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REVIEW

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The potential role of biosimilars in healthcare sustainability in Latin America

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ABSTRACT

Introduction: Latin American (LatAm) countries face significant increases in healthcare expenditure, driven largely by population growth and aging, and the rising prevalence of cancer and other chronic diseases. Growing demand and high costs of biologic medicines present barriers to patient access in this region. Biosimilars can improve the affordability and accessibility of biologics, supporting long-term healthcare sustainability. However, their uptake in LatAm has generally been slow.

Areas covered: Challenges and barriers to the use of biosimilars and potential strategies to increase biosimilar uptake in LatAm, drawing on learnings from Europe and the U.S.A.

Expert opinion: Potential initiatives to drive biosimilar uptake across LatAm include (1) harmonized regulatory processes for biosimilars, with reimbursement policies that prioritize their use and incentives to encourage prescribing; (2) education for key stakeholders to limit misinformation about biosimilars, provide reassurance about safety and efficacy, and increase understanding and acceptance; (3) simplified health technology assessment processes for biosimilars that expedite or adapt some aspects of the traditional approach; and (4) coordinated regional efforts to enable national healthcare systems to purchase medicines in the most cost-effective way, with value frameworks to support decision-making and the implementation of centralized purchasing, competition policies, and risk-sharing agreements.

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Biologic; biosimilar; cost saving; education; Latin America; policy; regulatory

1. Introduction

Latin American (LatAm) countries are facing significant increases in healthcare expenditure driven largely by population growth and aging, and the rising prevalence of chronic diseases [1–3]. The percentage of people aged 65 years and above is expected to more than double in the LatAm region by 2050, with a corresponding decrease in those of working age [4,5]. In 2020, there were over 1.4 million new cases of cancer and 600,000 cancer-related deaths in the LatAm region [6]. New cancer cases are predicted to increase by 64–98% across countries in this region between 2020 and 2040, with the most pronounced effect in Central and South America [4,7,8]. Cancer exerts a heavy economic burden in LatAm and costs are set to grow significantly [9].

In recent years, considerable progress has been made in LatAm in extending healthcare coverage and access to medicines across broader segments of the population [10]. Most LatAm countries have now brought nearly all of their citizens into a financial protection scheme for expenditure on healthcare [10,11]. However, increasing demand and high costs of novel drugs are persistent barriers for patients in this region [12]. Therefore, policy interventions to improve access to affordable medications and healthcare services are urgently needed [13].

Healthcare systems in LatAm are complex and fragmented, which can lead to inefficient delivery of care and unequal distribution of resources, with a lack of equitable access to healthcare evident throughout the region [4]. For example, an analysis of 132,621 cases from 19 hospital-based registries in one Brazilian state found that 5-year overall survival was higher for patients with private health insurance compared with those who had public insurance for 13 of the 17 cancers studied [14]. The authors hypothesized that these disparities may be due to differences in access to early diagnosis and optimal treatment [14]. On average, only 7.7% of the national wealth of LatAm countries is allocated to healthcare, compared to 10.9% in the European Union (EU) [15] and 18% in the United States of America (U.S.A.) [16].

Biologic medicines are an integral part of cancer care [17]. The high cost of biologics means that while their share of the total volume of medicines prescribed may be low, the proportion of drug budgets spent on these medicines is disproportionately high. Biosimilars increase price competition between different brands, and therefore improve the affordability and accessibility of biologic medicines, supporting the long-term sustainability of healthcare systems [18,19]. As of April 2022, over 200 biosimilars have been approved globally [20], including 86 approved by the European Medicines Agency (EMA)

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Article highlights

- Healthcare systems in Latin America (LatAm) face growing pressure, resulting from increasing expenditure due to population growth and aging, and the rising prevalence of cancer and other chronic diseases. Interventions to improve patient access to affordable medications and healthcare services are urgently needed in this region.
- Biosimilars increase price competition, thereby improving the affordability and accessibility of biologic medicines. However, the uptake of biosimilars in LatAm has generally been slow, and strategies are needed to encourage broader use of these cost-effective medicines.
- Several potential strategies to increase biosimilar uptake in LatAm were identified, including developing: standardized and streamlined regulatory processes for biosimilars across LatAm; education initiatives to limit misinformation about biosimilars; simplified health technology assessment processes for biosimilars; guideline recommendations based on the value of medicines; and coordinated regional efforts to enable national healthcare systems to purchase medicines in the most cost-effective way.
- Cost savings achieved with the use of biosimilars can be reinvested to improve healthcare services and increase access to treatment, helping to support long-term healthcare sustainability in the LatAm region.

and 48 approved by the US Food and Drug Administration (FDA), as of March 2024 [21,22].

The use of biosimilars is widely acknowledged as a key strategy to improve the affordability of medicines. However, their uptake in LatAm has generally been slow, and patient access to biologic medicines and their benefits remains restricted [17,23]. The countries with the highest number of approved biosimilars are Argentina, Brazil, and Mexico (44 products approved as of 2020), followed by Bolivia, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay, and Venezuela (Mercosur trade bloc; 32 products) [24]. The potential market for biosimilars in the LatAm region is estimated to grow at an annual rate of around 33% and is expected to reach USD $3.9 billion by 2025 [17].

In oncology, rituximab was one of the first biologic medicines with available biosimilars. Rituximab is a chimeric monoclonal antibody that specifically binds to the CD20 transmembrane antigen on mature pre-B and B lymphocytes. It is approved by the EMA for the treatment of non-Hodgkin lymphoma (NHL), rheumatoid arthritis (RA), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (Wegener granulomatosis), and microscopic polyangiitis [25]. Following the patent expiry of the reference medicine (MabThera®/Rituxan®; Roche/Genentech), the approval of rituximab biosimilars has demonstrated substantial cost savings in many global countries; however, in some countries, suboptimal uptake of biosimilars has been observed [26,27]. For example, in the LatAm region, several factors have been identified as contributing to the suboptimal uptake of biosimilars, including a lack of stakeholder incentives to encourage uptake, lack of information regarding biosimilars, misperceptions and mistrust regarding biosimilars, and lack of reimbursement or health insurance coverage [28]. Furthermore, patient access to biosimilars may also be restricted due to regulatory challenges such as a lack of streamlined policies and nonadherence to regulatory pathways, limited market opportunities, the inadequate naming convention for biosimilars which uses only international nonproprietary names, imprecise use of the terms 'interchangeability' and 'substitution,' and insufficient traceability and pharmacovigilance [17,28].

