Pharmacy Education (2025) 25(1) 467 - 477
https://doi.org/10.46542/pe.2025.251.467477

RESEARCH ARTICLE

Assessing pharmacists' knowledge and perceptions of biosimilars: A cross-sectional study in Argentina

Javier Walter Opezzo, Luciana de Abrantes, Diana Gerarduzzi, María Isabel Sarabia, Romina Guidi, Susana Beatriz Gorlczalzany, Christian Höcht, María Sylvia Viola

Faculty of Pharmacy and Biochemistry, Department of Pharmacology, University of Buenos Aires, Buenos Aires, Argentina

Keywords
Biosimilar
Biosimilar substitution
Knowledge
Medicine access
Pharmacist
Survey

Correspondence
María Sylvia Viola
Faculty of Pharmacy and Biochemistry
Department of Pharmacology
University of Buenos Aires
Buenos Aires
Argentina
msviola@ffyb.uba.ar

Abstract

Background: As biosimilars become more widely used globally, pharmacists' knowledge and attitudes are pivotal to safe utilisation, substitution policies, and pharmacovigilance. This study assessed Argentinian pharmacists' knowledge and perceptions of biosimilars. **Methods:** A cross-sectional study was conducted between 26 August and 30 November 2023. An anonymous, validated, online questionnaire, comprising 18 questions across three sections, was administered to pharmacists of all specialties in Argentina. **Results:** Responses were received from 502 pharmacists; 75% had over six years' experience and 69% worked in community or hospital settings. Approximately half of the respondents demonstrated adequate knowledge (67% of correct answers). Topic-specific correctness was higher for bioequivalence (79%) and preclinical/clinical trials (83%) and lower for pharmacovigilance (43%). Most participants supported biosimilars' market entry (72%) and viewed local regulatory implementation as fundamental (84%), yet about half were unaware of current regulations. Only 16% had received adverse-event reports and 18% favoured pharmacist-led substitution. The need for further training was strongly endorsed (83%). **Conclusion:** Despite supportive attitudes and moderate knowledge, gaps persist in regulatory awareness, interchangeability, and pharmacovigilance. Targeted education and clearer national guidance are warranted to strengthen safe and effective biosimilar use and substitution.

Introduction

Biosimilars (BS) are biological medicines that are highly similar to an already approved reference (originator) biological product. Owing to the inherent complexity of biological molecules and manufacturing processes involving living organisms, biosimilars are not identical to their reference product. This intrinsic variability distinguishes BS from small-molecule generics and necessitates a more complex regulatory pathway focused on demonstrating similarity rather than identity (WHO Expert Committee on Biological Standardization, 2022).

The importance of biosimilars within healthcare lies in their ability to reduce treatment costs compared to originator biological medicines. Cost reductions from biosimilars can, in turn, significantly improve patient access to expensive therapies for chronic and serious conditions, such as arthritis, certain types of cancer, diabetes, and autoimmune diseases. Their introduction stimulates market competition, which can drive price reduction for both biosimilars and the reference products, potentially alleviating financial burdens on healthcare systems. Beyond cost and access, the availability of biosimilars can also foster innovation and efficiency within the pharmaceutical industry.

Argentina's investment in pharmaceutical research and development is among the highest in Latin America, but it remains below the average of developed countries. Hence, creating a domestic biosimilars sector represents substantial economic benefits for Argentina, including opportunities to export to new markets and strengthen the national pharmaceutical industry (Bas, 2016; Ortiz-Prado *et al.,* 2023). In line with this direction, Argentina has recently introduced a new regulation with improved definitions and criteria

for comparability between biosimilars and their reference medicines. These measures are expected to further strengthen and incentivise the system (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica [ANMAT], 2025).

Within this context, stakeholder and patient understanding and confidence in the quality and substitutability of biosimilars are crucial for increasing their use. Although few studies have examined acceptance among physicians and opinions of medical societies in Latin America (Reilly and Gewanter, 2015; Castañeda Hernández *et al.,* 2019; Goecke *et al.,* 2020; Aguilera *et al.,* 2023), the knowledge and views of pharmacists involved in biosimilars remain under-explored, unlike in other regions like Europe, North America, Oceania and Asia (Pawlowska *et al.,* 2019; Gasteiger *et al.,* 2022; Awada *et al.,* 2023; Stevenson *et al.,* 2023; Jarab *et al.,* 2025).

Pharmacists hold a central role in the dispensing and substitution of biosimilars. Therefore, adequate undergraduate education and continuing professional development are essential to support safe integration and protect patients and the healthcare system in Argentina (Armando *et al.,* 2020). Core topics, such as the concept of biosimilars, their distinction from generics, and their approval processes, are taught in undergraduate courses and specialisation programmes, for example, at the University of Buenos Aires (UBA). An assessment of pharmacists' knowledge in this area is warranted to determine whether educational reinforcement is needed, given the complexity of biological medicines and the implications for day-to-day practice. This study aimed to investigate pharmacists' knowledge and perception of biosimilars in Argentina, noting that no previous surveys on this topic have been conducted in Latin America, including Argentina.

