AMERICAS RISE for HEALTH

Regulatory Reliance as an Enabler of Efficiency and Access to Pharmaceuticals in the Americas

November 2025

About Americas RISE for Health

Americas RISE for Health is a health and economy public-private platform that identifies, catalyzes, and accelerates multisectoral collaborations that can be pursued on a voluntary basis to help bring about the resilient health ecosystems and economies that the Americas deserve. Americas RISE for Health works across five pillar workstreams: regulatory improvements, trade and investment, digital health, sustainable health systems, and ethics, to create a healthier more prosperous future for the Americas.

Americas RISE for Health was announced on the IX Summit of the Americas by the U.S. Department of Commerce, with support from the U.S. Department of Health and Human Services, to bolster resiliency of the hemisphere's health economies and ecosystems. To learn more, please reach out to the RISE Secretariat at olivia@americasriseforhealth.org and johan@americasriseforhealth.org

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Executive Summary

This analysis explains how unilateral regulatory reliance can help national regulatory authorities (NRAs) increase regulatory efficiency and accelerate patient access to quality-assured medicines. The analysis describes enabling procedures and operational approaches, highlights successful pilots and practical lessons, and identifies pragmatic, WHO-aligned actions to strengthen predictable and transparent reliance procedures. The analysis focuses on illustrative case studies, operational differences by regulatory function (marketing authorization, GMP inspections, pharmacovigilance) and product type (small-molecule medicines, biologics, vaccines), and practical recommendations.

Glossary

All terms used in this report are aligned with those described in the following documents: "Good reliance practices in the regulation of medical products: high level principles and considerations" (WHO Technical Report Series, No. 1033, 2021, Annex 10), "Good regulatory practices in the regulation of medical products" (WHO Technical Report Series, No. 1033, 2021, Annex 11), and "WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products - Revision VI".

Good Manufacturing Practices (GMP) Inspections: GMP inspections ensure that operations at manufacturing establishments that are part of the supply chain are carried out in accordance with approved standards, norms, and guidelines, and are in compliance with national legislation and regulations. Inspections reveal weaknesses and deficiencies, as well as actual or potential errors in the production, quality control, storage, or distribution of medical products. Therefore, inspection activities are fundamental to guaranteeing the quality, safety, and efficacy of medical products used by the population.

Marketing Authorization (MA): MA refers to a procedure for approval of a medical product for marketing after it has undergone a process of evaluation to determine the safety, efficacy and quality of the product and the appropriateness of the product information. The objective of this regulatory function is to provide a system which ensures that only medical products which have been duly authorized by the NRA are allowed to be manufactured, imported, distributed, sold, or supplied to end-users. The process of assessment for MA includes the review of data on quality, safety and efficacy submitted by the applicant.

Pharmacovigilance and Post-market Surveillance (PV): PV refers to the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medical product-related problems. These activities help guarantee safe and effective medical products of high quality are used within a country.

Reliance: The act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessments by another regulatory authority or trusted institution or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

- **Unilateral reliance**: When a regulator chooses to rely on an assessment from another regulator unilaterally and without reciprocity.

Regulatory framework: The collection of laws, regulations, guidelines, guidance documents and other regulatory instruments through which a government and a regulatory authority control particular aspects of a specific activity.

- **Regulations**: a diverse set of instruments by which governments place requirements on enterprises and citizens. Regulations usually state at high level the conditions to be met and the requirements defined in laws. For instance, a law may prohibit the manufacture, importation or sale of a medical product in the absence of specific authorization, while regulations would set out the conditions for obtaining authorization, such as the provision of certain types of information (the results of non-clinical testing and clinical trials, data on manufacturing and control) that allow the regulatory authority to establish the quality, safety and efficacy or performance of a medical product.
- **Guidelines and other guidance documents**: provide further detail on how the regulated stakeholders can comply with laws and regulations. Guidelines may also provide details of the processes of enforcement of the respective legislation (laws and regulations). Within a regulatory framework for medical products, such documents are usually non-binding and are generally more detailed and scientific in nature. They are thus appropriate for describing the approaches that are generally considered suitable for satisfying regulatory requirements but unsuitable for inclusion in legislation.

