

Act4Biosimilars Regional Deep Dive Report **The Americas**



Why Act4Biosimilars?

Biologic medicines have **transformed the lives** of many patients. However, with increasing pressures on healthcare systems, **not everyone is able to access the treatments** they need.

Biosimilars help more patients gain access to biologic medicines, and earlier in the patient treatment cycle. **Improved access to biosimilars leads to:**



Increased innovation by introducing competition



Better patient outcomes



Improved healthcare services

Act4Biosimilars is led by a multidisciplinary Steering Committee of patient advocacy leaders, healthcare professionals, biosimilar experts and industry leaders, representing views from around the world.

Driving Biosimilar Adoption

Act4Biosimilars is a global initiative that aims to increase patient access to biologic medicines by helping to accelerate the **4As of biosimilars**:

Approvability

Accessibility

Acceptability

Affordability

The Journey to 30-30-30

Act4Biosimilars' mission is to increase global biosimilar adoption **by at least 30 percentage points in 30+ countries by 2030.**



The Action Plan

The Action Plan is the global roadmap for Act4Biosimilars, and identifies the most relevant challenges and opportunities for increasing biosimilar adoption under each of the 4As. It provides stakeholders around the world with the strategies, tools and activities needed to accelerate adoption.

Within the Action Plan there are 3 steps to help achieve the Act4Biosimilars goals

Step 1 - Prepare:

Laying the foundations for steps 2 and 3. Essential for building knowledge and relevant connections with key stakeholders.

Step 2 - Act:

Using knowledge and connections created in step 1 to recruit supporters, educate stakeholders and advocate for change.

Step 3 - Maintain:

Building on progress made in step 2 to maintain momentum.

Taking Action in The Americas

The report developed by Act4Biosimilars outlines key challenges facing biosimilar adoption across the Americas. The countries included in the report are those in scope of tracking in the [Act4Biosimilars Impact Index](#), for the Americas this includes Brazil, Canada, Chile, Colombia, Ecuador, Mexico, and the United States.

This report can be used to complement the information found on the Impact Index, which measures the favorability of local policies, regulatory systems, and key stakeholders in relation to the 4As in each of the 30 countries in scope of tracking. It acts as guidance for where to focus efforts and resources to have the largest impact on biosimilar adoption.

In the report, challenges are linked to key initiatives in the [Action Plan](#), which provides the strategies, tools, and activities needed to improve adoption of biosimilars and achieve the Mission to increase biosimilar adoption by at least 30 percentage points in 30+ countries by 2030.



Overview of key challenges

- Varying levels of adoption are seen across the region¹, with Canada and Brazil leading, as public health systems have been actively addressing barriers to adoption.
- The United States (US) continues to face significant challenges, largely due to reimbursement policies and a healthcare delivery model with misaligned incentives.
- Across Latin America, a growing number of biosimilars continue to be introduced. However, policy-level and health infrastructure hurdles continue to limit the potential of biosimilars.

Snapshot across the 4As

In the following section, challenges that are either unique to the region or representative of a wider global issue have been outlined, and specific examples from the region demonstrate the impact.

Approvability



Across the seven target countries in scope of tracking, legal and regulatory pathways are in place to allow biosimilars to enter the market. However, the degree of rigor and suitability varies throughout the region, allowing the introduction of low-quality biocopies and creating confusion among stakeholders on what constitutes as a high-quality biosimilar.



Regulators must differentiate between biosimilars and biocopies.

In Colombia and Ecuador, gaps in their respective regulatory pathways allow biocopies to enter the market, thereby potentially creating patient safety risks.^{2,3} Biocopies are non-comparable biologics that do not meet strict regulatory requirements for biosimilar approval, such as those established by the World Health Organization (WHO).⁴



US interchangeability guidelines urgently need to be revised.

In the US, the interchangeability guidelines were created to address a hypothetical safety concern related to switching that over time has been shown not to exist. However, these guidelines have instead created confusion among stakeholders and helped propagate misperceptions about biosimilars.⁵

Ready to take action?

Have a look at the [Action Plan Key Initiative, Adoption of Rigorous Regulatory Pathways](#)

Ready to take action?

Have a look at the [Action Plan Key Initiative, Optimize Regulatory Review Procedures](#)

Acceptability



Throughout the Americas, there is a critical need to improve biosimilar education. A lack of education has led to confusion and concerns among stakeholders, particularly for patients transitioning to biosimilars. Comprehensive biosimilar educational programs developed through a multi-stakeholder approach is needed to increase stakeholder trust in biosimilars and to counter disinformation. Examples of comprehensive education opportunities include:



Biosimilar education needs to happen from a multi-stakeholder perspective.