Methods

Design and data collection

A cross-sectional study was conducted using a voluntary, anonymous, self-administered online questionnaire created on Google Forms. The survey link was sent three times over three months to 1072 pharmacists via email and WhatsApp. Contact details were obtained from pharmacists' associations and organisations across the country, supplemented by the author's contact list group. Data were collected between 26 August and 30 November 2023. Eligible participants were pharmacists practising in Argentina who completed the full questionnaire; partial responses were excluded.

The Google Form was configured to prevent duplicate submission. Anonymity and confidentiality were maintained, and no identifying information was collected. Data were stored and processed according to applicable data protection guidelines on an access-restricted not connected to external networks.

Ethical considerations

The study was conducted under a waiver of ethical approval granted by the Ethics and Clinical Investigation Committee of the Faculty of Pharmacy and Biochemistry, University of Buenos Aires (UBA). The survey landing page presented the study objectives and an electronic informed-consent statement. No personally identifying information (including email addresses) was collected, and no invasive procedures were involved.

Development of the survey questionnaire

Most knowledge and opinion questions were adapted from existing literature (Farhat *et al.,* 2016; Oqal *et al.,* 2022). Pharmacists from diverse specialities (industry, n=3; hospital, n=4; academia, n=2; and community, n=3), each with more than five years of professional experience, evaluated the study instrument for content and face validity. Their recommendations were incorporated into the finalised questionnaire. Minor adjustments were made after revision, including the addition of one question and correction of some spelling mistakes; pilot responses were excluded from the final analysis. The survey was prepared and reported in line with the Consensus-Based Checklist for Reporting of Survey Studies (CROSS) (Sharma *et al.,* 2021).

The final questionnaire consisted of three sections, comprising a total of 18 questions (Appendix A). The first section collected demographic and professional information, including years since graduation, country of residence, professional settings, and years of experience in their respective fields. This section also assessed pharmacists' familiarity with the term "*biosimilars*".

The second section involved eight statements about the knowledge of biosimilars, scored 1 point for correct and 0 for incorrect answers, yielding a maximum knowledge score of 8 (Table I). Although the sample mean was 5.1 correct answers, a stricter, a priori classification was applied for descriptive analyses and comparisons: scores >5/8 were classified as 'knowledgeable' and ≤5/8 as 'not knowledgeable', consistent with previous studies (Eppes *et al.,* 2013; Awada *et al.,* 2023).

The third section comprised nine statements exploring pharmacists' opinions on biosimilar medicines.

Response formats varied by item and included binary options ('Yes'/'No', with a third option where applicable) and a four-point frequency scale ('Never', 'Rarely', 'Sometimes', 'Always').

Table I: Full score answers to the different knowledge statements

Statement to scoring responses	Appropriate response (score)
It is chemically identical to an innovative biological drug.	Incorrect (1)
It has no significant differences from innovative biological medicine in terms of quality.	Correct (1)
It has no significant differences from an innovative drug in terms of safety.	Correct (1)
It has been approved with only one bioequivalence assay.	Incorrect (1)
The biosimilar has the same immunogenicity risk as the innovator drug.	Correct (1)
It does not require preclinical or clinical studies for approval.	Incorrect (1)
Substituting the innovative drug for its biosimilar is safe.	Correct (1)
It requires a mandatory pharmacovigilance plan.	Correct (1)

Sample size calculation

Assuming that 50% of the respondents would have a positive attitude towards biosimilars and their substitution, with a 5% margin of error and a 95% confidence interval, the minimum size was 378 participants. This calculation assumed a population of approximately 22,815 pharmacists in Argentina, considering five pharmacists per 10,000 inhabitants and a total population of 45,000,000 (Raosoft, 2004; Bates *et al.,* 2016; Merino, 2020).

Data analysis

Data were analysed using Minitab 19.1 (Minitab LLC., 2019) for Windows. Descriptive statistics summarised the data for the total sample. The results were analysed using the non-parametric Kruskal-Wallis test.

Results

Pharmacist population

A total of 502 pharmacists completed the questionnaire; two respondents were practising outside Argentina. Relevant characteristics are summarised in Table II. Most respondents (75%) had graduated more than six years before the survey, and 78% reported over six years of professional experience. Additionally, 29% reported working across two or more specialities. Nearly half practised in community pharmacies (47%), 22% in hospitals, 15% in industry, and 6% in academia.

Of the total sample, 80% were familiar with the term 'biosimilar'. More than 31% reported no knowledge of local regulations, and close to 20% were unfamiliar with the term. Sources of knowledge about biosimilars were diverse.

Table II: Description of the pharmacist population

Questions	Frequency	%
Graduation years		
Less than 1 year	32	6.4
Between 1-5 years	94	18.7
Between 6-15 years old	132	26.3
More than 15 years	244	48.6
Speciality*		
Community pharmacist	236	47.0
Industrial pharmacist	76	15.1
Hospital pharmacist	111	22.1
Regulatory authorities	20	4.0
Academia	29	5.8
Others	30	6.0
Length of professional experience		
Less than 1 year	21	4.2
Between 1 -5 years	89	17.7
Between 6-10 years	88	17.5
More than 10 years	304	60.6
Are you familiar with the term BS?		
Yes	420	83.7
No	8	1.6
Something	74	14.7
Where have you heard about BS? #		
Degree	230	23.1
Graduate	130	13.1
Work	229	23.0
Colleagues	185	18.6
Scientific Meetings	220	22.1
Do you know if there are regulatory legislations for BS in Argentina?		
Yes	250	49.8
No	94	18.7
I do not know if they exist	158	31.5

***29 % shared activities in different specialties; **BS**: biosimilar; **#**: Multiple sources were chosen

Pharmacists' knowledge of biosimilars

Overall, 66.7% of respondents answered between five and eight knowledge items correctly; only 3.8% (19/502) achieved a perfect score.

