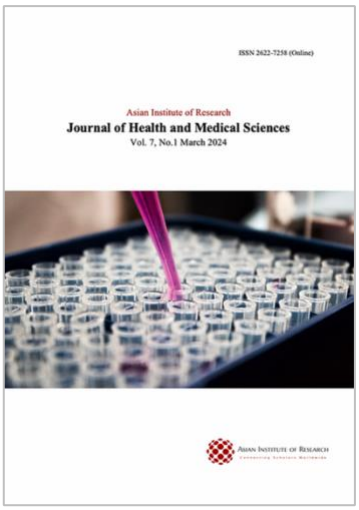


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# Advancing Biosimilars in Latin America: A Comprehensive Analysis of Regulatory Frameworks, Market Trends, and Future Perspectives

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**Abstract**
Introduction: With the struggle to find cost-effective therapeutic options, there has been increased market interest for biosimilars in the Latin American region. This paper presents an in-depth exploration of the biosimilar landscape in Latin America. Methods: Key recommendations from the "Recommendations for the regulation of biosimilars and their implementation in Latin America," as published in the Generics and Biosimilars Initiative Journal in 2014, were synthesized and integrated into insights from various reputable sources. Results: A nuanced perspective on the regulatory landscapes, market dynamics, and the challenges and opportunities that define the biosimilar ecosystem in Latin America. Discussion: There are persistent challenges in the Latin America, including physician and patient acceptance, pharmacovigilance, and the need for continuous education. However, there are several potential opportunities for growth and development within the region. Conclusion: Latin American countries would benefit from banding together to form an organization that allows all to contribute and benefit from relationships formed naturally by common geography, language, and goals

**Keywords:** Biosimilars, Latin America, Regulatory

## 1. Introduction

Latin America is a region characterized by great geographical, political, and social diversity, particularly with regards to with extreme differences in income and access to quality healthcare, a daunting problem throughout the region. In 2015, the average median price of drugs to fight cancer was north of $120,000 per year, vastly more than the per capita income of any country in Latin America (The World Bank, 2024). With the struggle to find cost-effective therapeutic options, there has been increased market interest for biosimilars in the region.

In 2022, Julie Reed, Executive Director at The Biosimilars Forum, said that "biosimilars are a ready-made solution that can address current healthcare pressures and provide equitable healthcare for patients" (Pfizer, 2019). The biggest advantage that biosimilars provide is cost reduction on the back end that is passed on to providers

and end-customers on the front end. When patents expire on an original pharmaceutical, there is a window of opportunity for biosimilars to rise. Rapidly ascending technologies like Artificial Intelligence (AI) not only cut costs during the research and development (R&D) phase of creating biosimilars but also lower the lead time to market arrival and make the process more efficient. Speed and cost are the two most vital keys in getting patients who have suboptimal resources the access they need to quality medicine.

## 2. Methods

This article synthesizes key recommendations from the "Recommendations for the regulation of biosimilars and their implementation in Latin America," as published in the Generics and Biosimilars Initiative Journal in 2014, and integrates insights from various reputable sources.

## 3. Results

### *3.1. Regulatory Frameworks for Biosimilars*

The landmark 2014 GaBI (Generics and Biosimilars Initiative) journal article, "Recommendations for the regulation of biosimilars and their implementation in Latin America" (Alvarez et al., 2014) was released at the forefront of the biosimilar wave, with countries all over the world breaking into new territory while Latin America struggled to make significant progress. The article made several recommendations for how to not only get biosimilars into the region but also how to make sure they were being dispensed properly, giving citizens the highest chance for success of using them effectively. These recommendations include:

- Training regulatory authorities on the process of evaluating biosimilars.
- Establishing a Latin America-wide group of regulatory authorities who are experts in biosimilars and who can share their experiences in regulating biosimilars.
- Establishing a native working group for each Latin American nation with the purpose of providing guidance to regulatory authorities as they begin to develop and subsequently introduce biosimilars in their countries.
- Utilizing the PRAIS website to encourage and explore healthy dialogue on biosimilars, including industry news, technological advances, problems in the industry, and so on, in order to provide transparency.
- Dedication by individual countries to promote pharmacovigilance by way of more training, more public and professional awareness, and better data analysis. A traceability system should also be put in place to ensure any negative events can be traced to the root and eliminated.
- Evaluate existing biological drugs classified as 'intended copies' to measure if they are truly biosimilars or if they are some other product that requires extra scrutiny. Intended copies are not true biosimilars and thus an unknown and potentially dangerous group of products.

