ACCSCIENCE PUBLISHING

Global Health Economics and Sustainability

MINI-REVIEW

Biosimilars in Argentina: Market and regulatory status

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Abstract

Biosimilars are biological drugs that closely resemble a reference product (RP) without clinically meaningful differences in quality, efficacy, or safety. Their primary objective is to enhance access to affordable treatments, necessitating adherence to varied global regulatory guidelines. This paper analyzes Argentina's biosimilar regulations, including the latest 2025 guidelines on comparability and the stance of medical societies, comparing them with international guidelines from Brazil, the European Union, and the United States – with a focus on definitions, comparability, interchangeability, extrapolation, pharmacovigilance, and traceability. A key finding of this study is Argentina's lack of specific regulatory guidance on interchangeability and substitution, which contrasts with international practices. Seven Argentinian medical associations generally support biosimilar use, particularly in fields, such as autoimmune, dermatological, gastrointestinal, rheumatic, and endocrine diseases, recognizing their potential to reduce costs and enhance patient access. However, these societies advocate caution regarding interchangeability and automatic substitution due to limited supporting evidence, favoring physician-approved product changes and robust pharmacovigilance. As of April 2025, Argentina's biosimilar market is expanding, with over 67 approved products and significant price reductions (39–88%) reported for biosimilars of adalimumab, infliximab, and etanercept compared to their RPs. Despite ongoing challenges, the new Argentinian regulations offer promising prospects for future advancements, with expectations that increased regulatory experience, harmonized health policies, and comprehensive pharmacovigilance will refine standards and address existing gaps.

Keywords: Biosimilars; Biosimilar substitution; Interchangeability; Extrapolations; Biological products; Biosimilar regulations

1. Introduction

Biosimilars are biological drugs designed to closely resemble an existing biological medication, known as a reference product (RP) (International Pharmaceutical Regulators Programme [IPRP], 2022). The World Health Organization (WHO) defines biosimilars as products comparable to an original biotherapeutic product, with no clinically meaningful differences in terms of quality, efficacy, and safety. The introduction of biosimilars to the market has the potential to enhance patient access

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Citation: Gerarduzzi, D.A., de Abrantes, L., Guidi, R., *et al.* (2025). Biosimilars in Argentina: Market and regulatory status. *Global Health Econ Sustain,* 3(4):170-180. https://doi.org/10.36922/GHES025210041

Received: May 23, 2025

Revised: July 4, 2025

Accepted: July 17, 2025

Published online: July 31, 2025

to more affordable treatments. Nonetheless, they must be developed and evaluated under strict regulatory guidelines to ensure their quality (WHO, 2022). More than 20 years after their initial introduction, the global use of biosimilars has expanded significantly. Numerous biosimilars have received approval for the treatment of autoimmune diseases, cancer, and other therapeutic conditions (Cencora, 2025; Generics and Biosimilars [GABI], 2024a; GABI, 2024b; Lyu *et al*., 2022).

Global biosimilar regulations – established in the early 2000s in the European Union (EU) and the United States of America (USA) – are based on the principle of demonstrating high similarity between a biosimilar and its RP (IPRP, 2022). The evaluation process incorporates structural and functional characterization, supported by non-clinical and clinical studies conducted in comparison with the RP.

Argentina's pharmaceutical market includes active participation from local companies engaged in biosimilar development and manufacturing. The country holds the potential to gain significant economic benefits through the establishment of a strong national biosimilar industry, including increased export capacity and greater global visibility for its pharmaceutical sector (da Silva Machado *et al*., 2024).

This study examines the present regulatory guidelines governing the approval of biosimilars in Argentina in comparison with global standards. It also reviews the number of approved biosimilars and summarizes the views of medical societies, with the aim of analyzing the regulation and use of these valuable therapeutic tools in Argentina and highlighting potential future challenges.