Table III presents the knowledge performance. The lowest percentages of correct responses (43%) were related to the requirement of a mandatory pharmacovigilance plan. In contrast, the highest proportions of correct answers were observed for recognising that approval requires preclinical or clinical studies (82%) and that it is not solely based on a single bioequivalence study (79%).

Across specialities, industry pharmacists achieved the highest knowledge score (6/8), but the difference was not significant (Kruskal-Wallis $p = 0.06$; Figure 1). Knowledge scores did not differ by years of experience or time since graduation.

Table III: Pharmacist knowledge about biosimilars (n = 502)

Statement	Correct answer*	Total of correct answers (%)	Community (%)	Industry (%)	Hospital (%)	Health or regulatory authorities (%)	Academia (%)	Others (%)
It is chemically identical to reference biological medicine	Incorrect	333 (66.3)	150 (63.6)	50 (65.8)	80 (72.1)	14 (70.0)	19 (65.5)	20 (66.7)
It has no significant differences from reference biological medicine in terms of quality.	Correct	306 (61.0)	135 (57.2)	59 (77.6)	60 (54.1)	11 (55.0)	22 (75.9)	19 (63.3)
It has no significant differences from reference biological medicines in terms of safety.	Correct	297 (59.2)	129 (54.7)	60 (78.9)	62 (55.9)	13 (65.0)	16 (55.2)	17 (56.7)
It has been approved with only one bioequivalence assay.	Incorrect	395 (78.7)	188 (79.7)	60 (78.9)	85 (76.6)	16 (80.0)	25 (86.2)	21 (70.0)
The biosimilar has the same immunogenicity risk as the reference medicine.	Correct	312 (62.2)	159 (67.4)	37 (48.7)	65 (58.6)	17 (85.0)	15 (51.7)	19 (63.3)
It does not require preclinical or clinical studies for approval.	Incorrect	414 (82.5)	193 (81.8)	60 (78.9)	95 (85.6)	15 (75.0)	27 (93.1)	24 (80.0)
Substituting the reference medicine for its biosimilar is safe.	Correct	291 (58.0)	144 (61.0)	46 (60.5)	61 (55.0)	9 (45.0)	16 (55.2)	15 (50.0)
It requires a mandatory pharmacovigilance plan.	Correct	217 (43.2)	87 (36.9)	49 (64.5)	42 (37.8)	12 (60.0)	15 (51.7)	12 (40.0)
Total number of correct answers:			**236 (47.0)**	**76 (15.1)**	**111 (22.1)**	**20 (4.0)**	**29 (5.8)**	**30 (6.0)**

*: see Table I

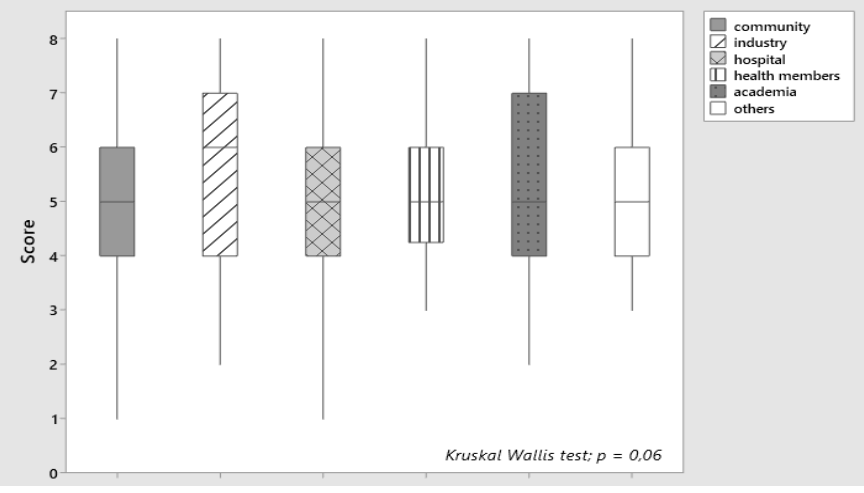

Figure 1: Score by pharmacists' knowledge about biosimilar medicines

Pharmacists' perception of biosimilars

Among 502 respondents, nearly 70% of pharmacists "*always*" or "*almost always*" agreed with the marketing of biosimilar medicines in Argentina. However, only 53% "*always*" or "*almost always*" considered that the prescription of these medicines could reduce healthcare costs. Additionally, 51% of the pharmacists believed that biosimilars approved in Argentina had demonstrated efficacy and safety comparable to their reference products.

Only 18% responded "*always*" in favour of pharmacist-led substitution between a reference and a biosimilar medicine. However, 83% strongly agreed that additional training is required for safe biosimilar substitution, and 68% expressed the need for further education on pharmacy-level substitution, reporting insufficient emphasis on biosimilar management within current academic programmes in the country.

Therapeutic areas in which biosimilars are mainly used

Respondents most commonly identified rheumatology (21%), immunology (17%), and oncology-oncohaematology (16%) as the therapeutic areas where biosimilars are most frequently prescribed (Figure 2).

