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Capacity building to support the uptake of biosimilars in a multistakeholder approach

AUGMENT Biosimilars
Country fiche SLOVENIA

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augment biosimilars

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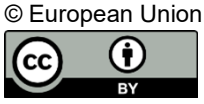

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Annex 7.28

AUGMENT Biosimilars country fiche: Slovenia 2025

Capacity building to support the uptake of biosimilars in a multistakeholder approach

The AUGMENT Consortium produced this country fiche as part of the project "Capacity building to support the uptake of biosimilars in a multistakeholder approach (HADEA/2023/OP/0040)" commissioned by the European Health and Digital Executive Agency (HaDEA). The AUGMENT Consortium consists of the Austrian National Public Health Institute (Gesundheit Österreich Forschungs- und Planungs GmbH / GÖ FP), as consortium lead; the Polish Agency for Health Technology Assessment and Tariff System (Agencja Oceny Technologii Medycznych i Taryfikacji / AOTMiT), the Medical University Sofia (MUS), and the NOVA National School of Public Health in Lisbon.

In this project (abbreviated AUGMENT Biosimilars project), the AUGMENT Consortium performed a **comprehensive study** which aimed to offer a **mapping and** an **analysis of existing policies and practices** to encourage biosimilar uptake and competition in 32 European countries (all European Union (EU) and European Free Trade Association (EFTA) Member States, and the United Kingdom). In the analysis, the impact of biosimilar policies on improving patient access to medicines as well as barriers and facilitators in the policy implementation will be studied. For further information see biosimilars.goeg.at.

Key terms related to biosimilar policies can be found in the project's Glossary.

Contributors

This country fiche was produced by GÖ FP based on information the PPRI network was used, and findings from systematic and narrative literature reviews.

We gratefully acknowledge the validation of this country fiche by:
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1 Summary of biosimilar policies and practice in Slovenia 2025

Key stakeholders

The Slovenian Agency for Medicinal Products and Medical Devices (JAZMP) is the main regulatory institution with regard to biosimilars, acting also as the pharmaceutical pricing authority and providing comprehensive information on biosimilars on the market in Slovenia. The National Health Insurance Fund (ZZZS) decides on inclusion into reimbursement and provides guidance on interchangeable medicines, including prescribing and switching to biosimilars. The Slovenian Competition Protection Agency (CPA) enforces competition regulation and treats anti-trust cased based on notifications. No case on biosimilars could be identified. Health care professionals including doctors, nurses and pharmacists are represented by associations. They inform patients, procure, prescribe and dispense biosimilars. Patients are organised in associations as well, some of which in disease areas of relevance for biosimilar use. The biosimilars industry is represented by the general Slovenian Pharmaceutical Manufacturers Association.

Major biosimilar policies and practices

Prices for biosimilar medicines are set in Slovenia through external price referencing applied both in the inpatient and outpatient sectors when the medicine aims to enter the market (no biosimilar price link). The lowest price of the compared countries is used as a maximum price, which then serves as negotiation basis to determine the reimbursement price. If biosimilars are not on the market in any of the compared countries, 68% of the lowest price of the relevant reference biological medicine is set as a maximum price and is used in reimbursement negotiations mentioned above. In addition, tendering for biosimilars is performed in the inpatient sector only, where usually one lot of the tender is reserved for originator medicines and the other(s) for biosimilars. Tenders are performed by individual hospitals based on various award criteria going beyond price, and they may be awarded to multiple winners. Biosimilars are also included in the reference price system in the outpatient sector and the outpatient reimbursement list (in some cases). In general, the reimbursement procedures are the same for biosimilars as for other medicines. No co-payments apply for biosimilars.

Doctors are recommended to prescribe biosimilars for naïve patients and to consider switching under specific conditions. INN prescribing is not allowed for biosimilars. Biosimilar substitution by community pharmacists is not permitted in Slovenia. No gain-sharing models are in place, neither for prescribers, dispensers nor patients.

Impact analysis

Literature on the impact by biosimilars specific to the Slovenian context is limited. There is evidence for savings for the public payers due to a change in the design of external price referencing, which also targets biosimilar medicines. Another article

pointed to actions of the originator industry to potentially hinder or delay the market entry of biosimilars in diabetes in Central Europe.