1.1. Comparison of biosimilars regulations

The present regulatory framework in Argentina has been evaluated and compared with those of other countries and regions, such as Brazil, the EU, and the USA. Online research was conducted using official websites – including the National Administration of Drugs, Foods, and Medical Devices (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* [ANMAT]), the Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária* [ANVISA]), the European Medicines Agency (EMA), and the Food and Drug Administration (FDA) – to review the most recent versions of relevant regulations available up to March 2025 (ANMAT, 2011a; ANMAT, 2011b; ANMAT 2012a; ANMAT, 2025; ANVISA, 2020; ANVISA, 2024; EMA, 2015; EMA, 2023; US FDA, 2015; US FDA, 2024a; US FDA, 2024b; US FDA, 2024c). Key regulatory aspects were analyzed and compared, including definition, comparability studies, interchangeability, extrapolation of indication, traceability, and pharmacovigilance (Table A1).

The EMA was among the first agencies to establish specific regulations for biosimilars and approved the first biosimilar in 2006. The FDA established specific guidelines for biosimilar evaluation and granted its first biosimilar approval in 2015 (Burki, 2015). In South America, Brazil was the first country to implement biosimilar regulations in 2010, which closely aligned with WHO guidelines. More recently, ANVISA has introduced minor revisions, particularly regarding the definitions of RP and biosimilarity, among other issues. Within this context, ANMAT established three biosimilar regulations in Argentina between 2011 and 2012. The first, Disposition 7075/2011 (ANMAT, 2011a), established the general conditions and requirements for registering biologic drugs. This was followed by Disposition 7729/2011 (ANMAT, 2011b), which provided guidelines for registering biologic products whose qualitative and quantitative composition, therapeutic indication, and route of administration are based on a previously registered biological product – either by ANMAT or by an equivalent health authority – with established marketing history and a characterized risk-benefit profile. Subsequently, Disposition 3397/2012 (ANMAT, 2012b) outlined specific requirements for the authorization and registration of biologic medicines and/or monoclonal antibodies produced using recombinant DNA technology. In 2019, Disposition 9709/2019 (ANMAT, 2019) established criteria for marketing authorization and distribution. Most recently, in March 2025, Disposition 1741/2025 (ANMAT, 2025) was issued, which introduced detailed guidelines for conducting comparability exercises for biosimilars and a technical glossary to complement the provisions set out in Disposition 7729/2011.

The FDA and EMA have contributed significant regulatory experience in establishing safety and efficacy requirements for biosimilars, supported by clear and well-defined guidelines. Furthermore, Argentina and Brazil have also established regulatory frameworks to guide biosimilar evaluation and approval.

Figure 1 illustrates the terminology used by each agency, highlighting slight variations in the definition of biosimilars across different regulatory guidelines. While the specific term "biosimilar" was not explicitly mentioned in Argentina's regulations until March 2025, Disposition 7729/2011 described the concept in alignment with approaches adopted by other international agencies. A similar situation was observed in Brazil until May 2024. The latest regulatory frameworks in both countries now include a formal definition of biosimilar.

Since all analyzed agencies require a comparison between biosimilars and the innovator or RP, the approved