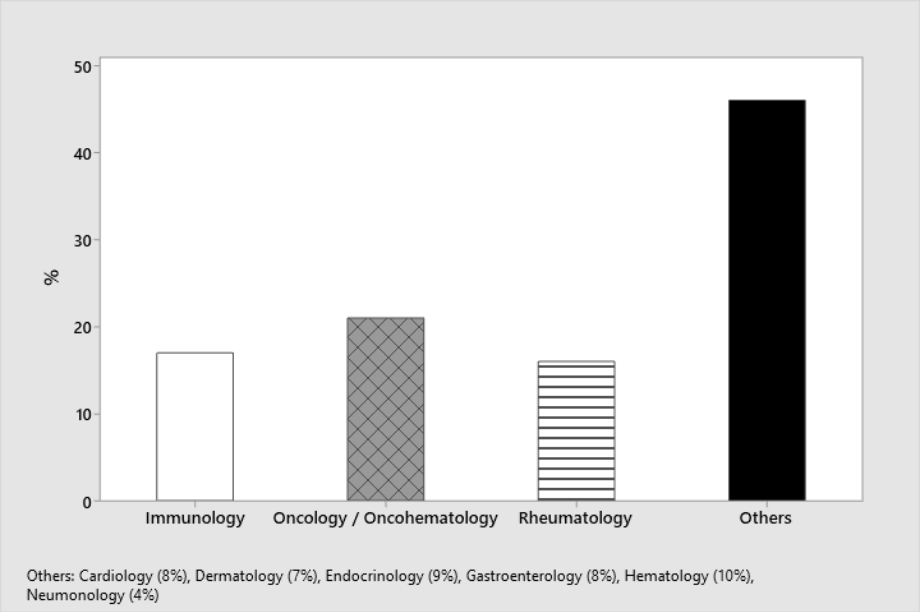

Figure 2: Therapeutic areas percentage where biosimilars are used according to pharmacists' knowledge.

Adverse event reports and pharmacists' responses

Only 83 respondents (16%) reported receiving reports of suspected adverse events (AE) related to biosimilar prescriptions, with community pharmacists representing the most involved professional profile in receiving such reports (39%). Additionally, 43% indicated that their current role does not involve biosimilar products.

Discussion

This study appears to be the first to explore Argentine pharmacists' knowledge, attitudes, and practices regarding biosimilars. The findings indicate commitment to improving professional development through education, particularly concerning regulations and pharmacovigilance. Taken together with the new ANMAT regulatory guidelines published in March 2025, the results underscore the need for a plan to enhance biosimilar knowledge at undergraduate and postgraduate levels.

This online survey, conducted in 2023, achieved a response rate of 47%, exceeding the 44% average reported in similar research (Menon & Muraleedharan, 2020; Heffernan & Macy, 2025). Self-reported time since graduation closely matched years in practice, supporting coherence in the sample's professional seniority. Importantly, familiarity with the term 'biosimilar' was high (84%), aligning with pre-2023 findings from other countries (O'Callaghan *et al.,* 2017; Pawlowska *et al.,* 2019). This familiarity likely stems

from routine exposure to biosimilars in contemporary practice, as well as coverage in undergraduate curricula, workplace learning, and participation in conferences or courses (Farhat *et al.,* 2016).

Although approximately 60% of respondents had graduated after the implementation of regulations governing biological medications in Argentina, around 50% of pharmacists were unfamiliar with those specific regulations. This pattern suggests that familiarity with biosimilars often stems from general scientific and technical education or common practice rather than from direct engagement with the national regulatory framework or hands-on product experience.

By speciality, community pharmacists formed the largest group (47%), consistent with the 40-65% range observed in other studies (Bates *et al.,* 2016; Oqal *et al.,* 2022). Representation of hospital pharmacists was comparable to figures from North and Latin America, whereas a higher proportion of academic and industry pharmacists participated. This distribution likely reflects differential willingness to respond rather than the underlying composition of the pharmacist workforce.

The overall correctness in the knowledge assessment was 67% (scoring >5-8 points), with no significant differences found across various practice settings, although industry pharmacists showed a slight, non-significant tendency towards higher scores. Role-related exposure may shape knowledge domains. For instance, hospital pharmacists are more likely to encounter biosimilars in daily practice and assess their pharmacological and safety profiles. Community pharmacists more often engage with economic aspects for high-cost therapies (e.g., cancer and inflammatory autoimmune diseases). Industry pharmacists are directly involved in development and regulatory processes, potentially increasing familiarity with quality and approval requirements for biosimilars and explaining their non-significant trend towards higher scores.

Regarding knowledge, half of the respondents believed that biosimilars do not differ from reference products in quality, safety, or immunogenic risk and considered pharmacist-led substitution safe. These results align with reports from 2022 (Oqal *et al.,* 2022). Notably, accuracy was high for two items, bioequivalence and preclinical/clinical evidence, with approximately 80% correct responses.

In contrast, only 43% answered pharmacovigilance items correctly. This finding is concerning, given the specific safety-monitoring requirements for biological medicines and biosimilars. Pharmacists play a crucial role in reporting suspected adverse events or therapeutic failures associated with biosimilars to ensure patient safety and product acceptance. Limited pharmacovigilance knowledge and under-reporting can impede biosimilar acceptability and use (Stevenson *et al.,* 2023). Therefore, reinforcing continuous post-authorisation safety monitoring remains essential (Zuñiga & Calvo, 2010).