More specific recommendations from the study include:

**Preclinical and Clinical Requirements**

- Quality, efficacy, and safety studies are all mandatory prerequisites for any company seeking to manufacture biosimilars.
- Examining the specific preclinical and clinical criteria recommended for biosimilar approval.
- Analyzing how these criteria contribute to ensuring the safety and efficacy of biosimilars.

**Extrapolation of Indications**

- Investigating the concept of extrapolation and its role in expanding the indications of biosimilars beyond those studied in clinical trials. Extrapolation is not a welcome addition when undergoing any sort of research, as it speculates without having hard evidence to back up its claims. Evaluating the regulatory considerations surrounding extrapolation and its impact on market access

**Post-marketing Surveillance**

- Assessing the post-marketing surveillance strategies recommended to monitor the long-term safety and

efficacy of biosimilars
- Exploring how robust pharmacovigilance contributes to building confidence in biosimilars among healthcare professionals and patients

*3.2. Market Dynamics of Biosimilars in Latin America*

In late August 2020, GaBi published "The biosimilars market in Latin America: a summary", an article covering the previous decade's movements in biosimilar research. In this section, we will explore the trends and challenges.

3.2.1. Market Trends

As of late 2020, Mexico, Brazil, and Argentina topped the list for the largest numbers of approved similar biotherapeutic products (SBPs) in Latin America. Mexico is also the largest exporter of pharmaceutical products in the region, followed by Brazil.

The Andean countries, including Peru, Ecuador, Colombia, and Bolivia, combine for just 14 SBPs. Meanwhile, the MERCOSUR trade bloc countries of Venezuela, Uruguay, Paraguay, and Chile have a total of 17, however, Uruguay significantly lags the rest with only one. This information is also flawed by the fact that some countries struggle to report accurately. The market for SBPs in Latin America, much like most economic conditions there, is quite fragmented, with only the largest countries being attractive homes to suppliers of biosimilars from outside their territories.

The factors driving the growth of the biosimilar market include increasing healthcare costs and the expiration of biologic patents. Discussing the evolving trends in physician and patient acceptance of biosimilars.

Mexico is the leading investor in biosimilars from 2010-2015, spending as much as $11.43 billion. Argentina ranks second at $6.1 billion, followed closely by Brazil at $4.9 billion (Ortiz-Prado et al., 2020). On the flip side, there are countries like Costa Rica investing just $24 million, Peru at $35 million, and no record of spending at all from Uruguay and Venezuela. Uruguay has the economic capability to produce biologics and only imports FDA and EMA-approved products. Venezuela keeps most of its activities clandestine from world forums. These numbers and traditional economic trends indicate the Latin America marketplace is divided into three groups.

The first group includes countries that are continuously growing and have few to no barriers when it comes to marketing and commercializing biosimilars. In addition to the Big Three mentioned above, this group also includes Chile, Colombia, Uruguay, and Peru. The second group, including Bolivia, Ecuador, Paraguay, and Uruguay, have smaller economies with less attractive investment opportunities for pharmaceutical companies, which reduces their ability to access biosimilars. These countries are largely consumers and importers of biological products on a much smaller scale. The final group is those whose information cannot be verified. The chief two entries in this category are Venezuela and Cuba.

3.2.2. Market Challenges

Market challenges are numerous and frustrating for the countries of Latin America, even beyond Venezuela's political turmoil. In 1952, French demographer Alfred Sauvy first coined the term "First World" countries, which has grown to mean "developed countries" that have advanced technology, high standards of living, are stable, have innovation taking place, have little-to-no risk of any form of insurgency, and have specific influence, both politically and culturally, around the rest of the world. Economic factors such as gross domestic product (GDP) and gross national product (GNP) both play a huge role in making this determination (World Population Review, 2024). As of 2022, the only Latin American countries to qualify to register First World status are:
- Argentina
- Chile
- Costa Rica
- Uruguay

This is a frightfully low number out of a region with 33 countries, coming in at barely 12%. The simple truth is that countries that don't fall under the First World designation typically are not focused on high-concept scientific advancements like biosimilars when they can't maintain a proper infrastructure and are swimming in debt. The market structure in countries that don't have First World advantages is based more on innovative drugs, and their small biotech companies cannot hope to compete with the large pharmaceutical companies that have multinational reach. The long reach of corruption may also rear its ugly head here.

Similarly, patients in Latin America will only switch from one form of treatment to another if there is a notably lower price point involved. In economies where wages are widely varied, and health care insurance ranges from top-end companies that cover costs to millions of people with no health insurance who have to rely on local physicians and homemade remedies to ward off injuries and illnesses, the idea of suddenly paying huge amounts of money for cutting edge technology in the form of bio-engineered drugs just isn't possible for an overwhelming majority of the citizen population.