Barriers, facilitators and good practice examples

Barriers to the uptake of biosimilars in Slovenia may include a partial lack of demand-side policies. For instance, INN prescribing for biologicals and biosimilars, as well as the substitution of biosimilars at the community pharmacy level, is not permitted. Additionally, there are no gain-sharing models in place.

JAZMP provides comprehensive educational information on biosimilars, guidelines on interchangeability, and various educational brochures and videos aimed at healthcare professionals and patients. ZZZS regularly sends clinicians pricing comparisons on expensive drugs including biologics and biosimilars. This may facilitate biosimilar uptake.

Recent developments

A major industry investment to build a state-of-the-art biosimilars technical development centre in Ljubljana is planned by 2026.

Highlights and learnings

Slovenia is one of the countries that employs External Price Referencing (EPR) for biosimilars, utilizing a combination of external and internal price referencing methods.

2 Key data regarding biosimilars in Slovenia

First biosimilar medicine launched (i.e. brought on the market):
Somatropin in January 2008.
Source: Medicines for Europe 2023

Number of the **biosimilars marketed**:
28 molecules with biosimilars available, as of February 2025.
Source: JAZMP 2025f

Biosimilar market shares in 2024 (or latest available data):

No information on market share in volume and value for the complete Slovenian market. Good prescribing of some (mostly hospital, inpatient) biosimilars in 2024: adalimumab 38 % (DDD), rituximab 57 % (mg), trastuzumab (iv, 96 %), bevacizumab (mg) 98 %, pegfilgastrim (outpatient, DDD) 59 %.

Source: ZZZS 2025

Key national publicly accessible sources reporting data on biosimilars
(e.g., on numbers of biosimilars marketed, reimbursed, dispensed, on (public) spending on biosimilars, on prices of biosimilars):

- Biosimilars markets: JAZMP. Biologicals/biosimilar approved in EU and marketed in SI. Last updated in April 2024. Agency for Medicinal Products and Medical Devices of the Republic of Slovenia. Available from: https://www.jazmp.si/en/human-medicines/biosimilars/biologicals-biosimilar-approved-in-eu-and-marketed-in-si/
- Biosimilar prescribing and switching guidance: JAZMP. Interchangeability of biologicals and biosimilars. Agency for Medicinal Products and Medical Devices of the Republic of Slovenia. Available from: https://www.jazmp.si/en/human-medicines/biosimilars/interchangeability-of-biologicals-and-biosimilars/)
- Biosimilar use: JAZMP. Use of biological and biosimilar medicinal products in Slovenia and in Europe. Agency for Medicinal Products and Medical Devices of the Republic of Slovenia. Available from: https://www.jazmp.si/en/human-medicines/biosimilars/use-of-biological-and-biosimilar-medicinal-products-in-slovenia-and-in-europe/
- Biosimilars monitoring of pharmacovigilance: JAZMP. Monitoring of biological and biosimilar medicinal products during period of use (pharmacovigilance). Agency for Medicinal Products and Medical Devices of the Republic of Slovenia. Available from: https://www.jazmp.si/en/human-medicines/biosimilars/monitoring-of-biological-and-biosimilar-medicinal-products-during-period-of-use-pharmacovigilance/
- ZZZS: Consumption of medicinal products 2015 - 2024: https://partner.zzzs.si/zdravila-in-zivila-za-posebne-zdravstvene-namene/podatki-o-porabi-zdravil/