Although respondents generally supported the marketing of biosimilars, they did not perceive them as inherently more cost-effective than innovators. While biosimilar development should foster competition and reduce prices, this effect is not always achieved in Argentina; some biosimilars are only marginally cheaper than reference products, and a few studies even reported higher prices in certain instances (Ortiz-Prado *et al.,* 2023; da Silva *et al.,* 2024).

Regarding substitution, 44% of pharmacists supported pharmacist-led substitution in principle, reflecting uncertainty and a cautious approach, echoing previous reports (O'Callaghan *et al.,* 2017; Stevenson *et al.,* 2023). This uncertainty likely stems from a lack of specific national guidelines on interchangeability and pharmacist-driven substitution; notably, Argentina does not currently designate "*interchangeable*" biosimilars in the manner of the U.S. Food and Drug Administration (Endrenyi & Markus, 2019).

Local medical societies, mirroring positions seen internationally, oppose automatic pharmacist-led substitution of biological products (Sociedad Argentina de Dermatología [SAD], 2018; Sarnola *et al.,* 2020; Marín-Jiménez *et al.,* 2021). Professional hesitancy, compounded by prescriber knowledge gaps, impedes significantly biosimilar adoption (Messner *et al.,* 2023). Moving forward, collaborative, evidence-based policies and sustained education are essential for supporting safe and effective biosimilar use (Meara, 2024).

Biosimilar adoption varies across countries due to non-clinical factors, such as policy frameworks, economic considerations, and divergent regulatory approaches (Rieger *et al.,* 2024). Uptake is also hindered by limited awareness among healthcare professionals and patients regarding the risks and benefits of biosimilars (Gibofky *et al.,* 2022; Stevenson *et al.,* 2023). Even in developed countries, physicians have concerns about biosimilar prescription and interchangeability, which pharmacists generally respect (Kolbe *et al.,* 2021; Messner *et al.,* 2023). However, pharmacists are well-positioned to lead across healthcare settings, as they understand the significant practice-changing effects and opportunities.

This study revealed a significant demand for further training, with 67% of respondents requesting additional education. This finding highlights the need to strengthen biosimilar education for pharmacists, other healthcare professionals, and patients, consistent with

previous reports (Gasteiger *et al.,* 2022; Shubow *et al.,* 2023). Continuous education is crucial for promoting the rational use of biosimilars and reinforcing the pharmacist's role as a medication expert and healthcare leader.

At the University of Buenos Aires (UBA), undergraduate and postgraduate curricula already address generics, biosimilars, and pharmacovigilance systems. Building on this foundation, priorities include strengthening and incentivising adverse event reporting in community pharmacies.

Given that approximately half of the respondents were unfamiliar with the applicable regulation, a national communication campaign is warranted to address this knowledge gap, followed by a re-evaluation using a tool similar to that analysed in this study.

This study appears to be the first in the region, including Argentina, and was conducted before the updated regulatory disposition (ANMAT, 2025), which introduced the definition of 'biosimilar' into official regulations and provided specific manufacturing guidelines, thus addressing a previously existing gap.

These findings are expected to enhance understanding of pharmacists' involvement in biosimilar management and inform future initiatives designed to increase the number of postgraduate courses while fostering dialogue with other healthcare professionals on recent developments. In addition, efforts should be made to enhance online outreach and educational materials (Li *et al.,* 2017; BioSIM, 2019; APhA, 2024).

Limitations

This study has several limitations. It did not collect geographical distribution data, which hinders the ability to assess national representation or identify regions with greater educational needs. Additionally, the specialities of the participating pharmacists were not balanced, as they lacked national distribution data for comparison.

The non-probability, online sampling approach (email/WhatsApp) used in the survey design may have introduced selection and non-response biases, which limits the generalizability of the results. Nevertheless, this method is useful when it is not feasible to access the entire target population.

Although knowledge was assessed using eight items with a predefined cut-off point for classification and the internal consistency of the items was acceptable, the thematic coverage was necessarily limited, which may have led to misclassification of some participants' knowledge levels.

Self-administered responses are susceptible to recall and social desirability biases and should ideally be independently verified; however, they have the advantage of reducing interviewer influence, which may enhance the honesty of responses.

Conclusion

The use of biosimilars is increasing in Argentina, accompanied by supportive attitudes and moderate knowledge among pharmacists. Critical gaps persist in regulatory awareness, interchangeability, and pharmacovigilance. This study revealed cautious views on pharmacist-led substitution. Targeted education in these areas is crucial for the safe and effective use of biosimilars in clinical practice. Greater awareness among pharmacists is particularly needed regarding regulatory guidelines and pharmacovigilance requirements.

Conflict of interest

Luciana de Abrantes works for Fresenius Kabi in Argentina. All other authors declare no conflict of interest.

Source of funding

The authors did not receive any funding.