3.2.3. Similar Biotherapeutic Products Approved and Marketed in Latin America

As of July 2019, there are 23 biosimilars that have gained a foothold in Latin America and have been made available to the general population (Generics and Biosimilars Initiative (GABI), 2013). The following chart lists their product names, areas of therapy, countries approved/marketed in, and Latin American partners, if applicable.

Table 1: Biosimilars in Latin America

| Product Name | Therapeutic Area | Countries approved/marketed | Latin American partner |
|---|---|---|---|
| Bevax | Cancer treatment | Argentina | N/A |
| Blastoferon | MS | Argentina | N/A |
| Bioferon | Hepatitis C | Argentina | N/A |
| Novex | Rheumatoid arthritis & Leukemia | Argentina | Laboratorio Elea |
| Osteofortil | Osteoporosis | Argentina | N/A |
| Reditux/Tiedcron | Rheumatoid arthritis & Leukemia | Bolivia, Chile, Ecuador, Paraguay, Peru | CF Reclacine, Western Pharmaceutical, Farmindustrya, FAPASA |
| Remsima | Crohn's disease, Psoriasis, Arthritis, Colitis | Brazil, Colombia, Venezuela | Amarey Nova Medical |
| Usmal | Rheumatoid arthritis & Leukemia | Bolivia, Honduras | N/A |
| Zedora | Breast cancer & gastric cancer | Brazil | N/A |

| | | | |
|---|---|---|---|
| Escleroferon | MS | Argentina | N/A |
| Etanar | Psoriasis | Colombia | La Sante |
| Etart | Psoriasis | Mexico | N/A |
| Fiprima | Neutropenia | Brazil | N/A |
| Granulosum | Neutropenia | Argentina | N/A |
| Hemax | Anemia & kidney failure | Argentina | N/A |
| HHT | Prader-Willi syndrome, Turner Syndrome | Argentina | N/A |
| Hypercrit | Anemia & kidney failure | Argentina | N/A |
| Infinitam | Psoriasis | Mexico | N/A |
| Inter 2A | Hepatitis C | Argentina | N/A |
| Kikuzubam | Arthritis & Leukemia | Mexico | N/A |
| Lenoboio | Kostman's syndrome | Argentina | N/A |
| Lumiere | Diabetic Retinopathy | Argentina | N/A |
| Neutromax | Neutropenia | Argentina | N/A |
| Novex | Rheumatoid arthritis & Leukemia | Argentina | Laboratorio Elea |
| Osteofortil | Osteoporosis | Argentina | N/A |
| Reditux/Tiedcron | Rheumatoid arthritis & Leukemia | Bolivia, Chile, Ecuador, Paraguay, Peru | CF Reclacine, Western Pharmaceutical, Farmindustrya, FAPASA |
| Remsima | Crohn's disease, Psoriasis, Arthritis, Colitis | Brazil, Colombia, Venezuela | Amarey Nova Medical |
| Usmal | Rheumatoid arthritis & Leukemia | Bolivia, Honduras | N/A |
| Zedora | Breast cancer & gastric cancer | Brazil | N/A |

The simplest takeaway from this chart is that Argentina is far and away the leader in biosimilars in Latin America, home to 13 of the 23 that have been released, amounting to approximately 57%. A second item to note is that very few of the biosimilars that have been released by larger companies are doing so with a Latin America partner, suggesting there is little to no movement in the region's market for biotechnology companies outside of Biosidus, Argentina's pioneer in the industry. Founded in 1983, Biosidus is the manufacturer of nearly one-half (11) of the biosimilars in the above chart. Just four of the 23 products, about 17%, have a Latin American partner as part of the equation.

## 4. Discussion

### *4.1. Challenges and Future Perspectives*

An analysis of the challenges faced by biosimilars in Latin America is crucial for understanding the road ahead. This section explores persistent challenges, including physician and patient acceptance, pharmacovigilance, and the need for continuous education. Additionally, it discusses future perspectives, highlighting potential opportunities for growth and development.

Unfortunately, problems have plagued Latin America at the beginning of the biosimilar era, including instability of economies, government regimes, and the like. A 2015 report, "Payer and physician evidence and discount requirements for biosimilars in three Latin American countries" published by the GaBI Journal showed that budgets are huge detractants from biosimilar adoption, representing one of the biggest barriers facing residents of Argentina, Brazil, and Mexico. The comfort level that payers have for using biosimilars, usually with little to no knowledge of what the drugs are or what they do, leads to a lack of interest in paying for them, even at a discounted rate (Sandorff et al., 2015).

