Strengthening Regulatory Systems Through Reliance: *Launch of the Latin America Monitoring Initiative*

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CIRS Centre for Innovation in Regulatory Science

Outline

- **Regulatory systems and their importance for ensuring timely availability of medicines**
- Regulatory reliance as an enabler of system strengthening
- A mechanism for monitoring reliance globally - CIRS study
- CIRS study results - Insights and opportunities for Latin America

The analysis aims to support constructive dialogue and continuous improvement in the implementation of regulatory reliance across the region

Regulatory Systems for Medicine Registration: A Key Component for Enabling Access to Safe and Effective Medicines

Regulatory systems are frameworks used by authorities to evaluate and approve medicines for safety, efficacy, and quality – an essential strategic component of public health infrastructure

- Rapid advances in medicine increase the need for efficient regulatory review processes
- Regulatory systems globally exhibit variability in capacity, efficiency, resource and maturity
- Harmonisation efforts (e.g., International Council for Harmonisation) have improved alignment, but gaps remain across agencies
- Efficient review systems are increasingly important to prevent patient delays

Regulatory Systems for Medicine Registration: Foundations of Effective Systems

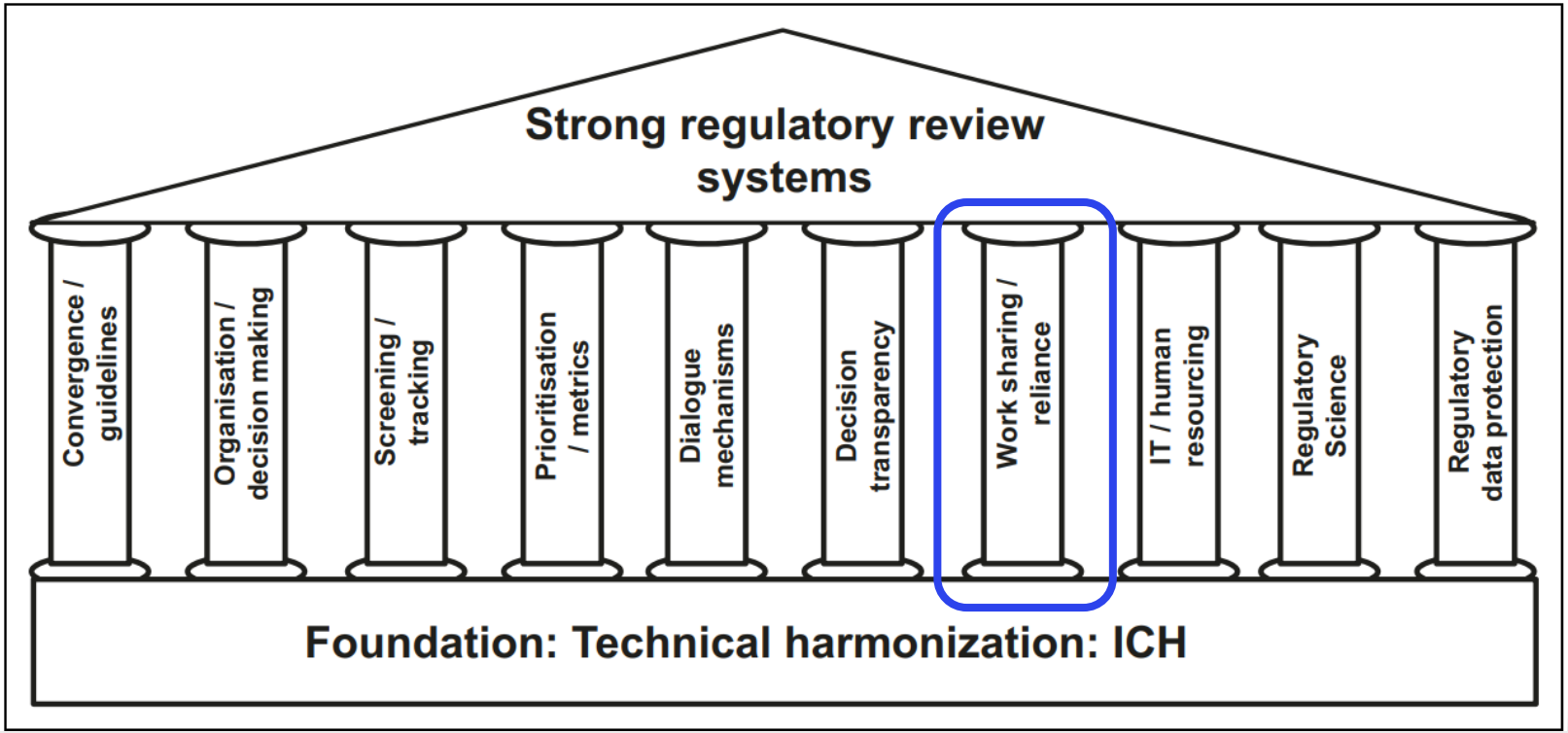
"Weak or inefficient regulatory systems do not serve interests of consumers, patients, industry nor the health care system