The aim of this paper is to consider current policies relating to biosimilars in LatAm, examine potential barriers to the use of biosimilars across the region, and discuss potential strategies to increase biosimilar uptake in LatAm, drawing on learnings from Europe and the U.S.A., with a particular focus on rituximab.

1.1. Manuscript development

This project convened physicians, pharmacists, and industry representatives with expertise in biosimilars from LatAm and Europe in an online forum. In total, six key opinion leaders were recruited across four countries, including Brazil, Chile, Mexico, and the United Kingdom. Furthermore, two industry representatives from LatAm and Europe were included to aid in moderation of discussions. Experts were selected based on their ability to provide insights on their experience across several areas, including pharmacology, hematology, oncology, and health economics. This allowed a range of perspectives to be collected on the barriers that impact the uptake of biosimilars across LatAm, whilst also providing comparisons to EU learnings. In addition, industry representatives from 12 countries across LatAm participated in a survey regarding policies on biosimilars in place in their country, the results of which are also summarized in this manuscript. The initial meeting featured individual presentations by the participants, highlighting insights from their respective or neighboring healthcare systems. These discussions led to the identification of the following six key themes that have impacted biosimilar acceptance in the LatAm region, which are expanded on in this report:

(1) Biosimilar policies
(2) Biosimilar communication
(3) Pharmacovigilance and traceability
(4) Health technology assessment
(5) Missed opportunities for cost savings with biosimilars in LatAm
(6) Realizing cost savings with biosimilars in LatAm

2. Biosimilar policies

2.1. Regulatory policies

Healthcare systems across LatAm have diverse, independent health-coverage schemes that result in healthcare inequalities [29]. The regulatory landscape in LatAm is heterogeneous, with each country having a unique market and regulatory situation [30]. Mexico, Argentina, and Brazil have well-established processes together with facilities for the development and manufacture of biosimilars, which has increased patient access to these drugs in these countries [17]. However, in other LatAm countries such as Paraguay, Bolivia, Peru, Dominican Republic, and Venezuela, where standardized regulatory processes were initiated more recently or are still in

development, biosimilar availability is limited. The lack of uniform regulatory guidelines across the LatAm region has impacted on the quality of patient care in every country [17].

Five different biosimilars of rituximab were approved in LatAm as of 2021, with nine different brand names commercialized in countries with highly regulated markets that follow the World Health Organization (WHO) guidance on comparability assessment [31,32]. Reference rituximab and the subsequent biosimilars are indicated in the EMA and FDA for NHL, CLL, RA, granulomatosis, microscopic polyangiitis, and pemphigus vulgaris [25]. In LatAm, although most biosimilars are approved for all indications of the reference medicine, reimbursement is limited to only a subset of labeled indications, based on cost-effectiveness and budget impact analyses, with no reimbursement options for other indicated conditions. For example, no reimbursement is given for the use of rituximab for vasculitis or pemphigus vulgaris in Brazil and Chile [33,34]. (Table 1: Policies on incentivizing the use of biosimilars across Latin America).

The Pan American Network for Drug Regulatory Harmonization (PANDRH) was established to standardize local regulations across LatAm. In 2011, the PANDRH's Biotechnological Products Working Group recommended that the region should follow WHO guidance for the evaluation of biosimilars [35,36]. However, Brazil is already notable in having two regulatory pathways (comparative and individual), introduced by the Agência Nacional de Vigilância Sanitária (ANVISA) in 2010 [37]. These are based on the same scientific

Table 1. Policies on incentivizing the use of biosimilars across Latin America.

	In the state health system, is rituximab reimbursed for all indications, or restricted to only a limited subset of the labeled indications?	Is there a national policy with an incentive for promoting the use of biosimilars? If so, what is the policy?
Brazil	In the public market, rituximab is available for RA, FL, DLBCL. No reimbursement is granted for granulomatosis and pemphigus vulgaris.	There is no current national policy on this issue.
Chile	All indications are reimbursed, except for granulomatosis.	Tenders for biologics in the public health care system tend to be won by biosimilars, when available; these are then distributed to the different public institutions and their use is thereby indirectly promoted.
Colombia	The Colombian healthcare system does not contemplate reimbursement, but all treatments prescribed by an HCP must be 100% covered; it does not matter if the product is a biosimilar or not.	There is no current national policy on this issue.
Mexico	In the public market, rituximab is not approved for RA; therefore, reimbursement is not applicable for patients with this disease.	There is no current national policy on this issue.
Ecuador	Rituximab is only approved for a limited subset of the labeled indications.	There is no current national policy on this issue.
Peru	Rituximab is only approved for a limited subset of the labeled indications.	There is no current national policy on this issue.
Costa Rica	The state health system is covered by Costa Rican Social Security Fund, which is an institution supplied by tender processes. However, and even though there are internal procedures that indicate which specialist and which indications can be covered, off label use is a reality in this region.	There is no current national policy on this issue.
Panama	The state health system is covered by Caja de Seguro Social, which is an institution supplied by tender processes. However, and even though there are internal procedures that indicate which specialist and which indications can be covered, off label use is a reality in this region.	There is no current national policy on this issue.
Dominican Republic	Reimbursement may be limited, as the dispensed product cannot be different from the one mentioned in the prescription. So, the state health system will cover the reimbursement only if indicated in the prescription (not related to indications). Off label use of products is also a reality in this region, even though there are internal procedures that indicate which specialist and which indications can be covered.	There is no current national policy on this issue.
El Salvador	The state health system is covered by Salvadoran Social Security Institute, which is an institution supplied by tender processes. However, and even though there are internal procedures that indicate which specialist and which indications can be covered, off label use is a reality in this region.	There is no current national policy on this issue.
Guatemala	The state health system is covered by Guatemalan Social Security Institute, which is an institution supplied by tender processes. However, and even though there are internal procedures that indicate which specialist and which indications can be covered, off label use is a reality in this region.	There is no current national policy on this issue.
Honduras	The state health system is covered by Honduras Social Security Administration, which is an institution supplied by tender processes. However, and even though there are internal procedures that indicate which specialist and which indications can be covered, off label use is a reality in this region.	There is no current national policy on this issue.

