



# Regulatory Reliance for Non-Prescription Medicines

Enabling Timely and Equitable Access  
on the Path to Universal Health Coverage

November 2025

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# Introduction

Self-care is a foundational element for achieving universal health coverage (UHC).



Empowering individuals to manage minor ailments through appropriate self-care reduces pressure on health services and improves overall health outcomes, even as healthcare systems grapple with demographic shifts, rising chronic disease burdens, and limited resources. Non-prescription medicines (NPM) play a central role in this transformation. These products, which can be used safely and effectively without the direct supervision of a healthcare provider, allow individuals to treat self-treatable conditions and minor ailments such as pain, allergies, and gastrointestinal discomfort, thereby reserving clinical care for more complex needs.

The World Health Organization (WHO) recognizes the importance of self-care – including access to NPM – as a critical strategy to achieve UHC, promote equity, and increase the efficiency of health systems <sup>1</sup>. It's estimated that by 2030, self-care enabled by NPM could save \$179 billion in healthcare costs, free up 2.8 billion hours in physician time, and generate 72 billion additional productive days globally <sup>2</sup>. Despite these immense benefits, access to these essential products remains uneven. Around 2 billion people lack access to essential medicines, including many widely available non-prescription products, largely due to regulatory capacity limitations, particularly in low- and middle-income countries <sup>2</sup>.

By 2030, self-care could:

**SAVE**

**\$179 billion**

in healthcare costs globally

**FREE UP**

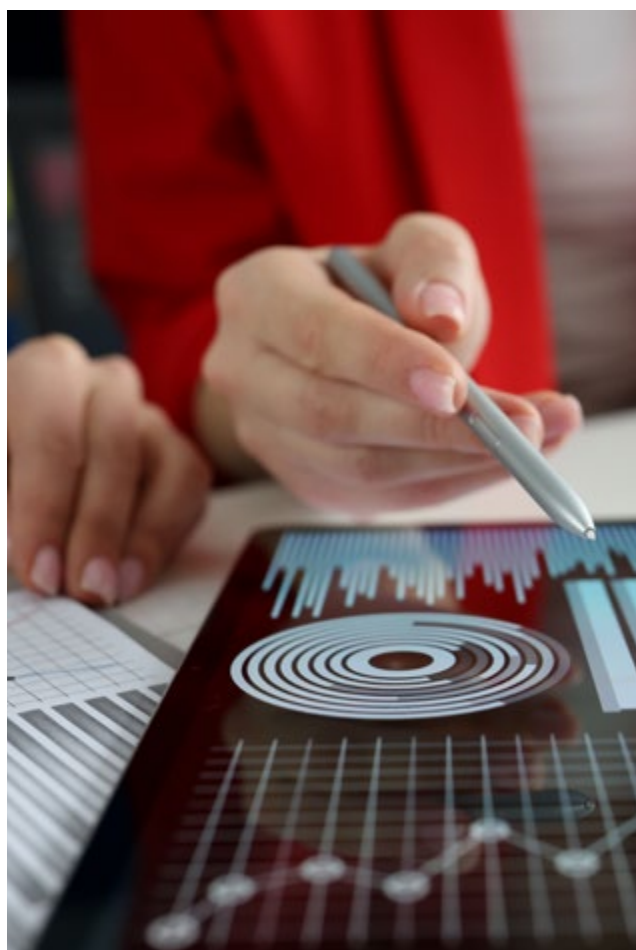
**\$2.8 billion**

hours in physician time

**GENERATE**

**72 billion**

additional productive days



Regulatory reliance offers a strategic, efficient, and scalable pathway to address this challenge.

The WHO defines regulatory reliance as a National Regulatory Authority (NRA) actively using assessments from another trusted regulator or institution to inform its own decisions, while retaining full independence, responsibility, and accountability in its final ruling<sup>3</sup>. Importantly, reliance does not imply a delegation of authority because the final decision always rests with the original NRA. Rather, it allows for a more strategic and efficient use of limited resources while preserving critical oversight functions.