Introduction

The World Health Organization (WHO) defines regulatory reliance "as the act whereby the National Regulatory Authority (NRA) in one jurisdiction may take into account and give significant weight (i.e., totally or partially reply upon) to evaluations performed by another NRA or trusted institution in reaching its own decision".[i] The value of regulatory reliance comes in the form of reducing workloads, speeding up processing times, and gaining efficiencies in approval decisions.[ii] Reliance can also support broader trade, investment, and innovation goals by reducing duplicative regulatory barriers, encouraging foreign investment and regional integration.

Lack of regulatory frameworks for NRAs to use reliance is a barrier to access to safe, high-quality, and effective medicines and health technologies. The formalization of reliance pathways in regulations and guidelines allow NRAs to rely on each other by:

- establishing the parts of the regulatory process eligible for reliance;
- codifying the regulatory authorities on which a country may rely;
- specifying the categories of medical products covered by a reliance mechanism; and
- facilitating authorities to develop formal agreements with other NRAs.[iii]

Objectives

This report explains how unilateral regulatory reliance can be used as a practical tool to increase regulatory efficiency and accelerate patient access to quality-assured medicines. It highlights procedural approaches and operational examples that demonstrate how reliance can reduce duplication, shorten timelines and optimize regulatory resources, and proposes pragmatic next steps for Americas RISE to support implementation in the region.

Scope

The analysis focuses on the use of unilateral reliance procedures on three stages of the regulatory process for pharmaceuticals: (1) marketing authorization; (2) good manufacturing practices (GMP) certification; and (3) pharmacovigilance and post-market surveillance and is non-exhaustive of the entire regulatory process. Regulatory authorities in scope are ANMAT (Argentina); ANVISA (Brazil); ISP (Chile); INVIMA (Colombia); and COFEPRIS (Mexico).

This analysis does not include the use of reliance procedures in medical devices or in-vitro diagnostics medical devices. A separate analysis with its corresponding report should be conducted separately given the differences in these types of products and regulatory landscape.

Methodology

This analysis is based on desk research, conducted from 2024-2025, of publicly available regulatory texts, official guidance, and documented pilot programs and case studies, to identify the presence of enabling procedures and practical examples of the use of reliance. A survey was disseminated to regional regulatory experts from private sector to validate findings from the desk research. Five multinational pharmaceutical companies responded.

Key Findings

Reliance can contribute to regulatory efficiency and access across different regulatory functions and product types when implemented effectively. Reliance provides an opportunity to address the current limited capture of new medicine launches in the region—averaging 26%—by streamlining processes, reducing duplication, and accelerating patient access to innovative therapies.[iv]

The analysis found that while the countries assessed have the legal authority for reliance, the extent of implementation of reliance, varies. There are three key findings:

1. **Countries have the enabling procedures to use reliance.**

The countries assessed have enacted regulatory texts, resolutions, or guidance that enable reliance for marketing authorization and GMP certification. These actions demonstrate a strong foundation for regulatory cooperation. However, countries have not provided authority for reliance to pharmacovigilance, leaving room to expand reliance across the full regulatory process.

2. **There is variation by regulatory function and product type.**

Some NRAs apply reliance differently by regulatory function—marketing authorization, GMP certification, or pharmacovigilance—and by product type—small molecules, biologics, or vaccines. This variation highlights regulatory authority's adaptability. At the same time, inconsistency across functions and products creates challenges in implementing reliance.

3. **While there is authority for reliance, it is not being fully leveraged to increase access and attract investment.**

The NRAs analyzed have applied enablers to facilitate the uptake of reliance such as: clear eligibility criteria, standardized application/documentation checklists for abridged pathways, defined process timelines, bilateral or multilateral information sharing agreements, and formal pilot protocols with monitoring metrics. However, uneven implementation of these enablers limits their impact. Expanding and harmonizing these practices across agencies and product categories offers an opportunity to improve efficiency and increase access.

