Assessing the Implementation of Regulatory Reliance in Latin America

Analysis of the Use of Regulatory Reliance for New Marketing Authorisations Across 10 Latin American Countries

Final report

1 September 2026

CIRS Centre for Innovation in Regulatory Science

Outline

Outline

Policy relevance

Click to go back to Outline

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

An essential strategic component of public health infrastructure

Regulatory systems provide the legal, institutional, and operational frameworks through which authorities evaluate and approve medicinal products for safety, efficacy, and quality

- **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., adherence to ICH guidelines) have improved alignment, but **gaps remain across agencies**
- **Efficient review systems are increasingly important** to prevent patient access delays

WHO and PAHO recognise that strong regulatory systems are fundamental to ensuring the quality, safety, and efficacy of medical products, strengthening health systems and enabling timely access to medicines.

ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; **WHO:** World Health Organisation; PAHO: Pan American Health Organisation.

Why does regulatory reliance matter now in Latin America?

WHO and PAHO define reliance as the act whereby an NRA considers and gives significant weight to the assessments of another trusted authority, while retaining independent responsibility for its decisions.

WHO considers that reliance represents a smarter, more efficient way of regulating medical products in the modern world.

Latin American regulatory authorities face increasing pressure to improve timeliness of access to safe, effective, and quality-assured medical products, while operating under resource and capacity constraints

In Latin America, collaboration and reliance initiatives are already in place, reflecting early-stage adoption and experimentation, but with heterogeneous levels of maturity and implementation across agencies

Reliance provides an opportunity to further strengthen regulatory performance in jurisdictions and across the region

World Health Organization. Good reliance practices in the regulation of medical products: high-level principles and considerations. WHO Technical Report Series, No. 1033, Annex 10; 2021.

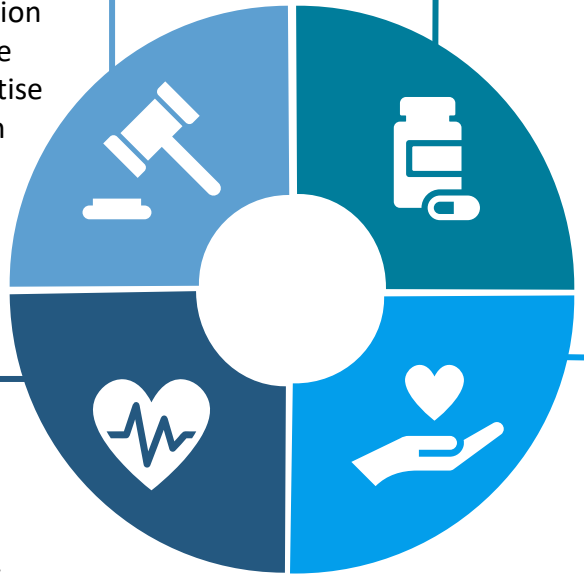
Shared Value of Reliance: Delivering Benefits Across the Health Ecosystem

Regulatory Agencies

- **Resource Optimisation:** Promotes reallocation in activities that only the NRA can undertake
- **Capacity Building:** Access to external expertise
- **Global Alignment:** Promotes harmonisation with international standards
- **Faster Approvals**
- **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

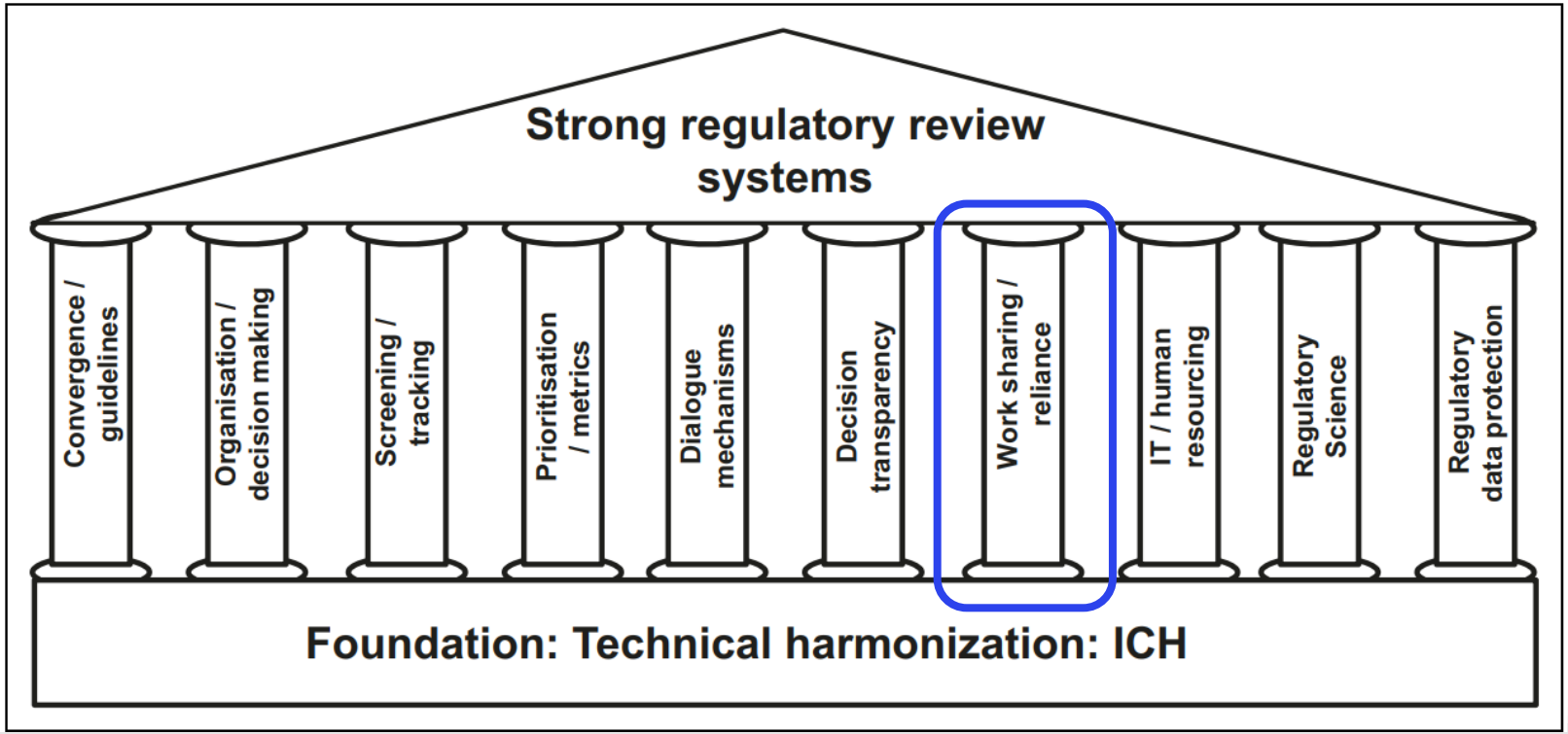
- **Timely Access to Medicines:** Faster availability of treatments
- **Confidence in Quality**
- **Better Continuity of Care:** Reduced delays in post-approval changes.

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

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.

Why is measuring the performance of reliance pathways important?

1

Implementation is only the first step

Adopting a reliance pathway does not by itself deliver regulatory benefit.

2

Systematic monitoring reveals performance

Evidence shows whether pathways meet their intended objectives.

3

Measurable outcomes demonstrate value

This may include shorter review timelines, optimized use of resources, greater efficiency and effectiveness.

4

Metrics support timely, assured roll out of medicines

Quicker availability of quality-assured medical products for patients.

5

Reporting drives improvement and trust

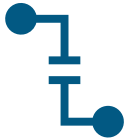
Transparency and accountability sustain alignment with WHO and PAHO good practices.

Reliance delivers value only when its performance is measured — systematic monitoring turns adoption into demonstrable regulatory impact.

Outline

Introduction

Problem statement



Despite increasing policy relevance, important gaps remain:

- Reliance is gaining traction globally and in Latin America, but implementation remains variable in scope, formality and operationalisation across agencies
- Approaches in Latin America have ranged from informal use of external assessments to more structured reliance pathways, reflecting differences in legal frameworks and institutional capacity

Challenges in operationalising reliance effectively:

- Limited clarity on how reliance should be applied in practice
- Leveraging reference NRA outcomes while maintaining national decision-making responsibilities and accounting for local regulatory context
- Building trust, transparency and consistency within and among authorities and the regulated industry

Problem statement

Alignment with good reliance practices is not well understood:

- The World Health Organization Good Reliance Practices (GRelP) provide a globally recognised framework for implementing reliance
- However, there is limited visibility on how closely current practices align with these principles across Latin American agencies

Lack of systematic monitoring limits progress:

- Data on practical implementation of reliance pathways are not consistently collected or analysed
- This constrains the ability to assess impact and effectiveness, identify good practices and gaps and support continuous improvement and regional convergence

Resulting need - A more systematic understanding of how reliance is implemented, monitored, and aligned with good practices is needed to support evidence-based strengthening of reliance pathways in Latin America

Objectives of the study

- Assess the implementation of reliance in selected countries
- Identify barriers and enablers (legal, operational and cultural factors) for effective implementation of reliance
- Assess the extent to which current reliance practices reflect good reliance principles, as stated by WHO Annex 10
- Identify opportunities for alignment with international good practice, identifying gaps and areas for improvement
- Create a platform for ongoing strategic discussions among multidisciplinary experts to enhance cooperation
- Foster collaboration and knowledge exchange within the region to build capacity, enhance regulatory efficiency and harmonisation

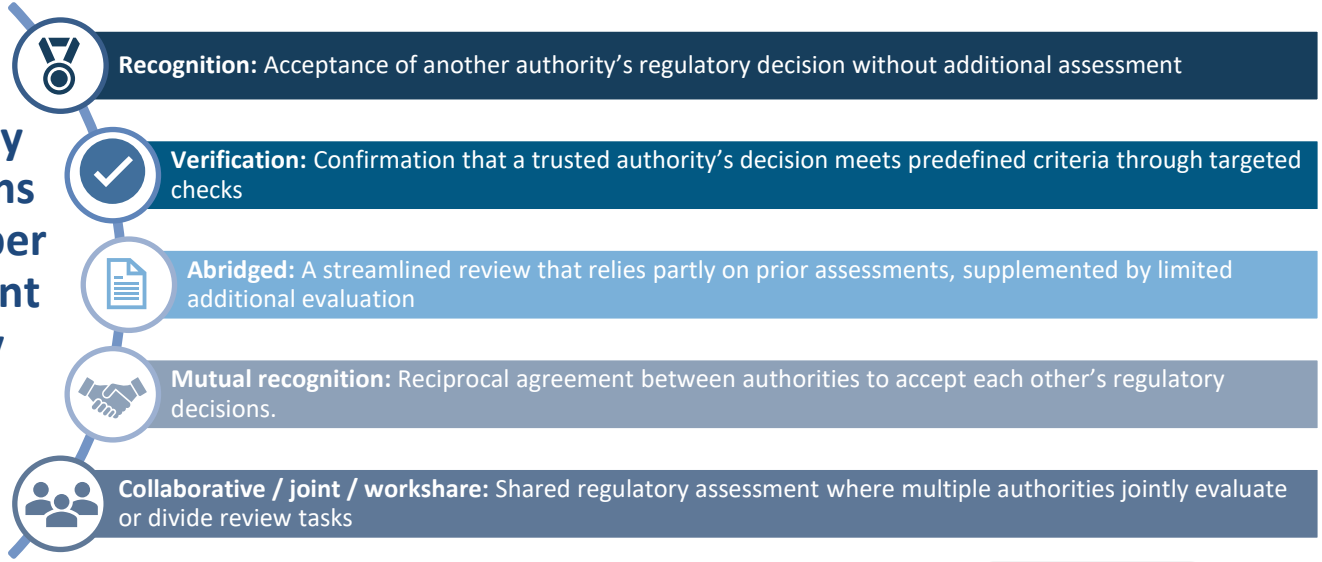
Study impact

Outline

Method

Regulatory Functions Assessed and Reliance Pathways in Scope

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



New marketing authorisations (MA)*

Post-approval changes

Good manufacturing practices inspections

Approval of clinical research protocols

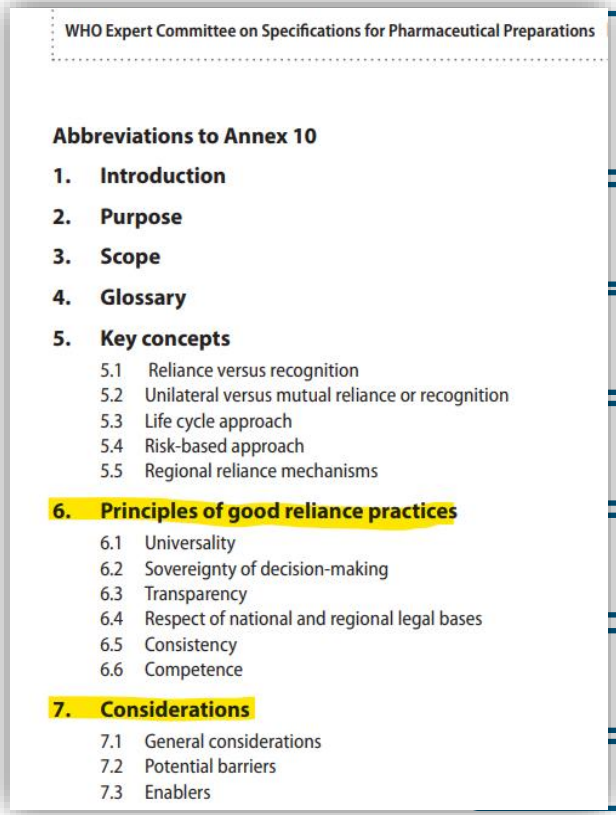
Batch release of biological products and vaccines

*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

Method



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

Governance: Research was supported by a Topic Group initiated by CIRS (under its Scientific Advisory Council) composed of all ten agencies studied, as well as Swissmedic (Chair), ANVISA (co-chair), the European Medicines Agency and expert industry representatives.

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

Tailored **Excel-based data collection tool** (45 questions and subquestions) - to ensure structured, comparable, and meaningful data across the participating countries

Desk based research: The tool was initially used to review publicly available guidelines and documents*

Interviews: The data collected was then validated and supplemented through interviews with agencies to obtain agency experience and perspectives

All 10 agencies have actively participated in the research - some agencies are still validating the information following structured interviews

Industry experts were also engaged and provided feedback on the information collected

*FIFARMA provided CIRS with the lists of the regulatory frameworks and guidelines for each country which was peer-reviewed by CIRS and then verified by each agency

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

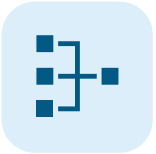
Country	Agency
Argentina	National Administration of Drugs, Foods and Medical Devices (ANMAT)
Brazil	Brazilian Health Regulatory Agency (ANVISA)
Chile	Institute of Public Health of Chile (ISP)
Colombia	National Institute for Food and Drug Surveillance (INVIMA)
Costa Rica	Department for the Regulation of Health Products of Interest (DRPIS, Ministry of Health)
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

Only regulatory frameworks meeting all four criteria were included in the analysis.

Existence of an official, written, and publicly available procedure

The country's regulatory authority had issued a formal regulatory document, publicly available, establishing a reliance mechanism.



Definition of recognised Reference Regulatory Authorities

The regulatory framework explicitly identified the international regulatory authorities whose assessments or decisions could be used as a basis for the reliance process.

Clear definition of the regulatory functions to which reliance applies

The framework specified whether reliance was applicable to areas such as new marketing authorisations, vaccine lot release, or other specific regulatory functions.

Description of how the reliance mechanism is implemented

The framework provided information on how the process operates in practice, including its main steps, documentation requirements, and the conditions under which the decision of a reference authority may be relied upon.