Answers provided by industry representatives for each country. Information on the policies within Argentina, Paraguay, and Uruguay were not provided.
DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; HCP, healthcare professional; RA, rheumatoid arthritis.

principles as the WHO recommendations, but with some differences specific to the needs of Brazil [37]. This two-pronged approach has resulted in Brazil having the most biosimilars approved within the LatAm region, together with medicines licensed via the comparative pathway considered to be biosimilars [37,38]. However, some biosimilars have not been commercialized for some indications because of patent claims from manufacturers of the reference products. In May 2024, the ANVISA in Brazil issued an updated Resolution of the Collegiate Board (RDC 875_2024, replacing RDC 55_2010) [39]. This requires biosimilar manufacturers to present protocols and data from the following clinical studies: pharmacokinetics; pharmacodynamics; and immunogenicity, safety, and clinical efficacy. The document also states that some clinical studies and/or comparative clinical evaluation parameters may be dispensed with, provided that high-quality comparability, functionality, and characterization of the biosimilar candidate is demonstrated, and there is technical and scientific justification that can be evaluated by ANVISA [39]. This now aligns ANVISA's guidance on comparative trials with current standards in Europe and the U.S.A. [40,41].

The regulatory landscape for biosimilars is evolving in LatAm. However, unlike the landscape in Europe, which has benefited from a more uniform approach to regulatory pathways, the pathways in LatAm are not yet standardized and remain inconsistent between countries, with not all regulatory processes meeting WHO guidance [17,42]. For example, in addition to complete dossier and comparative pathways similar to those used for evaluating novel biologics and biosimilars in other countries, regulations in Colombia include an additional abbreviated comparative pathway [42]. However, approval via this pathway does not provide certainty that such products would have an acceptable benefit–risk profile, or meet the standards established by regulatory processes in other regions [42]. Such alternatively regulated medicines are termed 'Intended Copy Biologics' (ICBs), as the development and/or regulatory processes leading to their approval fall short of the stringent requirements used in Europe and the U.S.A. [43].

As already noted, regulatory pathways for biosimilars should be harmonized across the LatAm region and updated to meet international standards, based on WHO recommendations, and also incorporate the existing processes implemented by the EMA or FDA [17]. This harmonization would save unnecessary duplication of effort, cut costs, accelerate development, and enable the clinical success of biosimilars in Europe and the U.S.A. to be repeated in LatAm regions. Nevertheless, it should be emphasized that biosimilars do not require local phase 3/4 clinical trials to be conducted and can be approved on the basis of noninferiority alone. These specific regulatory pathways for biosimilars differ from those of generic drugs and biologic reference products, and therefore require specific education and training for regulatory personnel on the biosimilar approval process [17]. Inadequate training resulting in insufficient regulatory expertise or lack of capacity to conduct the assessment of new biosimilars may result in either a delay in biosimilar approval or the approval of intended copies that do not meet the required criteria for biosimilarity [43,44]. Robust regulatory pathways and processes for biosimilars will help patients and healthcare providers (HCPs) gain trust in quality-assured products [45]. Regional working groups should be established to share experiences between local regulators and assist national authorities in biosimilar approval [17,46]. Extrapolation of indications approved by the EMA and FDA may be considered by LatAm regulatory authorities once it has been confirmed that there are no substantial clinical differences between the biosimilar and its reference product in terms of safety, efficacy, and biosimilarity.

The approval process for medicines in countries with limited regulatory resources can be lengthy, which in the case of biosimilars may delay access to affordable treatment. The WHO has tried to address this problem by proposing that the best resourced top-tier (level 4) medicine regulators be designated as 'WHO-listed authorities' (WLA). These agencies will then share their analyses of medicines with others with lower tiers of resources and experience (agencies at levels 1 to 3). This 'Recognize and Rely' process enables regulators in LatAm to either automatically 'recognize' approvals from a WLA, or 'rely' on the shared analytic data and assessment from a WLA as a part of their local regulatory decisions [47,48]. This cooperative system avoids duplication of effort and reduces resource and time requirements. Many regulators in Asia and the Middle East have now formally aligned their biosimilar approvals with the corresponding decisions from European and US regulators through this scheme [48].

2.2. Policies to increase biosimilar uptake

Approving biosimilars in LatAm does not automatically reduce healthcare costs; the economic benefits are only realized when these biosimilars are utilized by patients and included in competitive medicine procurement processes. Although an increasing number of biosimilars are being introduced across the LatAm region, expanding patient access remains a challenge in some countries as a result of policy-level and infrastructure hurdles [45]. Additionally, a gap in biosimilar uptake can be seen between the public and private healthcare sectors. The lack of reimbursement policies prioritizing the use of biosimilars and lack of incentives to prescribe biosimilars are the main barriers to their uptake in the private sector. Currently, most LatAm countries lack specific national policies that incentivize the use of biosimilars. However, in Chile, public health care tenders for biologics are often awarded to biosimilars when available. These biosimilars are then distributed to various public institutions, indirectly promoting their use (Table 1: Policies on incentivizing the use of biosimilars across Latin America).

In Europe, many policies have been implemented to increase biosimilar uptake. For example, in 2018, in Ireland, adalimumab and etanercept together comprised 86% of the total expenditure on biologic medicines (€224 million) [49]. The uptake of biosimilars of these tumor necrosis factor alpha inhibitors was slow prior to the implementation of the 'best-value biologic' medicine initiative. This initiative incentivizes clinicians to prescribe the biosimilars adalimumab and etanercept over their reference medicines by offering an enhanced prescriber payment [49]. In June 2019, just over 90 patients

had been initiated on, or switched to, a best-value biologic, either adalimumab or etanercept. Over the 12-month post-implementation period, this increased to over 8,500 patients, with best-value biologics accounting for around 50% of market share, generating estimated cost savings of €22.7 million [49].

National policies incentivizing the use of biosimilars are also widely used elsewhere in Europe. Countries such as Hungary, Poland, and Norway use a single national tender system [50], which has resulted in rates of biosimilar uptake of over 90% [51]. Other countries, including the United Kingdom (UK), Germany, and Spain, use multi-winner tender policies and regional quotas to incentivize the use of biosimilars. Multi-winner tenders offer advantages over single-winner approaches in terms of long-term sustainability and competition by avoiding the risk of a monopoly evolving, ensuring price efficiency, guaranteeing supply to help prevent shortages, and providing sales guarantees for the winners (a prerequisite for tender efficiency) [52]. A range of incentives are in place across Europe, which have been valuable in encouraging biosimilar uptake. France and the UK have implemented programs which set targets of 80% biosimilar utilization, and the benefits of biosimilar cost savings are shared with patients [53], while both Germany and Sweden have established payer gain-sharing arrangements, benefiting both the providers and the patients [53–55]. In the UK, National Health Service (NHS) England offers HCPs 1% of the contract value of biosimilars if they start 90% of new patients on a biosimilar and switch 80% of existing patients [53], and in Ireland, hospitals have been offered a €500 incentive for every patient they switch from two expensive biologics to more cost-effective biosimilars [53].