"All regulatory systems should be science based, respect international standards and best practices, and adopt an approach that focuses on what cannot be done by others while leveraging the work of other trusted NRAs and regulatory networks for the rest"

"Collaboration should lead to mutual benefit and measurable public health gains

Mike Ward, CIRS Workshop, 2017, Brazil

Reliance and Worksharing: A Key Pillar of Strong Regulatory Review Systems – Enabling Agencies to Use Resources More Strategically



O'Brien J, Lumsden R, Macdonald J. Strengthening regulatory systems for medicines in a changed world: where do we go from here? BMJ Glob Health. 2021 Jan;6(1):e004680. doi: 10.1136/bmjgh-2020-004680. PMID: 33495287; PMCID: PMC7839853.

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Reliance Supports Smarter Decision-making while Maintaining National Sovereignty

World Health Organization
Good Reliance Practices
2021

***Definition**: "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."*

Paul Dearden
Abbvie
CIRS Workshop
Sandton, S. Africa
March 2018

- Rather than a *"rubber stamping"* approach that cedes responsibility, reliance should be regarded as a regulatory enabler, facilitating decisions made as part of global alignment.
- The inherent value of this **pragmatic philosophy** is dependent on local needs, **enabling the optimal use** of available resources regardless of the application type and **freeing capacity to focus on progress toward convergence**.

EMA
CIRS workshop 2022

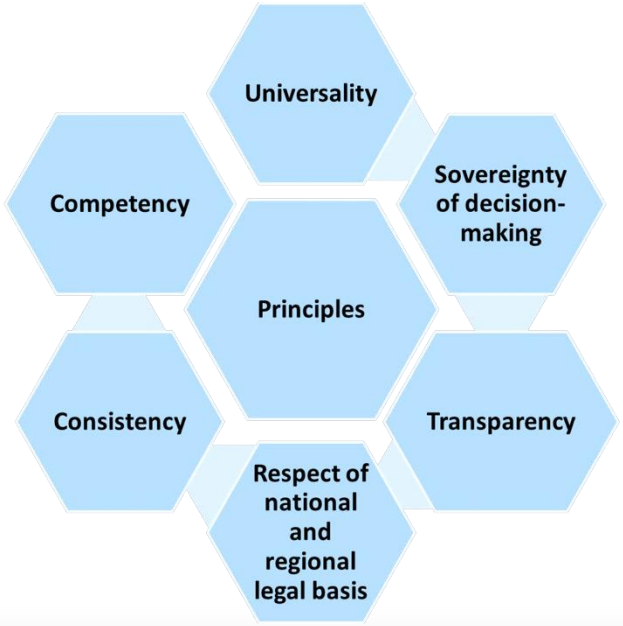
"Reliance and collaboration as 21st century regulatory tools"

World Health Organization

"Regulatory systems irrespective of maturity/resources can be effective if they use a risk-based approach and, take advantage of the work and decisions of other regulatory authorities"

Reliance is a Long-standing Regulatory Approach that is now Defined and Operationalised through Good Reliance Practices (GRelP)

WHO has been promoting the concept of *reliance* since the **1960s**, while the formal GRelP were established in **2021**.
The **principles and considerations underpinning WHO GRelP** are as follows:



Considerations

- Reliance anchored in a national regulatory authority strategy
- Cultural change
- **Flexibility in approach:** "one size doesn't fit all"
- Implementing reliance needs investment
- "Sameness" of the product in different jurisdictions
- The role of industry
- Reliance in case of a public health emergency

- Systems/Frameworks need to be placed
- Assessment template – specific to the review
- Standard operating procedures
- Transparent internal criteria & guidelines - published
- Strategy
- Legal Framework
- Change Management; management & reviewer buy in
- Resources – workshares/collaborations

World Health Organization (2021). Annex 10. WHO Technical Report Series No. 1033.

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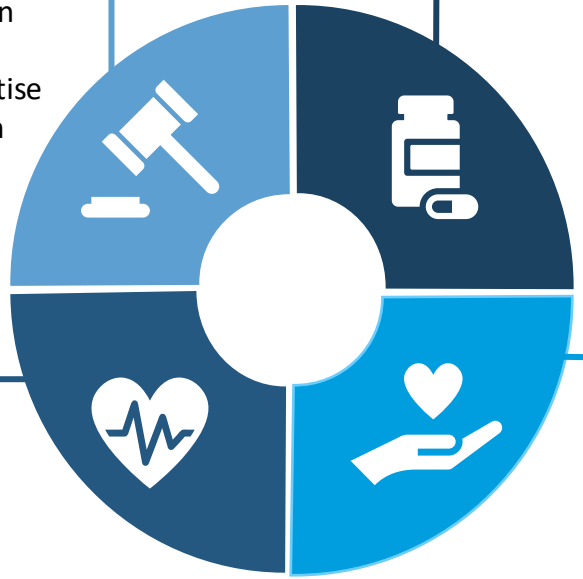
Shared Value of Reliance: Delivering Benefits Across the Health Ecosystem