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 May, 2026	***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.*** ***ASS-RSA-IN72 – Instructions for the Use of Regulatory Decisions of Other Jurisdictions (UDROJ); Reliance Project Presentation Form – UDROJ Type 1 and Type 2 (being published)***

This table reflect examples of regulatory documents for this research consulted as of 1st April 2024

Regulatory Reliance Pathways in Latin America: Regulations Used as the Formal Basis for the Analysis *(cont.)*

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*

This table reflect examples of regulatory documents for this research consulted as of 1st April 2024

Regulatory Reliance Pathways in Latin America: Regulations Used as the Formal Basis for the Analysis *(cont.)*

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*

This table reflect examples of regulatory documents for this research consulted as of 1st April 2024

Method - Phases

Phase 1:
Planning and preparation
Q3-4 2025

- Establish project framework
- Data collection tool (DCT) development – questions developed relating to GRelP Annex 10
- Topic Group formation and stakeholder engagement

Phase 2:
Data collection (MA function)
Q4 2025-Q1 2026

- Desk based research by CIRS to complete the DCT – focus on theoretical application based on guidelines and public domain data
- Interviews with agencies to validate the DCT – focus on practical application based on experience

Phase 3:
Analysis and reporting (MA function)
Q1 2026

- Analysis of reliance processes, practices in line with GRelP
- Development of recommendations

Phase 4:
Report launch, engagement and further research
Q2 2026

- Publication of main study report for MA function
- External presentations
- Continuation of analysis for 4 other functions

Topic group engagement

Method – Governance - Topic Group participants

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*
- Eight specialists from FIFARMA
- CIRS representatives

Method - Data collection tool - Background

Approach developed by **CIRS** to continuously monitor the use of regulatory reliance as well as to identify trends, differences and similarities within the region

Tailored Excel-based data collection tool to ensure structured, comparable, and meaningful data across the participating countries

The goal of the data collection is to assess the agency reliance mechanisms as well as implementation in line with WHO Annex **10 Good Reliance Practices**, based on existing guidances, as well as based on real-world application and stakeholder experience - the tool was firstly used for desk-based research and the information collected has being validated and completed through interviews with agencies (some agencies are still validating the information following structured interviews)

Feedback from industry was collected, reviewed and incorporated

Method - data collection tool - structure

45 Questions and subquestions were developed relating to the WHO Annex 10 GRelP:

- **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

Mix of question types: Single-choice, multiple-selection, and free-text ("specify," "examples") fields, enabling both quantitative and qualitative capture

Questions are asked either at:

- **Country level** - Focuses on governance, legal frameworks, stakeholder engagement, and enablers or barriers in reliance implementation
- **Function level** - Select a regulatory function (initial focus on MA only), then record pathway types, product scope, recognised reference authorities, and required documents—supporting granular, risk-based operational mapping
- **Marketing authorisation (MA)-specific question** - Captures publication practices, target timelines, access to confidential materials, utilisation rates, time-to-approval comparisons, cost impacts, and product sameness frameworks/tool

Method - Data Collection Tool - Example Questions

Type of question	Country level	Function level (for different pathways)	MA-specific
Example question	CL1. Does your agency have any of the following that support the use of regulatory reliance? (Multiple selection possible):	FL3. Which types of products are within the scope for reliance? (Multiple selection possible)	MA1. What information does your agency publish in relation to implementation of reliance? (Multiple selection possible)
Example responses	a) National law or regulation b) Ministerial policy or directive c) Formal mutual/bilateral agreement d) Agency guideline/guidance etc.	a) Chemical entities b) Biological products c) Biosimilars d) Cell and gene therapies e) Active pharmaceutical ingredients etc.	a) List of reference regulatory authorities b) The criteria used in identifying reference authorities c) General criteria for using reliance etc.
WHO GRelP	6.4 Respect of legal bases	6.1 Universality	7.1 General consideration

Data Sources and Validation Approach

Data collected on 10 regulatory agencies based on publicly available information*

Structured interviews with regulatory agencies to validate desk-based research and to obtain agency perspective

Publicly available agency information further reviewed by industry experts

*FIFARMA provided CIRS with regulatory frameworks for each country. These were peer-reviewed by CIRS, complemented with information gathered from agency websites, news releases, and other agency reports/publications, and subsequently validated by the respective agencies during the structured interviews.

Country	NRA	Role within the Observatory	Agency interview date	Status of DCT validation	Permission to share results	Additional notes
ARG	ANMAT	Member	04/03/2026	Completed	✓	Agency reps: IAO; MAO-SM
BRA	ANVISA	Member	12/02/2026	Completed	✓	Agency reps: IAO; MAO-SM
CHI	ANAMED-ISP	Member	02/03/2026	Completed	✓	Agency reps: HoA; MAO-BP
COL	INVIMA	Member	06/03/2026	Completed	✓	Agency reps: IAO; MAO-BP
CRI	DRPIRS-MINSA	Member	03/03/2026	Completed	✓	Agency reps: MAO-BP
DOM	DIGEMAPS-MINSA	Member	30/03/2026	Completed	✓	Agency reps: IAO; MAO-SM&BP
ECU	ARCSA	Member	12/03/2026	Completed	TBC	Agency reps: MAO-SM&BP
MEX	COFEPRIS	Member	NA	NA (data based on public domain only)	NA	Interview not held. DCT validated by IAO & SPO
PAN	DNFD-MINSA	Member	12/03/2026	Completed	✓	Agency reps: HoA; MAO-SM&BP
PER	DIGEMID-MINSA	Member	24/03/2026	Completed	✓	Agency reps: IAO; MAO-SM&BP

As of 26th June 2026

Abbreviations: TBC: To Be Confirmed; IAO: International Affairs Office; MAO: Marketing Authorisation Office; SM: Small Molecules; BP: Biological Products; HoA: Head of Agency; SPO: Sanitary Promotion Office; NA: Not applicable

Data governance

- All information collected from agencies through interviews kept strictly confidential and stored securely by CIRS
- All data handling and analysis undertaken by CIRS
- External reports or presentations of the confidential data to include only anonymous figures and any appropriate analytical interpretation
- Organisational data to be provided to the relevant organisation concerned
- No data that will identify an individual to be reported, or details made available to a third party
- Publishing of results in a country-identified (non-aggregated) format within the published study outputs - in line with the transparency principle – only to be possible with agency permission

The Centre for Innovation in Regulatory Science has over 25 years' experience in handling detailed, confidential information. The continuing and growing support for the CIRS surveys demonstrates the confidence which respondents place on its integrity.

Deliverables

Comprehensive report (to be published) integrating all findings of the study

- Overall results – analysis of process and practices across the countries
- Gap analysis and benchmarking against WHO recommendations and international best practices (GRelP) Strategic and actionable recommendations for improving reliance mechanisms
- Executive summary for dissemination among external audience

White Papers Per Country

Individual reports for each of the 10 countries, outlining the current status of regulatory reliance mechanisms and improvement opportunities in the key regulatory functions

Presentations and knowledge sharing session to present findings, discuss implications, and respond to questions

Interactive Monitoring Platform

Development of proposal for a digital dashboard that enables real-time, user-friendly monitoring and visualisation of key study results and indicators across countries. The actual development of the platform will be undertaken in subsequent project phases (post 2026)

Study limitations

- **Scope:** Limited to 10 LATAM agencies only, may not accurately reflect the region
- **Variability in public data availability:** Some agencies publish only limited information and documents relating to the reliance pathway
- **Differences in agency maturity levels:** Limit generalisability and the ability to draw direct comparisons across agencies, as outcomes may reflect capability and context rather than the degree of implementation of reliance pathways
- **Agency insights:** Based on perception rather than verification of evidence or practice; heterogeneity due to differences in who responded to the interview (e.g. different departments such as marketing authorisation and/or international office)
- **Industry insights:** Still being collected; currently the results do not take into account company feedback

Outline

Summary of Results

As of 26th June 2026

Click to go back to Outline

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 (70%)*
- *Fewer having formal mutual/bilateral agreements (40%) or internal SOPs (50%)*

Strategy:

- *Most agencies have a national reliance strategy in place (70%), 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 (90%)*

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

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 their reviewers, mainly through the involvement of senior staff in reliance activities (80%)* • *80% agencies undertake activities to foster cultural and organisational acceptance of reliance* • *90% 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 all agencies (100%)*

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

>50% agencies

≤50% agencies

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 utilising it for chemical entities and generics*

While

- *Use for other product types is more limited (combination products 50%, cell/gene therapies 40%, APIs 20%)*

Reference authority:

- *All agencies recognise multiple reference authorities, with FDA, Health Canada, MHRA and TGA 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

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 (90%)*
- *Good Manufacturing Practices certificates (90%)*
- *Approval letters from the reference authority (70%)*
- *Batch certificates (50%)*

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

- *While 90% of agencies have a framework for assessing product sameness compared to the reference product*
- *Only 50% (5 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

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 90% agencies*

However

- *Only 40% of 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 limited performance monitoring and variable transparency and publication practices

>50% agencies

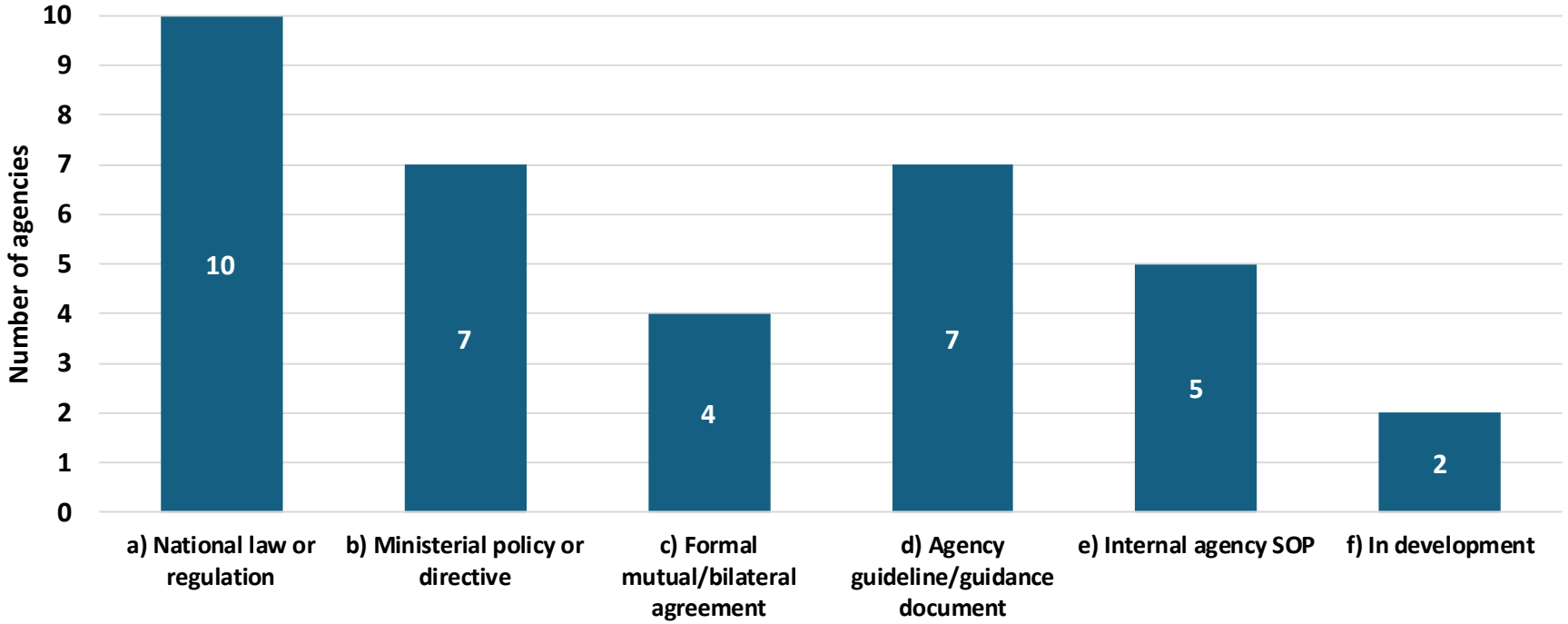
≤50% agencies

Country level questions

Click to go back to Outline

Regulatory Mechanisms Supporting the Use of Reliance Across Agencies

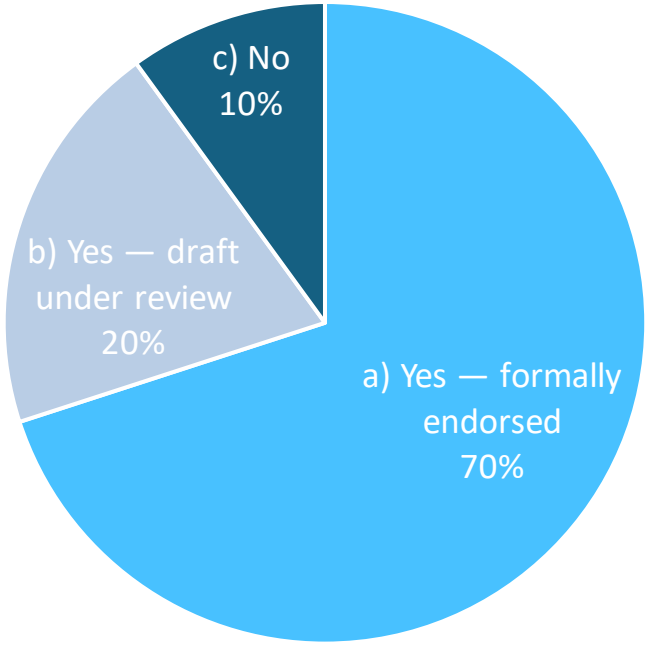
***CL-1:** Does your agency have any of the following that support the use of regulatory reliance?*



NOTE: Multiple selection possible across the 10 agencies

Status of National Reliance Strategies and Level of Endorsement by Senior Management Across Agencies

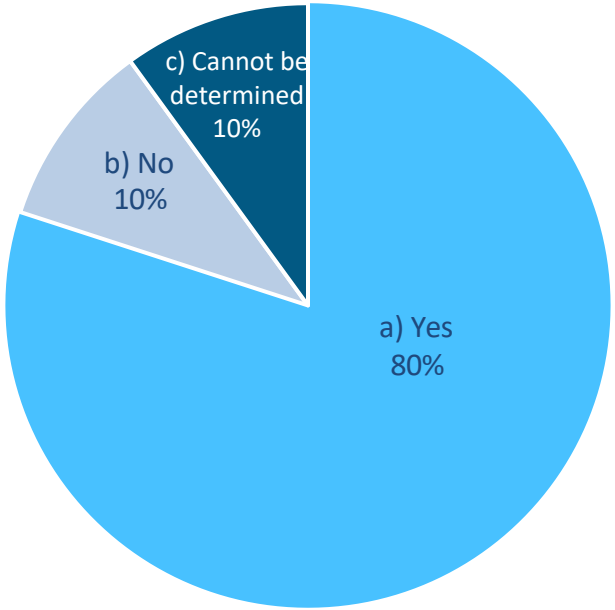
CL-2: *Does your agency have a national strategy (endorsed by senior management) on how to apply reliance?*



n = 10

Alignment of Reliance Strategies with Internal Capacity and Public Health Needs

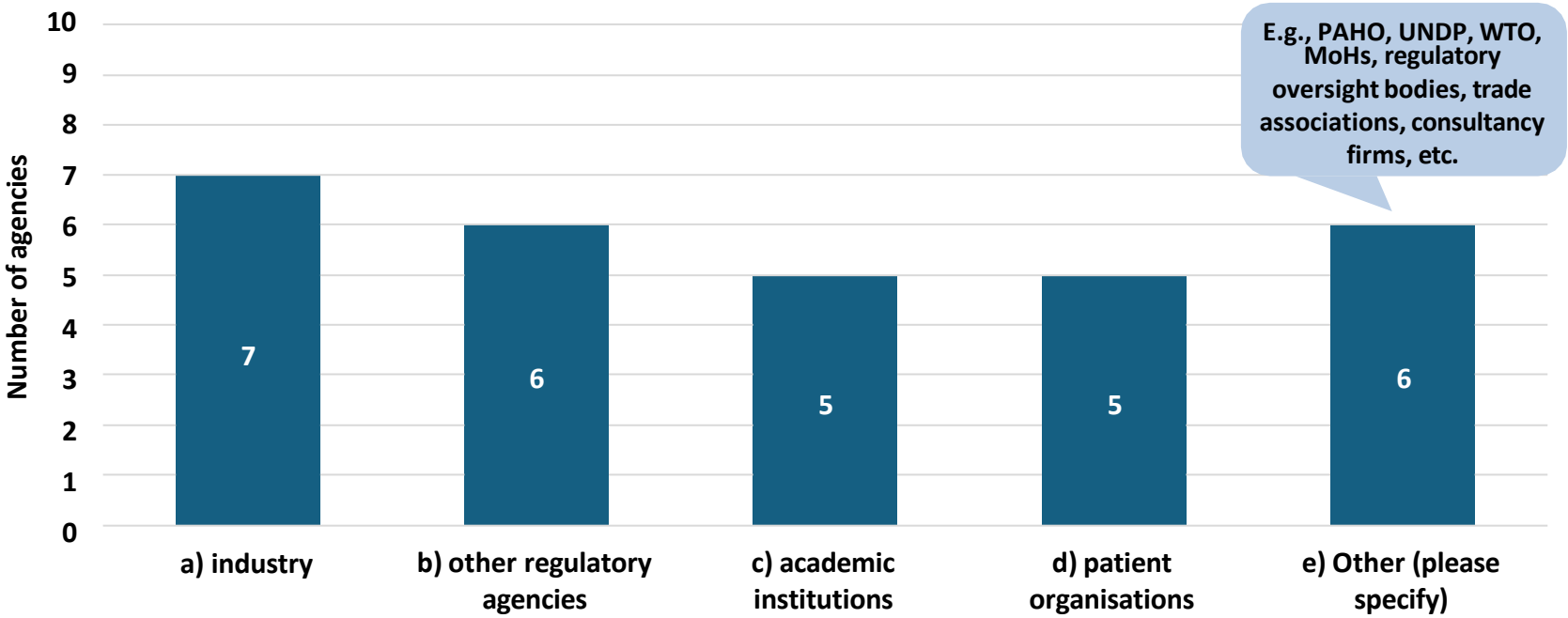
CL-3: *Has the agency tailored its reliance strategies to align with its internal resources/capacity and national public health needs?*