Furthermore, out-of-pocket patient expenses can contribute to the financial hurdles surrounding patient access to biologics. Many patients across LatAm have a financial responsibility for certain healthcare costs, such as co-payment or co-insurance costs [56,57]. Additionally, further indirect medical costs can include expenses such as transportation to hospitals/clinics, meals during the hospital stay, and labor income loss. A review of out-of-pocket expenditures for patients with breast cancer in LatAm reported costs of over USD $192.30 per month in Mexico, R$125.40 per day in Brazil, and USD $1,700 across 18 doses in Chile [58]. Oncology treatments can place a high economic burden on patients and their relatives, which needs to be taken into consideration when discussing ways to improve access to biosimilar medicines. For example, an analysis of biosimilar savings in a large medical center in the U.S.A. demonstrated that patients receiving an infliximab biosimilar or filgrastim biosimilar observed annual reductions in out-of-pocket costs by 12% and 45%, respectively. These findings highlight the benefits of policies that incentivize biosimilar uptake, which can redistribute healthcare costs and reduce out-of-pocket costs for patients, helping to lessen the financial burden of disease [51].

Despite the overall benefits of incentivizing the use of biosimilars, there are some European learnings that should be considered. In Poland, the introduction of biosimilar etanercept initially demonstrated a decrease in the overall medicine pricing due to tender competition. However, these savings were rapidly reversed after re-monopolization of the market by a biosimilar. As a result, mean pricing of the medicine increased, leading to negative downstream effects on hospital funds and potential treatment restrictions for patients. In this case study, the main reason for the market re-monopolization was the decision of the regulator to maintain only one available etanercept biosimilar on market, and to withdraw reimbursement for the reference medicine. This can serve as an example to LatAm markets of how to prevent market re-monopolization occurring, demonstrating that all forms of competition can ensure market stability and contribute to consistent reductions in healthcare costs [59].

3. Biosimilar communication

Biosimilars are developed and assessed using a development and regulatory approach that many HCPs may not be familiar with. Therefore, considerable educational efforts must be made to increase understanding and acceptance among both HCPs and patients, and limit misinformation.

3.1. Misinformation

3.1.1. Interchangeability

There is confusion regarding terminology such as ‘switching,’ ‘interchangeability,’ and ‘copies’ which can lead to misinformation, and which has arisen mainly due to a lack of reliable and trusted information for HCPs and patients, specifically in LatAm countries. It is important to differentiate the terms ‘interchangeability’ and ‘substitution’ from each other. The FDA describes an interchangeable biosimilar as a biosimilar that can be substituted for the reference product without the intervention of the prescribing HCP [60]. Substitution is the pharmacy-level practice of dispensing a biosimilar in place of a reference product without further input from the prescriber [60,61].

The EMA considers interchangeability to be when ‘one medicine is exchanged for another medicine that is expected to have the same clinical effect. For example, a reference product could be replaced with a biosimilar (or vice versa), or one biosimilar could be replaced with another’ [41]. According to the FDA, a biosimilar is designated as interchangeable if it is ‘expected to produce the same clinical result as the reference product in any given patient’ and, if a biologic product ‘is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the biologic product and reference product is not greater than the risk of using the reference product without such alternation or switch’ [60].

In recent years, biosimilar manufacturers have raised concerns over the lack of clarity regarding the FDA’s regulatory approach to interchangeability. This created two tiers of biosimilars, 'biosimilars’ and ‘interchangeable biosimilars,’ which required a further level of clinical data to support the designation [62]. Furthermore, it was suggested that this two-tier FDA definition of interchangeability could lead to a ‘nocebo’ effect, due to the generation of negative sentiment in patients who are unwilling or reluctant to switch brands [62], with an increased potential for medical errors [63]. Responding to

this, the U.S.A. FDA issued updated guidance on 'Labeling for Biosimilar and Interchangeable Biosimilar Products' [64]. In 2024, based on the successful US experience of 50 biosimilars approved for 17 different reference biologics over many years, the FDA highlighted that HCPs can be confident in the safety and effectiveness of biosimilar products, whether or not they have been approved as interchangeable, with the FDA stating 'experience has shown that for the products approved as biosimilars to date, the risk in terms of safety or diminished efficacy is insignificant following single or multiple switches between a reference product and a biosimilar product' [64–66].

In Europe, all biosimilars are interchangeable at a formulary level, which is beneficial for those countries with annual tender drug procurement systems. In LatAm, interchangeability should be considered on a country-specific basis; however, national guidelines on interchangeability and switching are still lacking in many LatAm countries (Table 2: Policies on naming conventions and switching of biologics across Latin America) [67]. In contrast to Europe and the U.S.A., the ANVISA in Brazil considers interchangeability to be 'more directly related to clinical practice than to regulatory status.' Without clear regulatory guidance, the decision to switch treatment between biosimilars and their reference products has to be made by the clinician and patient [52]. Furthermore, ANVISA has not yet recommended multiple switches between biosimilars and reference products, due to challenges relating to traceability [68,69]. This can be solved through biosimilar naming policies.

3.1.2. Naming

There is a lack of specific naming policies for biosimilars across the LatAm region which is a barrier to traceability and pharmacovigilance (Table 2: Policies on naming conventions and switching of biologics across Latin America). Furthermore, International Nonproprietary Names (INNs), which are

Table 2. Policies on naming conventions and switching of biologics across Latin America.