The analysis found that all countries assessed have the legal and procedural frameworks for reliance, and that greater consistency in implementation would allow governments to fully realize the benefits of reliance. By fully implementing reliance, governments can increase access to new medicines, closing the region's current limited capture of new medicine launches—averaging 26%—and strengthening the overall efficiency, transparency, and attractiveness of their regulatory systems to investment.

Country Analysis

Argentina

Argentina has a reliance pathway for marketing authorization for synthetic products. Decree 150/1992 provides a list of reference countries, referred to as Annex I countries. The decree authorizes those medications with marketing authorization in at least one Annex I country to be automatically registered with ANMAT, provided that the official certification and supporting documentation are submitted. ANMAT does not have a similar reliance pathway for biologics and vaccines.

Argentina partially implements reliance for GMP inspections. ANMAT relies on GMP inspections of synthetic products conducted by Annex I reference countries. Revisions to Decree 150/1992 also added a list of Annex II countries for which imports of synthetic products are allowed but require direct inspection by ANMAT or Annex I regulators to ensure compliance with health and safety standards. Similar to marketing authorization for biologics, the reliance pathway for GMP inspections of biologics is underdeveloped. Disposición 7075/2011 stipulates that ANMAT may verify documentation submitted for approval of biologics. ANMAT's verification may include inspections of foreign manufacturing plants.

ANMAT does not have codified any reliance pathways for pharmacovigilance.

Surveyed experts report that reliance is being applied for the approval of new medicines and for leveraging GMP inspections conducted by other NRAs. However, the requirement to submit a Certificate of Pharmaceutical Product (CPP) limits the efficiency and flexibility of the process in practice. ANMAT also relies on Latin American authorities, referencing inspections conducted by MERCOSUR regulators while retaining the authority to formally certify GMP compliance by issuing its own certification.

The use of reliance is particularly limited in the post-approval phase, where no clear pathways exist for post-approval changes to benefit from reliance mechanisms. That said, the recent inclusion of reliance as a priority in ANMAT's 2024–2027 Strategic Plan suggests that Argentina is looking to strengthen its use of reliance, closing the gap between the codified framework and its practical application across the regulatory lifecycle.

Brazil

In 2022, following the publication of the WHO reliance guideline, ANVISA published Resolution RDC 741/2022, which established general principles for regulatory reliance and criteria for defining reference authorities (AREEs, as per the acronym in Portuguese). This laid the foundation for revising and modernizing reliance pathways for drug registration and post-approval changes, which were already in use in Brazil since 2017.

So, before introducing changes to adapt and expand the scope of their reliance pathways for marketing authorization of pharmaceutical products, ANVISA launched a pilot program to test new criteria that could improve regulatory efficiency and practices. For that, ANVISA launched a temporary pilot reliance regulation, codified under Resolution RDC 750/2022.

Building on the pilot, ANVISA formalized its reliance practices in 2024 through Normative Instruction (IN) No. 289/2024. This framework introduced an "optimized analysis

procedure" that utilizes assessments from recognized AREEs to expedite regulatory approvals for pharmaceuticals, including biologics, vaccines, and APIs. The reliance mechanism applies to both initial drug registrations and post-approval changes, while ensuring adherence to rigorous safety and efficacy standards.

Normative Resolution 292/2024 strengthens Brazil's framework for reliance in GMP certification, and ANVISA retains the right to make independent decisions and diverge from AREE conclusions when deemed necessary for Brazilian regulatory and public health contexts. For example, ANVISA has retained the right to independently conduct international inspections when needed. While reliance may expedite dossier reviews or licensing approvals by utilizing documentation from recognized authorities, ANVISA's direct inspections can still be employed to validate manufacturing practices or address gaps in documentation.

Brazil's regulatory reliance provisions are comprehensive, but due to the recent introduction of revised regulation, gains from an accelerated approval pathway have yet to be realized. Surveyed experts from pharmaceutical companies cite procedural and administrative constraints' impact on review and approval times. For example, detailed form requirements for reliance application, the fact that technical country-specific documentation are required, and limited reference authorities eligible for certain medical products reduce the intended regulatory efficiency from an accelerated pathway.

