Global Policy Issue Brief –
Global Regulatory Efficiencies: Development, Approval & Post-Approval Changes

At Viatris, we see healthcare not as it is, but as it should be. This future-focused outlook drives our commitment to policy solutions that help increase access to a broad range of trusted, quality medications for patients worldwide, regardless of geography or circumstance. With a mission to empower people worldwide to live healthier at every stage of life, we provide access at scale, supplying high-quality medicines to approximately 1 billion patients around the world annually.[1] As an active contributor to international harmonization efforts such as the technical expert working groups of the International Council for Harmonization (ICH), Viatris is committed to actively engaging to fortify the regulatory frameworks that support the development, approval, and post-approval changes of our medicines worldwide.

Public Policy Statement
Streamlining regulatory frameworks that support the development, approval, and post-approval changes of medicines worldwide optimizes the use of both industry and health authority resources to create more efficient regulatory assessments, ultimately accelerating and expanding access for patients. Streamlining can be accomplished through harmonization, reliance, and agility, which expedites medicine approvals and enhances availability while upholding rigorous safety and efficacy standards.

Issue Background

Regulatory frameworks that govern the development, approval, and post-approval of medicines are comprised of a vast array of rules and regulations to ensure the safety, efficacy, and quality of medicines, ultimately, to protect public health. These frameworks encompass processes for how medicines are studied and tested, reviewed and authorized for public use, and monitored for safety and proper use after they are launched. While these frameworks are intended to facilitate access to medicines that are proven safe and effective, unnecessary divergence across regions, as well as limited agility and adaptability, can delay or prevent timely patient access to essential medicines.

Importance for Access

The pharmaceutical industry operates globally, and a single medicine may be marketed across numerous countries and territories. Despite this, local regulatory frameworks often differ, even when approving similar or equivalent medicines. This necessitates duplicative efforts to navigate varying, often overlapping requirements, leading to potential delays or

[1] Viatris, 2024 Sustainability Report

Published June 2025 | Approved for External Use

limitations to patient access, without offering any added value. Similarly, regulatory frameworks that are not optimized for the rapid development, assessment, approval, and distribution of medicines, especially in times of crises, may miss critical opportunities to maximize timely access to essential therapies. The COVID-19 pandemic underscored the critical need for flexibility across regulatory frameworks, demonstrating how agile systems can accelerate access to vaccines and treatments. As such, streamlining these frameworks can accelerate and expand access to essential treatments and optimize health system resources, all while maintaining robust safety and efficacy standards.

Viewpoint

Health authorities should streamline regulatory frameworks for development, approval, and post-approval changes through harmonization, reliance, and agility.

Regulatory harmonization. Health authorities should embrace regulatory harmonization, aligning technical requirements with internationally-recognized standards to promote consistency across markets, improve efficiency in the regulatory review process, and reduce duplication, including of unwarranted human and animal testing.

- Newer, innovative medicines offer novel ways to treat existing diseases and should be supported by science-based, internationally-aligned frameworks that promote their rapid development, assessment, and approval. These medicines can deliver valuable improvements for patients, healthcare professionals, and payers, and require fit-for-purpose regulatory frameworks unique to their complexities.
- Regional advances in regulatory science should be adopted globally through international standards, such as the product development and registration guidelines from the International Council for Harmonisation (ICH).[2] Establishing scientific consensus between health authorities and the global pharmaceutical industry on the technical aspects of drug registration is an important step for harmonization.
- Other avenues to promote international, multistakeholder collaboration, including consultation with industry on emerging regulatory challenges, strategic coordination, and alignment of technical and data standards, should be leveraged.

Regulatory reliance. A health authority in one region may rely upon assessments from another health authority to make its own regulatory decision. Efficient reliance pathways that allow health authorities to exchange information and reduce unnecessary divergence can streamline processes and conserve resources, promoting access to safe, effective, quality medicines for patients in regions with low-resourced regulatory systems and optimizing efficiencies in regions with more developed regulatory systems.

- Regulatory systems with limited resources should adhere to the World Health Organization's (WHO) recommendation to strengthen critical regulatory functions

[2] International Council for Harmonisation, Mission

Published June 2025 | Approved for External Use

and rely on the assessments of other advanced health authorities.[3] The WHO Prequalification pathway, the WHO Collaborative Registration Procedure (CRP), and Swissmedic Marketing Authorization for Global Health Products (MAGHP) are registration pathways that can facilitate faster approval and accelerate access to medicines, especially in low- and lower-middle income countries (LMICs).

- All regulatory systems should embrace reliance where appropriate and possible.
    - For example, the Access Consortium – comprising of regulators from Australia, Singapore, Canada, the United Kingdom, and Switzerland – implements a work-sharing model to jointly review medicinal product registrations.[4] Similarly, the United Kingdom's International Recognition Procedure (IRP),[5] which allows the UK's regulatory agency (MHRA) to take into account the expertise and decision-making of a trusted regulatory partner, serves as another opportunity for convergence. These approaches to reliance reduce duplication, conserve resources, and allow each authority to retain independent decision making.
    - Additionally, regulators should leverage Mutual Recognition Agreements (MRAs), enabling one national regulatory authority to rely upon information from drug inspections conducted by foreign regulatory authorities. By minimizing duplicative inspections, these agreements can help reduce delays and accelerate access to medicines across participating regions.
- Regulatory reliance should be used throughout a medicine's lifecycle, from initial research and development to approval and beyond, to avoid unnecessary duplication of the work of health authorities.

Regulatory agility. Health authorities should strive to update or amend technical requirements in response to scientific advances, improving efficiency without compromising the rigor of safety and efficacy standards. Regulatory agility can facilitate scientific advancements, fostering more efficient pathways to approval.

- Health authorities should adopt regulatory agilities that address unnecessary burdens and encourage the rapid development, assessment, approval of, and access to safe and effective medicines. This includes those that:
    - Enable timely updates and implement new guidance to regulatory requirements in response to advances in scientific knowledge, new technologies, or international best practices.
    - Enable developers to leverage digital technologies or real-world evidence to accelerate the generation of robust scientific evidence and improve access. For example, the adoption of electronic patient information leaflets (e-leaflets) as a digital substitute for paper leaflets could offer increased flexibility in medicine distribution by mitigating delays associated with

[3] WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory system of medical products: manual for benchmarking and formulation of institutional development plans, 2024
[4] The Access Consortium
[5] MHRA, International Recognition Procedure, 2025

repackaging and facilitate the collection of real-world data on medicine use from patients and healthcare professionals.
    - Mitigate international disruptions to supply chains or regulatory processes, such as those that may occur during a public health emergency or geopolitical crisis. For example, registrations of additional manufacturers for products in limited supply could be fast-tracked to widen the pool of suppliers as quickly as possible.
- Agilities implemented during the COVID-19 pandemic, including rolling submissions and reviews, expedited approvals, conditional or emergency use authorization pathways, label exemptions and waivers, and post-approval changes/post-approval change management protocols (PACs/PACMPs), should be sustained to help address current regulatory challenges or build resilience for future emergencies.[6] Their success in accelerating and expanding access to essential medicines and vaccines while upholding regulatory standards highlights the value of incorporating similar agilities into current regulatory practices. For example, to alleviate a drug shortage, an assessment of a new manufacturing site may be expedited, or expiration dates may be extended if stability and safety can be demonstrated.

For additional Global Policy Issue Briefs, refer to Viatris' Public Policy page.

[6] IFPMA, Regulatory Agilities Applied to Regulatory Processes, 2022

Published June 2025 | Approved for External Use