Physician Key Opinion Leaders (KOLs) indicate that most patients wouldn't consider biosimilars unless they were priced at a discount rate greater than 20 to 25% of the price of the referenced biologic medications. The survey in this study across Argentina, Brazil, and Mexico finds that total budget size is the number one worry for patients when it comes to utilizing biosimilars, particularly in Brazil. Other top concerns include how widespread the approved medications are, knowledge of information regarding how the treatment is used and how it assists their overall recovery, and how the treatments are ranked by their physicians and clinics of choice. For the physicians themselves, the value that offering biosimilars brings to their practices and clinics is the number one concern in all three countries, followed by the lack of information about clarity of treatment pathway, budget size to obtain the biosimilars, the complexity of the diseases they treat, and the value of acute versus chronic treatment duration offered by each.

In October 2023, both Brazil and Mexico's regulatory authorities voiced their desire to reduce the complexity of getting drugs approved, which would reduce their reliance on importing biologic agents at high costs and move into production faster (RAPS, 2023). Earlier in 2023, Brazil's National Health Surveillance Agency (ANVISA) commented publicly about a proposed rule change that would make an easier path for biologics and biosimilar drugs to receive marketing authorization. Mexico's Federal Commission for the Protection against Health Risks announced similar objectives a day later.

## 5. Conclusion

The only way forward for Latin America in the biosimilar industry is together. As in many things, the region could greatly benefit by emulating Europe's European Union (EU) structure in which countries form a naturally beneficial organization that allows all to contribute and benefit from relationships formed naturally by common geography, language, and goals. Each country in the region is focused on its own agenda, with no thoughts on assisting neighbors and finding mutually beneficial ways to thrive. Because of this, the cycle of struggling to afford, promote, and market biosimilars as an alternative to both painfully expensive traditional medications and the out-of-control market for illegal and fake pharmaceuticals will only continue. The region is in desperate need of a traceable, collaborative vision of pharmacovigilance that offers strength in numbers and security in the

supply chain to follow medicine from its point of origin to the end customer's hands, ensuring safety, health, and proper usage. The region desperately needs strong advisory forces to band together to form a framework that will start making this type of treatment available and recognizable to end consumers who often struggle with trusting new treatment plans, particularly those that challenge their economic needs. Strides must also be made to give more companies in more countries the opportunity to play a larger role in the production and distribution of biosimilars and their agents. Otherwise, the high price of exporting them will continue to be detrimental to the level of the economy.

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## References

Azevedo, V. F., Mysler, E., Álvarez, A. A., Hughes, J., Flores-Murrieta, F. J., & Ruiz de Castilla, E. M. (2014). Recommendations for the regulation of biosimilars and their implementation in Latin America. *Generics and Biosimilars Initiative Journal*, *3*(3), 143–148. https://doi.org/10.5639/gabij.2014.0303.032

Generics and Biosimilars Initiative. (2013, October 25). Similar biotherapeutic products approved and marketed in Latin America. GABI Online. https://www.gabionline.net/biosimilars/general/Similar-biotherapeutic-products-approved-and-marketed-in-Latin-America

Ortiz-Prado, E., Ponce-Zea, J., Vasconez, J. E., Castillo, D., Checa-Jaramilloz, D. C., Rodríguez-Burneo, N., Andrade, F., Intriago- Baldeón, D. P., & Galarza-Maldonado, C. (2020). Current trends for biosimilars in the Latin American market. *Generics and Biosimilars Initiative Journal*, *9*(2), 64–74. https://doi.org/10.5639/gabij.2020.0902.011

Pfizer. (2019, May 28). *How access to biosimilar drugs could boost healthcare equity*. https://www.pfizer.com/news/articles/how_access_to_biosimilar_drugs_could_boost_healthcare_equity

RAPS. (2023). *Latin America Roundup – Brazil*. https://www.raps.org/News-and-Articles/News-Articles/2023/10/Latin-America-Roundup-Brazil

Sandorff, E., Pinheiro, A. V., Bruni, D. S., Halbert, R. J., & Azevedo, V. F. (2015). Payer and physician evidence and discount requirements for biosimilars in three Latin American countries. *Generics and Biosimilars Initiative Journal*, *4*(1), 11–16. https://doi.org/10.5639/gabij.2015.0401.005

The World Bank. (2024). GDP per capita (current US$). https://data.worldbank.org/indicator/%20NY.GDP.PCAP.CD

World Population Review. (2024). First world countries 2024. https://worldpopulationreview.com/country-rankings/first-world-countries