For GMP inspections, Brazil has established provisions for reliance, but survey experts from pharmaceutical companies report that ANVISA often requires the issuance of a local GMP certificate even when recognized foreign certificates are available, limiting the intended efficiency benefits. No reliance mechanisms are in place for pharmacovigilance.

Chile

Chile's legal framework is grounded in its Sanitary Code, which authorizes the commercialization of medical products, and is complemented by Ministry of Health decrees.

Modifications to Supreme Decree No. 3 of 2010 introduced provisions to allow for abridged approval and expedited pathways for marketing authorization, leveraging prior approvals from trusted regulatory authorities.[v] These provisions allowed for the approval of marketing authorization applications for small molecule medicines that have already been registered with a WHO Listed Authorities (WLAs) or an NRAr.

Additionally, Resolution No. 679-2025 established the internal procedure for the application of a reliance mechanism for biologics. This resolution does not apply if the registration in the reference country receives conditional or emergency approval. Additionally, this resolution requires that the product be approved by at least two of the following NRAs: EMA, FDA, MHRA, TGA, and PMDA.

Modifications to Supreme Decree No. 3 also allowed ISP to accept GMP certificates of finished pharmaceutical products (FPPs) issued by the NRA in the country of origin.[vi]

Chile's legal provisions provide a framework for local pharmacovigilance systems but do not include explicit provisions for reliance on other NRAs or international data sources. However, in practice, Chile's ISP informally utilizes international data and collaborates with global entities like the WHO for pharmacovigilance activities.[vii] This reflects an informal reliance approach rather than a legally codified reliance mechanism.

Chile has established a comprehensive regulatory framework for marketing authorization that includes reliance mechanisms, particularly for synthetic products. Surveyed experts report that the reliance pathway for small molecules is widely utilized and generally accelerates approval timelines. However, for biological products, the reliance pathway remains under development. An internal pilot was launched in early 2025 but has not yet been fully implemented.

Certain regulatory requirements—such as the need for approvals from two reference countries and limitations on relying on conditional or emergency approvals—constrain the use of reliance for biologics. Additionally, post-approval changes are currently excluded from the reliance framework.

Colombia

Colombia has implemented Presidential Decrees that authorize the Ministry of Health to implement regulatory reliance. In 1995, Presidential Decree 677 provided general guidelines for a streamlined pharmacological evaluation of a product if registered in two reference countries. This decree allows the acceleration of the approval timeline to 30 days.

Presidential Decree 335 of 2022 authorizes INVIMA to accept the GMP certifications from other NRAs including the U.S., Canada, Germany, Switzerland, France, the United Kingdom, Denmark, the Netherlands, Sweden, Japan, and Norway. For some reference authorities, INVIMA will accept GMP certificates for products manufactured in the country of reference and/or a third country.

Presidential Decree 1782 of 2014 provides authority for INVIMA to use global evidence from established regulatory authorities in other countries to demonstrate the safety and efficacy of a medicine to reference products. Global evidence refers to the efficacy and safety profile, clinical trials and pharmacovigilance information available in the countries in which it is marketed and the time of marketing, both of the drug being evaluated and of the set of drugs containing a highly similar API.

Colombia's regulatory framework includes Decree 677 of 1995, which allows for a simplified pharmacological review if a product is approved in at least two reference countries. However, a lack of clear guidelines and uncertainty about how international approvals interact with domestic requirements result in a limited use of reliance for marketing authorizations. INVIMA retains significant autonomy to make independent assessments, and surveyed experts report that timelines for new marketing authorizations are lengthy, ranging from 36 to 48 months.

In contrast, reliance appears to be functioning more effectively for GMP inspections and pharmacovigilance, where surveyed experts report fewer barriers and smoother processes. This mixed experience highlights gaps in Colombia's regulatory provisions and the consistent application of reliance in practice, particularly for initial approvals.

Mexico

Mexico's Secretariat of Health has published subsequent regulations (called "Agreements") that legally authorize COFEPRIS to recognize the results of regulatory procedures conducted by a number of reference authorities as equivalent to those implemented by the Mexican regulator. These Agreements allow for unilateral reliance for marketing authorization (Agreement June 11, 2025)as well as GMP inspections (Ministerial Agreement of March 20, 2025), as COFEPRIS considers GMP certificates from

the reference countries as equivalent. These agreements also codify a maximum 60 business day review period for applications requested under these Agreements, providing an accelerated pathway for review.