In countries with readily available educational materials, such as Canada, the US, and Brazil, biosimilar education tends to be conducted by organizations representing a single stakeholder group, including trade associations as well as medical societies and patient organizations addressing a specific disease area.^{6,7} A multi-stakeholder approach would increase the relevance and trust of the information provided, however this information needs to be aligned across stakeholder groups to avoid conflicting messaging.



Biosimilar adoption must be accompanied by education.

While biosimilars continue to be introduced in Colombia, Ecuador, and Chile, biosimilar education for local healthcare stakeholders, including patients, by regulatory authorities or government bodies remains highly limited or simply not available. The production of educational materials has been led by the pharmaceutical industry, which may cause distrust among some stakeholders.

Ready to take action?

Have a look at the [Action Plan Key Initiative, Drive Publication of Authoritative Local Educational Content](#)

Accessibility



For patients, clarity is needed on how to access more affordable treatment options like biosimilars, as well as the processes involved in starting or transitioning to a biosimilar. However, such visibility remains limited across a number of countries, often hidden behind the complexities of a given health system or simply due to lack of communication from health officials. Examples include:

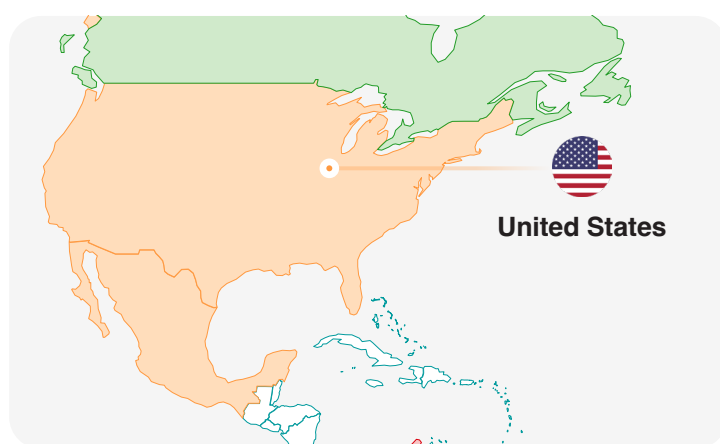


Health systems need to issue transition guidelines.

Brazil's federal government maintains the world's largest centralized health system, the Unified Health System (SUS). When the SUS began procuring and distributing biosimilars in 2019, local stakeholders, such as HCP and patient groups, were not informed or consulted about the transition process. This created a certain level of confusion among HCPs and patients, and even led to an influential HCP group publishing a whitepaper unfavorable to biosimilars.⁸ Creating an informed and positive transition process is key.

Ready to take action?

Have a look at the [Action Plan Key Initiative, Moving from Forced Transitions to Informed Transitions](#)



Streamline access to biosimilars.

In the US, structural complications of the healthcare system often disincentivize the use of biosimilars. In both the public and private markets, Medicare and pharmacy benefit managers often employ policies that favor higher-cost medicines as they are incentivized by rebates, making it difficult for biosimilars to match the economic incentives. Even for federally run Medicare Part D, there is little movement towards biosimilars replacing reference medicines once launched, preventing more patients from having access to these potentially life-changing medicines.

A decision by a US court against the use of “skinny labels” and a May 2023 US Supreme Court decision to let the decision stand without further appeal has put in danger the use of “skinny labels” for biosimilars.⁹ “Skinny labels” help to accelerate access to biosimilars by allowing biosimilar manufacturers to omit any indications still under patent by the reference medicine manufacturer on the label, bringing the biosimilar medicine to market quicker. In 2020 alone, “Skinny labels” on biosimilars generated savings of \$857 million and this act therefore puts in jeopardy access for patients to advanced medicines and the millions of dollars’ savings that could be generated from early biosimilar access.¹⁰

Affordability



In some countries, unsustainable procurement practices continue to take place. These include tenders that determine winners solely by price and tenders with a single winner. Doing so limits health systems' ability to benefit from greater competition while creating an array of risks, including those related to supply continuity. In contrast, multi-criteria and multi-winner tenders foster a competitive environment, in which manufacturers are expected to exert greater effort in contributing to the overall sustainability of health systems. Examples include:

Generate more competition via multi-winner tenders.