Regulatory Agencies

- **Resource Optimization:** Reduces duplication
- **Faster Approvals**
- **Capacity Building:** Access to external expertise
- **Global Alignment:** Promotes harmonization with international standards
- **Reduced Backlog**

Pharmaceutical Companies

- **Accelerated Market Entry**
- **Lower Costs:** e.g. reduced need for multiple inspections
- **Predictability:** Reliance frameworks often provide clearer pathways and timelines



Healthcare Providers

- **Timely Access to Medicines:** Faster availability of treatments
- **Confidence in Quality**
- **Better Continuity of Care:** Reduced delays in post-approval changes.

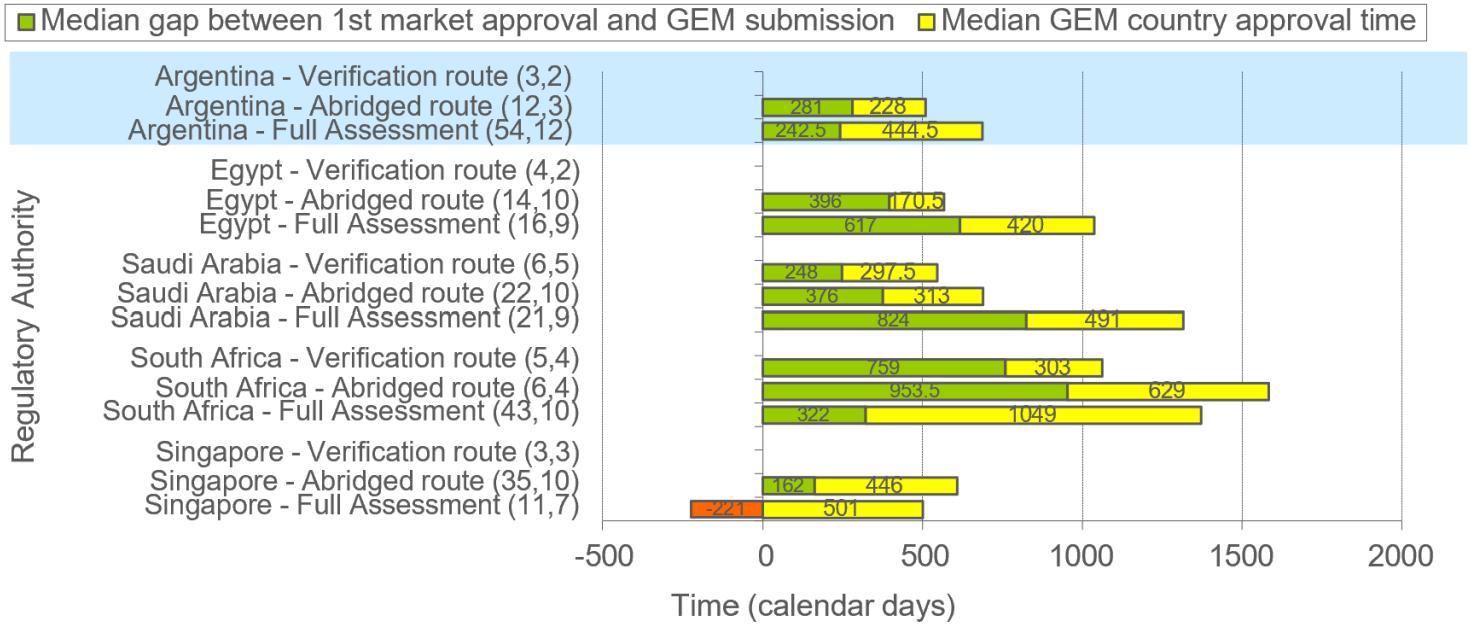
Patients

- **Quicker Access to Needed Medicines:** Especially critical for emergencies.
- **Equity in Access:** Reliance can help smaller or resource-limited countries access innovations
- **Improved Health Outcomes**

Source: CIRS Workshop/Surveys

Evidence Suggests that Well-implemented and Clearly Defined Reliance Pathways can Improve Regulatory Timelines and Support Faster Rollout of Medicines

Median roll out time for new medicines approved in Growth and Emerging Market (GEM) countries in 2019-2023 by type of Reliance Route



Source: CIRS Industry Metrics Programme
NOTE: Data are shown for New Active Substances (NASs) that were approved between 01/01/2019 and 31/12/2023.
(n1,n2) = number of NASs, number of companies.
If n1 is less than 5 or if n2 is less than 3, data is not shown. Authorities shown are limited to those where data can be displayed for more than one assessment route.
Denotes the submission to GEM country was prior to first world approval.

