, World Health Organizaton. WHO Activities: focus on reliance. 10th Asia Regulatory Conference.

Should you have any questions, please contact me via yasha.huang@roche.com