## WHO's Good Reliance Practices stress two guiding principles:

**PROPORTIONALITY** ensures that the regulatory requirements imposed are aligned with the product's risk level: an especially relevant consideration for NPM, which generally exhibit well-established safety and efficacy profiles.



**EFFICIENCY** calls for a prudent use of resources by aligning national processes with international standards and minimizing redundant regulatory effort<sup>3</sup>.



In operational terms, reliance supports the adoption of simplified, risk-based registration pathways, particularly for products already approved by reference authorities with recognized scientific rigor. This approach applies to all categories of medicines. Prescription medicines typically require extensive benefit–risk evaluations and ongoing post-market surveillance due to their safety, efficacy, or use patterns in the general population.

By contrast, NPM generally have well-characterized safety profiles, with potential risks already identified, managed, and monitored through decades of widespread use and regulatory oversight, often beginning during their time as prescription products. These products are supported by consistent safety and efficacy data across multiple jurisdictions, making them suitable for simplified, risk-proportionate regulatory pathways.

Although NPM provide an ideal starting point for leveraging reliance pathways, today the possibility remains extremely limited.



For NRA, implementing a reliance framework can safely and efficiently streamline decision-making while maintaining full oversight. A strong framework begins with clear legal authority and a well-defined scope, ensuring that NRAs can consider assessments from trusted reference authorities without compromising their ultimate responsibility for final decisions, including labeling, recalls, and post-market safety monitoring. Trust in the scientific rigor and independence of reference authorities is essential and can be reinforced through access to complete, unredacted assessment reports, participation in international harmonization networks, and formal agreements. Structured procedures, transparent timelines, and mechanisms to manage differences with reference decisions further strengthen confidence in the process.

Many NRA remain hesitant to adopt reliance pathways due to common misperceptions, such as loss of sovereignty, lack of legal framework, misalignment of standards with reference authorities including risk-based approach (e.g. Monographs), and overall lack of trust in the technical standards of reference authorities. These concerns can be mitigated through clear policies, transparent procedures, stakeholder engagement, and support from trusted global partners. It would enable reliance to be implemented without compromising national sovereignty or public health safeguards.

NPMs provide an ideal starting point for reliance because of their well-established safety profiles, low inherent risk, and long histories of use supported by extensive real-world and post-marketing data. Core assessments of quality, safety, and efficacy are generally transferable across jurisdictions, requiring minimal local adaptation beyond labeling or cultural considerations. Many NPM are harmonized internationally in terms of active ingredients and indications, further reducing the need for repeated evaluation. At the same time, NPM represent a high volume of submissions that are individually low complexity. Applying reliance to these products allows NRAs to achieve immediate efficiency gains, allocate resources to higher-risk or novel products, and gain practical experience with reliance pathways, all of these while maintaining rigorous oversight and protecting public health.



Unfortunately, the possibility to leverage reliance pathways for NPMs today is extremely limited. Many NRAs do not have reliance mechanisms in place at all, and for those that do, the systems are primarily geared toward the needs of prescription medicines, reflecting their more recent development. For example, many NRAs do not accept proof of authorization from the US and Canada as suitable because products under their monograph systems are not individually approved. Additionally, some NRAs require that products be manufactured at the same site as the reference product – a requirement that may be appropriate for biologics but is often impractical for NPMs, which are frequently produced locally. Furthermore, many jurisdictions do not include national medicines agencies in Europe as acceptable reference authorities, recognizing only the European Medicines Agency, which does not evaluate NPMs.

# Tools to Support Regulatory Reliance

Digital tools to facilitate information sharing and enhance reliance can be divided into two categories:



## SECURE INFORMATION-SHARING PLATFORMS

which can be implemented to exchange unredacted assessment documents between NRAs, enhancing transparency of processes and mutual trust.