n = 10

Involvement of External Stakeholders in the Development of Reliance Strategies

***CL-4:** Has the agency involved external stakeholders in developing its reliance strategy?*

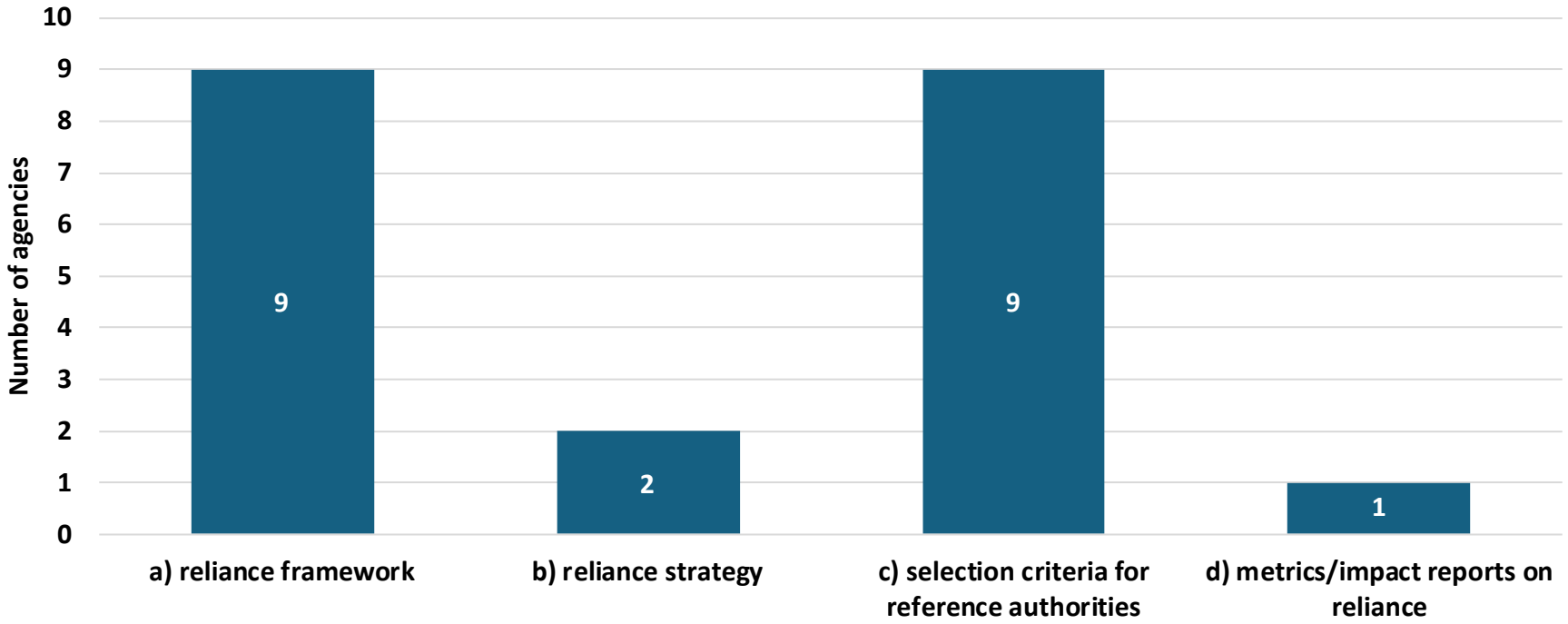


All ten jurisdictions legally allow participation beyond industry through procedurally open consultations.

NOTE: Multiple selection possible across the 10 agencies

Publication Practices of Regulatory Agencies on Reliance

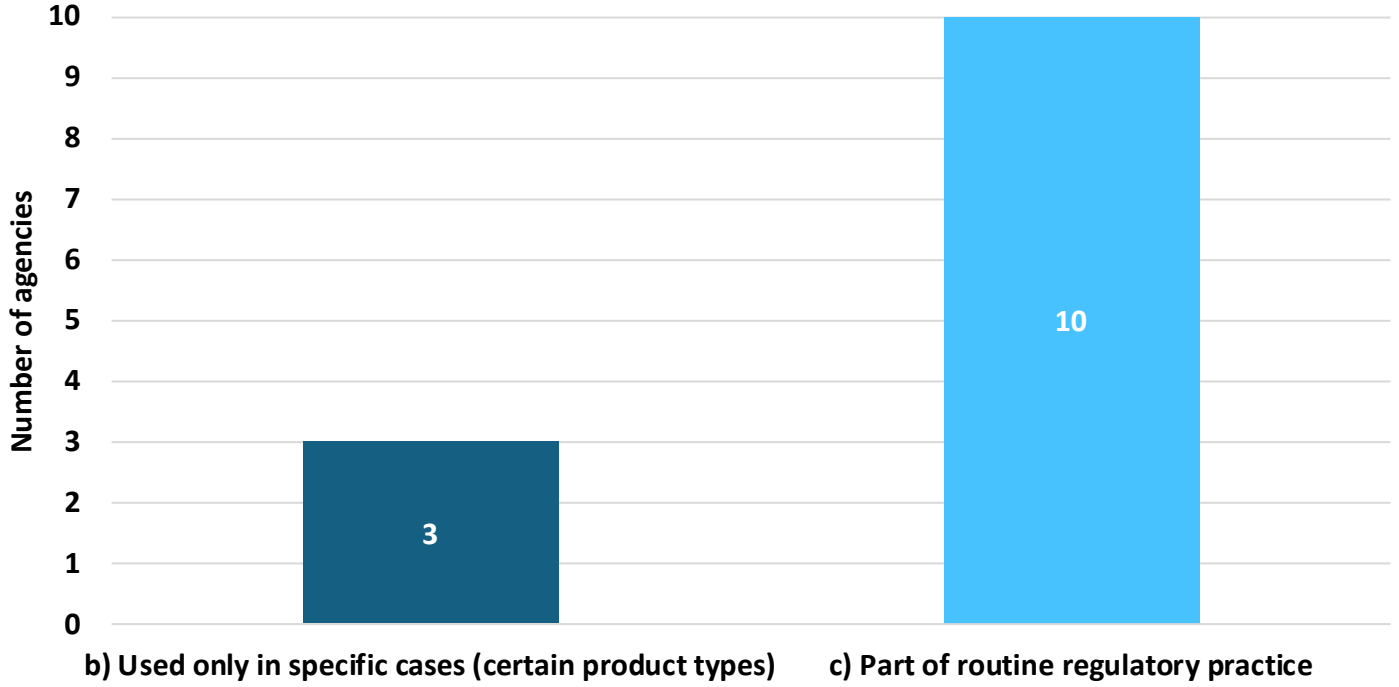
CL-5: *Does your agency publish any of the following?*



NOTE: Multiple selection possible across the 10 agencies

Reliance as a Routine Regulatory Practice Across Agencies

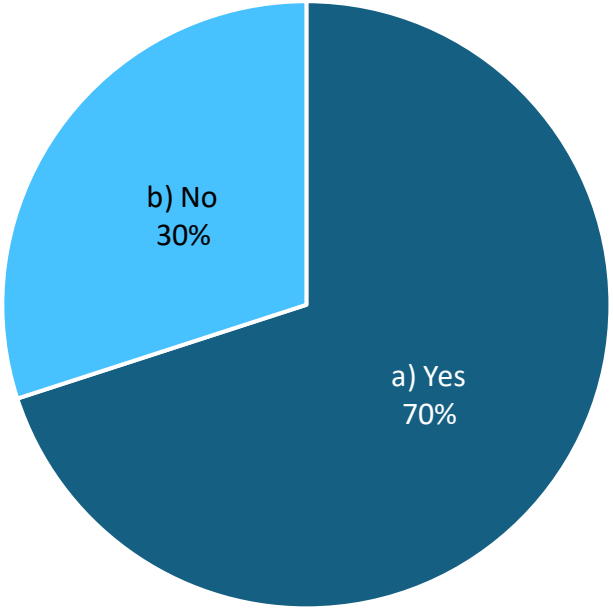
CL-6: *Is reliance used only in specific cases (e.g., emergencies, certain product types), or is it part of routine regulatory practice?*



Note: Multiple selection possible across the 10 agencies. Several agencies operate multiple reliance pathways, which may be used in routine or specific regulatory contexts.

Use of Reliance to Accelerate Access During Public Health Emergencies

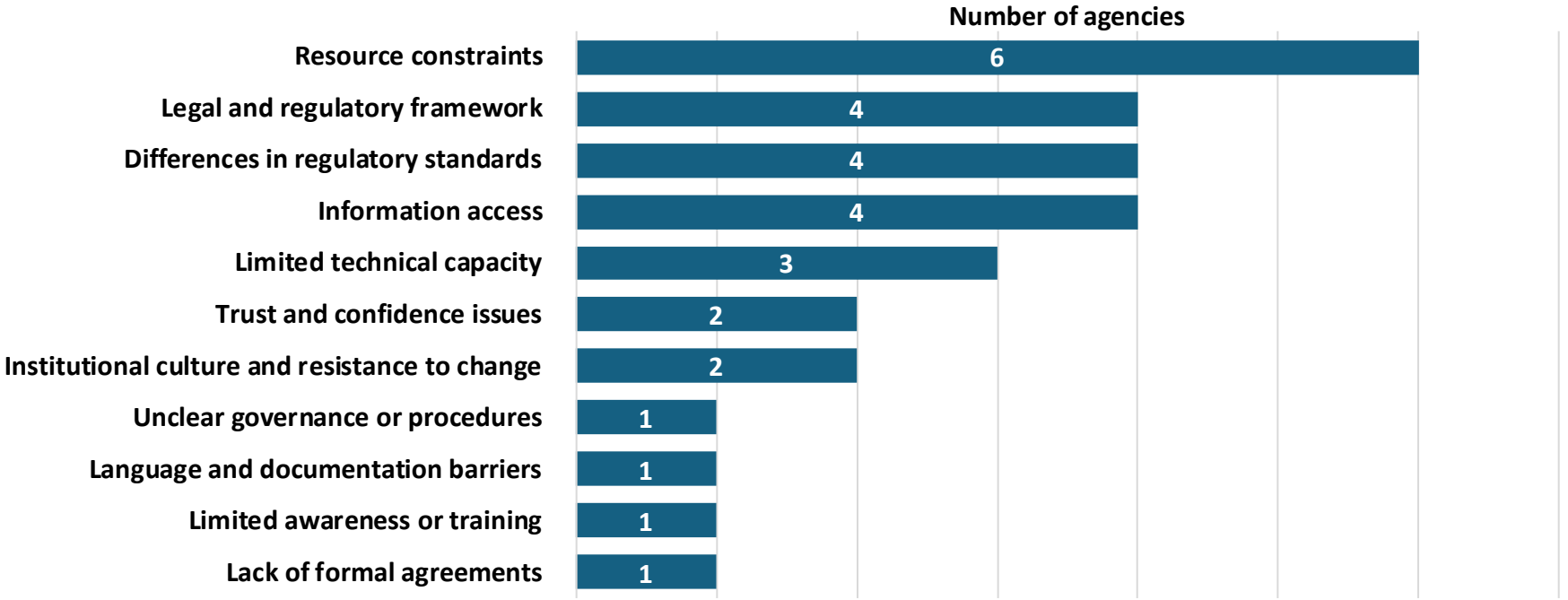
CL-7: *In case of a public emergency, are reliance approaches prioritised to accelerate access to the medical products required?*



n = 10

Key Barriers to the Implementation of Reliance Across Agencies

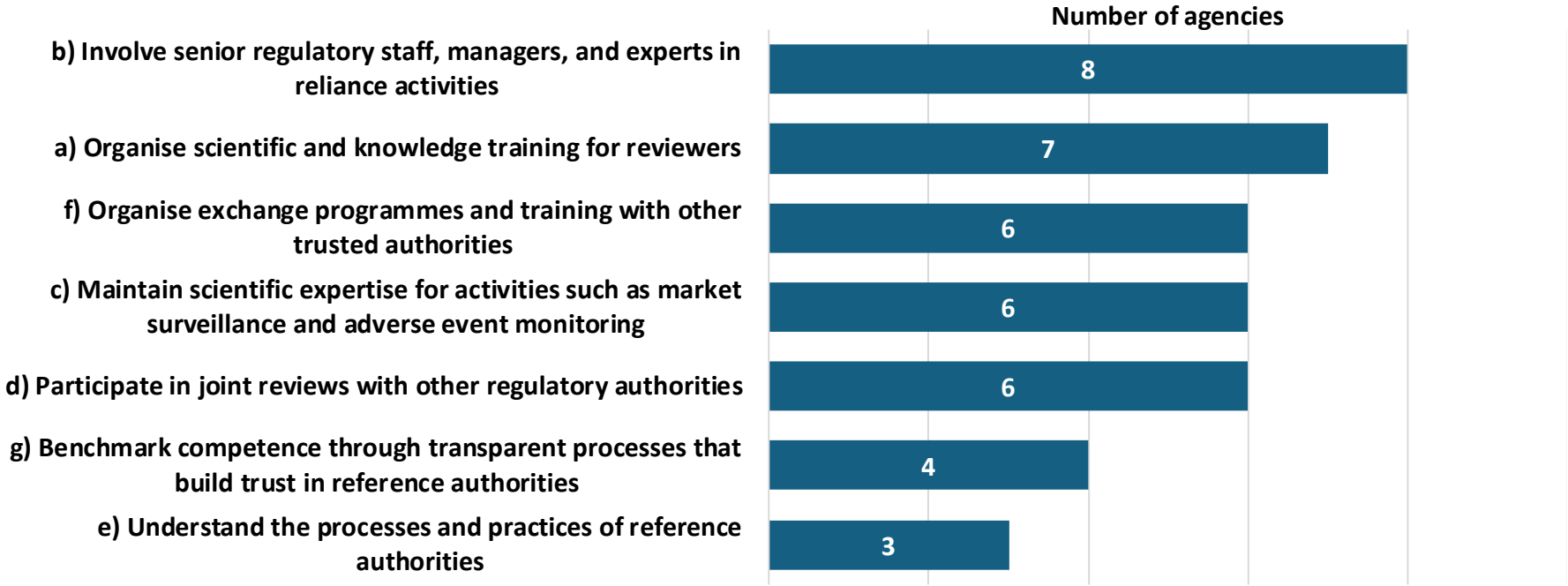
CL-8: *Which of the following are the main barriers to the implementation of reliance in your agency? (Top three per agency)*



NOTE: Multiple selection possible across the 10 agencies

Approaches to Building Regulatory Capacity of Reliance

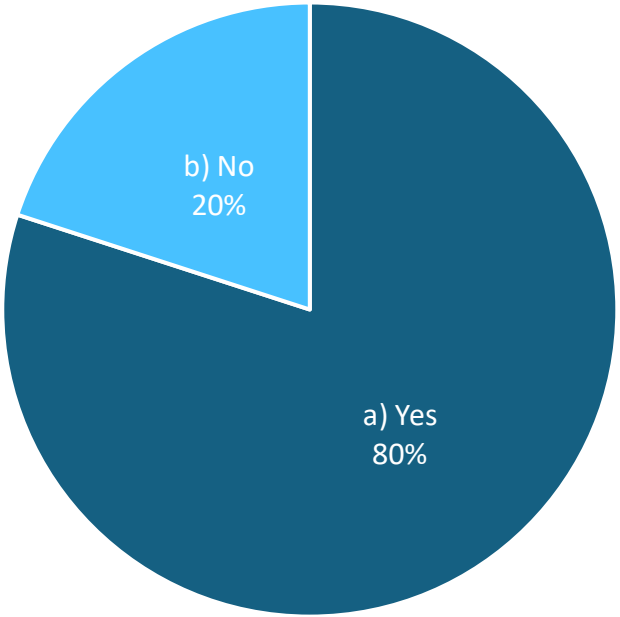
CL-9: *How does the NRA ensure the necessary competence for reliance-based decision-making across its reviewers?*