References

Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT). (2025). *Guía de comparabilidad de Biosimilares Disposición 7014/2025*. Accessed May 25, 2025. https://www.boletinoficial.gob.ar/detalleAviso/primera/322607/20250317

Aguilera B., Peña S., Morales J.P. (2023). Knowledge, perceptions, and utilization of generics and biosimilars in Latin America and the Caribbean: A scoping review. *The Journal of Law, Medicine & Ethics,* **51**(S1), 100–115. https://doi.org/10.1017/jme.2023.117

APhA (American Pharmacists Association). (2024). *Interchangeable biosimilars: pharmacist's guide to frequently asked questions.* Accessed May 25, 2025. https://www.pharmacist.com/Advocacy/Issues/Biosimilars/Biologics-and-Biosimilar-Drug-Products-Pharmacist-Guide-to-Patients-Frequently-Asked-

Armando, P. D., Uema, S. A., & Vega, E. M. (2020). Integration of Community pharmacy and pharmacists in primary health care policies in Argentina. *Pharmacy Practice (Granada),* **18**(4), 2173. https://dx.doi.org/10.18549/pharmpract.2020.4.2173

Awada, S., Sayah, R., Mansour, M., Nabhane, C., & Hatem, G. (2023). Assessment of community pharmacists' knowledge of the differences between generic drugs and biosimilars: A pilot cross-sectional study. *Journal of Medical Access,* **7**, 27550834231167049. https://doi.org/10.1177/27550834231167049

Bas, T. (2016). Biosimilars in two developing economies of South America (Argentina and Brazil) and one developed economy of Oceania (Australia). Facts, regulations, and evolution. *Research Journal of Pharmaceutical, Biological and Chemical Sciences,* **7**, 1794–1809. https://www.rjpbcs.com/pdf/2016_7(5)/[228].pdf

Bates, I., John, C., Bruno, A., Fu, P., & Aliabadi, S. (2016). An analysis of the global pharmacy workforce capacity. *Human Resources for Health,* **14**(1), 61. https://doi.org/10.1186/s12960-016-0158-z

BioSIM, Asociación Española de Biosimilares. (2019). *GUÍA DE MEDICAMENTOS Biosimilares para farmacéuticos.* Accessed May 25, 2025. https://www.sefac.org/sites/default/files/2019-03/GUIA-BIOSIMILARES-FARMACEUTICOS.pdf

Castañeda-Hernández, G., Sandoval, H., Coindreau, J., Rodriguez-Davison, L. F., & Pineda, C. (2019). Barriers towards effective pharmacovigilance systems of biosimilars in rheumatology: A Latin American survey. *Pharmacoepidemiology and Drug Safety,* **28**, 1035–1044. https://doi.org/10.1002/pds.4785

da Silva Machado, F. L., Cañás, M., Urtasun, M. A., Marin, G. H., Albuquerque, F. C., Pont, L., Convertino, I., Bonaso, M., Tuccori, M., Kirchmayer, U., & Cruz Lopes L. (2024). A cross-national comparison of biosimilars pricing in Argentina, Australia, Brazil, and Italy. *Therapeutic Innovation & Regulatory Science,* **58**, 549–556. https://doi.org/10.1007/s43441-024-00623-8

Endrenyi, L., & Markus, R. (2019). Interchangeability of biological drug products-FDA draft guidance. *Journal of Biopharmaceutical Statistics,* **29**(6), 1003–1010. https://doi.org/10.1080/10543406.2019.1607369

Eppes, C., Wu, A., You, W., Cameron, K. A., Garcia, P., & Grobman, W. (2013). Barriers to influenza vaccination among pregnant women. *Vaccine,* **31**(27), 2874–2878. https://doi.org/10.1016/j.vaccine.2013.04.031

Farhat, F., Othman, A., El Karak, F., & Kattan, J. (2016). Review and results of a survey about biosimilars prescription and challenges in the Middle East and North Africa region. *SpringerPlus,* **5**(1), 2113. https://doi.org/10.1186/s40064-016-3779-8

Gasteiger, C., Gasteiger, N., & Petrie, K. J. (2022). Pharmacists' confidence in explaining biosimilars to patients before a nationwide medicine change: A cross-sectional study. *Exploratory Research in Clinical and Social Pharmacy,* **8**, 100199. https://doi.org/10.1016/j.rcsop.2022.100199

Gibofsky, A., Evans, C., & Strand, V. (2022). Provider and patient knowledge gaps on biosimilars: Insights from surveys. *American Journal of Managed Care,* **28**(12 Suppl), S227–S233. https://doi.org/10.37765/ajmc.2022.89297

Goecke, A., Trigueros, P. D., Vargas, A., Babini, A., Graf, C., Provenza, J. R., Ferreira, W. H., Andrade, A., Gimenez, M., & Cabrera, E. (2020). The patients' knowledge and perception about biologics and biosimilars: Results of a survey at the South Cone Zone of Panlar. *JCR-journal of Clinical Rheumatology,* **26**(3), 107–108. https://repositorio.uchile.cl/handle/2250/175268

Heffernan, M. E., & Macy, M. L. (2025). Survey response rates: Reassessing expectations. *Journal of the Pediatric Infectious Diseases Society,* **14**(5), piaf031. https://doi.org/10.1093/jpids/piaf031

Jarab, A. S., Al-Qerem, W., Alzoubi, K. H., Abu Heshmeh, S. R., Al Hamarneh, Y. N., Alefishat, E., & Aburuz, S. (2025). Understanding community pharmacists' knowledge, attitudes, and practices regarding biosimilar drugs: A cross-sectional survey. *International Journal of Clinical Practice,* **2025**(1), 2248512. https://doi.org/10.1155/ijcp/2248512