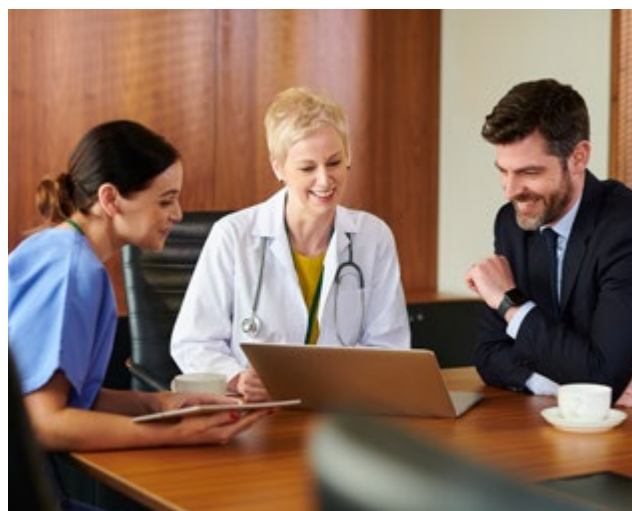
## USE OF E-SUBMISSIONS AND E-DOCUMENTS

such as the ICH eCTD format, that could be used to speed up approval processes as it standardises requirements and makes updating of information more efficient <sup>4</sup>.

Moreover, modernization of authentication methods for Certificate of Pharmaceutical Product (CPP) and other Government issued documents (GIDs), e.g GMP certificates and Manufacturing and Importation Authorisation Licences (MIAs), address concerns about authenticity and eliminate the time-consuming and costly need for legalization and notarization. eGIDs are a valuable tool for reliance, providing standardized confirmation that a product is authorized for marketing in the issuing country and manufactured according to Good Manufacturing Practices (GMP). Other tools that can support reliance for NPMs include compendial standards, WHO prequalified lists, and unredacted assessment reports from trusted regulators, where available.

For NRAs interested in leveraging reliance for NPM, initial practical steps may include mapping national priorities to identify high-demand NPM, selecting trusted reference authorities with established systems, and adopting clear pilot guidance that explicitly describes how reliance will be used. Proactive stakeholder engagement is crucial to build trust and support for the new approach. Finally, starting with a limited set of products to pilot the reliance pathway allows an NRA to track performance, identify bottlenecks, and adjust processes based on continuous learning and feedback <sup>4</sup>.

Regulatory reliance pathways should be expanded to cover post-approval changes (PACs) where initial product approvals were supported by reliance mechanisms by assuring ‘sameness of product’.

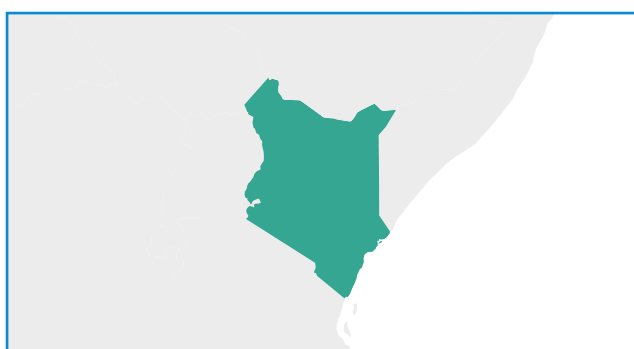


# Reliance in Action: Case Examples

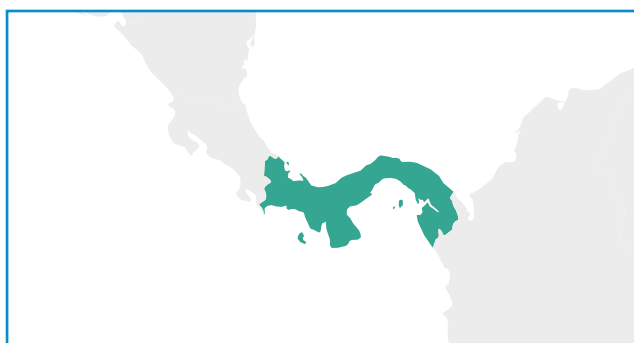
Countries globally have successfully demonstrated how reliance can be operationalized to increase access to medicines.