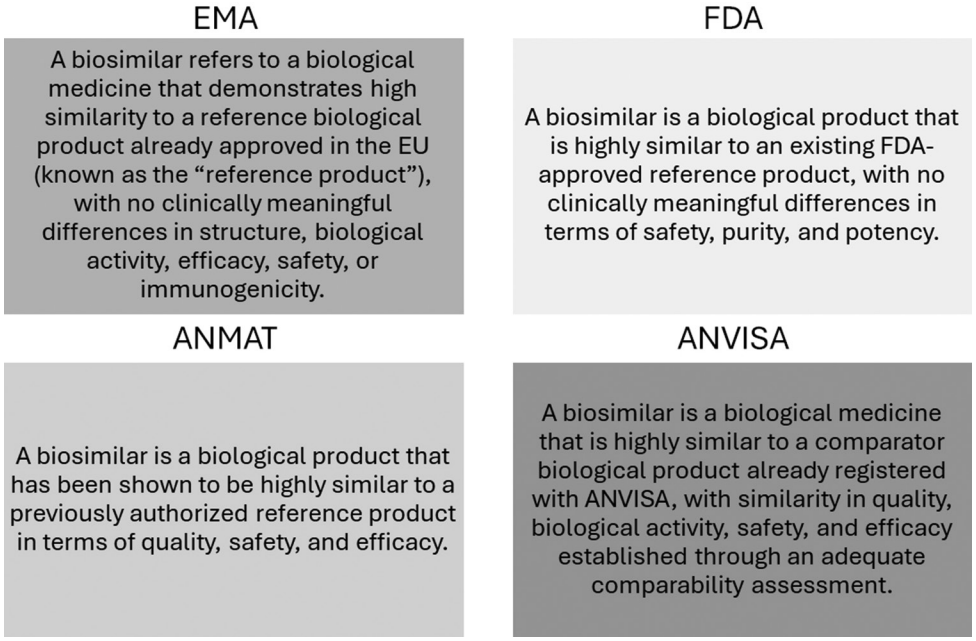

Figure 1. The definition of biosimilar across various agencies. Image created by the authors.
Abbreviations: ANMAT: National Administration of Drugs, Foods, and Medical Devices; ANVISA: Brazilian Health Regulatory Agency; EMA: European Medicines Agency; EU: European Union; FDA: Food and Drug Administration.

indications must be identical to those of the RP. In this regard, similar to other agencies, the regulations established by ANMAT require physicochemical and biological characterization in comparison with the RP (ANMAT, 2011a; ANMAT, 2011b; ANMAT, 2012a; ANMAT, 2019; ANVISA, 2020; ANVISA, 2024).

The comparability exercise mandated by ANMAT must be supported by non-clinical and clinical studies to assess the safety and efficacy of biosimilars before marketing authorization. The type and extent of required studies are determined by factors, such as the nature and complexity of the biological molecule, data on *in vivo* behavior, comparative impurity profiles, and post-marketing adverse events associated with similar products. Since March 2025, Disposition 1741/2025 has introduced detailed guidelines for the comparability exercise, which were not explicitly outlined in previous regulations.

The terms interchangeability, switching, and substitution are not explicitly addressed in Argentina's regulatory frameworks, whereas Brazil defines these terms as being more relevant to clinical practice than to regulation. In particular, the FDA designates a product as either a biosimilar or an interchangeable biosimilar, depending on the information and methodology submitted by the manufacturer (US FDA, 2024a; US FDA, 2024c). Recently, the FDA drafted a proposal to revise the labeling of interchangeable biosimilars (US FDA, 2024b), thereby modifying the requirement to conduct switching studies to demonstrate interchangeability. When a biosimilar is approved as interchangeable, the RP may be substituted at the pharmacy level without additional input from the prescriber, subject to individual state laws (US FDA, 2024a; US FDA, 2024b; US FDA, 2024c). In contrast, once a biosimilar is approved by the EMA (EMA, 2022; EMA, 2023), it is considered interchangeable by the European Community; however, substitution policies are managed independently by each member state (Table A1).

As recently discussed by various health authorities, an international consensus has been reached to reduce the requirement of comparative efficacy clinical studies (IPRP, 2024). In this context, the EMA has presented a concept paper proposing the waiver of comparative efficacy clinical trials in cases where analytical and functional characterization demonstrates a high degree of similarity with the RP (EMA 2024, 2025). Similarly, ANVISA – in Resolution 875/2024 (ANVISA, 2024) – states that certain comparative clinical studies may be waived if robust evidence of comparability in terms of functionality and physicochemical properties is provided (Table A1).

Overall, after more than two decades of biosimilar approvals, regulatory agencies are progressively simplifying the approval process. In this context, Argentina's updated regulations allow for the possibility of waiving efficacy studies if sufficient evidence has been obtained through

other comparability assessments. Nevertheless, clinical trials must be conducted in Argentina and must include a significant number of national participants (ANMAT, 2025).

Furthermore, to ensure patient safety, it is crucial that all stakeholders monitor immunogenicity and adverse drug reactions throughout the biosimilar development process and during post-marketing surveillance, to obtain real-world clinical insights (Nikitina *et al.*, 2023). All agencies emphasize the importance of pharmacovigilance plans. In line with other regulatory agencies, ANMAT requires the submission of a post-marketing pharmacovigilance plan as part of the biosimilar approval process (ANMAT, 2012b; ANMAT, 2025).