Kolbe, A. R., Kearsley, A., Merchant, L., Temkin, E, Patel, A., Xu, J., & Jessup Amber. (2021). Physician understanding and willingness to prescribe biosimilars: Findings from a US national survey. *BioDrugs,* **35**, 363–372. https://doi.org/10.1007/s40259-021-00479-6

Li, E., Liu, J., & Ramchandani, M. A. (2017). Framework for integrating biosimilars into the didactic core requirements of a Doctor of Pharmacy curriculum. *American Journal of Pharmaceutical Education,* **81**(3), 57. https://doi.org/10.5688/ajpe81357

Marín-Jiménez, I., Carrascosa, J. M., Guigini, M. A., & Monte-Boquet, E. (2021). Knowledge, perceptions, attitude, barriers and facilitators of biosimilars use across specialty physicians and hospital pharmacists: A national survey. *Farmacia Hospitalaria,* **45**(5), 240–246. https://www.revistafarmaciahospitalaria.es/es-pdf-S1130634323005299

Meara, K. (2024). Pharmacist education, knowledge key to fostering biosimilar adoption. *Drug Topics Journal,* **168**(02). https://www.drugtopics.com/view/pharmacist-education-knowledge-key-to-fostering-biosimilar-adoption

Menon, V., & Muraleedharan, A. (2020). Internet-based surveys: relevance, methodological considerations and troubleshooting strategies. *General Psychiatry,* **33**(5), e100264. https://doi.org/10.1136/gpsych-2020-100264

Merino, Á. (2020). *¿Cuántos farmacéuticos hay en el mundo?* El Orden Mundial (EOM). https://elordenmundial.com/mapas-y-graficos/cuantos-farmaceuticos-hay-mundo/

Messner, K., Eickhoff, C., Schulz, M., Allemann, S. S., & Arnet, I. (2023). Knowledge and attitudes of German and Swiss community pharmacists towards biologicals and biosimilars – a prospective survey before and after the COVID-19 pandemic. *BMC Health Services Research,* **23**, 1432. https://doi.org/10.1186/s12913-023-10475-x

Minitab, LLC. (2019). *Minitab*. https://www.minitab.com

O'Callaghan, J., Bermingham, M., Leonard, M., Hallinan, F., Morris, J. M., Moore, U., & Griffin, B. T. (2017). Assessing awareness and attitudes of healthcare professionals on the use of biosimilar medicines: A survey of physicians and pharmacists in Ireland. *Regulatory Toxicology and Pharmacology,* **88**, 252–261. https://doi.org/10.1016/j.yrtph.2017.06.013

Oqal, M., Hijazi, B., Alqudah, A., Al-Smadi, A., Almomani, B., Alnajjar, R., Ghunaim, M., Irshaid, M., & Husam, A. (2022). Awareness and knowledge of pharmacists toward biosimilar medicines: A survey in Jordan. *International Journal of Clinical Practice,* **27**, 8080308. https://doi.org/10.1155/2022/8080308

Ortiz-Prado, E., Izquierdo-Condoy, J. S., Vasconez-González, J. E., Dávila, G., Correa, T., & Fernández-Naranjo, R. (2023). The pharmaceutical market for biological products in Latin America: A comprehensive analysis of regional sales data. *Journal of Law, Medicine & Ethics,* **51**(S1), 39–61. https://doi.org/10.1017/jme.2023.112

Pawłowska, I., Pawłowski, L., Krzyżaniak, N., & Kocić, I. (2019). Perspectives of hospital pharmacists towards biosimilar medicines: A survey of Polish pharmacy practice in general hospitals. *BioDrugs,* **33**, 183–191. https://doi.org/10.1007/s40259-019-00341-w

Raosoft Inc. (2004). *Raosoft Sample Size Calculator.* Seattle, USA. http://www.raosoft.com/samplesize.html

Reilly, M. S., &. Gewanter, H. L. (2015). Prescribing practices for biosimilars: Questionnaire survey findings from physicians in Argentina, Brazil, Colombia and Mexico. *Generics and Biosimilars Initiative Journal,* **4**, 161–167. https://doi.org/10.5639/gabij.2015.0404.036

Rieger, C., Dean, J. A., Hall, L., Vazquez, P., Merlo, G. (2024). Barriers and enablers affecting the uptake of biosimilar medicines viewed through the lens of actor network theory: A systematic review. *BioDrugs,* **38**, 541–555. https://doi.org/10.1007/s40259-024-00659-0

Sarnola, K., Merikoski, M., Jyrkkä, J., & Hämeen-Anttila, K. (2020). Physicians' perceptions of the uptake of biosimilars: a systematic review. *BMJ Open,* **10**(5), e034183. https://doi.org/10.1136/bmjopen-2019-034183

Sharma, A., Minh Duc, N. T., Luu Lam Thang, T., Nam, N. H., Ng, S. J., Abbas, K. S., Huy, N. T., Marušić, A., Paul, C. L., Kwok, J., Karbwang, J., de Waure, C., Drummond, F. J., Kizawa, Y., Taal, E., Vermeulen, J., Lee, G. H. M., Gyedu, A., To, K. G., Verra, M. L., Jacqz-Aigrain, É. M., Leclercq, W. K. G., Salminen, S. T., Sherbourne, C. D., Mintzes, B., Lozano, S., Tran, U. S., Matsui, M., & Karamouzian, M. (2021). A consensus-based checklist for reporting of survey studies (CROSS). *Journal of General Internal Medicine,* **36**(10), 3179–3187. https://doi.org/10.1007/s11606-021-06737-1