Despite the availability of some biosimilars, Mexico has continued to award tenders for each molecule to a single winner, a practice which dates back to the days before biosimilar availability. In so doing, the risks for supply disruption increase, while manufacturers are discouraged from launching or keeping their products available in the country as they need to balance the high risk of not winning the tender with the amount of investment needed.

Ready to take action?

Have a look at the [Action Plan Key Initiative, Increase Local Market Competition](#)



Enhance health system sustainability via multi-criteria tenders.

In Brazil, national tenders are awarded strictly based on price. As evidenced across a growing number of European countries, tenders can take into consideration a diversity of criteria beyond price, including clinical data, product characteristics with benefit to patients, and supply capability, as well as environmental, social, and governance.¹¹ In so doing, health systems are able to procure high-quality products with a value proposition for a multitude of stakeholders.

Ready to take action?

Have a look at the [Action Plan Key Initiative, Introduce and Widen Adoption of Sustainable Biosimilar Pricing Policies](#)

Raising awareness of how society can benefit from biosimilars.

In Chile, there are currently no regulations to support HCPs transitioning patients to biosimilars when available. The HCP is responsible for the decision to transition and as patient co-payments are not impacted, there is no motivation to transition or start patients on biosimilars. A 2022 study by Pro Salud Chile calculated estimated yearly savings of \$48 million by opting for biosimilars rather than reference medicines.¹² There is a need to educate HCPs and patients on the benefits biosimilars can provide to society, particularly in regards to protecting healthcare system sustainability and expanding patient access to much-needed medicines.

Ready to take action?

Have a look at the [Action Plan Key Initiative, Biosimilars for the Greater Good](#)

References

1. Act4Biosimilars Data on File (IQVIA MIDAS 2022)
2. Generics and Biosimilars Initiative. Biosimilars approved in Columbia. Available from: <https://www.gabionline.net/biosimilars/general/biosimilars-approved-in-colombia> [Accessed May 2023]
3. Generics and Biosimilars Initiative. Biosimilars approved in Ecuador. Available from: <https://gabionline.net/biosimilars/general/biosimilars-approved-in-Ecuador> [Accessed May 2023]
4. World Health Organization. Guidelines on Evaluation of Biosimilars (2022). Available from: <https://www.who.int/publications/m/item/guidelines-on-evaluation-of-biosimilars> [Accessed May 2023]
5. Park, J.P., Jung, B., Park, H.K. et al. (2022). *Interchangeability for Biologics is a Legal Distinction in the USA, Not a Clinical One*. Biodrugs (36), 431-436 [Accessed May 2023]
6. Ontario Ministry of Health. Biosimilars: Information for Patients. Available from: <https://www.health.gov.on.ca/en/pro/programs/biosimilars/default.aspx#section-6> [Accessed May 2023]
7. U.S Food and Drug Administration. Biosimilar Basics for Patients. Available at: <https://www.fda.gov/drugs/biosimilars/biosimilar-basics-patients> [Accessed May 2023]
8. Sociedade Brasileira de Reumatologia (2019). Biossimilares e Intercambialidade. Available at: <https://www.bioredbrasil.com.br/wp-content/uploads/2019/12/Nota-SBR-Biossimilares-Intercambialidade-Outubro2019.pdf>
9. Kansteiner, Fraser (2023). GSK throws counterpunch as ‘skinny’ label feud with Teva circles Supreme Court. Fierce Pharma. Available from: <https://www.fiercepharma.com/pharma/gsk-throws-counterpunch-skinny-label-feud-teva-circles-supreme-court>
10. Egilman AC, Van de Wiele VL, Rome BN, et al. Frequency of Approval and Marketing of Biosimilars With a Skinny Label and Associated Medicare Savings. JAMA Intern Med. 2023;183(1):82–84. doi:10.1001/jamainternmed.2022.5419
11. MedTech Europe (2018). Most Economically Advantageous Tender Value-Based Procurement (MEAT VBP): initiative overview (2018). Available from: <https://www.medtecheurope.org/resource-library/most-economically-advantageous-tender-value-based-procurement-meat-vbp-initiative-overview-january-2018/>
12. Pro Salud Chile. Health could have saved more than \$19 billion if it had preferred to buy biosimilar drugs in the first semester. Available at: <https://prosaludchile.cl/salud-pudo-haber-ahorrado-mas-de-19-mil-millones-si-hubiera-preferido-comprar-farmacos-biosimilares-en-el-primer-semester/> [Accessed: May 2023]