Although ANMAT has issued specific regulations for biological products, certain aspects – such as nomenclature based on the International Nonproprietary Names, trade name, manufacturer, and batch number for traceability and pharmacovigilance – are regulated under broader regulatory provisions that are not exclusively applicable to biosimilars.

2. Opinion of argentine medical societies

Published medical opinions on the prescribing and dispensing of biosimilars were compiled through online searches in PubMed, Google, and other websites using the following keywords: "medical societies," "opinion or positioning," and "biosimilars." The inclusion criteria comprised medical societies established in Argentina, while the exclusion criteria encompassed societies from other Spanish-speaking countries, non-medical press articles, statements by pharmaceutical companies, and positions issued by patient organizations. A total of 29 websites of medical societies that fulfilled the inclusion criteria were reviewed. Only seven Argentine medical societies have issued official statements, as detailed in Table A2.

Societies related to autoimmune, dermatological, gastrointestinal, and rheumatic diseases – including the Latin American Psoriasis Society (*Sociedad Latinoamericana de Psoriasis*) (Raimondo *et al.*, 2018); the Argentine Society of Gastroenterology (*Sociedad Argentina de Gastroenterología* [SAGE]); the Argentine Federation of Gastroenterology (*Federación Argentina de Gastroenterología* [FAGE]); the Argentinian Chron's Disease and Ulcerative Colitis Group (*Grupo Argentino de Enfermedad de Crohn y Colitis Ulcerosa* [GADECCU]) (GADECCU, 2023; Matar *et al.*, 2021; SAGE, 2021); and the Argentine Society of Rheumatology (*Sociedad Argentina de Reumatología* [SAR]) (SAR, 2023) – have issued clear statements supporting the development of biosimilars, while also highlighting certain limitations and concern. Furthermore, pediatrics and diabetes societies, such as the Argentine Society of Pediatrics (*Sociedad Argentina de Pediatría* [SAP]) and the Argentine Society of Diabetes (*Sociedad Argentina de Diabetes* [SAD]), have expressed position statements limited to specific biological drugs, namely, growth hormone and insulin, respectively (Alonso *et al.*, 2019; SAD, 2019).

In general, all societies acknowledged the relevance of biosimilars in reducing costs and improving patient access. GADECCU, however, emphasized that biosimilar prices should be significantly lower – a condition that is not consistently met. To date, no information has been found regarding the position of Argentine hematology–oncology associations, in contrast to other countries (Abad Hernández *et al.*, 2021; Digestive Cancers Europe, 2019; SEOM, 2018; Tabernero *et al.*, 2017).

Until 2023, medical societies consistently emphasized that ANMAT should enforce rigorous standards for biosimilar approval studies (Table A2) and that the supporting evidence from such studies should be readily accessible to prescribers. In addition, most societies discouraged automatic switching or substitution between brands. If substitution is deemed necessary, it must remain a physician-led decision made in consultation with the patient. Only GADECCU provided detailed recommendations, identifying specific clinical scenarios in which substitution should be avoided (GADECCU, 2023). The SAP explicitly rejected substitution without prescriber consent, particularly concerning growth hormone, based on insufficient supporting evidence. They also highlighted additional concerns regarding device-related differences among brands that could impact clinical practice (Alonso *et al.*, 2019).

Regarding the use of biosimilars in non-approved indications, medical societies agreed that extrapolation should not be granted automatically, whereas regulatory agencies may allow extrapolation under certain evidentiary conditions (Tables A1 and A2).

All societies expressed the need to reinforce the pharmacovigilance system to generate additional evidence on the efficacy and safety of biosimilars, as most reluctance remains theoretical rather than evidence-based (Azevedo *et al.*, 2017; Halimi *et al.*, 2020). Promoting education among health professionals and patients is essential to enhance local safety reporting (Jordan & Christl, 2020; Mohd Sani *et al.*, 2024).