Reliance Route Types

Verification: Confirmation that a trusted authority's decision meets predefined criteria through targeted checks.

Abridged: A streamlined review that relies partly on prior assessments, supplemented by limited additional evaluation.

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Expanding Opportunities and Patient Benefit through Effective Implementation of Reliance Pathways in Regulatory Frameworks

Reliance

Problem statement

Agencies around the world have been proactively implementing reliance approaches as part of their toolkit to enhance efficiency of regulatory processes and functions

The principles for good reliance have already been identified by the WHO (Annex10), however it is not clear how well agencies have been incorporating these principles into their reliance mechanisms

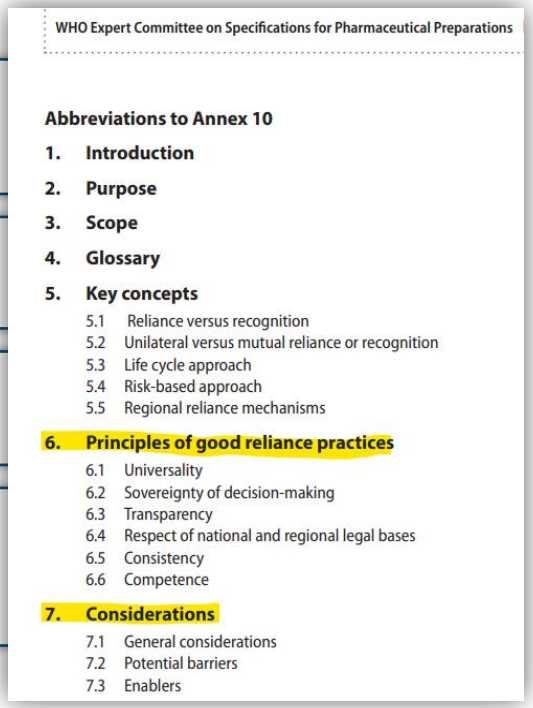
Although WHO has been applying the Global Benchmarking Tool (GBT)* to measure regulatory capacity, and this has been used to evaluate agencies in LATAM through PAHO, there is currently lack of systematic monitoring of reliance pathways

Monitoring reliance is nevertheless important for enabling continuous improvement by agencies and alignment with good practice

*The WHO Global Benchmarking Tool (GBT) is a structured framework developed by WHO to evaluate the maturity level and performance of national regulatory authorities across key regulatory functions.

From Analysis to Action: Objectives of CIRS project Developing a Mechanism to Monitor Regulatory Reliance

- Assess the implementation of reliance in selected countries in Latin America with a possibility of expanding the study globally
- Identify barriers and enablers for effective implementation of reliance
- Identify areas for improvement and alignment compared to Good Reliance Practices
- Foster collaboration and knowledge exchange within the region to build capacity, enhance regulatory efficiency and support continuous improvement



WHO Expert Committee on Specifications for Pharmaceutical Preparations

Abbreviations to Annex 10

1. **Introduction**
2. **Purpose**
3. **Scope**
4. **Glossary**
5. **Key concepts**
   - 5.1 Reliance versus recognition
   - 5.2 Unilateral versus mutual reliance or recognition
   - 5.3 Life cycle approach
   - 5.4 Risk-based approach
   - 5.5 Regional reliance mechanisms
6. **Principles of good reliance practices**
   - 6.1 Universality
   - 6.2 Sovereignty of decision-making
   - 6.3 Transparency
   - 6.4 Respect of national and regional legal bases
   - 6.5 Consistency
   - 6.6 Competence
7. **Considerations**
   - 7.1 General considerations
   - 7.2 Potential barriers
   - 7.3 Enablers

Scope of Analysis: Understanding Different Regulatory Reliance Pathways and Their Application Across Regulatory Functions

Assessment of different reliance mechanisms as per WHO across different agency regulatory functions

- **Recognition:** Acceptance of another authority's regulatory decision without additional assessment
- **Verification:** Confirmation that a trusted authority's decision meets predefined criteria through targeted checks
- **Abridged:** A streamlined review that relies partly on prior assessments, supplemented by limited additional evaluation
- **Mutual recognition:** Reciprocal agreement between authorities to accept each other's regulatory decisions.
- **Collaborative / joint / workshare:** Shared regulatory assessment where multiple authorities jointly evaluate or divide review tasks

New Marketing authorisations (MA)*	Post-approval changes	Good manufacturing practices inspections	Approval of clinical research protocols	Batch release of biological products and vaccines

**as initial focus and deep dive*

High-level analysis of 4 other functions to be undertaken as next phase

Reliance mechanisms can take different forms depending on the depth of regulatory review and the level of cooperation between authorities

Strong Commitment from 10 Latin American Countries to Strengthen Regulatory Reliance Mechanisms