Shubow, S., Sun, Q., Nguyen Phan, A. L., Hammell, D. C., Kane, M., Lyman, G. H., Gibofsky, A., Lichtenstein, G. R., Bloomgarden, Z., Cross, R. K., Yim, S., Polli, J. E., & Wang, Y. M. (2023). Prescriber perspectives on biosimilar adoption and potential role of clinical pharmacology: A workshop summary. *Clinical Pharmacology & Therapeutics,* **113**(1), 37–49. https://doi.org/10.1002/cpt.2765

Sociedad Argentina de Dermatología (SAD). (2018). COMUNICADO | Declaración de la SAD sobre medicamentos de origen biológico*. Otra Medicina,* **78**, 272–281. https://sad.org.ar/comunicado-declaracion-de-la-sad-sobre-medicamentos-de-origen-biologico/

Stevenson, J. G., McCabe, D., McGrath, M., & McBride, A. (2023). Pharmacist biosimilar survey reveals knowledge gaps. *Journal of the American Pharmacists Association,* **63**(2), 529–537.e7. https://doi.org/10.1016/j.japh.2022.11.001

WHO Expert Committee on Biological Standardization. (2022). *Annex 3: Guidelines on evaluation of biosimilars. Replacement of Annex 2 of WHO Technical Report Series, No. 977.* Retrieved February 24, 2023, from https://cdn.who.int/media/docs/default-source/biologicals/who_trs_1043_annex-3_biosimilars_tk.pdf

Zuñiga, L., & Calvo, B. (2010). Biosimilars: pharmacovigilance and risk management. *Pharmacoepidemiology and Drug Safety,* **19**(7), 661–669. https://doi.org/10.1002/pds.1948

Appendix A: Survey questionnaire used in the study

This is a work of the Department of Pharmacology, Pharmacy and Biochemistry School, University of Buenos Aires. Pharmacists are invited to participate in this voluntary and anonymous survey. If you accept, please answer the questions truthfully, answering will only take less than 5 minutes. Thanks a lot. ***All questions are required.***

Questions	Answer options
1. How many years ago did you graduate as a pharmacist? Check only one option	Less than 1 year ago Between 1-5 years ago Between 6-15 years ago More than 15 years ago
2. Country where you work	Argentina Other
3. Pharmaceutical area where you work or have worked? Select all that apply.	Community Pharmacy Industrial Pharmacy Hospital Pharmacy Health or regulatory authorities Academia Other
4. How much experience do you have in your area of work? Check only one option	Less than 1 year Between 1-5 years Between 6-10 years More than 10 years
5. Are you familiar with the term biosimilar medicine? Check only one option	Yes No Something
6. Where have you heard about Biosimilars? Check only one option per row	Degree Postgraduate degree Work Colleagues Conferences / Meetings
7. Do you know if there are regulatory legislation for biosimilars in Argentina? Check only one option	Yes No I don't know if they exist.
8. What statements are applicable to biosimilar medicine? Select all that apply	It is chemically identical to reference biological medicine. It does not differ significantly from a reference biological medicine in terms of quality. It has no significant differences from reference medicine in terms of safety It has been approved with only one bioequivalence assay. The biosimilar has the same immunogenicity risk as the reference medicine. It does not require preclinical or clinical studies for approval. Substituting the reference medicine for its biosimilar is safe. It requires a mandatory pharmacovigilance plan.
9. Biosimilars approved in Argentina have demonstrated efficacy and safety compared to the innovator biological medicine. Check only one option	Never Sometimes Always
10. In which medical specialties do you think the indication for using biosimilars is most frequent? Select all that apply	Cardiology Dermatology Endocrinology Gastroenterology Haematology Immunology Pulmonology Oncology / oncohaematology Rheumatology
11. Prescribing biosimilars can reduce sanitary costs. Check only one option	Never Rarely Sometimes Almost always Always

Questions	Answer options
12. Regarding the commercialization of biosimilar medicines in Argentina's health system, I agree: Check only one option	Always Almost always Occasionally Rarely Never
13. Do you agree with pharmacist substitution the innovator biological for a biosimilar? Check only one option	Always Almost always Occasionally Rarely Never
14. Do you think that guidelines should be established to regulate the substitution of biosimilars. Check only one option	Yes No I don't have an opinion
15. Treatment failures and/or adverse effects can be a serious problem with some biosimilars. Check only one option	Always Occasionally Never
16. Have you ever been informed of any adverse events that may be related to the use of a biosimilar? Check only one option	Yes No I am not in contact with the type of medication
17. Do you consider that enough emphasis is placed on the situation and management of biosimilars in Argentina in academic study programs? Check only one option	Yes No I do not know
18. Do you think you need more training in terms of the substitution of biosimilars? Check only one option	Yes No Maybe

Thank you very much, you can leave your comments here. (box for comments)

Please send this survey to your colleagues. Share the following link: https://forms.gle/f4zNePr1NvtSqq6E6