	Is there a national policy for naming biosimilars? Is it the same as the policy in the EU, U.S.A., or another region?	Is there a national policy for switching of biologics?
Brazil	The national policy uses the brand name followed by the INN, adhering to the US naming convention.	A national policy permitting or approving brand switching does not exist. However, switching is possible. ANVISA states that it is not their responsibility and the decision must be made by the attending physician or Ministry of Health.
Chile	The national health institute adheres to EU/U.S.A. standards.	Switching is allowed under the following conditions: 'in an escalated matter, with patient consent and the treating physician as the final responsible.' Although allowed, the specific conditions given for switching (individual responsibility of the physician)interfere with nationwide adoption of switching.
Colombia	There is no current national policy on this issue.	There is no current national policy on this issue.
Mexico	There is differentiation in the labeling as the acronym MBB (Medicine Biotechnological Biocomparable), the brand name is optional, INN is mandatory.	Switching of brands is permitted.
Ecuador	Products are required to be labeled as biosimilars.	There is no current national policy on this issue.
Peru	There is no specific naming policy. Current regulations request that the product is labeled as a biosimilar in the SmPC and PI.	There is no policy, but as of 2024, all biologics need to present studies of biosimilarity, but doesn't match European or US regulations.
Costa Rica	There are no limitations concerning the naming of a biosimilar. There are no specific differences in naming for biosimilars compared to any other pharmaceutical product.	Currently, the health authorities have not announced any policies regarding switching. Discussions have been made with the authorities regarding these topics, but their argument mentions that as the regulation does cover this topic, there is no current need.
Panama	There are no limitations concerning the naming of a biosimilar. There are no specific differences in naming for biosimilars compared to any other pharmaceutical product.	Currently, the health authorities have not announced any policies regarding switching. Discussions have been made with the authorities regarding these topics, but their argument mentions that as the regulation does cover this topic, there is no current need.
Dominican Republic	There are no limitations concerning the naming of a biosimilar. There are no specific differences in naming for biosimilars compared to any other pharmaceutical product.	Currently, the regulation does not authorize the pharmacist to change a medicine mentioned in the prescription. The regulation for biosimilars is not being considered (from an official point of view or from the health authorities)
El Salvador	There are no limitations concerning the naming of a biosimilar. There are no specific differences in naming for biosimilars compared to any other pharmaceutical product.	Currently, the health authorities have not announced any policies regarding switching. Discussions have been made with the authorities regarding these topics, but their argument mentions that as the regulation does cover this topic, there is no current need.
Guatemala	There are no limitations concerning the naming of a biosimilar. There are no specific differences in naming for biosimilars compared to any other pharmaceutical product.	Currently, the health authorities have not announced any policies regarding switching. Discussions have been made with the authorities regarding these topics, but their argument mentions that as the regulation does cover this topic, there is no current need.
Honduras	There are no limitations concerning the naming of a biosimilar. There are no specific differences in naming for biosimilars compared to any other pharmaceutical product.	There is no current national policy on this issue.

Answers provided by industry representatives for each country. Information on the policies within Argentina, Paraguay, and Uruguay were not provided.
ANVISA, Agência Nacional de Vigilância Sanitária; EMA, European Medicines Agency; FDA, US Food and Drugs Administration; INN, international nonproprietary names; PI, prescribing information; SmPC, summary of product characteristics.

intended to provide a unique standard name to a drug to avoid prescribing errors, are widely used for biologics but rarely used for biosimilars [17]. Experience with existing commercially available biologic medicines, including biosimilars that share INNs with their reference medicine, shows that these products can be adequately distinguished by existing identifiers, for example, their brand name. New naming systems (for example, an additional suffix) that deviate from well-established systems for other pharmaceuticals may lead to treatment errors by introducing unnecessary complexity into the pharmacovigilance system. Europe has overcome this issue by requesting that all biologics are prescribed by both INN and the brand name identifier, for example using identifiers 'filgrastim-Zarzio®' or 'filgrastim-Neupogen®' for the biosimilar and reference products, respectively. The U.S.A. has followed a similar approach by using INN and a unique identifier for each biosimilar, a four-letter suffix, which is listed in the American 'FDA Purple Book,' detailing all biologics approved in the U.S.A. [70]. For the same example, the unique prescribing names for the U.S.A. would be 'filgrastim-sndz' and 'filgrastim-Neupogen®' [71]. Similar clarity could be achieved in LatAm through formal national naming and prescribing rules. In the absence of such rules, LatAm prescribers could follow the European naming convention, as using brand names is a simple approach that does not require access to additional suffix names from a central regulatory document.

3.1.3. Intended copy biologics, noncomparable biologics, or biocopies

Some countries have licensed copies of biotherapeutic products, known as noncomparable biologics, biocopies, biogenerics, or ICBs. Such biologic follow-on products are often approved based on regulations that are closer to those used for generic drugs, rather than the rigorous regulatory pathways for biosimilars that are implemented in Europe and the U.S.A. This means ICBs might have clinically relevant differences in formulation, efficacy, and/or safety compared with their reference medicines [17]. Use of ICBs may generate an increase in adverse events or lower efficacy, which can impact the physicians' and patients' negative perceptions of biosimilars. For example, the rituximab ICB Kikuzubam® (Probiomed, Mexico) was approved in Mexico without published efficacy or safety data from comparative clinical studies [72]. In 2012, the Mexican Pharmacovigilance Program issued a warning about possible anaphylactic reactions with Kikuzubam®, which was subsequently withdrawn from the market by the regulatory authority in 2014 due to higher than expected serious side effects [72,73].

Many LatAm countries still use price-only tenders for biologic medicines, rather than specifying the minimum regulatory standards required for the medicines procurement program [45]. In countries such as Colombia and Ecuador, where ICBs are available, such tenders can drive their uptake, undermining trust in regulatory-approved biosimilars among prescribers and patients, and potentially making it more difficult for biosimilars to enter the market [45]. A potential solution to these barriers could be the alignment of different national regulators to match the WHO international standard. The resulting harmonization could create not only confidence in the products, but may also permit the WHO 'Recognize and Rely' program to support faster approvals, while sharing the workload between different regulators [74].

3.2. Stakeholder communication and education

Education and training should be provided for regulatory personnel to ensure the implementation of smooth and efficient biosimilar approval pathways that differ from those of the reference product. HCPs (clinicians, nurses, and pharmacists) in LatAm may lack national regulatory guidance and training programs to communicate effectively with patients about biosimilars and provide reassurance about their safety and efficacy. Therefore, the provision of key information to support HCPs in making informed decisions about the use of biosimilars versus reference medicines is essential, as the HCPs' understanding of, and confidence in, biosimilars also influences patient perceptions of these medicines. In Brazil, the importance of switching from a reference medicine to a biosimilar is discussed with clinicians before initiating the switching process. Topics covered include pharmacoeconomics, the broader benefits of biosimilars for the healthcare system, and the concept of equivalence between biosimilars and their reference medicines [75].