NOTE: Multiple selection possible across the 10 agencies

Fostering Organisational Acceptance of Reliance Across Agencies

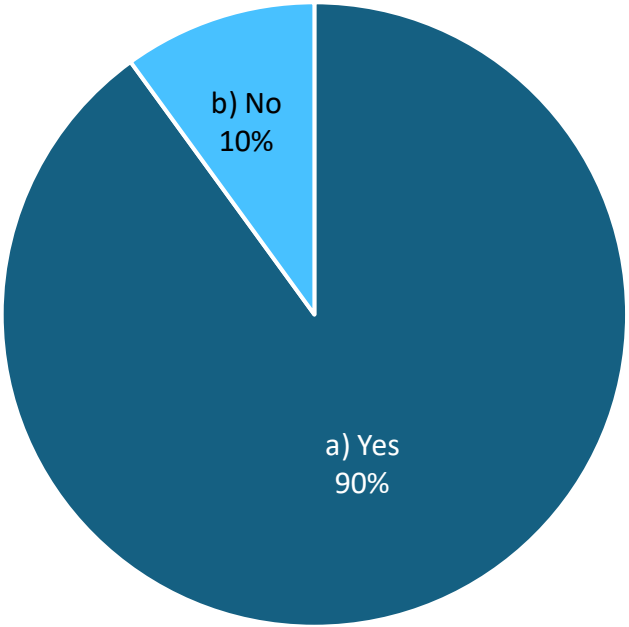
CL-10: *Has your agency undertaken activities to foster cultural and organisational acceptance of reliance (e.g., internal communications, trainings, pilot projects)?*



n = 10

Allocation of Resources to Support Reliance Implementation

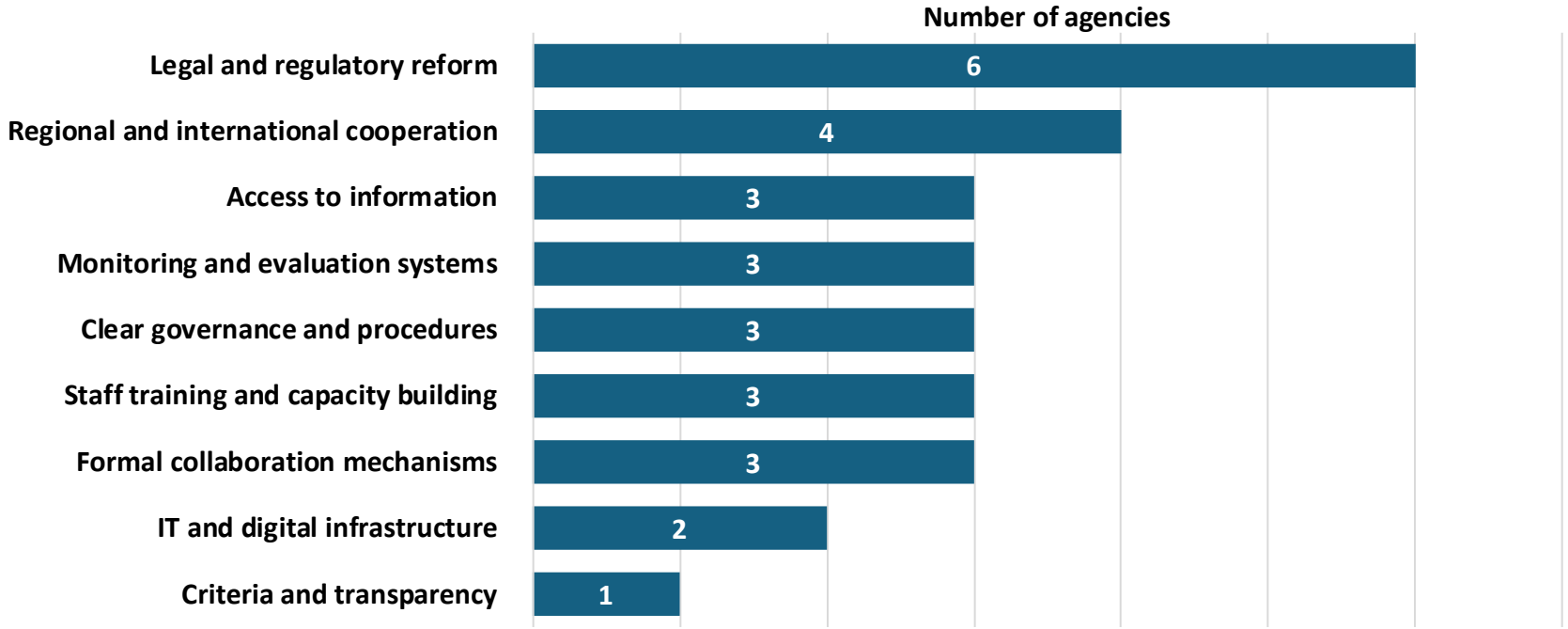
CL-11: *Has your agency allocated resources for training, legal updates, and IT systems to support reliance?*



n = 10

Priority Areas for Strengthening Reliance Across Agencies

CL-12: *What improvements or changes would be necessary to strengthen the use of reliance in your regulatory system across the five functions? (Top three per agency)*

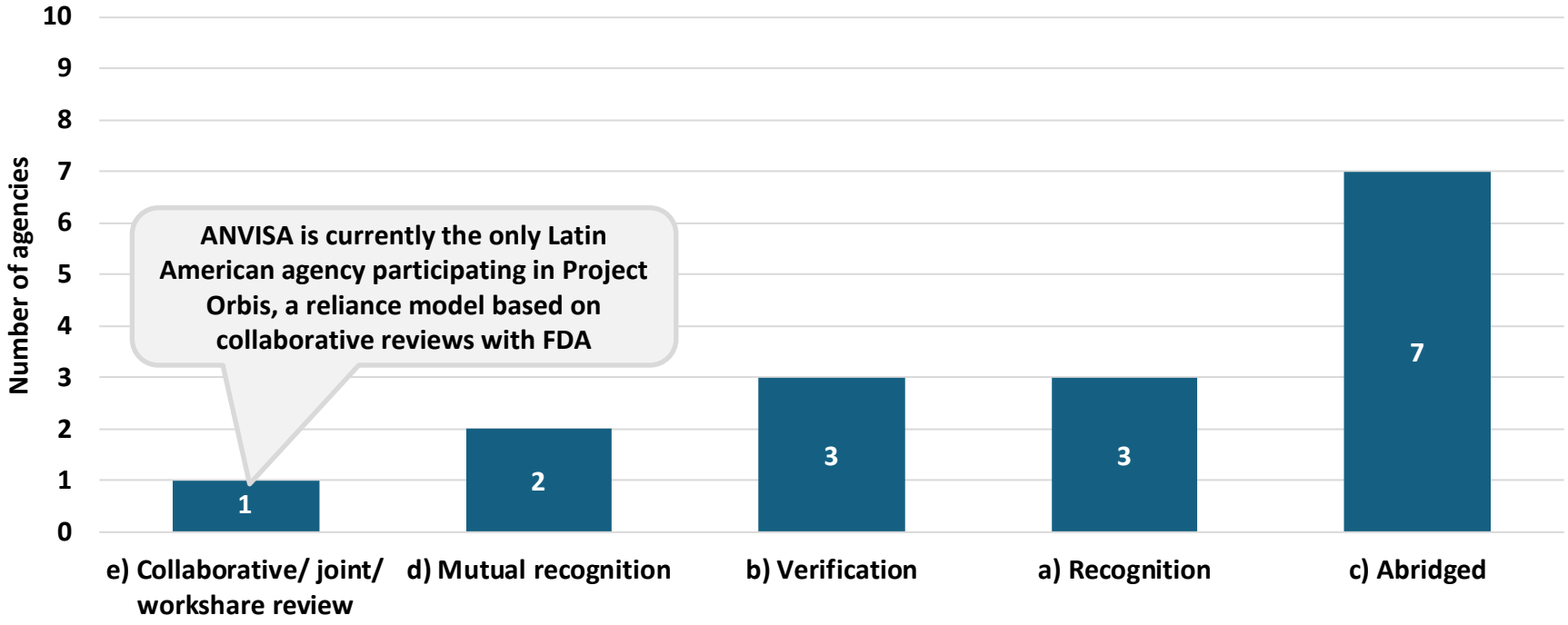


NOTE: Multiple selection possible across the 10 agencies

Function-level questions: Marketing authorisation

Types of Reliance Pathways Implemented Across Agencies

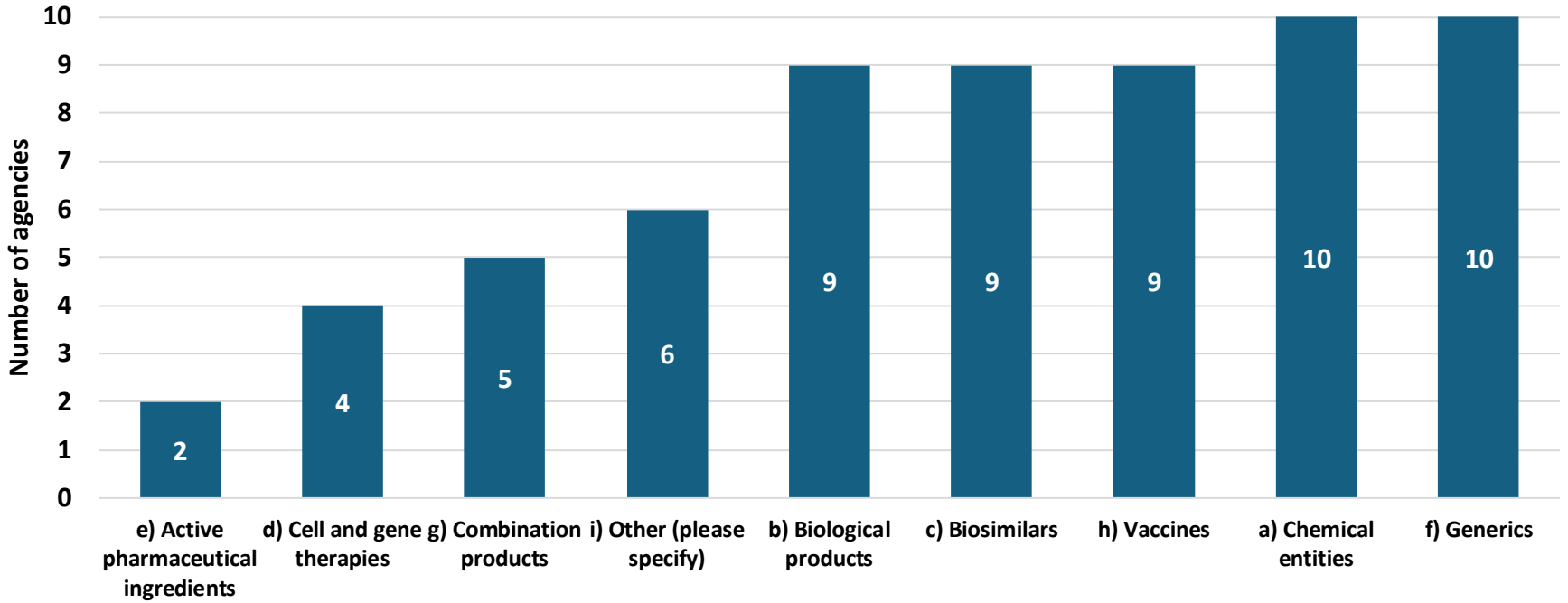
FL-2: Which reliance pathways/modalities are available?



NOTE: Multiple selection possible across the 10 agencies. Project Orbis is a global collaborative review initiative established by the FDA in 2019 to facilitate the concurrent assessment of innovative oncology products by multiple regulatory authorities, supporting earlier patient access and enhanced international regulatory collaboration.

Product Types within the Scope of Reliance Across Agencies

FL-3: Which types of products are within the scope for reliance?



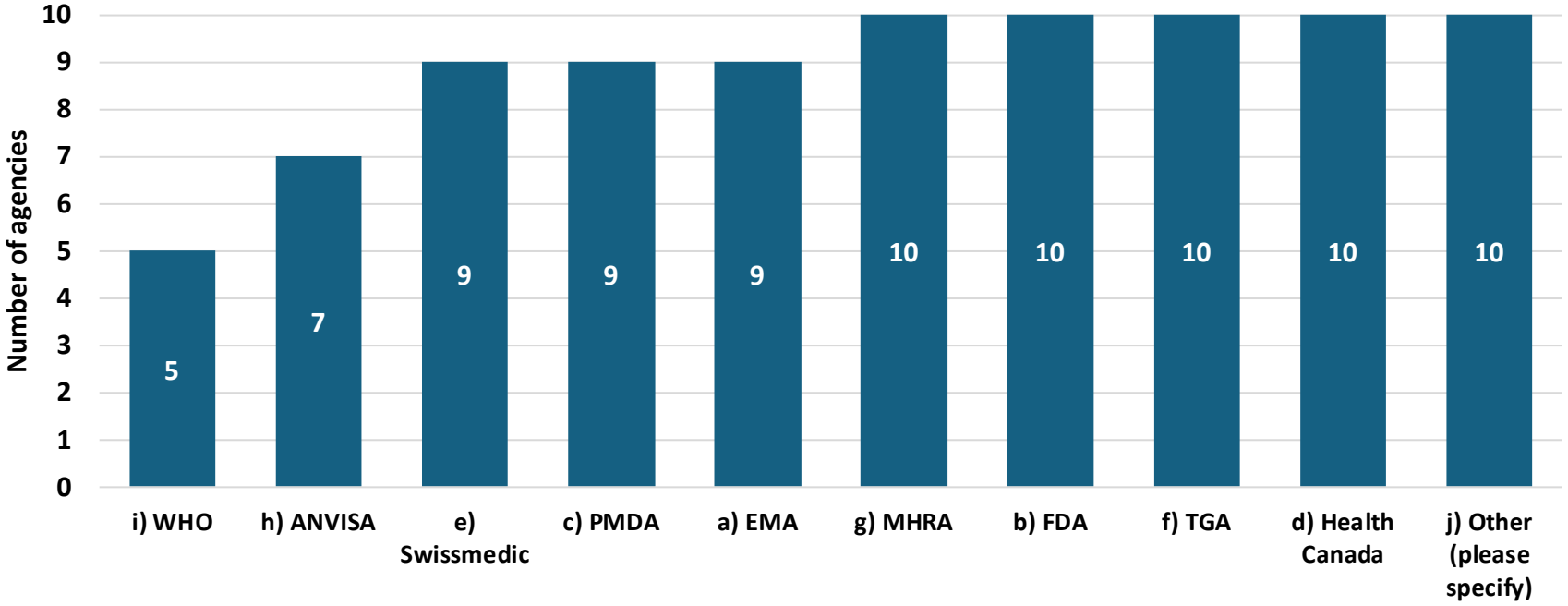
NOTE: Multiple selection possible across the 10 agencies

Eligible Medical Products for Regulatory Reliance in New Marketing Authorisations

Country	Chemical entities	Biological Products	Vaccines	Biosimilars	Generics	Active pharmaceutical ingredients	Combination Products	Cell and gene therapies	Other
Argentina	✓	X	X	X	✓	X	X	X	✓
Brazil	✓	✓	✓	✓	✓	✓	✓	X	✓
Chile	✓	✓	✓	✓	✓	X	X	✓	✓
Colombia	✓	✓	✓	✓	✓	X	X	X	X
Costa Rica	✓	✓	✓	✓	✓	X	X	X	✓
Dominican Republic	✓	✓	✓	✓	✓	X	✓	X	X
Ecuador	✓	✓	✓	✓	✓	X	✓	✓	X
Mexico	✓	✓	✓	✓	✓	✓	✓	✓	✓
Panama	✓	✓	✓	✓	✓	X	X	X	X
Peru	✓	✓	✓	✓	✓	X	✓	✓	✓

Officially Recognised Reference Authorities for Reliance

FL-4: Which reference regulatory authorities are officially recognised by your agency for the application of reliance mechanisms?



NOTE: Multiple selection possible across the 10 agencies

Officially Recognised Reference Regulatory Agencies for Regulatory Reliance in New Marketing Authorisations

Country	EMA	FDA	PMDA	Health Canada	Swissmedic	TGA	MHRA	ANVISA	WHO	Other
Argentina	✓	✓	✓	✓	X	✓	✓	✓	X	✓
Brazil	✓	✓	✓	✓	✓	✓	✓	X	✓	✓
Chile	✓	✓	✓	✓	✓	✓	✓	✓	X	✓
Colombia	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Costa Rica	✓	✓	X	✓	✓	✓	✓	✓	X	✓
Dominican Republic	✓	✓	✓	✓	✓	✓	✓	✓	X	✓
Ecuador	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mexico	✓	✓	✓	✓	✓	✓	✓	X	✓	✓
Panama	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Peru	X	✓	✓	✓	✓	✓	✓	X	X	✓

Latin American countries also recognise other regulatory agencies and global organisations within the region—such as Chile, Colombia, Cuba, and Mexico—as reference authorities. In addition, they consider authorities from countries including Finland, Hungary, Ireland, China, Luxembourg, Norway, New Zealand, and India.