Country	Agency
Argentina	National Administration of Drugs, Foods and Medical Devices (ANMAT)
Brazil	Brazilian Health Regulatory Agency (ANVISA)
Chile	Institute of Public Health of Chile (ISP)
Colombia	National Institute for Food and Drug Surveillance (INVIMA)
Costa Rica	Directorate for the Regulation of Health Products of Interest and Sanitary Risk (DRPIS)
Dominican Republic	General Directorate of Medicines, Food and Health Products (DIGEMAPS)
Ecuador	National Agency for Health Regulation, Control and Surveillance (ARCSA)
Mexico	Federal Commission for the Protection against Sanitary Risks (COFEPRIS)
Panama	National Directorate of Pharmacy and Drugs (DNFD)
Peru	General Directorate of Medicines, Supplies and Drugs (DIGEMID)

Vision to expand to other agencies in future and continuously measure in LATAM

Method: A Robust and Scientifically Grounded Collaborative Learning Initiative to Assess Regulatory Reliance

Governance

Research was supported by a Topic Group initiated by CIRS (under its Scientific Advisory Council) composed of:

- All ten agencies studied
- *Swissmedic (Chair)*
- *ANVISA (co-chair)*
- *European Medicines Agency*
- Expert industry representatives.

Approach

CIRS developed a method to monitor the use of regulatory reliance - a questionnaire relating to the WHO Annex 10 GRelP

- **Data collection tool was developed (45 questions) -** to ensure structured comparable and meaningful data across the countries
- **Desk-based research:** the tool was initially used to review publicly available guidelines and documents
- **Interviews with agencies:** The data collected was then validated and supplemented through interviews with the 10 agencies
- **Industry input:** is also being incorporated to continuously strengthen the analysis and ensure a comprehensive perspective

Regulatory Reliance Pathways in Latin America: Regulations Used as the Formal Basis for the Analysis

Country	Date of last update of the regulation	Name of the regulation
Argentina	August 8, 2014	***Decree 150/1992.*** *Rules for the registration, manufacturing, subdivision, prescribing, dispensing, marketing, export, and import of medicines. Scope of application. General Provisions.*
Brazil	March 20, 2024	***Normative Instruction No. 289.*** *Establishes, pursuant to Resolution of the Collegiate Board (RDC) No. 741, the criteria applied to the optimized review procedure that makes use of assessments conducted by an Equivalent Foreign Regulatory Authority (AREE) for the evaluation of applications for marketing authorization, post-authorization changes of medicines, biological products, vaccines, and for the letter of adequacy of the active pharmaceutical ingredient dossier (CADIFA) within the national territory.*
Chile	August 21, 2020 January 27, 2025	***Decree 3.*** *Regulation of the National System for the Control of Pharmaceutical Products for Human Use. - Section 3rd On the accelerated registration procedure* ***Exempt Resolution No. E679-2025.*** *Establishes an internal procedure for the application of a reliance mechanism in the granting of marketing authorizations for biological pharmaceutical products*
Colombia	April 26, 1995	***Decree 677/1995.*** *By which the Regime of Registrations and Licenses, Quality Control, as well as the Regime of Sanitary Surveillance of Medicines, Cosmetics, Pharmaceutical Preparations based on Natural Resources, Cleaning, Hygiene and Sanitation Products, and other household products is partially regulated, and other provisions on the matter are enacted –* ***Articles 27 and 28.***

Regulatory Reliance Pathways in Latin America: Regulations Used as the Formal Basis for the Analysis

Country	Date of last update of the regulation	Name of the regulation
Costa Rica	July 22, 2025	***MS-DM-3979-2025.*** *Procedure for facilitating the sanitary registration of medicines that hold a marketing authorization issued by regulatory authorities included in the list of authorities designated by the World Health Organization.*
Dominican Republic	December 28, 2017	***Resolution No. 000021:*** *Which amends Articles Two and Three of Resolution No. 000004 dated January 27, 2016, which establishes the criteria for the application of sanitary registration through a simplified procedure and the recognition of certificates of free sale of products and Good Manufacturing Practice Certificates of establishments issued by Stringent Regulatory Authorities (WHO), Regional Reference Regulatory Authorities (NRRAs) of the PAHO PARF Network, and by authorities from countries with High Health Surveillance.*
	February 16, 2023	***Decree No. 58-23.*** *Establishes that medical products approved by the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) may be registered in the country within 48 hours.*
Ecuador	December 30, 2024	***Resolution ARCSA-DE-2024-058-DASP:*** *Substitute sanitary technical regulation for obtaining sanitary registration, control, and surveillance of medicines for human use in general.*
	December 20, 2024	***Resolution ARCSA-DE-2024-049-DASP:*** *Substitute sanitary technical regulation for obtaining sanitary registration, control, and surveillance of biological products for human use*

Regulatory Reliance Pathways in Latin America: Regulations Used as the Formal Basis for the Analysis