Different communications from pharmaceutical manufacturers can create confusion for both HCPs and payers, and there is a need for consistent messaging for all stakeholders on the benefits of biosimilars. Trusted medical societies can play an important role by providing local language materials on a range of topics including the benefits of the use of biosimilars, good clinical practice, pricing, and access to biologic medicines.

Most European countries have developed educational initiatives on biosimilars. The UK's first large-scale switching program was initiated following the approval of biosimilar infliximab in 2015 [76]. At this time, there was no clear framework or existing guidance in the UK and, therefore, biosimilar experience across Europe was used as a guide. As a result, this provided educational content for stakeholders, highlighting the importance of biosimilar use in the markets. Following this, the Commissioning Framework for Biological Medicines was published in the UK in 2017, which details accepted practices for switching within the NHS and is intended to support commissioners to maximize the opportunities presented by increased competition from biosimilars [77].

The Latin American Forum on Biosimilars (Fórum Latinoamericano de Biossimilares [FLAB]) celebrated its 15th meeting in 2024. Since its initiation, FLAB has provided an opportunity for debate between multiple stakeholders including industry, HCPs, regulators, and public and private institutions, together with education on biosimilars and policies regulating their access. There is an opportunity for similar initiatives to be held in other LatAm countries, to help provide educational forums. In Brazil, an educational workshop on biologic medicines and biosimilars titled 'Ensuring the Quality of Biological and Biosimilar Products' was held virtually in April 2023, the first organized by ANVISA. Topics discussed included the regulatory requirements for registration and post-registration of biologic

medicines in Brazil, and how health authorities in Argentina, Colombia, and Chile strive to ensure the quality of biologics and biosimilars [78]. Other workshops on these topics have previously been held in Brazil.

As discussed previously, misperceptions about biosimilars, negative information received from clinicians or other sources, lack of knowledge about biosimilars, and inadequate communication can all lead to a nocebo effect when patients switch from a reference medicine to a biosimilar [75]. Appropriate patient education and a well-managed switching process can reduce or eliminate this risk. An example which can be adapted for use in the LatAm region is from a UK program. Clinicians from the NHS discussed the concept of biosimilars with patients during their routine clinical reviews, well in advance of initiating a switch [75]. This was supported by centrally approved printed information, as well as by education of all the HCPs involved in the process, including specialized nurses and pharmacists. Decision-making for switching was shared between the clinician and patient, and the biosimilar uptake rate reached 86–90% after 3 years of the program [75,79]. In Brazil, patients often allow themselves to be guided by the opinion of their clinician because of a lack of knowledge about biosimilars. Therefore, providing patients with clear information and a simple, easy-to-understand explanation about the concept of biosimilars is very important [75].

4. Pharmacovigilance and traceability

Pharmacovigilance is essential to adequately assess the safety of new medicines in LatAm populations. However, many LatAm countries have suboptimal pharmacovigilance systems, with five countries across LatAm (El Salvador, Haiti, Honduras, Nicaragua, and Suriname) stated to have a low level of pharmacovigilance regulatory requirements [80] (Table 3: Key regulatory requirements for pharmacovigilance across Latin America). This can lead to barriers to effective pharmacovigilance, including a lack of consensus on the definitions of interchangeability and substitution, inadequate resources leading to lack of routine monitoring, and frequent underreporting of adverse events [17,61,80]. To address these issues, better systems to record and analyze data should be implemented, more staff should be trained to monitor and report adverse events, and initiatives need to be introduced to raise awareness among HCPs and patients of the importance of reporting adverse events [17,23]. Additionally, the lack of consistency in biosimilar nomenclature makes traceability and recording adverse events associated with biosimilar use difficult, particularly with regard to switching [61]. As such, the regulatory authorities should also establish a process to determine the traceability and attribution of adverse events [23].

5. Health technology assessment

Full health technology assessments (HTAs) identify the clinical value of a treatment, as well as its cost-effectiveness and the potential budget impact on health spending. For biosimilars, an HTA may not be necessary, given that the benefits of biosimilars are similar to those of the reference product. However, these may be required in cases where the reference biologic is not currently reimbursed, the biosimilar has a different route of administration to the reference product, or the biosimilar provides added value compared to the reference product [81]. In Europe, some countries, such as the Netherlands, do not require HTAs for biosimilars provided the indications in the biosimilar label are the same as those of the reference product [81]. Other countries, such as France, have simplified requirements for HTA submissions [81].

Table 3. Key regulatory requirements for pharmacovigilance across Latin America.

Country	Immediate Reporting of AE	Periodic Reporting of AE	Vaccine-Specific Requirements	Clinical Trials: Immediate Reporting of AE	Clinical Trials: Periodic Reporting of AE
Argentina	Yes	Yes	Yes	Yes	Yes
Bolivia	Yes	No	No	No	No
Brazil	Yes	Yes	Yes	Yes	Yes
Chile	Yes	Yes	Yes	Yes	Yes
Colombia	Yes	Yes	Yes	Yes	Yes
Costa Rica	Yes	No	No	No	No
Cuba	Yes	No	No	No	No
Dominican Republic	Yes	No	No	No	No
Ecuador	Yes	No	No	No	No
El Salvador	No	No	No	No	No
Guatemala	Yes	No	No	No	No
Haiti	No	No	No	No	No
Honduras	No	No	No	No	No
Mexico	Yes	Yes	Yes	Yes	Yes
Nicaragua	No	No	No	No	No
Panama	Yes	No	No	No	No
Paraguay	Yes	No	No	No	No
Peru	Yes	Yes	Yes	Yes	Yes
Suriname	No	No	No	No	No
Uruguay	Yes	No	No	No	No
Venezuela	Yes	Yes	Yes	Yes	Yes

Data on pharmacovigilance regulatory requirements governing pharmaceutical industry activities in 21 countries in Latin America from 2012 (Hoffmann E, et al. Pharmaceutical Medicine. 2012;26:153–164).
AE, adverse event.