Although earlier opinions in Europe, the USA, and other regions were cautious about biosimilar substitution, after 20 years of positive clinical experience, prescribers are now more confident in using biosimilars without hesitation regarding substitution. In this regard, meta-analyses and

real-world pharmacovigilance studies provide sufficient evidence supporting the efficacy and safety of biosimilars (Mohd Sani *et al*., 2024). However, in Argentina, barriers remain for physicians to prescribe and switch biosimilars, at least as expressed in formal statements by medical societies. This challenge is a common issue in many countries, as interchangeability is not only a scientific issue but also a significant regulatory concern (Druedahl *et al*., 2022; European Association of Hospital Pharmacists [EAHP], 2023). The medical societies that have issued positions thus far, as mentioned above, have not yet issued an opinion on the latest ANMAT regulation, likely due to its recent publication.

While hospital pharmacists in Argentina are knowledgeable in biologics and can play a crucial role in promoting their rational use and substitution, their perspectives have not yet been formally integrated into national guidelines – in contrast to practices in other countries, such as those recommended by the EAHP (EAHP, 2023). Coordinated actions are needed to reduce these barriers and strengthen regulatory, academic, and clinical understanding of biosimilars (Shubow *et al*., 2023).

3. Number of biosimilars and prices

This study investigated the biosimilars currently marketed in Argentina by searching brand names and active components on ANMAT's publicly accessible Vademecum website in April 2025 (http://anmatvademecum.servicios.pami.org.ar/index.html). The biological medicines identified, along with the number of corresponding biosimilars, were: adalimumab (n = 5), bevacizumab (n = 6), infliximab (n = 3), rituximab (n = 4), trastuzumab (n = 5), denosumab (n = 2), eculizumab (n = 1), pembrolizumab (n = 1), enoxaparin (n = 5), filgrastim (n = 6), pegfilgrastim (n = 1), erythropoietin (n = 5), etanercept (n = 2), teriparatide (n = 1), insulin glargine (n = 3), recombinant human insulin (n = 2), insulin aspart (n = 1), somatropin (n = 6), alpha follitropin (n = 1), recombinant interleukin-2 (n = 1), recombinant human interferon alpha-2b (n = 1), and recombinant human beta-1a interferon (n = 5) (Figure 2). As of April 2025, at least 67 biosimilars were available on the Argentine market. Several of these biologics had been introduced before the establishment of biosimilar-specific legislation, including some cases in which the reference biologic had not yet been marketed in Argentina.

The updated prices – as of April 24, 2025 – of three biological medicines used in the treatment of rheumatoid arthritis – adalimumab (40 mg/0.8 mL autoinjector), infliximab (100 mg/vial), and etanercept (100 mg/vial) – were retrieved from KAIROS, Argentina's public pharmaceutical pricing database (KAIROS, 2025). The prices of biosimilars were expressed as a percentage relative to the RP, set at 100%, for equivalent doses and pharmaceutical formulations (Figure 3).

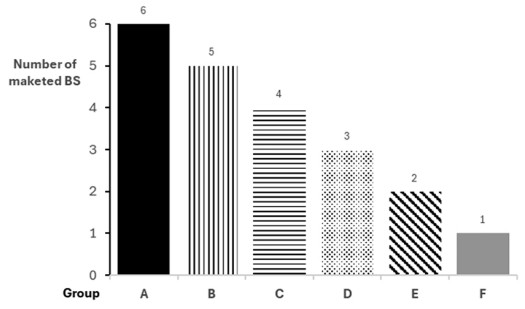

Figure 2. Number of biosimilars marketed in Argentina. Each bar represents the number of approved biosimilars available on the market for each reference product within the corresponding group. Image created by the authors.
Abbreviations: BS: Biosimilars; Rec: Recombinant.

For adalimumab, two biosimilars were priced significantly lower (39% and 31%) than the other three biosimilars (88%, 88%, and 53%). Notably, the lower-priced biosimilars were marketed by multinational companies, while the higher-priced ones were of national origin. For infliximab, the prices of two biosimilars were 96% and 85% of the RP.

Among the three drugs analyzed, biosimilars of etanercept showed minimal price variation, with the two biosimilars priced at 40% and 47% of the RP. Nevertheless, drug prices in Argentina fluctuate monthly due to the absence of medicine price regulation. These results, therefore, represent a snapshot in time and cannot be generalized to all biosimilars marketed in the country.