Country	Date of last update of the regulation	Name of the regulation
Mexico	July 18, 2025	***Agreement 18/07/2025.*** *General guidelines for the application of the abbreviated regulatory pathway for the granting of sanitary registrations of health supplies, in which the requirements, tests, and evaluation procedures issued by reference regulatory authorities and by the World Health Organization's prequalification program are recognized as equivalent.*
Panama	June 25, 2025	***Executive Decree No. 12 of June 25, 2025.*** *Which amends Articles 1, 2, and 5 of Executive Decree No. 2 of January 7, 2025, which establishes the procedure for the recognition of sanitary registrations of medicines manufactured and registered in countries with regulatory authorities that are part of the World Health Organization's list of authorities (WLA), as amended by Executive Decree No. 4 of February 5, 2025.*
Peru	October 01, **2024** May 1, **2025**	***Directoral Resolution No. 092-2024:*** *Approves the Institutional Guidelines for the implementation of good practices in the use of regulatory decisions from other jurisdictions within the regulatory functions of the Directorate General of Medicines, Health Supplies, and Drugs (DIGEMID), which, as an annex, form an integral part of this Directoral Resolution.* ***Law No. 32319.*** *Establishes measures to facilitate access to medicines and biological products registered in countries with high health surveillance, intended for the treatment of rare, orphan, cancer, and other diseases*

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Current State of Regulatory Reliance at Country Level: High Adoption but Variable Implementation – Findings Based on Desk-based Research and Interviews with 10 agencies

Legal basis:
All agencies have a national law or regulation for reliance, supported by

- *Guidelines/guidance documents (70%)*
- *Ministerial policies/directives (60%)*
- *Fewer having formal mutual/bilateral agreements (40%) or internal SOPs (30%)*

Strategy:

- *Most agencies have a national reliance strategy in place (60%), formally endorsed by management*
- *National reliance strategies are largely aligned with internal resources/capacity and public health needs (80%)*

Transparency:
All agencies involved external stakeholders, primarily industry, in the development of their reliance strategy; all offer public consultations

- *Most agencies publish the reliance framework (90%) and selection criteria (80%)*

But far fewer publish

- *Reliance strategies (20%)*
- *Metrics/impact reports on reliance (10%)*

Reliance is increasingly formalised through frameworks and strategies, but operationalisation varies and there is limited publication of detailed strategies and impact metrics

≥50% agencies | **<50%** agencies

NOTE: Results in the process of validation

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Current State of Regulatory Reliance at Country Level: High Adoption but Variable Implementation – Findings Based on Desk-based Research and Interviews with 10 agencies

Competence:

- *All agencies ensure the necessary competence for reliance-based decisions across its reviewers, mainly through training and involvement of senior staff (80%)*
- *70% agencies undertake activities to foster cultural and organizational acceptance of reliance*
- *80% agencies allocated resources for training, legal updates, and IT systems to support reliance use*

Flexibility:

- *Reliance is used as part of routine regulatory practice by most agencies (80%)*

Reliance is largely embedded in routine practice, supported by strong capacity and organisational uptake

≥50% agencies | **<50%** agencies

NOTE: Results in the process of validation

Current State of Regulatory Reliance within the Marketing Authorisation Function: High Adoption but Variable Implementation – Findings Based on Desk-based Research and Interviews with 10 agencies

Pathway type:

- *Most agencies have an abridged pathway in place (70%)*
- *Fewer having other reliance pathways in place i.e. recognition, verification, collaborative (<30%)*

Product type:

- *Reliance can be applied to multiple product types, with all agencies utilizing it for chemical entities and generics*

While

- *Use for other product types is more limited (combination products 40%, cell/gene therapies 30%, APIs 10%)*

Reference authority:

- *All agencies recognize multiple reference authorities, with FDA and Health Canada consistently included by all agencies*

Reliance is primarily implemented through abridged pathways across a wide range of product types, using established reference authorities

≥50% agencies | **<50%** agencies

NOTE: Results in the process of validation

Current State of Regulatory Reliance within the Marketing Authorisation Function: High Adoption but Variable Implementation – Findings Based on Desk-based Research and Interviews with 10 agencies

Most Common Reference Authority Documentation Requirements for Reliance

- *Certificate of Pharmaceutical Product (100%)*
- *Good Manufacturing Practices certificates (90%)*
- *Approval letters from the reference authority (80%)*
- *Batch certificates (50%)*

Sameness:
Confirming that the product is essentially the same as the one approved by the reference authority

- *While 70% agencies have a framework for assessing product sameness compared to the reference product*
- *Only 40% (4 agencies) use a specific template to undertake sameness evaluation*

Reference agency documentation requirements are largely aligned, while approaches to assessing product sameness are established but less consistently operationalised through structured templates

≥50% agencies | **<50%** agencies

NOTE: Results in the process of validation

Current State of Regulatory Reliance within the Marketing Authorisation Function: High Adoption but Variable Implementation – Findings Based on Desk-based Research and Interviews with 10 agencies

Target timelines:

- *Specified by 80% agencies*

However

- *Only 40% agencies monitor or evaluate the performance of reliance-based decisions*

Transparency:

- *All agencies publish information relating to implementation of reliance – list of reference authorities, list of documents required to undertake a reliance review*

However

- *Only 20% publish national adaptations/context-specific considerations*
- *Only 1 agency publishes rationale for reliance-based decisions*

Reliance systems are widely established, but operationalisation varies, with partial use of structured sameness tools, limited performance monitoring and variable transparency

≥50% agencies | **<50%** agencies

NOTE: Results in the process of validation

What Is Holding Back the Implementation of Regulatory Reliance? Insights from the 10 Regulatory Agencies

- **Top three per agency**

d) Resource constraints

a) Legal and regulatory framework

i) Differences in regulatory standards

f) Information access

g) Limited technical capacity

m) Unclear governance or procedures

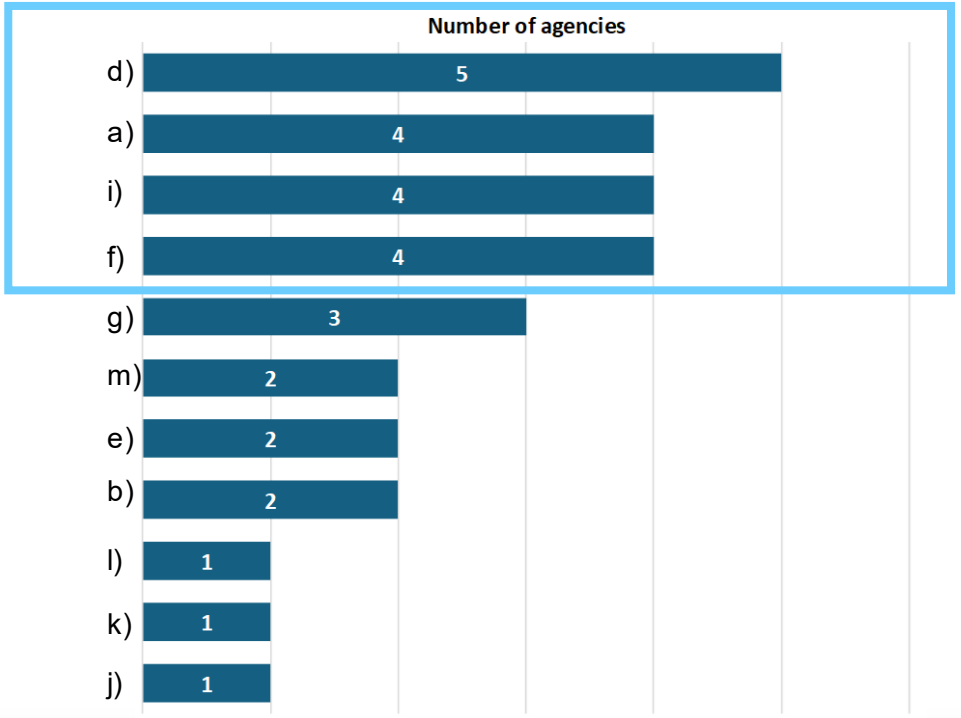
e) Trust and confidence issues

b) Institutional culture and resistance to change

l) Language and documentation barriers

k) Limited awareness or training

j) Lack of formal agreement



What are the Priority Actions Needed to Strengthen the Implementation of Regulatory Reliance? Insights from the 10 Regulatory Agencies