Over the past decade, HTAs have expanded across the LatAm region but their implementation in individual countries has not been uniform due to challenges related to the characteristics of individual healthcare systems and differing political or economic environments [82]. Leading the way is Brazil, where the Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde (CONITEC) has adopted a systematic HTA process that includes decision-making with broad public participation [83]. Colombia has a national HTA agency (Instituto de Evaluacion de Tecnologíca en Salud (IETS), but HTAs are not systematically used to inform coverage decisions. In Mexico, the HTA body, Centro Nacional de Excelencia Tecnológica en Salud (CENETEC), produces reports and clinical recommendations [83], while in Chile, a formal HTA process is used to inform high-cost coverage decisions only [84]. In contrast, there are countries like Nicaragua and Bolivia where HTA is not yet included in the policy agenda [83]. Effective implementation of HTA processes requires the sharing of information and collaboration between patients, payers, regulators, and manufacturers [82]. Education about biosimilars for key stakeholders involved in the process is also important. Countries with well-established HTAs can provide a benchmark for those countries where processes are still in development [82].

One suggested approach for the LatAm region would be to promote an adaptive HTA process for biosimilars that expedites or adapts some aspects of the 'traditional' HTA approach. Adaptive HTAs are already used in high-income countries such as the UK and Canada, as well as in the EU [85]. For consistency with the alternative pathways adopted in these countries, LatAm countries could develop simpler approaches to characterize the value of biosimilars. In addition to demonstrating clinical noninferiority of biosimilars to their reference medicines, economic evidence such as cost-minimization and budget impact analyses may be helpful for decision-makers to justify the need for rapid adoption of biosimilars. Understanding the impact of funding biosimilars over reference medicines on the health equity of the population is particularly important in countries with large socio-economic disparities, such as Chile [86]. Knowledge of patients' perceptions of biosimilars, and how these may affect timely access to biosimilars, is also relevant to facilitate their incorporation [87].

In Brazil and Mexico, HTAs are not usually taken into consideration during the development of medical society guidelines, which typically use an evidence-based approach only [81]. In future, guideline development should take HTAs into account to ensure that recommendations are based on the value of medicines, as well as evidence supporting their efficacy and safety.

6. Missed opportunities for cost savings with biosimilars in Latin America

Healthcare costs associated with advanced-stage cancers are high in the LatAm region [58]. A systematic review of studies evaluating treatment costs of breast cancer in LatAm countries reported average annual direct costs per patient of international dollars (I$)13,179 for stage I disease to I$28,910 for stage IV disease, based on 2020 data [58]. Delays in diagnosis and treatment contribute to the increasing rates of cancer-related morbidity and mortality seen across the LatAm region, where fragmented healthcare systems mean that there is limited access to services and poor coordination of care [88]. Expenditure on cancer care is predicted to increase in this region, emphasizing the need for steps to cut the costs of treatments, such as harmonized regulatory processes, to ensure faster approval and greater confidence in the use of oncology biosimilars at all clinically appropriate stages of the treatment pathway.

In Brazil, breast cancer is the leading cancer diagnosis among women, with 66,280 new cases in 2020, 20% of which exhibited overexpression of human epidermal growth factor receptor 2 (HER2). The introduction of trastuzumab biosimilars in 1999 marked the first approval of biosimilar in Brazil for HER2-positive patients with breast cancer. Data from a national survey of Brazilian oncologists demonstrated that despite many respondents being open to using a biosimilar, there were several concerns relating to switching. These included a lack of comprehensive studies on the optimal timing and methods for switching regimens, and the expense of HER2-targeted therapy, despite the cost of the biosimilar being approximately 40% lower than that of the reference medicine [89]. This highlighted a need for future educational initiatives among Brazilian oncologists to help contribute to a broader understanding of biosimilar concepts and costings.

7. Realizing cost savings with biosimilars in Latin America

Healthcare systems in the LatAm region have an increasing opportunity to purchase medicines in the most cost-effective way, for example, by bulk buying over long periods, enabling competitive tenders, using performance-based risk-sharing arrangements, and prioritizing the best-value medicines, which are usually biosimilar and generic medicines. However, achieving these strategies will require coordinated regional efforts.

More transparent regulatory processes should be adopted to build trust in biosimilars, with communications and educational initiatives led by respected medical societies and industry. Value frameworks should be established to support decision-making and the implementation of centralized purchasing, competition policies, and risk-sharing agreements [82].

Pricing policies that facilitate competition for clinically substitutable medicines generally lead to lower prices for biosimilars compared with their reference products, thereby increasing patient access [17]. However, there are a number of hurdles introduced by holders of the reference product patents that can impede the introduction of these pricing policies. Evergreening refers to the implementation of strategies by pharmaceutical manufacturers before the patent expiry of a reference medicine that result in an extension of the patent protection period or a new patent for a minimally modified version of the drug. A consequence of evergreening

is often delayed entry of biosimilars into the market by preventing competition [90].

Strategies can be put in place which identify commonalities across the LatAm region and make use of approved processes from other regions where these can be easily incorporated or adapted. However, national policies need to be taken into consideration when addressing biosimilar uptake as these differ between countries. Guidance should promote the cost benefit of using biosimilars and be accompanied by local language educational initiatives on the science and benefits of biosimilars, and the multiple factors associated with pricing of these medications. National policies incentivizing the use of biosimilars, such as prescribing quotas, should be used to encourage prescribing.

An area of growing interest in both LatAm and worldwide is the implementation of more strategic purchasing mechanisms, such as managed entry agreements. These schemes redistribute financial risk between manufacturers and payers, facilitating earlier drug access for patients, with better financial control for the health system [91,92]. Several LatAm countries have recently implemented managed entry agreements, most commonly for reference medicines [17,93,94]. These should be extended to any medicine or technology where there is an opportunity to redistribute financial risk, as is the case for many biosimilars. In Uruguay, performance-based risk-sharing arrangements are used to enhance the affordability and value of new medicines at the time of launch and post-launch [17,93]. In addition to the National Health System, the National Resources Fund (Fondo Nacional de Recursos [FNR]) finances highly specialized medical procedures and high-cost medicines in Uruguay, based on approved coverage protocols. The FNR has various confidential trading agreements with pharmaceutical companies including volume, fixed monthly payments, and discounts/rebates based on agreed performance metrics. As an example, patients with advanced non-small cell lung cancer typically have a survival of 12 months after starting treatment with erlotinib. As part of the agreement with the FNR, the costs of subsequent doses after 12 months are covered by the pharmaceutical company [93].