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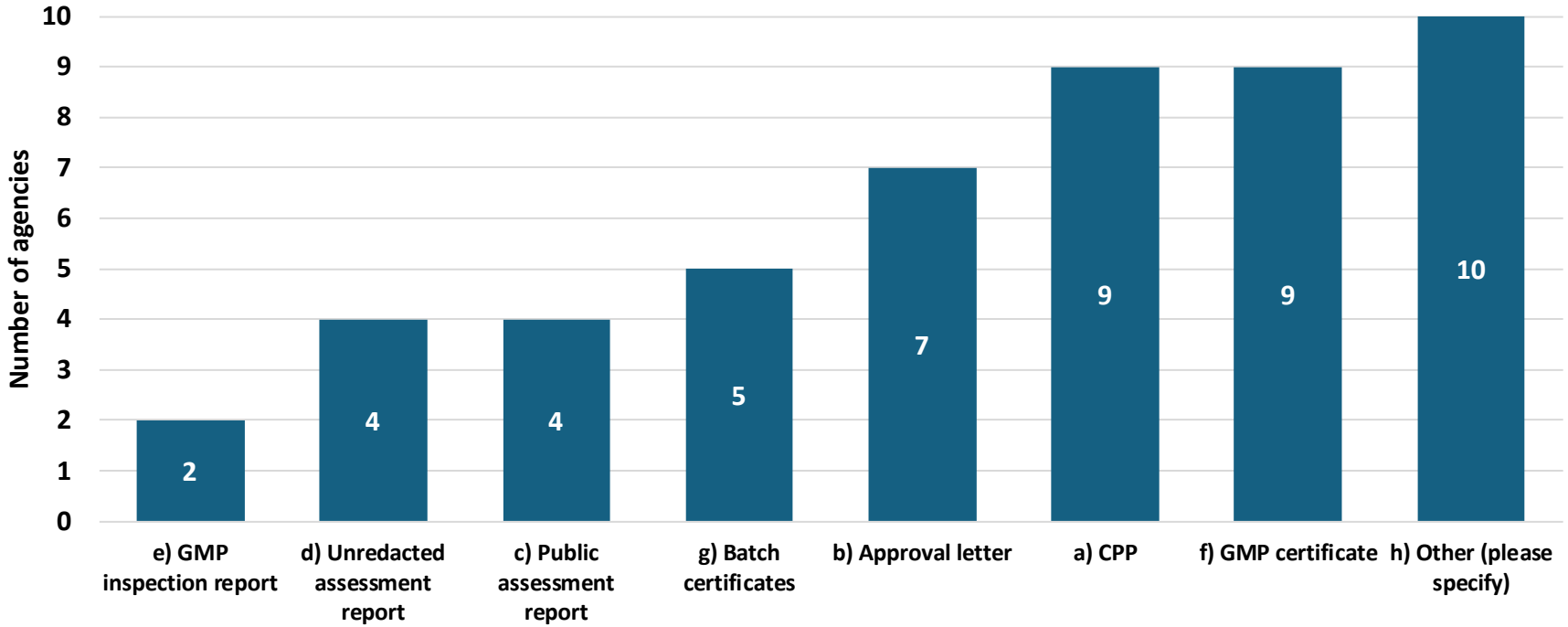
Documentation Requirements for the Application of Reliance Across Agencies

FL-5: What type(s) of documents are required from the reference authority to apply reliance?



NOTE: Multiple selection possible across the 10 agencies. WHO recognises that reliance may be supported through different types of regulatory evidence depending on the legal framework and regulatory function involved (see Glossary). Access to an Unredacted Assessment Report is not always a prerequisite for implementing reliance.

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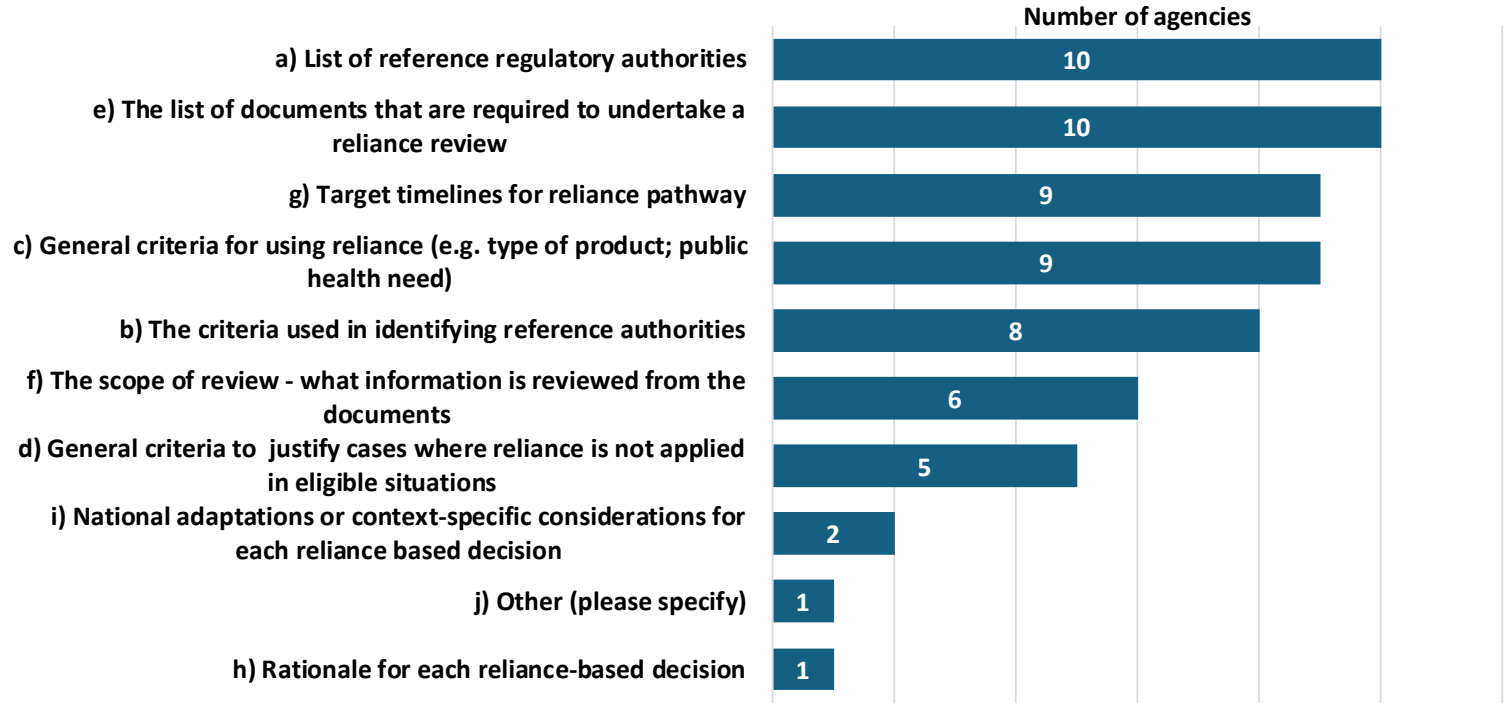
Availability of Public Information on Reliance Across Agencies

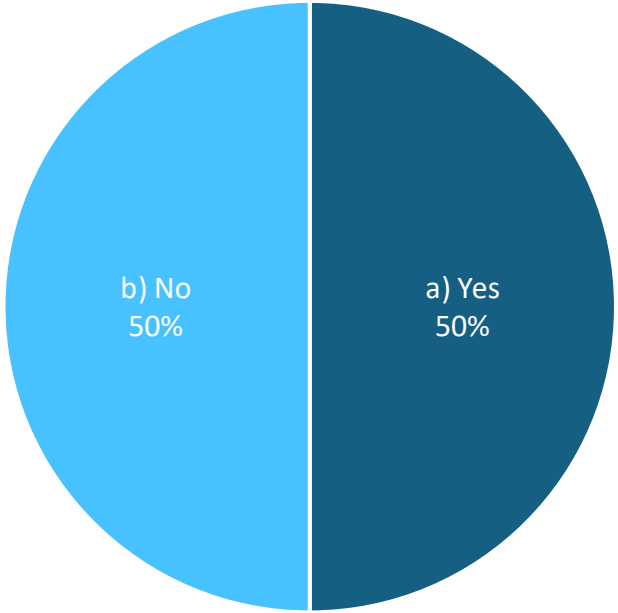
MA-1: What information does your agency publish in relation to implementation of reliance?



NOTE: Multiple selection possible across the 10 agencies

Access to Confidential Assessment Information for Reliance

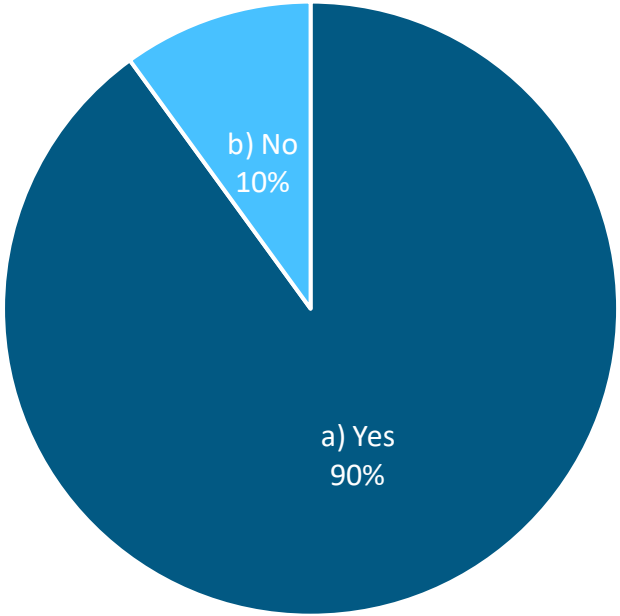
MA-2: Does the agency have mechanisms (legal or operational) to access unredacted dossiers or confidential assessment reports from reference authorities or manufacturers when needed?



n = 10

Specification of Target Timelines for Reliance Reviewers Across Agencies

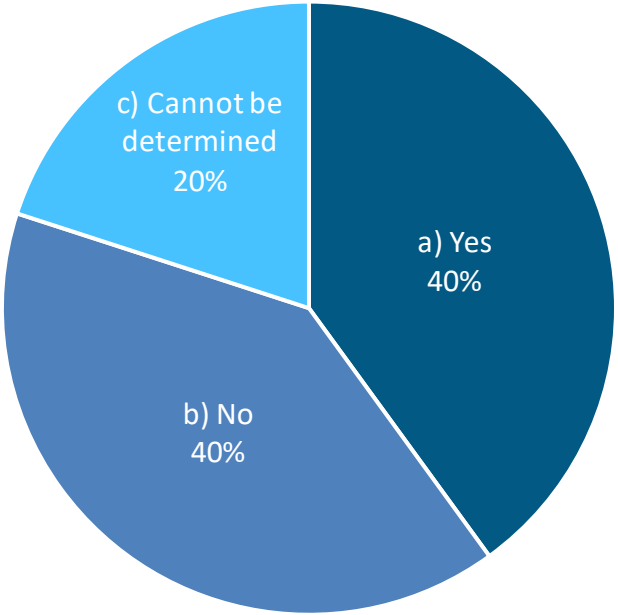
MA-3: Does the agency specify target timelines for the reliance review procedure?



n = 10

Monitoring and Evaluation of Reliance–Based Decisions Across Agencies

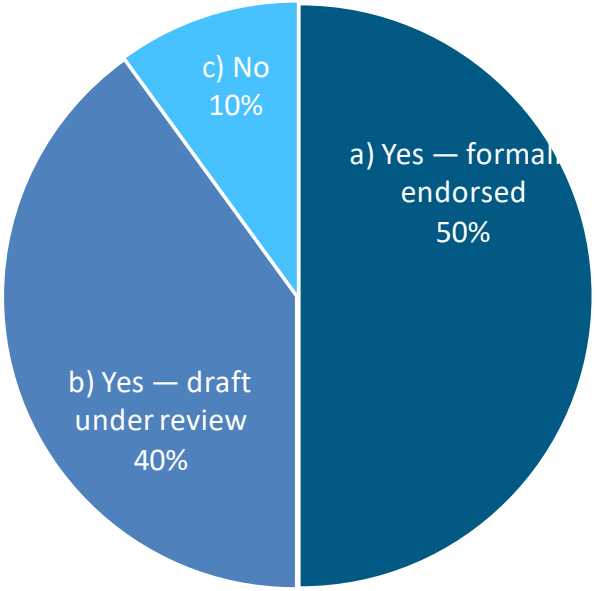
MA-4: Does your agency monitor or evaluate the performance and impact of reliance-based decisions in the regulatory function of new marketing authorisations?



n = 10

Frameworks for Assessing Product Sameness for Reliance–Based Authorisations

MA-5: Is there a formal framework or guidance in place that defines how product sameness is evaluated for reliance-based new marketing authorisations?

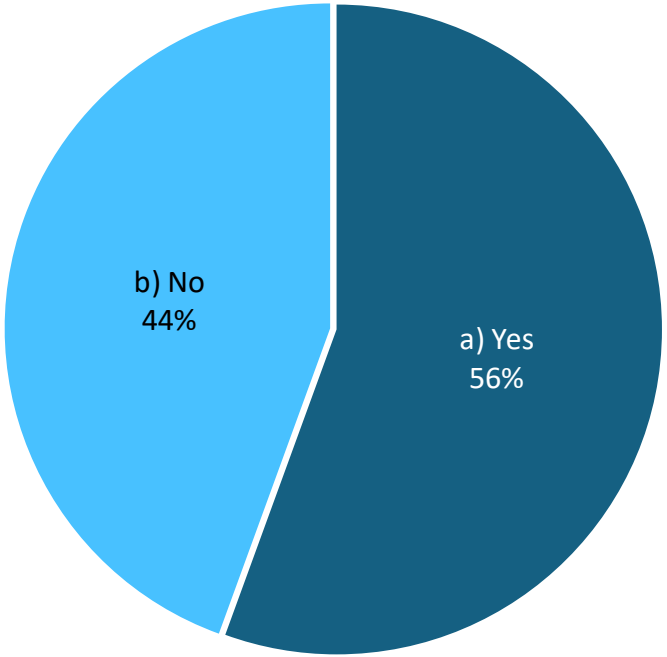


n = 10

Please see Appendix 2 – Glossary (Core reliance concepts) for the definition of “sameness of product” applied throughout this analysis.

Used of Structured Tools for Assessing Product Sameness for Reliance–Based Authorisations

MA-6: Does the agency use a specific template, matrix or tool to map and assess differences between the reference product and the locally submitted product for reliance-based new marketing authorisations?

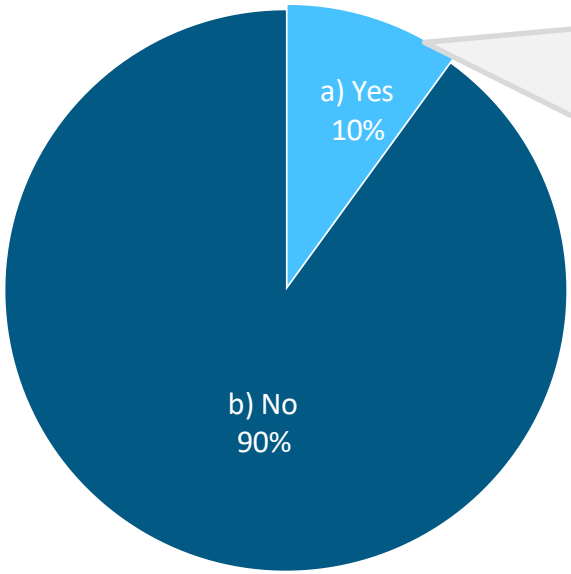


n = 9*

*1 agency excluded due to not having a framework for assessing sameness

Time Limits for Local Submission After Reference Authority Approval

MA-7: After the product is approved by the reference regulatory authority, has the local authority established a timeframe within which the product must be submitted in the country through the reliance pathway?



While COFEPRIS has a recency requirement that foreign reference approvals should be issued within '*a period no greater than 5 years*', it was confirmed that this 5-year limit serves as the maximum window for submission via reliance, though technical confirmation remains pending.

n = 10

Outline

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

Click to go back to Outline

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 standardised, 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

Key regional trends

Reliance has legal bases and is being operationalised

All 10 agencies have a legal basis for reliance (GRelP 6.4); **70% have a formally endorsed national strategy**, yet **only 50% have an internal SOP in place** (GRelP 7.1.1).

Broader scope of application

Reliance is no longer limited to innovative products: it covers **chemical entities, generics, biological products and biosimilars**, while use for combination products (50%), cell and gene therapies (40%) and APIs (20%) remains limited.

Abridged pathways dominate

70% of agencies operate an abridged pathway, while recognition, verification and collaborative pathways are utilised by few agencies.

Wider set of reference authorities

All agencies recognise multiple reference authorities, with FDA, Health Canada, MHRA and TGA included by all.

Sameness not fully standardised

90% of agencies have a framework to assess product sameness, but only **50% use a structured template — suggesting that GRelP 7.1.5 is unevenly operationalised**.