3 Stakeholders involved in and targeted by biosimilar policies in Slovenia

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Ministry of Health of the Republic of Slovenia	Prepares legislation.	
National regulatory authority	Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP) / Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance.	Biosimilars Marketed in SI (JAZMP 2024a) Biosimilar use (JAZMP 2024b) Biosimilars Interchangeability (JAZMP 2024c) Biosimilars authorised (JAZMP 2024d) Pharmacovigilance (JAZMP 2024e) Additional information (JAZMP 2024f) Q&A Biosimilars (JAZMP 2024g)
Pharmaceutical pricing authority		Implements pricing legislation regarding biosimilars, decides on the prices.	
Pharmaceutical reimbursement authority	Zavod za zdravstveno zavarovanje Slovenije (ZZZS) / The National Health Insurance Fund	Decides on inclusion into reimbursement for biosimilars and their prices. Provides guidance on interchangeable medicines. Informs providers on prices of expensive drugs including biologicals and biosimilars.	Prescription medicines (ZZZS 2024a) Interchangeable medicines list (ZZZS 2024b)
Procurement agency	Not applicable		
HTA agency / body			And see above.
National competition authority	Javna Agencija Republike Slovenije Za Varstvo Konkurence / Slovenian Competition Protection Agency (CPA)	Enforces competition regulation and investigates anti-trust cases based on notifications.	
National patent office	Urad za intelektualno lastnino / Slovenian Intellectual Property Office	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Zdravniška zbornica Slovenije / Medical Chamber of Slovenia Medical societies: • Slovensko endokrinološko društvo / Slovenian Endocrinology Society • Slovensko združenje za gastroenterologijo in hepatologijo (SZGH) / Slovenian Gastroentero-logy Society • Slovensko hematološko društvo / Slovenian Hematology Society • Slovensko onkološko društvo (SOD) / Slovenian Oncology Society • Slovensko reumatološko društvo / Slovenian Society of Rheumatology	Prescribe biosimilars. Inform patients about biosimilars. Several medical societies in disease areas with biologics use identified (see left).	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
	• Zveza Društev za Pomembne Rijetke Bolezni / Association of Societies for Rare Diseases		
Nurses	*Represented by:* Zbornica-Zveza / Nurses and Midwives Association of Slovenia		
Community pharmacists	*Represented by:* Lekarniška Zbornica Slovenije / Slovenian Chamber of Pharmacy	Dispense medicines, inform patients.	
Hospital pharmacists	*Represented by:* Slovensko farmacevtsko društvo (SFD) / Slovenian Pharmaceutical Society, Section of Hospital Pharmacists	Procure medicines, inform patients.	
Patient organisations	*Several disease related patient organisations in connection with biosimilars:* • Zveza društev diabetikov Slovenije / Diabetes Association of Slovenia • Slovensko združenje za Crohnovo bolezen in ulcerozni kolitis / Slovenian Crohn's and Colitis Association • Drustvo bolnikov z limfomom / Lymphoma Patients Association • Slovensko združenje bolnikov z rakom / Slovenian Cancer Patients Association • Društvo revmatikov Slovenije / Slovenian Rheumatism Association	Patient organisations in diseases with particular biologics use and organisations with specific advocacy or education work on biosimilars identified (see left).	
Consumer organisations	*Represented by:* Zveza potrošnikov Slovenije (ZPS)		
Biosimilar industry	*Represented by:* Lekova Domaca Lekarna / The Slovenian Pharmaceutical Manufacturers Association (SPMA)	Represents biosimilar and generic industry.	
Generic industry			
Pharmaceutical industry in general	The Slovenian Pharmaceutical Manufacturers Association (SPMA)		
Pharmaceutical industry for new biological medicines	*Represented by:* Forum of International Research & Development Pharmaceutical Companies (FIRDPC)		

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium)

4 Biosimilar policies and practices in Slovenia 2025

Note that the information relates to the year 2025, to the national level and to outpatient and inpatient sectors, unless specified differently.

4.1 Pricing and procurement policies

Biosimilar price link

A **biosimilar price link** is in place.	Yes
It applies for the following situations:	
Price reduction of the first biosimilar compared to the reference product	- 32% compared to originator price (maximum price). Reference pricing is basis for maximum allowed price calculation. Maximum allowed price is basis for negotiation for reimbursed price confirmation
Price reduction of the second, third and further biosimilars	There is no defined price reduction for subsequent biosimilars.
Price reduction for the reference product	
Any further specificities	
Generic price link	- 32% compared to originator price (maximum price). Reference pricing is basis for maximum allowed price calculation. Maximum allowed price is basis for negotiation for reimbursed price confirmation

Source: PPRI 2025

External price referencing

External price referencing is applied for biosimilars.	Yes, in place.
If yes, it is applied for the following situations:	EPR is applied for biosimilar medicines in the outpatient and inpatient sectors for medicines entering the market. The lowest price of the same originator biological and equivalent biosimilar product in the country basket is used as maximum price.
Any specificities	
External price pricing is in place for other medicines than biosimilars.	Yes, in place.