A previous study reported a median price reduction of approximately 18% for biosimilars compared to their RPs and noted that, at the time, one infliximab biosimilar was priced higher than the RP (da Silva Machado *et al*., 2024). If biosimilar prices were significantly lower, they could represent a more cost-effective option for patients, aligning with the WHO's recommendation that countries should adopt policies to improve the accessibility and affordability of biosimilars for both patients and health systems (WHO, 2020).

After many years of biosimilars being available on the market, Argentina's regulatory requirements for biosimilar approval have recently been strengthened, particularly in terms of definitions and methodological guidelines. Establishing an accessible public database containing information on biosimilar comparability and interchangeability could

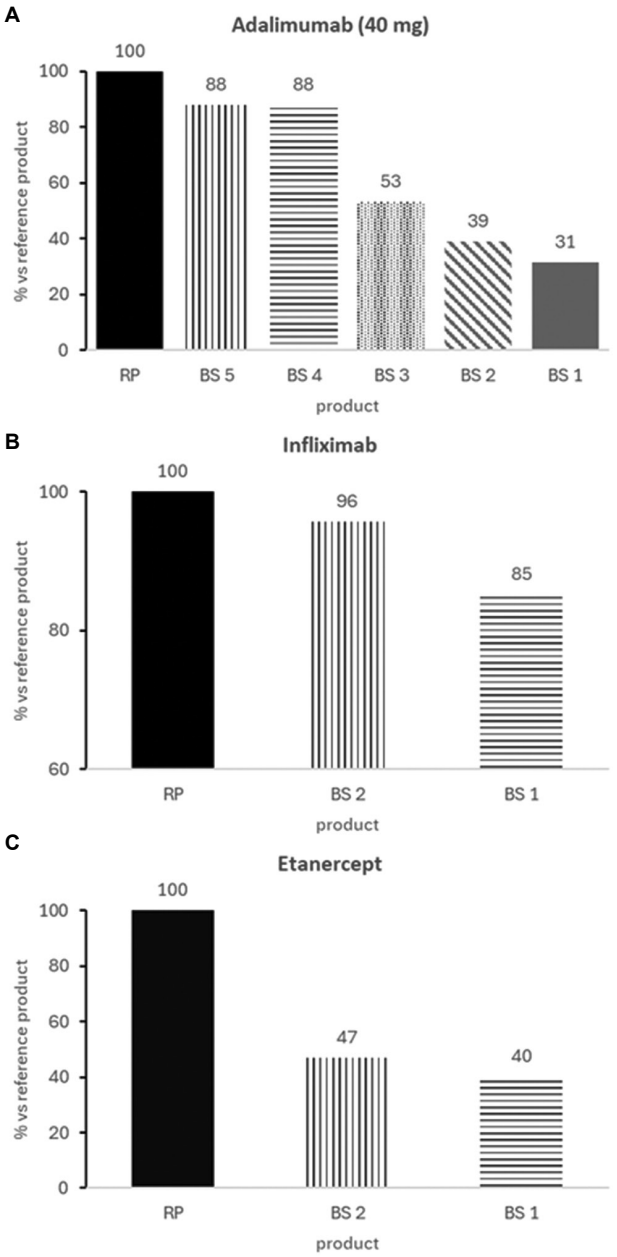

Figure 3. Comparison of biosimilar prices with the reference product: (A) Adalimumab (40 mg), (B) Infliximab, and (C) Etanercept. Image created by the authors.
Abbreviations: BS: Biosimilar; RP: Reference product.

increase confidence among both patients and health professionals regarding their use. The implementation of such frameworks may facilitate the development, approval, and commercialization of biosimilars, thereby fostering a more favorable environment for innovation and improved access to healthcare. The key points are summarized as follows:

(i) Regulatory agencies, such as ANVISA, the EMA, and the FDA had more detailed and specific biosimilar regulations compared to those of ANMAT, until March 2025, when ANMAT published updated guidelines detailing the comparability exercise required for biosimilars

(ii) After almost 20 years of experience, the EMA and FDA are now reconsidering the need for large comparative efficacy studies in biosimilar approval. In contrast, ANMAT's most recent biosimilar regulation does not yet reflect such a reduction in the requirements for clinical comparison trials

(iii) Seven Argentine medical societies support the use of biosimilars to reduce costs but have expressed concerns regarding their interchangeability and substitution. At present, Argentine pharmacy associations have not issued a formal position on this issue

(iv) As of April 2025, at least 67 biosimilars have been approved in Argentina, comparable to approvals in other highly regulated countries.