Lack of impact measurement

90% of agencies specify target timelines, yet only 40% monitor the performance of reliance-based decisions. Efficiency gains from reliance remain largely unmeasured across the region.

Uneven transparency

Frameworks and selection criteria are widely published **(90%),** but **reliance strategies (20%), impact metrics (10%) and decision rationale (10%)** are rarely published — falling short of the transparency principle (GRelP 6.3).

Reliance is now firmly institutionalised across the region — the frontier has shifted from adoption to needing consistent operationalisation, measurable performance and transparency

Main Barriers

Resource constraints

Insufficient staffing, IT and digital tools to operationalise reliance. GRelP 7.1.4 is explicit that reliance first requires investment of resources and time in pathways, guidance, training and systems.

Legal and regulatory framework

40% of agencies consider that their regulatory framework prevents them (to some extent) from effectively implementing reliance (e.g., requirements fixed in law (GRelP 6.4), and reform depending on political will (GRelP 7.2.1))

Differences in regulatory standards

Misalignment of technical guidelines, processes and benefit-risk frameworks (GRelP 7.2.3), which convergence and harmonisation (GRelP 7.3.2) are designed to reduce.

Information access

Limited availability of assessment reports and scientific justification from reference authorities (GRelP 7.2.2).

Limited technical capacity

Lack of trained staff to assess, adapt and integrate reliance pathways. The competence principle (GRelP 6.6) requires expertise both to rely confidently on the outputs and processes of reference agencies and to sustain independent scientific judgement.

Trust and cultural resistance

Internal resistance and low uptake persist, even where the legal basis exists. Reliance depends on confidence in another authority's outputs (GRelP 7.3.1) and on cultural change within the agency (GRelP 7.1.2)

The barriers agencies report map directly onto the potential barriers anticipated by WHO Good Reliance Practices — they are structural and solvable, not intrinsic to reliance itself

Opportunities

Legal and regulatory reform

Legal frameworks and governance structures need clarification and reform **to ensure reliance is efficiently and consistently operationalised across national laws, regulations, guidance, and SOPs** (GRelP 6.4).

Clear governance and procedures

SOPs, guidelines, decision criteria and structured sameness of product templates need to be embedded in the agency's quality management system, turning reliance from a stated policy into a documented, repeatable process.

Access to information

Ensuring timely access to reference authority assessment reports either through confidentiality arrangements or information-sharing approaches (GRelP 7.2.2 and 7.3.3).

Regional and international cooperation

Strengthening regional and global partnerships (e.g., deeper engagement with PANDRH, PAHO, and global initiatives) to build convergence, trust, and networks (GRelP 7.3.2).

Training and capacity building

Sustained investment in reviewer training, staff exchanges and joint reviews to build competence (GRelP 6.6) and organisational acceptance of reliance (GRelP 7.1.2).

Formal collaboration mechanisms

Work-sharing, joint assessments and mutual recognition — in place in a few agencies — **to broaden reliance beyond abridged pathways.**

Monitoring and evaluation systems

Defined KPIs, digital infrastructure and published impact metrics to evidence efficiency gains, supporting a risk-based approach (GRelP 5.4) and reinforcing the transparency principle (GRelP 6.3).

Agencies converge on the same priorities: clearer legal mandates, documented procedures, better information flows, stronger capacity and, above all, systems to measure what reliance delivers

Policy implications

Reliance is not a standalone solution

Reliance delivers efficiency only when underpinned by strong foundations of Good Regulatory Practices and robust institutional frameworks; without them it displaces workload rather than reducing it.

From adoption to performance

Regional policy should shift from counting reliance frameworks to measuring outcomes — timelines met, resources released, decisions published — making efficiency gains visible and defensible.

Institutional development plans

Reliance priorities should be embedded in a costed institutional development plan with milestones, owners, legal reforms, procedures, required capacity and IT to advance together rather than in isolation.

Quality management systems

Reliance pathways belong inside the agency's QMS: documented procedures, defined competences, records and internal audit.

Quality risk management

A risk-based approach (GRelP 5.4) lets each authority calibrate the depth of its own review to product and process risk, concentrating scarce scientific capacity where it adds most value.

PAHO's accompanying role

PAHO is supporting agencies in their assessment with the WHO Global Benchmarking Tool, translating benchmarking results into institutional development plans and regional convergence.

Public health impact

Effective reliance strengthens regulatory systems and facilitates timely access to safe, effective, and quality-assured medicines, contributing to universal health coverage.

The challenge is no longer whether to rely, but how well — converting legal mandates into sustainable and measurable regulatory performance for timely access to quality-assured medicines

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

Initial project focused on evaluating 10 LATAM agencies – all were actively engaged in the study process through CIRS Topic Group and structured interviews; industry experts were also engaged and provided feedback on the information collected

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

There is interest to expand this study globally - continuous monitoring of reliance is key to enabling 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!

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The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. Its mission is to identify and apply scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes in developing and facilitating access to pharmaceutical products. CIRS provides an international forum for industry, regulators, HTA bodies and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy. It is governed and operated by Clarivate for the sole support of its members' activities. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, and grants.

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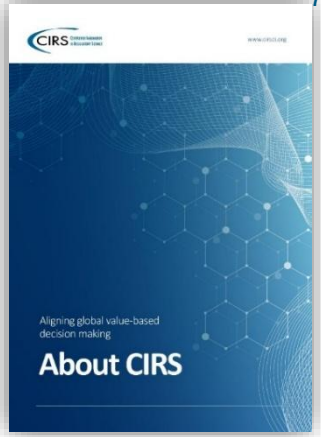

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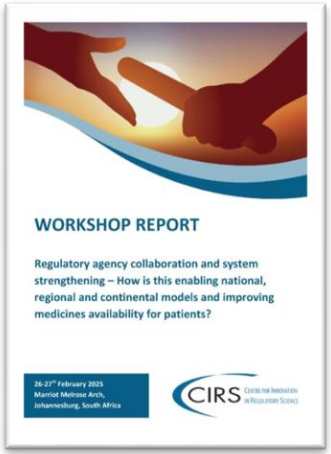

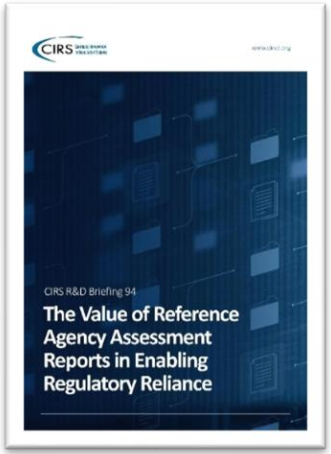

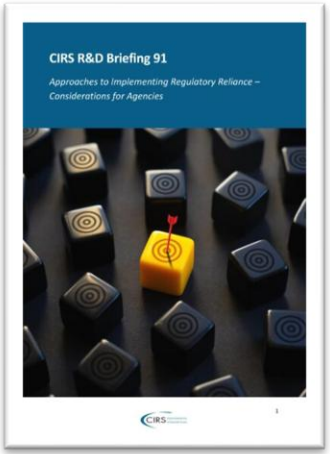

Further CIRS publications on reliance
https://cirsci.org/tag/reliance

Outline

Outline

Appendix 2: Glossary and References

Glossary – Core reliance concepts (1/2)	Definition	References
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 decision taken.	WHO's Annex 10, 55th report, 2021
Reference regulatory authority	A national or regional authority, or a trusted institution such as WHO Prequalification, whose regulatory decisions and/or work products are relied upon by another authority to inform its own decisions.	WHO's Annex 10, 55th report, 2021
Trusted institution	An institution other than a national or regional regulatory authority, such as WHO Prequalification, whose assessments, inspection outcomes or work products an authority may rely upon.	WHO's Annex 10, 55th report, 2021
Equivalence of regulatory systems	Strong similarity between two regulatory systems, mutually established and documented through objective evidence: similar frameworks and practices, adherence to the same international standards, experience in using each other's assessments, joint activities and staff exchanges. Usually a precondition for mutual recognition.	WHO's Annex 10, 55th report, 2021

Glossary – Core reliance concepts (2/2)	Definition	References
Good regulatory practices (GRP)	Internationally recognised processes and practices applied by regulatory authorities so that regulation of medical products is transparent, proportionate, consistent and evidence-based. They provide the institutional foundation on which reliance is built.	WHO's Annex 11, 55th report, 2021
Good review practices (GRevP)	Documented best practices for any aspect related to the process, format, content and management of a medical product review.	WHO's Annex 9, 49th report, 2015
Good reliance practices (GRelP)	WHO high-level principles and considerations for regulating medical products through reliance, covering legal basis, transparency, competence, sameness, risk-based review and monitoring of impact. They complement GRP and GRevP.	WHO's Annex 10, 55th report, 2021
Harmonisation (regulatory)	The process by which technical guidelines are developed to be uniform across participating authorities.	WHO's Annex 4, 51st report, 2017
Regulatory convergence	A voluntary process whereby the regulatory requirements, approaches and practices of different jurisdictions become more aligned over time through adoption of internationally recognised technical guidance and shared principles. It does not require harmonisation of national laws.	WHO's Annex 11, 55th report, 2021

Glossary – Sameness of product	Definition	References
Sameness of product	The product submitted to the relying authority and the product approved by the reference authority have identical essential characteristics – same qualitative and quantitative composition, strength, pharmaceutical form, intended use, manufacturing process, API suppliers and quality of excipients. IFPMA notes that product sameness can be supported through a risk-based, lifecycle approach to quality management. Drawing on internationally recognized standards and guidelines, including ICH Q10 Pharmaceutical Quality Systems, ICH Q5E comparability principles for biotherapeutics, ISO 13485 quality management systems, WHO technology transfer guidance (TRS Annex 7), and GMP oversight within the PIC/S framework, this approach relies on pharmaceutical quality systems, comparability assessments, change management processes and regulatory oversight to provide assurance that any differences do not result in meaningful changes to product quality, safety, efficacy, performance, or the overall benefit-risk profile. Under this approach, differences in manufacturing sites, suppliers, dossier content, labelling, or approved indications may be acceptable when appropriately justified and supported by scientific evidence	WHO's Annex 10, 55th report, 2021 IFPMA, position on product sameness ICH Q10 ICH Q5E ISO 13485 WHO TRS Annex 7 PIC/S GMP

Glossary – Regulatory system and legal basis	Definition	References
Regulatory system	The set of institutions, legal instruments, resources and processes through which a country regulates medical products across the regulatory functions – marketing authorisation, inspection, market surveillance, licensing, laboratory testing, clinical trial oversight and vigilance.	WHO Global Benchmarking Tool; WHO's Annex 11, 55th report, 2021
Regulatory framework	The complete architecture of laws, regulations, policies, guidelines and procedures, together with the institutional arrangements to implement and enforce them, that governs how medical products are regulated in a jurisdiction.	WHO's Annex 11, 55th report, 2021
Legal framework	The body of binding legal instruments – laws and regulations – that establishes the mandate and powers of the regulatory authority. It should explicitly enable cooperation, work-sharing, reliance and recognition.	WHO's Annex 10, 55th report, 2021
National law or regulation	A binding legal instrument forming part of the national legal framework that sets objectives, powers, products and activities to be regulated, including the legal basis for cooperation, work-sharing, reliance and recognition.	WHO's Annex 10, 55th report, 2021
Ministerial policy or directive	High-level, system-wide policy or strategy issued by the Ministry of Health or the authority's senior leadership setting out how and for what purpose reliance will be used (objectives, principles, scope). It provides the umbrella for procedures and technical guidelines.	WHO's Annex 10, 55th report, 2021
Agency guideline / guidance document	Non-binding document detailing how to comply with laws and regulations, describing regulatory processes and acceptable approaches; usually more technical and specific than the legislation itself.	WHO's Annex 11, 55th report, 2021

Glossary – Reliance governance	Definition	References
Reliance framework	Structured set of provisions, processes and tools describing when and how reliance is applied – scope, reference authorities, documentation, metrics and national adaptations – normally published and accessible to stakeholders.	WHO's Annex 10, 55th report, 2021
Reliance strategy	High-level strategy embedded in the authority's overall strategy and endorsed by senior management, setting objectives, scope and approach for applying reliance, later detailed in procedures.	WHO's Annex 10, 55th report, 2021
Internal agency SOP	Authorised written standard operating procedure giving instructions on how to perform general or specific operations within the authority – review steps, assessment templates, quality checks – as part of its quality management system.	WHO's Annex 13, 54th report, 2020
In development / not formally codified	"In development" is an instrument (law, policy, guideline or SOP) drafted or under formal review but not yet endorsed. "Not formally codified" is reliance applied through interpretation of existing regulations or administrative practice, without being set out in laws, policies or SOPs.	WHO's Annex 10, 55th report, 2021
Selection criteria for reference authorities	Transparent criteria used to choose reference authorities – application of international standards, WHO-Listed Authority status, maturity level, regulatory proximity – which should be published alongside the list of recognised authorities.	WHO's Annex 10, 55th report, 2021
Metrics and impact reporting	Indicators and reports quantifying the impact of reliance: approval timelines, resources saved, products reaching the market and reallocation of resources to higher-risk regulatory activities.	WHO's Annex 10, 55th report, 2021

Glossary – Reliance models (1/2)	Definition	References
Recognition	Acceptance of the regulatory decision of another regulator or trusted institution. Recognition should be based on evidence that the regulatory requirements of the reference regulatory authority are sufficient to meet those of the relying authority. It may be unilateral or mutual and, in the latter case, may be the subject of a mutual recognition agreement.	WHO's Annex 10, 55th report, 2021; WHO's Annex 11, 55th report, 2021
Unilateral recognition	Acceptance by one authority of the regulatory decision of another authority or trusted institution, which generally removes the need for additional assessment. It is decided by the relying authority alone, usually requires formal legal provisions, and does not require reciprocity.	WHO's Annex 10, 55th report, 2021; WHO's Annex 4, 51st report, 2017
Mutual recognition	Form of recognition based on binding agreements (mutual recognition agreements or treaties) under which the parties mutually recognise each other's assessments or regulatory decisions, after demonstrating equivalence of their regulatory systems.	WHO's Annex 10, 55th report, 2021; WHO's Annex 11, 55th report, 2021
Collaborative procedure	A registration procedure in which assessment and national registration of pharmaceutical products and vaccines already approved by a reference (stringent) regulatory authority is facilitated and accelerated by the sharing of the detailed assessment and inspection outcomes generated by that reference authority. Distinctive feature: sequential reliance on an already completed assessment.	WHO's Annex 11, 52nd report, 2018; WHO's Annex 10, 55th report, 2021

Glossary – Reliance models (2/2)	Definition	References
Work-sharing	A process by which the authorities of two or more jurisdictions share the activities needed to accomplish a specific regulatory task – for example authorisation of clinical trials or marketing authorisations, inspections, post-marketing surveillance, or development of guidelines and standards. It also entails exchange of information consistent with existing agreements and each authority's legislative framework. Distinctive feature: division of work between authorities.	WHO's Annex 11, 52nd report, 2018; WHO's Annex 10, 55th report, 2021
Joint activity / joint assessment	A form of work-sharing whereby a regulatory task is conducted by two or more authorities in collaboration, to share assessments, benefit from each other's expertise and discuss shortcomings of the data. In a joint assessment the same application is submitted simultaneously to the participating authorities, which evaluate in parallel (modules may be assigned to different authorities), may combine their lists of questions, and each then takes its own independent decision. Distinctive feature: simultaneous, collaborative evaluation.	WHO's Annex 11, 52nd report, 2018; WHO's Annex 7, 2025
Regional or centralised procedure	A procedure in which a single assessment is conducted at regional level, or by a regional body on behalf of participating countries, and its outcome is used as the basis for national decisions across the region. Distinctive feature: one assessment serving many jurisdictions.	WHO's Annex 10, 55th report, 2021
Collaborative Registration Procedure (CRP)	WHO-led application of the collaborative model in which participating authorities rely on a prior WHO prequalification or reference authority assessment to accelerate national registration, using verification or abridged review. It covers initial registrations and post-approval changes.	WHO's Annex 11, 52nd report, 2018; WHO's Annex 6, 53rd report, 2019

Glossary – Depth of scientific review	Definition	References
Full (independent) review	Complete independent assessment of the full dossier on quality, safety and efficacy or performance, carried out by the national authority without relying on another authority's assessment. It is the standard pathway against which reliance-based pathways are compared.	WHO's Annex 10, 55th report, 2021
Verification review	The procedure by which the authority only validates the product or submission and verifies the sameness of the medical product, ensuring that the product for local marketing is equal or similar to that approved by the reference authority or trusted institution, without re-reviewing the data. Sameness should always be verified in any reliance approach.	WHO's Annex 10, 55th report, 2021; WHO's Annex 6, 53rd report, 2019
Abridged review / assessment	Abridged assessment of data on quality, safety and efficacy or performance, taking into account the information in the assessment reports of the reference regulatory authority; that is, a limited independent assessment of specific parts of the dossier or of its suitability for use under local conditions and regulatory requirements, while relying on prior assessment and inspection outcomes to inform the local decision.	WHO's Annex 6, 53rd report, 2019; WHO's Annex 10, 55th report, 2021
Risk-based approach	The principle by which the depth of national review – full, abridged or verification – is calibrated to the risk of the product and the confidence in the reference authority's assessment, so that regulatory resources are concentrated where risk is highest.	WHO's Annex 10, 55th report, 2021 (section 5.4)