Source: PPRI 2025, Medicines for Europe 2023

Tendering

Some (or all) **biosimilars are procured through tendering** (or tendering-like) processes.	Yes.
If yes, the scope with regard to the care sector:	Inpatient sector only.
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	Several off-patent biological medicines. "The aim is to use biosimilars instead of original medicines. In tenders usually one lot is reserved for original medicines and the other(s) for biosimilars. If more than one biosimilar is used, there are several slots for biosimilars in the tender."
Institutional framework	Conducted by individual hospitals through their procurement departments, with oversight and governance provided by the Ministry of Health and influenced by reimbursement decisions from the National Health Insurance Fund (ZZZS).

Information available on procurement procedures and practices	Award criteria includes price, quality, supply security, and the ability to provide multiple biosimilars. Multiple-winner tenders are more common.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	Not applicable as not in place.
Institutional framework	
Information available on procurement procedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes. Outpatient: No.

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Medicines for Europe 2023, Machado et al. 2025

4.2 Reimbursement policies 2025

Reference price system

Biosimilars are **included into the reference price system (RPS)** applied in the outpatient sector.	Yes (in some cases)
If yes, how many and under which specifications	Clustering by active substance (ATC-5) including biologics and biosimilars (somatropin, filgrastim, pegfilgrastim, low-molecular heparins, adalimumab)
If publicly accessible, indicate URL of RPS list	
When were first biosimilars included in the reference price system?	2013
Any further specificities	
In general, a reference price system is in place, and how those medicines are clustered?	Yes, broader clusters than ATC 5.

Source: PPRI 2025, Medicines for Europe 2023, Machado et al. 2025

Inclusion into reimbursement and co-payments

Reimbursement in the outpatient sector	
Apart from their potential inclusion into the reference price system (see above), biosimilars are **included in outpatient reimbursement** (positive list).	Yes. In general, the reimbursement procedure is the same as for other medicines.
If yes, how many and date of inclusion into reimbursement, if known)	
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	
Indicate URL of outpatient positive list	Centralna baza zdravil 2 - Iskanje
Co-payments for biosimilars for outpatient use	No co-payments for biosimilars (except due to the co-payments in the reference price system).
For medicines for outpatient use in general (other medicines than biosimilars) Positive list for medicines in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	A positive list is in place. Percentage reimbursement rates were in place till end of 2023. Since Jan. 2024 all drugs are 100 % covered (or to the reference price). There is NO prescription fee, percentage co-payments and deductibles.

Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes, additionally to the originator biological (and doctors are recommended to switch)
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	Not publicly available.
Co-payments for biosimilars for inpatient use	No co-payments for biosimilars.
For medicines for inpatient use in general (other medicines than biosimilars): Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	No co-payments for medicines for inpatient use

Source: PPRI 2025, Medicines for Europe 2023, ZZZS 2016

4.3 Specific pricing, procurement and funding policies 2024

For defined medicines, public payers and payers have been piloting and implementing specific funding models (such conditional reimbursement, managed-entry agreements, and subscription models such as the Netflix models). Typically, these funding models apply for high-priced medicines with high uncertainties (e.g., originator biologicals) or for medicines with small populations whose uptake is aimed to be encouraged. The section provides information whether biosimilar medicines are also subject to specific funding models. Furthermore, it also looks into possible anti-trust cases.

Application of special pricing, procurement and reimbursement models for biosimilars (e.g., delinkage / subscription-model, management-entry agreements (MEA))	No.
Enforcement of anti-trust policies	Yes, the Slovenian Competition Protection Agency (CPA) enforces competition rules in the country based on notifications. No specific case regarding biosimilars was identified.
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Predominantly financial and some performance-based MEAs

Source: PPRI 2025

4.4 Supportive tools and practices for policy-makers 2025

Horizon scanning

Public authorities or public payers use a **horizon scanning** system to identify loss of exclusivity (patent expiry) of biologics	No, not in place.
If yes, describe the process and the tools (e.g. regular consultation of a database, horizon scanning scoping meeting with stakeholders), including who use horizon scanning	Not applicable as not in place.

Source: PPRI 2025

Health technology assessment

HTA is applied for biosimilar medicines	No, not applied. *"In the Republic of Slovenia, HTA is currently not performed in a dedicated HTA institution. JAZMP is currently not an HTA competent authority, but is in the position to perform HTA-related tasks in pricing procedures as defined in Article 182 of the Medicinal Products Act (Uradni list RS [Official Gazette of the Republic of Slovenia], No. 17/14 and 66/19).*"
If yes, in which situations and settings (outpatient and inpatient)	Not applicable as not in place.
Differences in criteria and processes of HTA for biosimilars compared to other medicines	
Any specificities	

Source: PPRI 2025, JAZMP 2025h

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Country context: Only doctors may prescribe medicines.