The Act4Biosimilars Action Plan is a global roadmap launched in 2022 with the aim of increasing the adoption of biosimilars globally by at least 30% in over 30 countries by 2030 [95]. The Action Plan identifies critical challenges preventing patient access to biosimilars and provides actionable steps across the '4As,' namely Approvability, Acceptability, Accessibility, and Affordability, which are designed to help local stakeholders foster a more favorable environment for biosimilars in their country, and ultimately drive global uptake [95].

Cost savings achieved with the use of biosimilars can be reinvested to improve healthcare services and increase access to treatment, potentially improving patient outcomes and helping to support long-term healthcare sustainability. For example, in the UK, savings of GDP2.5 million with the use of biosimilars in gastroenterology and a benefit-share agreement, whereby some of those savings could be reinvested directly back to the hospital department involved, enabled recruitment of additional inflammatory bowel disease nurses at the Royal Free London Foundation Trust [96]. Scaled up to a national level, such initiatives for biosimilars and generic medicines led to a saving of GDP1.2 billion (USD16 billion) for NHS England over 3 years to 2022 [97].

In Brazil, partnerships between national government-owned companies, private technology holders, and the Ministry of Health, known as Parcerias para o Desenvolvimento Produtivo (Productive Development Partnerships [PDPs]), have been implemented [98]. PDPs establish local manufacturing capabilities for essential medicines at reduced cost to the public health system, and offer advantages to both the government and patent holders [99]. The Ministry of Health commits to purchasing a particular medicine for a fixed period, ensuring exclusive sales of the product for the manufacturer. During this 'technological transfer' period, production is transferred to a local public facility, which must be self-sufficient by the end of the agreement [98,99]. The aim of PDPs is to expand access to essential medicines and enable autonomy, allowing countries to manufacture cost-effective medicines at a national level [98].

In 2019, a partnership was established between Sandoz and the Brazilian biotechnology companies Bio-Manguinhos /Fiocruz and Bionovis, which serve as technology transfer facilities. As a result of this partnership, the Brazilian Ministry of Health was able to provide rituximab biosimilar free of charge for patients through the Unified Health System [98]. The availability of locally produced rituximab biosimilar increased access to rituximab for the Brazilian population. In 2019 (prior to the introduction of the PDP agreement), approximately USD $23.2 million was spent by the government on acquiring rituximab. By 2023, following the introduction of locally produced rituximab biosimilar into the public healthcare system, this had reduced to USD $18.6 million, representing a cost saving of around 20%. Over the same period, the number of rituximab doses administered to patients increased by 28% from 30,068 to 38,970. Between 2019 and 2023, the rituximab market in Brazil reduced in value by around 8.7% from USD $36.6 million to USD $33.4 million [98].

8. Conclusion

Healthcare systems in LatAm are facing growing pressures which threaten their long-term sustainability, and interventions to improve patient access to affordable medications and healthcare services are urgently needed. The introduction of biosimilars increases price competition, thereby improving the affordability of biologic medicines and expanding patient access. A multifaceted approach will be needed to drive the uptake of biosimilars across the LatAm region. This should include harmonized regulatory processes for biosimilars, with reimbursement policies that prioritize their use and prescribing incentives; educational initiatives for HCPs, patients, and other key stakeholders; simplified or adapted HTA processes for biosimilars; and coordinated regional efforts to enable national healthcare systems to purchase medicines in the most cost-effective way. Cost savings achieved with the use of biosimilars can be reinvested in healthcare services, thereby helping to reduce health

inequalities and supporting long-term healthcare sustainability across the LatAm region.

We hope that our report encourages others to publish more data and information about biosimilars in the LatAm region. This will provide researchers and policymakers with a comprehensive understanding of the crucial issue of access to affordable, safe, and effective biologic medicines.

9. Expert opinion

The impact of high-cost biologics is felt greatly in the LatAm region, where most of the population depends on underfunded public health systems. Moreover, there are considerable differences in the epidemiology and burden of cancer among countries in this region [8] that further impact on patient outcomes. Based on the European experience, it is well accepted that the introduction of biosimilars leads to increased competition, lowering of prices, and expanded access to biologic medicines. However, regulatory frameworks for biosimilars are not as well established in LatAm as in Europe and North America, and the efficacy and safety of approved biosimilars are still not widely accepted. Furthermore, concepts such as 'extrapolation,' 'interchangeability,' 'substitution,' and 'immunogenicity' are frequently raised in discussions about biosimilars, which makes gaining acceptance of these agents even more difficult. The development and implementation of a standardized and streamlined regulatory process for biosimilars across the LatAm region, including translation into daily practice in a timely manner, is crucial. Furthermore, adherence to any new policy updates or regulatory changes will also be very important. Local HCP and patient educational initiatives will be needed for individual LatAm countries, and new disease registries will need to be established to gather data to guide decision-making.

Barriers to the successful uptake of biosimilars vary between LatAm countries, but several commonalities have been identified [28]. It is important to distinguish countries with mature markets and advanced technical capabilities from those at an earlier stage of development, because the former may be better placed to increase patient access to biosimilars [28]. Ensuring local production facilities have the technology needed to manufacture biosimilars is very important.

We can envision a future scenario for the position of biosimilars in LatAm based on what is currently taking place in Europe. The Brazilian agency, ANVISA, which has previously avoided producing a statement regarding the 'interchangeability' of biosimilars, has recently issued a document reinforcing this position [100]. The expansion and reinforcement of this position across all of LatAm could lead to higher sales, increasing competition and lowering the cost with high impact, mainly in those countries that have licitation, such as Brazil. The acceptance by physicians of biosimilar substitution according to those large processes can be encouraged by reassurance of the regulated steps for biosimilar manufacture, analysis by the regulatory agencies, and availability of post-marketing studies and pharmacovigilance data, created by trusted pharmaceutical companies. Another area that we may foresee is that LatAm could benefit from a simplification of the registration process. In fact, ANVISA has issued a document addressing this issue, which has already led to the approval of a biosimilar administration expansion (from intravenous [iv] only to iv and subcutaneous) based on a simplified analysis [100]. Moreover, the necessity for phase 3 clinical trials can result in elevated production costs, which many LatAm countries may find unaffordable [39]. Finally, one may expect that more partnership agreements between private pharmaceutical companies and public institutions could result in technology transference, potentially leading to benefits such as higher-paying jobs and greater accessibility to biologic therapies for low-income individuals [98]. It is crucial to continue discussing and considering these future developments throughout LatAm, especially as an increasing number of biologic reference drugs lose their patents and become targets for biosimilar development.

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