Glossary – Authorities	Definition	References
National regulatory authority (NRA)	The agency responsible for the registration of, and other regulatory activities concerning, medical products; a government body that exercises a legal right to control their use or sale within its jurisdiction and may take enforcement action to ensure compliance.	WHO's Annex 9, 49th report, 2015; WHO's Annex 4, 51st report, 2017
WHO-Listed Authority (WLA)	A regulatory authority or regional regulatory system that WHO has evaluated against the WLA performance framework and publicly designated as meeting the required standards – including a Global Benchmarking Tool maturity level 3 or 4 – and whose decisions and work products other authorities may use for reliance.	WHO policy on evaluating and publicly designating regulatory authorities as WLAs, 2021
Transitional WLA (tWLA)	Interim designation granted by WHO to authorities previously recognised as stringent regulatory authorities, allowing their decisions to continue being used for reliance and procurement during the transition period until they are formally evaluated as WLAs.	WHO WLA framework – transitional arrangements, 2022
Stringent regulatory authority (SRA)	Authority meeting WHO-defined criteria of robustness and maturity, historically used as reference authority in reliance, procurement and prequalification mechanisms; progressively replaced by the WLA framework.	WHO's Annex 11, 52nd report, 2018
NRA of regional reference (NRAr)	National authority in the Americas designated by PAHO as a regional reference authority after evaluation against PAHO/WHO indicators, having demonstrated competence in the regulatory functions for medicines and/or vaccines; its decisions may be used by other countries of the region for reliance.	PAHO Regional System for Regulatory Reference Authorities, Resolution CD50.R9, 2010
List of reference regulatory authorities	Published list issued by the national regulatory authority identifying the reference authorities accepted for reliance and, ideally, the criteria used to select them.	WHO's Annex 10, 55th report, 2021

Glossary – Organisations	Definition	References
Pan American Health Organization (PAHO)	Specialised international health agency for the Americas and the WHO Regional Office for the Region; supports the strengthening of national regulatory authorities, coordinates regulatory convergence in the Region and administers the regional reference authority (NRAr) system.	PAHO Basic Documents; Resolution CD50.R9, 2010
United Nations Development Programme (UNDP)	United Nations agency for sustainable development that assists countries in strengthening institutions, governance and capacity, including support to health systems, procurement of medical products and initiatives that reinforce regulatory capacity.	UNDP Strategic Plan 2022–2025
World Trade Organization (WTO)	Intergovernmental organisation that administers the rules of international trade, including the TRIPS Agreement and the Agreement on Technical Barriers to Trade, which shape intellectual property and regulatory convergence conditions affecting access to medical products.	WTO TRIPS Agreement, 1995; WTO TBT Agreement, 1995

Glossary – Authorisation and review process	Definition	References
Marketing authorisation	A legal document issued by the national regulatory authority for the marketing or free distribution of a product after evaluation for safety, efficacy, performance (where applicable) and quality. Also referred to as a licence or product licence.	WHO's Annex 7, 54th report, 2020
Assessment	Any evaluation conducted for a regulatory function – for example evaluation of a clinical trial application, of an initial marketing authorisation or subsequent post-authorisation changes, of safety data, or evaluation as part of an inspection.	WHO's Annex 10, 55th report, 2021
Validation / screening	The first stage of the review process, which occurs before the scientific review with the aim of ensuring completeness of the application in order to subsequently facilitate the scientific review.	WHO's Annex 9, 49th report, 2015
Scientific review	A highly complex, multidisciplinary assessment of medical product applications to assess whether they meet scientific and evidentiary standards for safety, efficacy and quality. It forms the scientific foundation for regulatory decisions.	WHO's Annex 9, 49th report, 2015
Review strategy	The approach or plan of action that a reviewer or review team uses to review a medical product application.	WHO's Annex 9, 49th report, 2015

Glossary – Products (1/2)	Definition	References
Medical product	Umbrella term covering medicines, vaccines, blood and blood products, and medical devices including in vitro diagnostics. It defines the scope of the regulatory functions to which reliance may be applied.	WHO's Annex 10, 55th report, 2021
Pharmaceutical product	Any medicine intended for human use, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in the exporting or importing state.	WHO's Annex 10, 34th report, 1996
Active pharmaceutical ingredient (API)	Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that dosage form, furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease.	WHO's Annex 6, 48th report, 2014
Multisource (generic) product	Pharmaceutically equivalent or pharmaceutically alternative products marketed after expiry of patent or exclusivity, that may or may not be therapeutically equivalent; those that are therapeutically equivalent are interchangeable with the reference product.	WHO's Annex 7, 49th report, 2015
Biological product / biotherapeutic	A pharmaceutical substance used in treatment, prevention or diagnosis that is classified as a biological on the basis of its source, its amenability to physicochemical characterisation, or the requirement for biological assays. A biotherapeutic is a biological product indicated for treating human diseases.	WHO's Annex 7, 49th report, 2015; WHO's Annex 11, 52nd report, 2018
Similar biotherapeutic product (biosimilar)	Biotherapeutic product developed to be highly similar in quality, safety and efficacy to a licensed reference biotherapeutic product, demonstrated through a comprehensive comparability exercise.	WHO guidelines on evaluation of similar biotherapeutic products

Glossary – Products (2/2)	Definition	References
Vaccine	Biological preparation containing antigens capable of inducing a specific and active immune response against an infecting agent or the disease it causes, thereby conferring protection.	WHO guidelines on the regulation of vaccines
Cell and gene therapies (ATMPs)	Advanced therapy medicinal products based on genes, cells or tissues, including gene therapy products, somatic cell therapy products and tissue-engineered products. Their complexity and individualised manufacture require specific regulatory oversight and are frequently addressed under dedicated pathways.	WHO considerations on regulatory convergence for cell and gene therapy products
Fixed-dose combination (FDC)	Finished pharmaceutical product containing two or more active substances in a single dosage form and in fixed proportions, intended for simultaneous use in a specific indication.	WHO's Annex 5, 39th report, 2005
Combination product (medicine and device)	Product in which a medicinal product and a medical device are combined as a single integral product – for example pre-filled syringes, auto-injectors, inhalers or drug-eluting implants – requiring assessment of both the medicinal and the device components.	WHO's Annex 4, 51st report, 2017
Medical device	Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software or related article intended by the manufacturer to be used for medical purposes on human beings, and which does not achieve its principal action by pharmacological, immunological or metabolic means.	WHO's Annex 4, 51st report, 2017

Glossary – Reference documents that enable Reliance (1/2)	Definition	References
Approval letter	Official document from the regulatory authority confirming approval of an activity or product – for example GMP compliance, a marketing authorisation or a post-approval change.	WHO's Annex 9, 52nd report, 2018
Batch certificate	Certificate issued by the manufacturer, or exceptionally by the competent authority of the exporting country, confirming that a specific batch complies with agreed specifications; particularly used for vaccines and biological products.	WHO's Annex 10, 34th report, 1996
Bridging report	Documentation submitted by the applicant to demonstrate that the product for which reliance is sought is the same as, or adequately linked to, the product authorised by the reference authority, identifying and justifying any differences – for example in manufacturing site, presentation, labelling or product information.	WHO's Annex 10, 55th report, 2021; IFPMA reliance principles
Certificate of Pharmaceutical Product (CPP)	WHO-type certificate issued by a regulatory authority attesting to the registration status and conformity of a pharmaceutical product, used to facilitate international trade and to support regulatory decisions in importing countries.	WHO's Annex 10, 34th report, 1996
Dossier	The complete set of documentation submitted by an applicant to a regulatory authority in support of an application for marketing authorisation, containing the quality, non-clinical and clinical information on the medical product; commonly compiled in the ICH Common Technical Document (CTD) format and shared, in whole or in part, to enable reliance.	WHO's Annex 10, 55th report, 2021; WHO's Annex 9, 52nd report, 2018

Glossary – Reference documents that enable Reliance (2/2)	Definition	References
GMP inspection report and GMP certificate	The inspection report records observations, findings and conclusions on a manufacturing site's compliance with Good Manufacturing Practice; the certificate is issued by an authority stating that an establishment complies with GMP.	WHO's Annex 9, 52nd report, 2018; WHO's Annex 10, 34th report, 1996
List of Questions (LoQ)	The consolidated set of queries raised by assessors during the scientific review and communicated to the applicant, requesting clarification, justification or additional data before a regulatory decision is taken; the questions and the applicant's responses form part of the assessed dossier.	WHO's Annex 9, 52nd report, 2018 (Good review practices)
Post-approval commitments	Obligations agreed with, or imposed by, the regulatory authority at the time of marketing authorisation, requiring the holder to generate and submit further data or complete specified activities within defined timelines – for example confirmatory studies, stability data or process validation. They are documented in the approval decision and can be relied upon by other authorities.	WHO's Annex 9, 52nd report, 2018; WHO's Annex 10, 55th report, 2021
Public and unredacted assessment reports (PARs and UARs)	A public assessment report summarises the scientific assessment and regulatory decision of a reference authority and is a primary source for reliance. An unredacted report is the complete report without commercially confidential information removed, usually shared authority-to-authority under a confidentiality agreement.	WHO's Annex 10, 55th report, 2021
Risk management plan (RMP)	Document describing the safety profile of a medical product, the important identified and potential risks and missing information, together with the pharmacovigilance activities and risk minimisation measures planned to characterise and manage those risks, and the means of measuring their effectiveness.	WHO's Annex 9, 55th report, 2021 (pharmacovigilance); ICH E2E, adopted by WHO

Outline

Appendix 3: Bibliography

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News release	ISP. Instituto de Salud Pública reúne a agencias reguladoras de 16 países de América. Santiago: ISP. Available at: https://www.ispch.gob.cl/noticia/instituto-de-salud-publica-reune-a-agencias-reguladoras-de-16-paises-de-america/

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Colombia: Regulatory Framework and Institutional Sources

ACCESS DATE 22 June 2026

Reference Type	Reference
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Regulation	Ministerio de Salud y Protección Social. Decreto 1782 de 2014: Requisitos y procedimiento para evaluaciones farmacológica y farmacéutica de medicamentos biológicos. Bogotá: Ministerio de Salud y Protección Social; 18 September 2014. Available at: https://www.minsalud.gov.co/normatividad_nuevo/decreto%201782%20de%202014.pdf
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Costa Rica: Regulatory Framework and Institutional Sources

ACCESS DATE 1 April 2026

Reference Type	Reference
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News release	DIGEMAPS. DIGEMAPS fortalece su sistema regulatorio al ingresar al ICH e IPRP en Singapur. Santo Domingo: DIGEMAPS. Available at: https://digemaps.gob.do/general/digemaps-fortalece-su-sistema-regulatorio-al-ingresar-al-ich-e-iprp-en-singapur/
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Ecuador: Regulatory Framework and Institutional Sources

ACCESS DATE 20 April 2026

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Manual/Guidance document	ARCSA. IE-B.3.2.1-MB-02: Inscripción, reinscripción, modificación y cancelación voluntaria del registro sanitario de productos biológicos de uso humano, versión 3.0. Quito: ARCSA; 2025. Available at: https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2025/06/IE-B.3.2.1-MB-02_Inscripcion-reinscripcion-modificacion-y-cancelacion-voluntaria-del-registro-sanitario-de-productos-biologicos-de-uso-humano-version-3.0.pdf
News release	Organización Panamericana de la Salud. OPS capacitó a ARCSA Ecuador en lectura crítica de evidencia biomédica. Quito: Organización Panamericana de la Salud; 30 September 2024. Available at: https://www.paho.org/es/noticias/30-9-2024-ops-capacito-arcsa-ecuador-lectura-critica-evidencia-biomedica
Other official publication	ARCSA. Lista de Agencias Reguladoras de Alta Vigilancia reconocidas por ARCSA. Quito: ARCSA; 17 July 2025. Available at: https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2025/07/25.07.17_Lista-de-Agencias-Reguladoras-de-Alta-Vigilancia-reconocidas-por-ARCSA.pdf
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Mexico: Regulatory Framework and Institutional Sources

ACCESS DATE 7 April 2026

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Regulation	Poder Ejecutivo Federal. Reglamento de Insumos para la Salud. Mexico City: Poder Ejecutivo Federal. Available at: https://www.ordenjuridico.gob.mx/Documentos/Federal/pdf/wo88318.pdf
Regulation	Secretaría de Salud. Acuerdo por el que se establecen acciones de simplificación para trámites que se realizan ante COFEPRIS. Mexico City: Secretaría de Salud; 22 August 2025. Available at: https://www.dof.gob.mx/nota_detalle.php?codigo=5766390&fecha=22/08/2025
Regulation	Secretaría de Salud. Acuerdo publicado en el Diario Oficial de la Federación el 18 de julio de 2025. Mexico City: Secretaría de Salud; 18 July 2025. Available at: https://www.dof.gob.mx/nota_detalle.php?codigo=5763319&fecha=18/07/2025
Manual/Guidance document	Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS). Guía CTD, versión 2.0. Mexico City: COFEPRIS. Available at: https://www.gob.mx/cms/uploads/attachment/file/1025617/Gu_a_CTD_V2.0_Formato_finalVF.pdf
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Official form	COFEPRIS. COFEPRIS-04-004-K. Mexico City: COFEPRIS. Available at: https://www.catalogonacional.gob.mx/FichaTramite?traHomoclave=COFEPRIS-04-004-K
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Panama: Regulatory and institutional sources

ACCESS DATE 13 March 2026

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Regulation	Ministerio de Salud. Decreto Ejecutivo No. 12 de 25 de junio de 2025. Panama City: Ministerio de Salud; 25 June 2025. Available at: https://dnfd.minsa.gob.pa/sites/default/files/2026-01/Decreto%20Ejecutivo%2012%20de%2025%20de%20junio%20de%202025.pdf
Regulation	Ministerio de Salud. Decreto Ejecutivo No. 2 de 7 de enero de 2025: Procedimiento de reconocimiento automático de registro sanitario de medicamentos. Panama City: Ministerio de Salud; 7 January 2025. Available at: https://dnfd.minsa.gob.pa/sites/default/files/2025-08/Decreto%20Ejecutivo%20No.%202%20de%207%20de%20enero%20de%202025.pdf
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Regulation	Ministerio de Salud. Decreto Ejecutivo No. 29 de 28 de junio de 2023: Requisitos para solicitud de registro sanitario de medicamentos abreviado. Panama City: Ministerio de Salud; 28 June 2023. Available at: https://www.minsa.gob.pa/sites/default/files/normatividad/decreto_ejecutivo_no_29_de_28_de_junio_de_2023_-_requisitos_para_solicitud_registro_sanitario_medicamentos_abreviado_-_normativa.pdf

Panama: Regulatory Framework and Institutional Sources

ACCESS DATE 13 March 2026

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Government webpage	Dirección Nacional de Farmacia y Drogas. Convenios. Panama City: Dirección Nacional de Farmacia y Drogas. Available at: https://dnfd.minsa.gob.pa/convenios
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ACCESS DATE 24 March 2026

Reference Type	Reference
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Government webpage	Dirección General de Medicamentos, Insumos y Drogas (DIGEMID). Agencias reguladoras de países de alta vigilancia sanitaria. Lima: DIGEMID. Available at: https://bvcenadim.digemid.minsa.gob.pe/index.php/enlaces/agencias-reguladoras-de-paises-de-alta-vigilancia-sanitaria
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News release	DIGEMID. DIGEMID trabaja en la mejora del proceso de registro sanitario de productos biológicos y medicamentos nuevos. Lima: DIGEMID; 2024. Available at: https://www.digemid.minsa.gob.pe/webDigemid/notas/2024/digemid-trabaja-en-la-mejora-del-proceso-de-registro-sanitario-de-productos-biologicos-y-medicamentos-nuevos/
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WHO Good Reliance and Regulatory Practices (1/2)

ACCESS DATE 28 August 2026

Reference Type	Reference
WHO guideline	World Health Organization. Good reliance practices in the regulation of medical products: high level principles and considerations. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fifth report. Geneva: WHO; 2021 (WHO Technical Report Series, No. 1033, Annex 10). Available at: https://www.who.int/publications/m/item/annex-10-trs-1033
WHO guideline	World Health Organization. Good regulatory practices in the regulation of medical products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fifth report. Geneva: WHO; 2021 (WHO Technical Report Series, No. 1033, Annex 11). Available at: https://www.who.int/publications/m/item/annex-11-trs-1033
WHO guideline	World Health Organization. Guidelines on the implementation of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. Geneva: WHO; 2021 (WHO Technical Report Series, No. 1033, Annex 9). Available at: https://www.who.int/publications/m/item/annex-9-trs-1033
WHO guideline	World Health Organization. Good review practices: guidelines for national and regional regulatory authorities. Geneva: WHO; 2015 (WHO Technical Report Series, No. 992, Annex 9). Available at: https://www.who.int/publications/m/item/annex-9-trs-992
WHO guideline	World Health Organization. WHO good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. Geneva: WHO; 2018 (WHO Technical Report Series, No. 1010, Annex 9). Available at: https://www.who.int/publications/m/item/trs1010-annex9