- **Top three per agency**

a) Legal and regulatory framework

b) Clear governance and procedures

i) Regional and international cooperation

h) Access to information

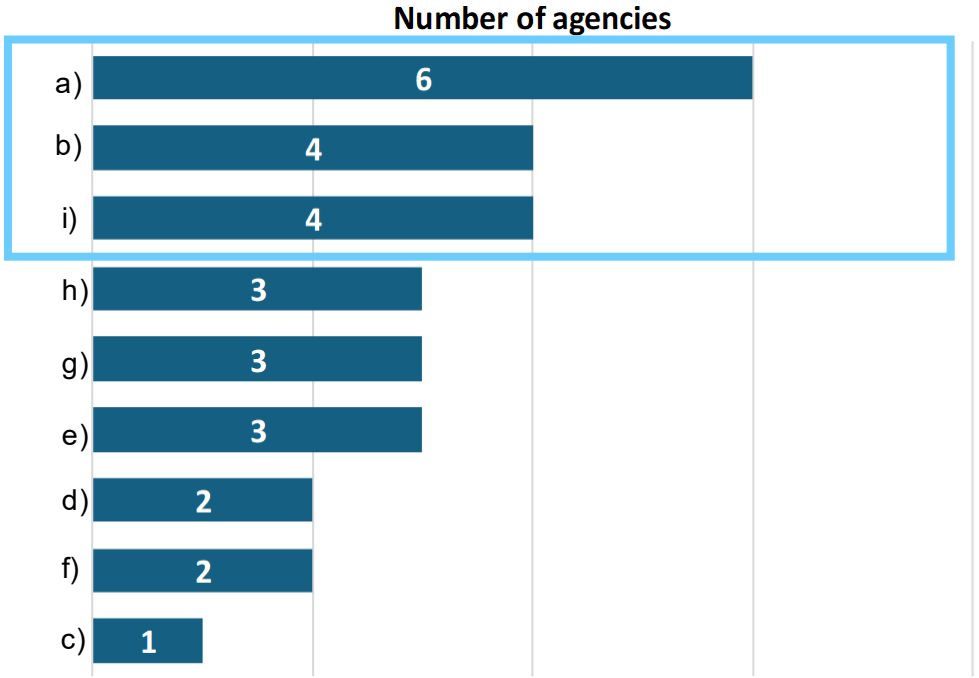
g) Monitoring and evaluation systems

e) Formal collaboration mechanisms

d) IT and digital infrastructure

f) Staff training and capacity building

c) Criteria and transparency



Key insights from agencies

What Is Established

- Reliance is legally enabled and increasingly institutionalised across the agencies
- Reliance is operational and routinely applied, particularly via abridged pathways
- WHO Good Reliance Practices are generally reflected and implemented
- Core implementation elements (documentation, reference authorities, target timelines) are largely defined
- Stakeholder engagement and consultation are consistently embedded
- Agencies are investing in capacity, training, and systems to support reliance

Key insights from agencies

What Could be Improved

- Legal frameworks and governance structures require further strengthening and clarification
- Operationalisation through SOPs, guidelines and structured processes is needed
- **Monitoring and evaluation of reliance performance and impact are underdeveloped**
- Technical implementation is not fully standardized, particularly in the assessment of product sameness, including limited use of structured templates
- Limited resource, differences in regulatory standards, as well as access to information continue to constrain implementation
- Regional and international cooperation needs to be expanded

Summary and next steps

Regulatory reliance is critical for strengthening regulatory systems globally and ensuring timely availability of medicines

CIRS has been developing a mechanism to monitor regulatory reliance reflecting the WHO Good Reliance Practices to support its effective implementation

Initially project focused on evaluating 10 LATAM agencies – all were actively engaged in the study process through CIRS Topic Group and structured interviews

Initial insights demonstrate that reliance is widely established and routinely implemented with strong legal foundations, stakeholder engagement and growing capacity, but its full effective operationalisation is constrained by the need for improved legal, governance and procedural clarity as well as resources

Continuous monitoring of reliance is key to enable collaborative learning, regulatory strengthening, improved predictability and consistency of processes and ultimately timely access of medicines to patients

Thank you to the 10 agencies and industry experts for their proactive engagement!
Gracias! Obrigada!

THANK YOU!

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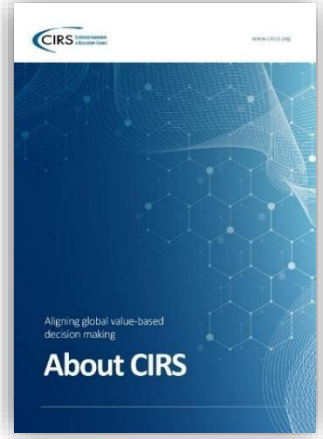
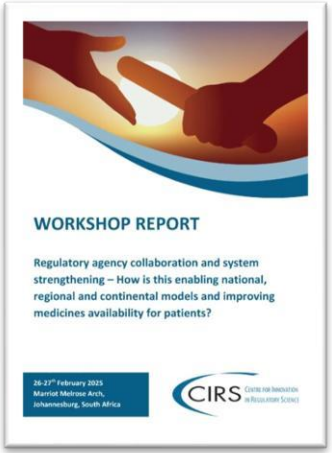
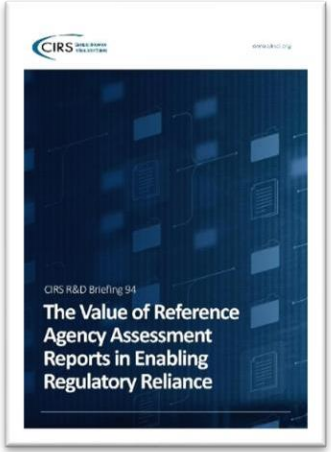
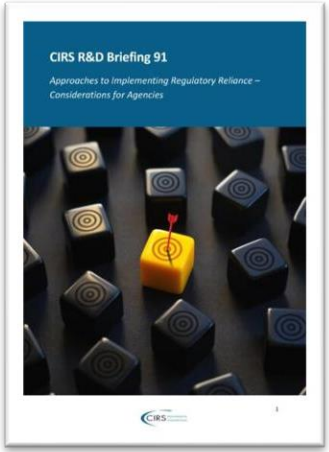


About CIRS







Further CIRS publications on reliance

https://cirsci.org/tag/reliance