While Mexico has published across the year several Agreements codifying reliance, the persistence of national requirements has limited the extent to which reliance has been adopted in day-to-day regulatory practice. The codified equivalence pathway retains requirements for country-specific documentation, which diminishes the efficiency gains expected from reliance. For example, surveyed experts report that timelines are often unpredictable, with delays even when reliance-based applications are submitted.

In June 2025, Mexico published a new Agreement, applicable to the marketing authorization of medicines and medical devices that have already been approved by Reference Regulatory Authorities (RRAs) or prequalified by the WHO. It facilitates the importation of unregistered health products in cases of national emergencies or for the treatment of neglected and emerging diseases. The agreement seeks to reduce approval timelines, streamline administrative processes, and accelerate patient access to essential and innovative health products, while aligning Mexico's regulatory practices with international standards and WHO recommendations. This agreement will take effect in September 2025.

Conclusion and Recommendations

The overall conclusion from the analysis is that unilateral regulatory reliance, when implemented through clear procedures, transparency and capacity building, is a practical mechanism to reduce regulatory duplication, shorten time to decision and support more timely patient access to quality-assured medicines. The codification of reliance in regulations and guidelines is of utmost relevance to ensure its adequate, consistent, and sustainable implementation.

Furthermore, the data collected and the interaction with stakeholders from the pharmaceutical sector some best practices which can be translated into strategic recommendations to advance the safe and effective use of reliance in the region:

Support pilot programs and peer learning: Facilitate replication of successful pilots through peer exchanges, technical assistance and regional learning events. Provide a simple pilot protocol template that NRAs can adapt.

Encourage measurement and validation: Collect minimal, comparable metrics from pilots (e.g., median timelines, number of reliance applications, time to patient availability) and require a validation consultation with NRAs before broader procedural adoption.

Promote procedural clarity: Encourage NRAs to publish clear procedural guidance for reliance that sets eligibility criteria, required documentation, timelines and public decision templates. The broad consultation and dialogue with stakeholders prior to the adoption of any regulation or guideline is a key step for building effective reliance pathways.

Avoid prescriptive legal mandates: Recommend procedural adoption and gradual scaling via pilots and guidance rather than immediate legislative mandates; consider legal reform only when operational benefits are validated and broadly agreed.

Strengthen capacity and trust mechanisms: Support technical training, joint inspections, information-sharing agreements and platforms for sustained NRA cooperation to build trust and technical alignment.

Emphasize transparency and documented decision-making: Advocate for public summaries of reliance-based decisions and documented rationales that safeguard confidentiality while promoting stakeholder confidence.

Develop monitoring indicators: Performance-based indicators and internal reviews are important in ensuring consistency in the application of reliance, to ensure that the procedures in place are translated into desired outcomes.

Annex

Acronyms

ANMAT: Administración Nacional de Medicamentos, Alimentos y Tecnología Médica, Argentina

ANVISA: Agência Nacional de Vigilância Sanitária, Brazil

AREE: Equivalent Foreign Regulatory Authority

COFEPRIS: Comisión Federal para la Protección contra Riesgos Sanitarios, Mexico

CPP: Certificate of Pharmaceutical Product

EMA: European Medicines Agency

FPP: Finished Pharmaceutical Product

GMP: Good Manufacturing Practices

INVIMA: Instituto Nacional de Vigilancia de Medicamentos y Alimentos

ISP: Instituto de Salud Pública de Chile

MHRA: Medicines and Healthcare products Regulatory Agency, United Kingdom

NRA: National Regulatory Authorities

NRAr: National Regulatory Authorities of reference

PMDA: Pharmaceuticals and Medical Devices Agency, Japan

PV: Pharmacovigilance

TGA: Therapeutic Goods Administration, Australia

U.S. FDA: U.S. Food and Drug Administration

WHO: World Health Organization

WLA: WHO Listed Authority

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