WHO Good Reliance and Regulatory Practices (2/2)

ACCESS DATE 28 August 2026

Reference Type	Reference
WHO guideline	World Health Organization. Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products. Geneva: WHO; 2019 (WHO Technical Report Series, No. 1019, Annex 6). Available at: https://www.who.int/publications/m/item/annex-6-trs-1019
WHO guideline	World Health Organization. Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities. Geneva: WHO; 2018 (WHO Technical Report Series, No. 1010, Annex 11). Available at: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/trs1010-annex11.pdf

WHO Product and Registration Guidelines (1/2)

ACCESS DATE 28 August 2026

Reference Type	Reference
WHO guideline	World Health Organization. Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. Geneva: WHO; 2015 (WHO Technical Report Series, No. 992, Annex 7). Available at: https://www.who.int/publications/i/item/9789241209922
WHO guideline	World Health Organization. Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part. Geneva: WHO; 2014 (WHO Technical Report Series, No. 986, Annex 6). Available at: https://www.who.int/publications/m/item/annex-6-trs-986
WHO guideline	World Health Organization. Guidelines for registration of fixed-dose combination medicinal products. Geneva: WHO; 2005 (WHO Technical Report Series, No. 929, Annex 5). Available at: https://www.who.int/publications/m/item/annex-5-trs-929
WHO guideline	World Health Organization. WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices. Geneva: WHO; 2017 (WHO Technical Report Series, No. 1003, Annex 4). Available at: https://www.who.int/publications/m/item/annex-4-trs-1003
WHO guideline	World Health Organization. WHO guideline on the implementation of quality management systems for national regulatory authorities. Geneva: WHO; 2020 (WHO Technical Report Series, No. 1025, Annex 13). Available at: https://www.who.int/publications/i/item/9789240001824
WHO guideline	World Health Organization. Good storage and distribution practices for medical products. Geneva: WHO; 2020 (WHO Technical Report Series, No. 1025, Annex 7). Available at: https://www.who.int/publications/m/item/trs-1025-annex-7

WHO Product and Registration Guidelines (2/2)

ACCESS DATE 28 August 2026

Reference Type	Reference
WHO guideline	World Health Organization. WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-fourth report, Annex 10. Geneva: WHO; 1996 (WHO Technical Report Series, No. 863). Available at: https://www.who.int/publications/i/item/WHO_TRS_863

WHO Benchmarking, Listed Authorities and Technical Guidance (1/2)

ACCESS DATE 28 August 2026

Reference Type	Reference
WHO guideline	World Health Organization. WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products, revision VI. Geneva: WHO; 2021. Available at: https://www.who.int/publications/i/item/9789240020245
WHO guideline	World Health Organization. Evaluating and publicly designating regulatory authorities as WHO listed authorities: policy document. Geneva: WHO; 2021. Available at: https://www.who.int/publications/i/item/9789240023444
WHO guideline	World Health Organization. Evaluating and publicly designating regulatory authorities as WHO listed authorities: interim operational guidance, version 1.0 (transitional arrangements). Geneva: WHO; 2022. Available at: https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/wla-interim-operational-guide-combined.pdf
WHO guideline	World Health Organization. WHO guidelines on transfer of technology in pharmaceutical manufacturing. Geneva: WHO; 2011 (WHO Technical Report Series, No. 961, Annex 7); updated as TRS No. 1044, Annex 4, 2022. Available at: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs961-annex7-transfer-technology-pharmaceutical-manufacturing.pdf
WHO guideline	World Health Organization. Guidelines on evaluation of similar biotherapeutic products (SBPs). Geneva: WHO; 2010 (WHO Technical Report Series, No. 977, Annex 2); superseded by Guidelines on evaluation of biosimilars, TRS No. 1043, Annex 3, 2022. Available at: https://www.who.int/publications/m/item/sbp-trs-977-Annex-2

WHO Benchmarking, Listed Authorities and Technical Guidance (2/2)

ACCESS DATE 28 August 2026

Reference Type	Reference
WHO guideline	World Health Organization. Guidelines for independent lot release of vaccines by regulatory authorities. Geneva: WHO; 2010 (WHO Technical Report Series, No. 978, Annex 2). Available at: https://www.who.int/publications/m/item/guidelines-for-independent-lot-release-of-vaccines-annex-2-trs-no-978
WHO guideline	World Health Organization. WHO considerations on regulatory convergence of cell and gene therapy products (public consultation draft). Geneva: WHO; 2021. Available at: https://cdn.who.int/media/docs/default-source/biologicals/ecbs/who-public-consultation_cgtp-white-paper_16_dec_2021.pdf

International References: International Standards and Industry Guidance (1/2)

ACCESS DATE 28 August 2026

Reference Type	Reference
ICH guideline	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH harmonised tripartite guideline: Pharmaceutical quality system Q10. Geneva: ICH; Step 4 version, 4 June 2008. Available at: https://database.ich.org/sites/default/files/Q10%20Guideline.pdf
ICH guideline	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH harmonised tripartite guideline: Comparability of biotechnological/biological products subject to changes in their manufacturing process Q5E. Geneva: ICH; Step 4 version, 18 November 2004. Available at: https://database.ich.org/sites/default/files/Q5E%20Guideline.pdf
ICH guideline	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH harmonised tripartite guideline: Pharmacovigilance planning E2E. Geneva: ICH; Step 4 version, 18 November 2004. Available at: https://database.ich.org/sites/default/files/E2E_Guideline.pdf
ISO standard	International Organization for Standardization. ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes. 3rd ed. Geneva: ISO; 2016. Available at: https://www.iso.org/standard/59752.html
PIC/S guidance	Pharmaceutical Inspection Convention / Pharmaceutical Inspection Co-operation Scheme. Guide to Good Manufacturing Practice for Medicinal Products, PE 009-17. Geneva: PIC/S; 25 August 2023. Available at: https://picscheme.org/docview/6605

International References: International Standards and Industry Guidance (2/2)

ACCESS DATE 28 August 2026

Reference Type	Reference
Industry publication	International Federation of Pharmaceutical Manufacturers and Associations. Points to consider: the importance of sameness of product in the context of regulatory reliance. Geneva: IFPMA; 26 September 2022. Available at: https://www.ifpma.org/publications/points-to-consider-the-importance-of-sameness-of-product-in-the-context-of-regulatory-reliance/

Outline

Appendix 4: Data Collection Tool

Questions:

- CL (country level)
- FL (function level)
- MA (specific to marketing authorisation function

DCT – CL (1/4)	Question	Answer options
CL-1	Does your agency have any of the following that support the use of regulatory reliance? (Multiple selection possible):	a) National law or regulation • b) Ministerial policy or directive • c) Formal mutual/bilateral agreement • d) Agency guideline/guidance document • e) Internal agency SOP • f) In development • g) Not formally codified but implemented informally through practice • h) None
CL-2	Does your agency have a national strategy (endorsed by senior management) on how to apply reliance? (Single choice):	a) Yes — formally endorsed • b) Yes — draft under review • c) No • d) Not applicable
CL-3	Has the agency tailored its reliance strategies to align with its internal resources/capacity and national public health needs?	a) Yes • b) No • c) Cannot be determined
CL-4	Has the agency involved external stakeholders in developing its reliance strategy? (Multiple selection possible):	a) industry • b) other regulatory agencies • c) academic institutions • d) patient organisations • e) Other (please specify)
CL-4.1	If "Other" was selected please specify in the following cell:	Open text response
CL-5	Does your agency publish any of the following? (Multiple selection possible):	a) reliance framework • b) reliance strategy • c) selection criteria for reference authorities • d) metrics/impact reports on reliance
CL-6	Is reliance used only in specific cases (e.g., emergencies, certain product types), or is it part of routine regulatory practice? (Multiple selection possible)	a) Used only in specific cases (emergencies) • b) Used only in specific cases (certain product types) • c) Part of routine regulatory practice • d) Not applicable • e) Other (please specify)
CL-6.1	If "Other" was selected please specify in the following cell:	Open text response

DCT – CL (2/4)	Question	Answer options
CL-7	In case of a public emergency, are reliance approaches prioritised to accelerate access to the medical products required?	a) Yes • b) No • c) Not applicable
CL-7.1	If yes please provide examples and specify procedures used	Open text response
CL-8	Which of the following are the main barriers to the implementation of reliance in your agency? Select top 3 (Multiple selection possible):	a) Legal and regulatory framework – National laws do not allow for reliance or recognition of external regulatory decisions • b) Institutional culture and resistance to change – Preference for conducting full independent reviews rather than relying on external work • c) Limited technical capacity – Lack of trained staff to assess, adapt, and integrate reliance pathways effectively • d) Resource constraints – Insufficient funding, staffing, or digital tools to operationalize reliance mechanisms • e) Trust and confidence issues – Concerns about the quality, transparency, or applicability of another regulator's decisions • f) Information access – Limited availability of assessment reports, data, or scientific justifications from reference authorities • g) Perception that reliance could reduce regulatory sovereignty • h) Reduced public confidence in the national agency • i) Differences in regulatory standards – Misalignment of technical guidelines, processes, or benefit–risk frameworks • j) Lack of formal agreements – Absence of memoranda of understanding (MoUs), confidentiality agreements, or mutual recognition arrangements • k) Limited awareness or training – Staff and stakeholders not adequately informed about the benefits or processes of reliance • l) Language and documentation barriers – Reliance materials may not be available in the local working language • m) Unclear governance or procedures – Lack of standard operating procedures (SOPs) or structured pathways for reliance decisions • n) Other (please specify)
CL-8.1	If "Other" was selected please specify in the following cell:	Open text response

DCT – CL (3/4)	Question	Answer options
CL-9	How does the NRA ensure the necessary competence for reliance-based decision-making across its reviewers? (Multiple selection possible)	a) Organise scientific and knowledge training for reviewers • b) Involve senior regulatory staff, managers, and experts in reliance activities • c) Maintain scientific expertise for activities such as market surveillance and adverse event monitoring • d) Participate in joint reviews with other regulatory authorities • e) Understand the processes and practices of reference authorities • f) Organise exchange programmes and training with other trusted authorities • g) Benchmark competence through transparent processes that build trust in reference authorities • h) Other (please specify)
CL-9.1	If "Other" was selected please specify in the following cell:	Open text response
CL-10	Has the agency undertaken activities to foster cultural and organisational acceptance of reliance (e.g., internal communications, trainings, pilot projects)?	a) Yes • b) No • c) Cannot be determined
CL-10.1	If yes, please provide examples.	Open text response
CL-11	Has your agency allocated resources for training, legal updates, and IT systems to support reliance?	a) Yes • b) No • c) Cannot be determined

DCT – CL (4/4)	Question	Answer options
CL-12	What improvements or changes would be necessary to strengthen the use of reliance in your regulatory system across the five functions assessed? Select top 3 (Multiple selection possible):	a) Legal and regulatory reform – Adapting laws, regulations, or policies to enable reliance pathways • b) Clear governance and procedures – Developing and institutionalizing SOPs, guidelines, and structured processes • c) Criteria and transparency – Publishing criteria for reliance and a list of recognized reference authorities • d) IT and digital infrastructure – Establishing or enhancing platforms for dossier sharing, data exchange, and workflow management • e) Formal collaboration mechanisms – Creating MoUs, confidentiality agreements, or joint review arrangements with other regulators • f) Staff training and capacity building – Building technical expertise to evaluate, adapt, and implement reliance approaches • g) Monitoring and evaluation systems – Setting up tools to track, assess, and improve reliance implementation • h) Access to information – Ensuring timely access to assessment reports, data, or unredacted dossiers from reference authorities • i) Regional and international cooperation – Strengthening partnerships and networks for reliance at the regional/global level • j) Change management and awareness – Addressing institutional culture, stakeholder communication, and trust-building • k) Other (please specify)
CL-12.1	If "Other" was selected please specify in the following cell:	Open text response
FL-1	Please select one of the following regulatory functions for which you will provide information about reliance practices:	a) New marketing authorisations (MA) • b) Post-approval changes (PAC) • c) GMP inspections (GMP) • d) Batch release of biological products (BatRel) • e) Clinical trial protocol approvals (CT)
FL-2	Which reliance pathways/modalities are available? (Multiple selection possible)	a) Recognition • b) Verification • c) Abridged • d) Mutual recognition • e) Collaborative/ joint/ workshare review • f) Other (please specify)
FL-2.1	If "Other" was selected please specify in the following cell:	Open text response

DCT – FL (1/1)	Question	Answer options
FL-3	Which types of products are within the scope for reliance? (Multiple selection possible)	a) Chemical entities • b) Biological products • c) Biosimilars • d) Cell and gene therapies • e) Active pharmaceutical ingredients • f) Generics • g) Combination products • h) Vaccines • i) Other (please specify)
FL-3.1	If "Other" was selected please specify in the following cell:	Open text response
FL-4	Which reference regulatory authorities are officially recognized by your agency for the application of reliance mechanisms? (Multiple selection possible)	a) EMA • b) FDA • c) PMDA • d) Health Canada • e) Swissmedic • f) TGA • g) MHRA • h) ANVISA • i) WHO • j) Other (please specify)
FL-4.1	If "Other" was selected please specify in the following cell:	Open text response
FL-5	What type(s) of documents are required from the reference authority to apply reliance? (Multiple selection possible)	a) CPP • b) Approval letter • c) Public assessment report • d) Unredacted assessment report • e) GMP inspection report • f) GMP certificate • g) Batch certificates • h) Other (please specify)
FL-5.1	If "Other" was selected please specify in the following cell:	Open text response
MA-1	What information does your agency publish in relation to implementation of reliance? (Multiple selection possible)	a) List of reference regulatory authorities • b) The criteria used in identifying reference authorities • c) General criteria for using reliance (e.g. type of product; public health need) • d) General criteria to justify cases where reliance is not applied in eligible situations • e) The list of documents that are required to undertake a reliance review • f) The scope of review - what information is reviewed from the documents • g) Target timelines for reliance pathway • h) Rationale for each reliance-based decision • i) National adaptations or context-specific considerations for each reliance based decision • j) Other (please specify)

DCT – MA (1/2)	Question	Answer options
MA-1.1	If "Other" was selected please specify in the following cell:	Open text response
MA-2	Does the agency have mechanisms (legal or operational) to access unredacted dossiers or confidential assessment reports from reference authorities or manufacturers when needed?	a) Yes • b) No • c) Not applicable
MA-2.1	If yes, please specify	Open text response
MA-3	Does the agency specify target timelines for the reliance review procedure?	a) Yes • b) No • c) Not applicable
MA-3.1	If yes, please specify (days)	Open text response
MA-4	Does your agency monitor or evaluate the performance and impact of reliance-based decisions in the regulatory function of new marketing authorizations?	a) Yes • b) No • c) Cannot be determined
MA-4.1	If yes, specify the proportion of applications in the last 12 months that used reliance. Numeric % or “Not measured/No data available”.	Open text response
MA-4.2	If yes, specify the median (or if not available, average) total approval time (in calendar days) in the last 12 months for reliance vs non-reliance procedures.” Numeric in calendar days (for reliance vs non reliance) or “Not measured/No data available”.	Open text response

DCT – MA (2/2)	Question	Answer options
MA-4.3	If yes, specify if cost reductions were observed	a) Yes • b) No • c) Cannot be determined
MA-4.3.1	If yes, specify the main drivers for cost reduction	a) Lower administrative and operational workload • b) Reduced time spent on assessment activities • c) Other (please specify)
MA-4.3.1.1	If "Other" was selected please specify in the following cell:	Open text response
MA-5	Is there a formal framework or guidance in place that defines how product sameness is evaluated for reliance-based new marketing authorizations?	a) Yes — formally endorsed • b) Yes — draft under review • c) No • d) Not applicable
MA-6	Does the agency use a specific template, matrix or tool to map and assess differences between the reference product and the locally submitted product for reliance-based new marketing authorisations?	a) Yes • b) No • c) Not applicable
MA-6.1	if yes, please specify	Open text response
MA-7	After the product is approved by the reference Regulatory Authority, has the local authority established a timeframe within which the product must be submitted in the country through the reliance pathway?	a) Yes • b) No • c) Not applicable
MA-7.1	If that timeframe expires, must the product then follow the ordinary approval pathway instead of reliance?	a) Yes • b) No • c) Not applicable