Source: ZZZS 2024a

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes, in place.
If yes, what is recommended for naïve patients?	Recommendation to prescribe the cheapest biosimilars for naïve patients. ZZZS informs providers regularly on prices of expensive drugs including biologics and biosimilars (for instance, to rheumatologists rheumatologic drugs etc.)
If yes, what is recommended for patients already on biologic treatment	Recommendation that doctors should consider switching under specific conditions.
Prescription guidelines (including switching guidelines) were issued by	*„The JAZMP's position is that a physician-led switching between authorized versions of a given biologic medicine at treatment initiation or during ongoing treatment is safe. Switching can apply to the following situations:* • *switching from reference medicine to biosimilar medicine* • *switching from biosimilar medicine to reference medicine* • *switching from a biosimilar medicine to another biosimilar medicine, based on the same reference product.* *The decision to prescribe a biological medicine for an individual patient, whether it is a reference product or a biosimilar, is limited to performed in the clinical environment and is subject to the clinician's medical consultation with the patient. As with all biologic medicines, adequate clinical monitoring in line with clinical guidelines should be envisaged.*"
URL of prescription & switching guidelines	Interchangeability of biologicals and biosimilars – JAZMP

Prescribing quotas	
Prescribing quota for doctors with regard to prescription of biosimilars exist	No, not in place.
If yes, which quota are defined for biosimilars	Not applicable as not in place.
Any exemptions	
Any sanctions in case of non-achievement	
Any (financial) incentives for achieving the quota	
Prescribing quota were issued by	
URL of prescribing quota	
Prescribing quota for other non-biosimilar medicines exists	No, not in place.
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	No, not in place.
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	Not applicable as not in place.
Publicly accessible information	
INN prescribing	
In general, prescribing by **INN is in place** (information not focused on biologics)	Yes, indicative.
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	Exemptions for biologicals from INN prescribing: biologics and biosimilars may not be prescribed by INN.
Further measures targeted at doctors	
Information materials for doctors	Yes, handbooks, videos, handbooks, websites. Mainly developed by biosimilars industry. Some information is available from the Medicines Agency website as well.
Information events for doctors (e.g., seminars, trainings)	Yes, including seminars, conferences or workshops as well as training or continuous professional development for healthcare professionals.
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	No.

Source: PPRI 2025, Medicines for Europe 2023, JAZMP 2025c, ZZZS 2016

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense.

Source: ZZZS 2025b

Substitution policies	
(Automatic) substitution for biosimilars	No, not allowed.
If yes, for which biologic substances and under which prerequisites?	Not applicable as not allowed.
If yes, since when, and when was it extended? (process of implementation)	
Any specificities	
URL of underlying law	
Generic substitution in place	Yes, indicative.
Gain-sharing models	
Gain-sharing models for pharmacists	No, not in place.
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	Not applicable as not in place.
Publicly accessible information	

Further measures targeted at pharmacists	
Information materials for pharmacists	Yes, guidelines and supplementary information. Available from the JAZMP website (JAZMP 2024a-g).
Information events for pharmacists (e.g., seminars, trainings)	Yes, including seminars, conferences or workshops as well as training or continuous professional development for healthcare professionals.

Source: PPRI 2025, Medicines for Europe 2023, JAZMP 2024a-g, ZZZS 2016

Patients

Information and educational measures	
Information materials for patients	Yes, guidelines, videos, handbooks, websites.
If yes, provide URL of most common materials	Biosimilars – JAZMP
If yes, key producers of education measures	JAZMP website (JAZMP 2024b)
Information events for patients (e.g., seminars, trainings)	No, not in place.
If yes, key providers of educational events	Not applicable as not in place.
Gain-sharing models	
Gain-sharing models for patients	No, not in place.
If yes, pls. describe	Not applicable as not in place.
Publicly accessible information	

Source: PPRI 2025, Medicines for Europe 2023, JAZMP 2025b

5 Impact of biosimilar policies and practices in Slovenia

The table below informs about outcome indicators on patient access (e.g., higher number of patients treated), affordability (e.g, savings for the public payers, savings for patients) and availability (presence at the reimbursement list, time between market authorisation and reimbursement / market entry) which were caused by specific biosimilar policies or practices.