The 2025 ANMAT biosimilar guidelines are expected to significantly advance biosimilar development and accessibility in Argentina and potentially across Latin America. By incorporating a detailed Comparability Guide, the new regulations will streamline the approval process, making it more efficient and less costly for manufacturers. Alignment with international standards is likely to promote increased competition and affordability of biologic medicines, enhance patient access, and encourage local production and pharmaceutical innovation. In this way, Argentina may serve as a regional model for biosimilar advancement.

4. Conclusion

Argentina has maintained a regulatory framework for biosimilars since 2011, resulting in the approval of 67 products as of April 2025. The latest regulatory update aligns national policies with international standards. To date, only seven local medical societies have issued official positions on key aspects of biosimilars, including their use, interchangeability, and substitution. The country's growing expertise in regulatory procedures, supported by active health policy development and strengthened pharmacovigilance, is expected to contribute to more advanced regulatory standards and helps address present gaps and emerging challenges related to biosimilar adoption.

Acknowledgments

None.

Funding

None.

Conflict of interest

Luciana de Abrantes works for Fresenius Kabi in Argentina. This has not influenced the content of the manuscript. No reference to the author's company is made, but it is declared for full transparency. Other authors declare no conflict of interest.

Author contributions

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Writing – review & editing: All authors

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data

Not applicable.

Further disclosure

Part of the findings was presented at the 7th International Meeting on Pharmaceutical Sciences (*7ma Reunión Internacional de Ciencias Farmacéuticas*, RICiFa 2023), held on November 16–17, 2023, in Rosario, Argentina. The presentation was titled Biosimilars in Argentina: A present perspective and the authors were Opezzo, J., de Abrantes, L., Gerarduzzi, D., Guidi, R., Gorzalczany, S., Höcht, C., Sarabia, I., and Viola, M.

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Appendix

Table A1. Summary of biosimilar regulations

Topic	Agency			
	EMA	FDA	ANMAT	ANVISA
Comparability studies to demonstrate biosimilarity	A stepwise approach, starting with a comprehensive physicochemical and biological characterization. The extent and nature of the non-clinical *in vivo* studies and clinical studies to be performed depend on the level of evidence obtained in the previous step (s).	A stepwise approach can include a comparison of the proposed product and the reference product with respect to structure, function, animal toxicity, human PK and PD, clinical immunogenicity, and clinical safety and effectiveness.	Quality comparability studies will determine the extent and type of non-clinical and clinical studies required in subsequent phases of development, following a stepwise approach. Clinical studies must include a statistically significant proportion of participants recruited within the country and be conducted at research centers approved by ANMAT.	To demonstrate that the physicochemical and biological characteristics, as well as the quality, PK, PD, immunogenicity, safety, and efficacy parameters of the molecule, are comparable to those of the RP.
Interchangeability considerations	Once a biosimilar is approved in the EU, it is interchangeable.	According to the 2019 Interchangeability Guidance for Industry, there are biosimilars and interchangeable biosimilars, the latter designated upon sponsor request. Depending on state laws, a biosimilar typically must be prescribed by name, whereas an interchangeable biosimilar may be substituted for the RP at the pharmacy level without prescriber intervention.	There is no current regulation or mention of interchangeability.	Specific studies to demonstrate interchangeability are not required for the regulatory approval of a biosimilar.
Switching	Decisions regarding the implementation of switching and/or substitution fall outside the remit of the EMA and are determined by individual member states.	The term "switching study" refers to a clinical study or studies designed to assess the impact of alternating or switching between the proposed interchangeable product and the RP.	There is no definition.	There is no definition.
Substitution	Decisions regarding the implementation of switching and/or substitution fall outside the remit of the EMA and are determined by individual member states.	FDA-approved interchangeable biosimilars may be substituted for the RP, subject to state laws.	There is no mention or definition in the ANMAT regulations	Interchangeability and substitution are more directly related to clinical practice than to regulatory status.
Extrapolation of indications	Extrapolation to other indications is permitted if biosimilarity has been established and the mechanism of action is the same for each indication, based on adequate scientific justification, including clinical evidence or experience with the RP.	The sponsor must provide sufficient scientific justification to support the extrapolation of data and information for approval of other conditions of use for which licensure as a biosimilar is sought. Additional data may be required.	When comparability has been demonstrated in one indication, extrapolation to other indications may be permitted, provided it is supported by adequate scientific justification. However, if it is unclear whether the safety and efficacy demonstrated in one indication are applicable to another, additional data may be required.	In the absence of specific guidelines published by ANVISA, the extrapolation of safety and efficacy data will be guided by the frameworks established by other regulatory agencies.