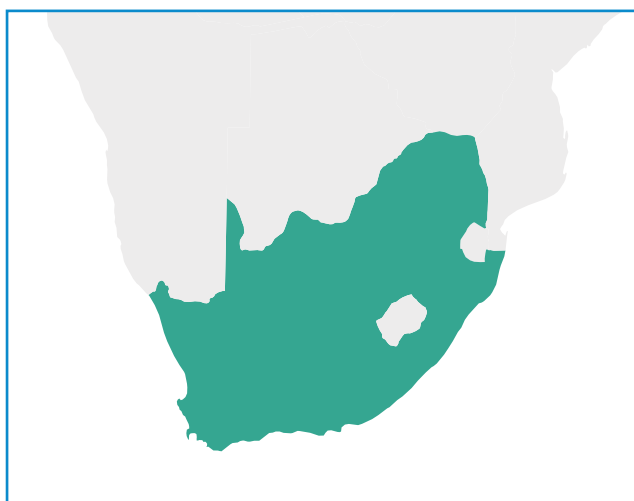
For NPMs specifically, this can mean significantly faster access to individuals:



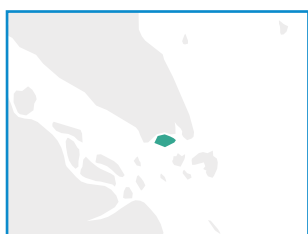
In **Kenya**, a fast-track reliance pathway has enabled medicine registration in as little as 90 days, a substantial improvement compared to the typical 6 months required for a full assessment <sup>5</sup>.



In **Panama**, recent guidelines now allow for the recognition of approvals from WHO-listed authorities, which significantly reduces duplicative testing and speeds up product registration <sup>6</sup>.



**South Africa's** SAHPRA utilizes a structured reliance framework to evaluate products approved by recognized reference authorities, considering the local context while minimizing redundant effort <sup>7</sup>. Their approach to reliance is modular, for instance, authorities could apply reliance for the safety and efficacy components while still conducting a full review of Module 3 to assess quality aspects, such as when a different manufacturing site is used compared to the reference product.



**Singapore, Australia, and Canada** already use streamlined or reliance-based pathways for OTC switch decisions or NPM approvals, often referencing EU, US, or WHO evaluations <sup>1</sup>.



The **International Recognition Procedure (IRP)** introduced by the UK **Medicines and Healthcare products Regulatory Agency (MHRA)** provides a strong and practical example of a modern reliance approach currently being tested in real-world regulatory practice. The IRP allows the MHRA to recognize assessments and approvals conducted by trusted reference authorities, including Australia's TGA, Health Canada, SwissMedic, Singapore's HSA, Japan's PMDA, the US FDA, and the EMA along with EU/EEA Member State competent authorities (including those using centralized, MRP/DCP, and national routes). This model demonstrates how structured international recognition can accelerate access to quality-assured medicines while maintaining rigorous oversight and leveraging established regulatory expertise.

# Call to Action

**National Regulatory Authorities (NRAs)** should implement reliance pathways and ensure they are:

A close-up photograph of a person's hands holding two blister packs of medication. One blister pack contains white capsules, and the other contains green capsules. The background is slightly blurred, showing more medical supplies.

01

Suitable for use with NPMs.

Capable of delivering faster conclusions compared to standard assessments.

A blurred photograph of a busy hospital corridor. Several people, including healthcare workers and patients, are moving through the hallway. The motion blur suggests a fast-paced environment.

02

Clearly defined reliance procedures should be published, outlining the required abbreviated data package to be submitted. Countries with established monograph or listing systems such as the United States, Canada, and Australia should be recognized as acceptable reference authorities for NPMs, given that their NRAs have conducted robust safety, efficacy, and quality evaluations, even if these assessments were performed at the monograph or list level rather than on a per-product basis. Similarly, national regulatory authorities in Europe should be accepted as reference agencies, not only the European Medicines Agency, which does not evaluate NPMs.