Evidence from the literature on impacts of biosimilar policies and practices in Slovenia

Outcome indicator	Caused by (specify policy, if applicable)	Findings	Publication (citation or URL)
Biosimilar market share (of second biosimilar)	No specific policy mentioned	The study showed that the second biosimilars of adalimumab achieved a higher market share in Croatia, Slovenia, Austria, and Belgium. Similarly, the second set of infliximab biosimilars captured a higher market share than the first ones in Slovenia, Finland, and Portugal.	Car et al. 2023
Delayed market entry or limited uptake for biosimilars for diabetes	Limited competition due to action of originator industry to hinder market entry of biosimilars	The study indicated that the increasing use of long-acting insulin analogues across Europe, including both Western and Central and Eastern European countries, typically reflects perceived patient benefits despite higher prices. However, efforts by the originator company to switch patients to more concentrated insulin glargine and to lower prices towards biosimilars have limited the uptake of biosimilars, which have not yet been launched in a minority of European countries. Various activities have been named to address this issue.	Godman et al. 2021
Public savings (in general, including biosimilars)	Changes in the design of the external price reference policy (also applicable for biosimilars)	The study highlighted that unlike other countries that use a single method for determining reference prices, Slovenia employs the lowest price among reference countries for originators and biosimilars, while the average price of reference countries is considered for generics. The study indicates that upgrades to the ERP policy*, introduced between 2007 and 2012, led to a €13 mio. cost decrease or a 5.5% reduction in costs when comparing the assumed annual medicine consumption based on the 2012 Rules with that of the 2007 Rules. On average, this equates to approximately a 1.5% decrease in the assumed annual medicine expenditure, or roughly €3 mio. per ERP policy update introduced by changes or supplements to the Rules. * The upgrades of the ERP policy comprise using the lowest price among reference countries for originators and biosimilars, considering the average price for generics, regular updates to reference prices, expanding the number of reference countries, and implementing price reduction agreements.	Mardetko et al. 2017

Source: see last column and further details on the full citation in the bibliography at the end of this country fiche.

6 Barriers for biosimilar uptake and policy implementation in Slovenia

Legal barriers

Interchangeability of biologicals is only suggested. Biologics and biosimilars are not included into the JAZMP (national) list of interchangeable drugs. Different applicators make switching/substitution policies much more complicated than for small molecules.

Organisational barriers (health-systems or health institutions-related)

Different applicators make automatic substitution in pharmacies impossible without education of the patient.

Financial barriers

In Slovenia, there is a lack of incentives for health professionals or patients to prescribe, dispense, or use biosimilars (no gain-sharing models). Neither are prescribing quotas for biosimilars in place. In case of low biosimilar uptake there is risk of leaving the market, which is small (only 2,1 million population).

Evidence and communication-related barriers

Clinicians with long-term experiences with biosimilars (for instance rheumatology, gastroenterology, oncology) use more biosimilars as the ones who have no experiences (for instance ophthalmology in 2024); the new ones have much more prejudices.

Policy-related barriers

In Slovenia, prescribing by the International Non-proprietary Name (INN) is allowed in general, except for biologics and biosimilars. Substitution of Biosimilars at community pharmacy level is also not permitted. This may act as a barrier to biosimilar uptake.

Stakeholder-related barriers

Mistrust of less-experienced specialists, motivated by the originator companies.

7 Facilitators and good practice examples in Slovenia

JAZMP (Agency for Medicinal Products and Medical Devices of the Republic of Slovenia) has developed a range of educational activities and materials to support

the understanding and uptake of biosimilars. These include comprehensive information on biosimilars, guidelines on interchangeability, and various educational brochures and videos aimed at healthcare professionals and patients (JAZMP 2024a-g). These initiatives may act as facilitators in promoting the acceptance and utilization of biosimilars in Slovenia.

Systematic informing of providers about pricing of most expensive medicines by ZZZS.

8 Developments in Slovenia

Recent changes

In 2025, public procurement of hospitals for expensive drugs, financed by ZZZS, has improved. The amended bylaw on financing of health care programmes stipulates that the ZZZS pays only the cheapest parallels (ATC 5).

Plans or under discussion

There is a planned industry investment of approximately USD 90 mio. / € 83 mio. to build a state-of-the-art Biosimilar Technical Development Center in Ljubljana by 2026 (Sandoz 2023).

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