(*Cont'd...*)

Table A1. (*Continued*)

Topic	Agency			
	EMA	FDA	ANMAT	ANVISA
Traceability rules and pharmacovigilance systems	The EMA does not impose specific traceability rules; however, the identification and tracking of medicines are ensured through the use of trade names and batch numbers.	Biosimilars are identified by a nonproprietary name consisting of the INN followed by a four-letter, lowercase, meaningless suffix.	A pharmacovigilance plan must be submitted, outlining the activities relevant to the product, including risk minimization measures. Specific identification is essential to ensure traceability – in addition to the INN, the brand name, manufacturer's name, and batch number must be recorded—to comply with all established pharmacovigilance requirements.	Barcodes (GTIN) must be included for all product presentations, or alternative identification and security mechanisms must be implemented to enable traceability; however, these requirements are not specific to biologics or biosimilars.

Abbreviations: ANMAT: National Administration of Drugs, Foods, and Medical Devices; ANVISA: Brazilian Health Regulatory Agency; EMA: European Medicines Agency; EU: European Union; FDA: Food and Drug Administration; GTIN: Global Trade Item Number; INN: International Nonproprietary Names; PD: Pharmacodynamics; PK: Pharmacokinetics; RP: Reference product.

Table A2. Positions of Argentine societies on biosimilars

Opinions	Society (year)				
	SOLAPSO (2018)	SAGE, FAGE, and GADECCU (2021)	SAD (2019)	SAR (2023)	SAP (2019)
Cost and access	✓	✓ Prices should be significantly lower than RP.	-	✓	-
Biosimilarity	✓ Meets quality, biological activity, safety, and efficacy requirements.	✓ Equivalence clinical trials must meet regulatory standards.	✓ Equivalence clinical trials must comprehensively comply with regulatory requirements as outlined by the EMA and FDA. It should be comprehensive as proposed by EMA and FDA.	✓ Equivalence clinical trials must comply with regulatory requirements outlined by the WHO.	-
Extrapolation to other indications should not occur automatically	✓	✓	Only refers to insulin.	-	Only refers to GH.
Discourage interchangeability and switching	✓	✓ Advises against multiple switches.	✓ Aligns with IDF Europe's November 2017 position.	✓	✓ Rejected due to insufficient scientific evidence of safety and efficacy.
Patient–physician switch decision	✓ Switch only if agreed by physician, patients, and health system.	✓ Switch only with evidence, physician documentation, and patient consent.	✓ Switch restricted to prescriber.	✓ Specialist therapeutic sovereignty; specific substitution protocol.	✓ GH exchange rejected without prescriber consent.
Strengthen pharmacovigilance and nomenclature requirements	✓ Differentiated nomenclature essential for pharmacovigilance.	✓ Unique and distinguishable identification ensures traceability and reporting of adverse events.	-	✓	✓

Abbreviations: EMA: European Medicines Agency; FAGE: Argentine Federation of Gastroenterology; FDA: Food and Drug Administration; GADECCU: Argentinian Chron's Disease and Ulcerative Colitis Group; GH: Growth hormone; IDF: International Diabetes Federation; RP: Reference product; SAD: Argentine Society of Diabetes; SAGE: Argentine Society of Gastroenterology; SAP: Argentine Society of Pediatrics; SAR: Argentine Society of Rheumatology; SOLAPSO: Latin American Psoriasis Society; WHO: World Health Organization.