A pragmatic approach should be applied to the definition of “sameness,” consistent with the WHO interpretation that “two products have identical essential characteristics.” For example, it should not be mandatory for products to be manufactured at the same site as the reference product, provided that the qualitative and quantitative composition, pharmaceutical form, and active ingredient suppliers remain the same. Where full reliance cannot be implemented, partial or modular approaches should be considered for instance, applying reliance to safety and efficacy evaluations while conducting a full Module 3 (quality) review to accommodate a different manufacturing site.

At minimum, lower levels of reliance such as acceptance of GMP certificates issued by another recognized regulatory authority should be implemented to promote efficiency and maintain regulatory rigor.

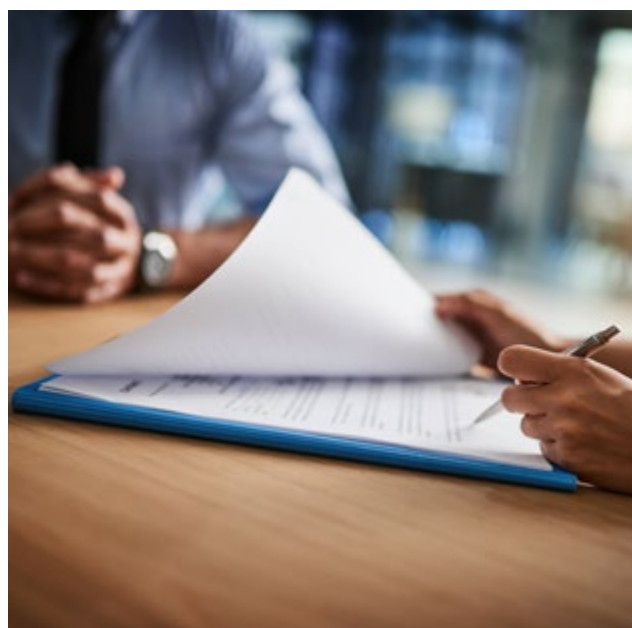


In parallel, NRAs should be encouraged to pursue **convergence of regulatory requirements and streamlining of standards** by adopting internationally recognized guidelines into national regulations.

This approach fosters mutual trust, reduces technical barriers to market entry, and enhances predictability of regulatory processes. Additionally, **collaboration and information sharing among NRAs** should be strengthened to build confidence, harmonize approaches, and facilitate the exchange of best practices ultimately supporting a more efficient and trusted global reliance framework for NPMs.

The **World Health Organization** can support these efforts by facilitating the creation of a secure, centralized platform for the confidential sharing of unredacted assessment reports among regulators.

Furthermore, expanding the WHO Prequalification Scheme to cover a defined list of essential NPM would accelerate access to quality-assured NPM in low- and middle-income countries. There is also a need for clarifications that the recommendations apply to NPMs. E.g. through guidelines and points to consider documents, put forward principles that are unique to NPMs. WHO should review and modernize the Certificate of Pharmaceutical Product (CPP) format, including electronic verification features, to enhance its authenticity and support for streamlined international registration.



By embracing these strategies, NRAs can significantly improve access to essential NPM, while the WHO strengthens global regulatory collaboration, ultimately supporting better public health system and furthering an adoption of the Universal Health Coverage worldwide.



# Conclusion



**Regulatory reliance is an evidence-based, efficient, and scalable approach to strengthening national regulatory systems.**



By adopting robust reliance frameworks across all medicine categories, and particularly for NPM, NRAs can dramatically improve patient access to essential products, strategically focus their limited resources on higher-risk areas, and accelerate their path toward regulatory maturity. The WHO and numerous global regulatory networks consistently endorse reliance as a practical and powerful solution to a common challenge: how to do more, with less, without compromising public health.

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# About GSCF

The Global Self-Care Federation is dedicated to a world where self-care increasingly contributes to better health and more sustainable healthcare systems. We represent associations and manufacturers in the self-care industry, working closely with our members and relevant stakeholder groups to ensure evidence-based self-care products and solutions are recognized as key contributors to health for individuals and systems worldwide.

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