Global Policy Issue Brief –

Improvements to Existing Medicines

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]

Public Policy Statement

Improvements to Existing Medicines covers products based on known molecules that address healthcare system needs and deliver relevant improvement for patients, healthcare professionals, and payers. A **dedicated regulatory pathway for abbreviated development** should be established for improvements to existing medicines that encompasses drug repurposing, drug reformulation, and drug combinations. Further, improvements to existing medicines should be recognized as a **separate category of innovation with the appropriate incentives**, including appropriate and proportionate exclusivity protections and pricing & reimbursement frameworks that recognize the value differentiated products offer to improve patient access and health outcomes while reducing health system costs.

Issue Background

Improvements to Existing Medicines covers products based on known molecules that address healthcare needs and deliver valuable improvements for patients, healthcare professionals, and payers. This category of products includes drug repurposing (a new indication), drug reformulation (finding a better formulation or dosage) and drug combination (developing a new combined drug regimen, adding a new device, or providing a new service).

In the United States (US), these products are approved for use and marketing under a dedicated regulatory pathway known as the 505(b)(2) New Drug Application (NDA) regulatory pathway. Established by the Hatch-Waxman Amendments of 1984, the pathway allows manufacturers to leverage existing data to develop clinically significant improvements to a previously approved drug. This can result in a faster route to approval and reduce development costs while creating new, differentiated products that have the potential to improve health outcomes and reduce health system costs. Between 2010 and 2020, over half of the new drug applications were approved via the 505(b)(2) pathway, with consistent growth in the use of the pathway during this 10-year period.

[1] Viatris, 2023 Sustainability Report

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At present, there is no specific regulatory pathway for Improvements to Existing Medicines outside the US. The EU, Australia and Japan are currently considering frameworks to facilitate the approval and authorization of repurposed drugs, yet some jurisdictions have neglected to recognize the importance of other clinically significant improvements including reformulated and combination drugs. Lack of a specific regulatory pathway has resulted in high complexity for manufacturers trying to determine a suitable pathway for approval and navigating different levels of evidence generation required for the relevant improvement. This prolongation of the development and regulatory timeline and increased cost may prevent registration of these medicines resulting in delayed access to patients.

Further, despite the necessary investment and time needed to develop drug improvements, many health systems do not provide adequate incentives to support manufacturers' investment in their development. Many regions have failed to differentiate between improvements to existing brands and generics, since they are both based on existing molecules. The lack of any process to recognize the additional value of drug improvements fails to acknowledge the additional development costs compared to a generic and the undervaluation of the innovation provided by the drug improvement. Without any mechanism to price incremental innovation differently than generics, it may not be viable for manufacturers to invest in their development, reducing patient access to enhanced alternative therapies.

Importance to Access

Enhanced customization of existing therapies can lead to better efficacy, safety and/or tolerability profile, and offer a better way of administration and/or ease of use to address existing patient or healthcare need. For example, Viatris leveraged the 505(b)(2) pathway to reformulate a treatment for patients with chronic obstructive pulmonary disease (COPD) from a dry powder inhaler to a nebulizer improving ease of use for patients while contributing to cost savings. 80% of patients with COPD and their caregivers have reported that using a nebulizer was better than using an inhaler alone, primarily due to easier breathing.[2] Additionally, substituting nebulizers for inhaler medications was found to reduce costs and the number of wasted doses without increasing the average number of respiratory care practitioner visits per hospital stay.[3]

Improvements to medicines also provide new therapeutic uses creating alternative treatment options to assist with disease management that can lead to better outcomes for the entire healthcare community. In the U.S., Viatris successfully repurposed the active ingredient from a smoking cessation medicine to develop a treatment for dry eye disease providing superior improvement to vehicle control in both signs and symptoms across all disease severities when compared to other dry eye disease therapies.[4] The 505(b)2

[2] Taylor & Francis Online, Perceptions and Attitudes Toward the Use of Nebulized Therapy for COPD: Patient and Caregiver Perspectives, 2013
[3] AJHP, Economic and workload impact of therapeutic interchange of inhaler medications and nebulizer solutions, 2021
[4] National Library of Medicine, National Center for Biotechnology Information, 2022

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pathway enabled approval of this new medicine without resource wastage from conducting redundant studies and trials.[5]

Continuous innovation to existing therapies can also play an important role in patient adherence to therapies. Fixed dose combinations can reduce the pill burden, which is associated with improved adherence, lower healthcare costs, enhance clinical outcomes, and higher patient satisfaction.[6] Poor or non-adherence to antiretroviral therapies (ART) among children and adolescents has been attributed to medication formulation, palatability, and frequency of dosing.[7] Viatris developed a flavored, fixed dose combination pill for pediatric patients with HIV, reducing the pill burden into a single regimen and improving palatability[8] to improve adherence and health outcomes.

Viewpoint

Improvements to existing medicines should be recognized as a separate category of innovation linking approval pathways, innovation frameworks, and pricing and reimbursement policies to create an ecosystem that delivers better health to patients and solutions for healthcare systems. Health systems should:

Design a fit-for-purpose regulatory framework. A dedicated regulatory pathway for abbreviated development of repurposed, reformulated, and drug combinations should be established.

Recognize Improvements to Existing Medicines as a category of innovation with proportionate incentives. To enable developers to invest in drug improvements, the recognition of improvements to existing medicines should be treated as a separate category of innovation with proportionate incentives.

- **Exclusivity Protections to support market entry:** Currently, developers of new, innovative medicines as well as manufacturers of off-patent medicines are offered limited exclusivity protections as an incentive to bring products to market. Regulatory frameworks should recognize improvements to existing medicines as a separate category of innovation with equivalent exclusivity protection that serves as an incentive proportionate to the costs of bringing these products to market.
- **Define the value of Improvements to Existing Medicines for healthcare systems.** Improvements to existing medicines should be recognized as a separate category of innovation allowing for a differentiated value assessment from generics in pricing and reimbursement mechanisms. Assessments of these products should adequately reflect the clinical and patient-centered benefits these medicines bring to patients and support the investment needed in their development.

[5] FDA, FDA's 505(b)(2) Explained: A Guide to New Drug Applications, 2024
[6] American College of Clinical Pharmacology, The Journal of Clinical Pharmacology, 2024
[7] HIV.Gov, Adherence to Antiretroviral Therapy in Children and Adolescents with HIV, 2024
[8] Viatris, Investors News Release, 2023

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