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

AUGMENT Biosimilars
Country fiche SLOVAKIA

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augment biosimilars

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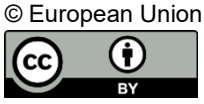

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Annex 7.27

AUGMENT Biosimilars country fiche: Slovakia 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 Slovakia 2025

Key stakeholders

In Slovakia, the key stakeholders involved in designing and implementing biosimilar policies are the Ministry of Health and the State Institute for Drug Control (ŠÚKL).

Major biosimilar policies and practices

Pricing and procurement policies in Slovakia include a biosimilar price link to the first biosimilar entering the market (from 1 august 2022 the legislation was changed, there is no regulation for the second or the third biosimilars, anymore), external price referencing as well as tendering (inpatient and outpatient sectors).

Biological medicines are clustered using reference price system that is paired with coverage and patients co-payments.

Slovakia published prescribing and switching recommendations, i.e. to prescribe biosimilars to treatment naïve patients, and to switch patients for non-medical reasons. Other demand-side measures include prescribing quotas (it is used only for generics not biosimilars). Biosimilars are exempted from substitution.

Impact analysis

While availability and reimbursement of biosimilars improves gradually (from only 19% of marketed biosimilars being reimbursed in Slovakia in 2018 to 58% being reimbursed in 2020), the overall availability of biosimilar medicines is low. 2018, Health insurance funds in Slovakia could have saved 35 to 50 million euros per year if biosimilars with marketing authorisations had been available on the Slovak market. (reference: doi: 10.3389/fpubh.2020.00431)

Barriers, facilitators and good practice examples

The biosimilar market in Slovakia is said to face a significant barrier due to external price referencing (the ex-factory prices of biosimilars approved for the Slovak reimbursement list may not exceed the average of the three lowest prices of the same biosimilars available on pharmaceutical markets across the European Union.).

Main facilitators and good practice examples include—publication of prescribing guidelines for switching from the Slovak Ministry of Health. On the other hand, there are no sanctions for failure to comply with the prescribing guidelines for switching, so implementation is very limited in reality.

Recent developments

Since 1st August 2022: A medicinal product cannot be included in the Reimbursement list of medicinal products if:

it is the first biosimilar medicinal product that, by its characteristics, belongs to the reference group or reference subgroup included in the list of categorized medicinal products and the proposed maximum price of this medicinal product in a public pharmacy, converted to a standard dose of the medicinal product, is higher than 75% of the lowest maximum price of the medicinal product in a public pharmacy valid on the date of submission of the application, converted to a standard dose of the medicinal product included in the reference group or reference subgroup.

Highlights and learnings

The coverage and discussion of biosimilar policies in the literature (while impact assessments tend to be missing) is rather outstanding.

2 Key data regarding biosimilars in Slovakia

First biosimilar medicine launched (i.e. brought on the market):
Filgrastim in 2010
Source: Medicines for Europe 2023

Number of the **biosimilars marketed**:
18 molecules with biosimilars available, as of September 2024
48 biosimilars (per trade name), as of September 2024
Source: MZ SR 2024

Biosimilar market shares in 2022 (or latest available data):

80% **in value** in 2022
Value is defined as **share of total pharmaceutical expenditure or**

Market to which the biosimilar market shares data relate to:
total market (outpatient and hospital, public and private sectors)
Source: IQVIA 2023

Key national publicly accessible sources reporting data on biosimilars
Reimbursement list: https://www.health.gov.sk/?zoznam-kategorizovanych-liekov

3 Stakeholders involved in and targeted by biosimilar policies in Slovakia

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant publications by this stakeholder group
Legislator	Ministerstvo zdravotníctva Slovenskej Republiky / Ministry of Health of the Slovak Republic	Ensures compliance with EMA guidelines Legal framework	MZ SR 2024a
National regulatory authority	Štátny ústav pre kontrolu liečiv / State Institute for Drug Control	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance	SUKL 2025
Pharmaceutical pricing authority	Ministerstvo zdravotníctva Slovenskej Republiky / Ministry of Health of the Slovak Republic	Implements pricing legislation regarding biosimilars, decides on the prices	Act No. 363/2011 Coll.
Pharmaceutical reimbursement authority	Ministerstvo zdravotníctva Slovenskej Republiky / Ministry of Health of the Slovak Republic	Decides on inclusion into reimbursement list and pricing	Act No. 363/2011 Coll.
Procurement agency	Tendering is used for procurement of biosimilar medicines by health insurance funds (at the national level) and in the hospital setting (at the hospital level)	Tendering is used for procurement of biosimilar medicines by health insurance funds (at the national level) and in the hospital setting (at the hospital level)	-
HTA agency / body	Národný inštitút pre hodnotu a technológie v zdravotníctve/ National Institute for Value and Technologies in Healthcare	The HTA agency in Slovakia does not directly manage, procure, or negotiate the prices of biosimilars. Its role is limited to scientific and economic evaluations, which supports the MoH in making decisions on the reimbursement and use of these medicines within the healthcare system.	-
National competition authority	Protimonopolný Úrad Slovenskej Republiky / Antimonopoly-/ Office of the Slovak Republic	Enforcement of the competition law, anti-trust cases	
National patent office	Urad Republike Slovenije za intelektualno lastnino / Slovenian Intellectual Property Office	Granting and managing patents on biologic medicines	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant publications by this stakeholder group
Doctors	*Represented by:* Slovenská lekárska komora / Slovak Medical Chamber *Examples of Medical societies (there are 87 medical societies under Slovak medical Chamber):* - Diabetes: Slovenská diabetologická spoločnosť / Slovak Diabetes Society, - Gastroenterology: Slovenská gastroenterologická spoločnosť / Slovak Gastroenterology Society, - Hematology: Slovenská hematologická spoločnosť (SHS) / Slovak Society of Hematology, - Oncology: Slovenská onkologická spoločnosť (SOS) / Slovak Oncology Society, - Rheumatology: Slovenská reumatologická spoločnosť (SRS) / Slovak Society of Rheumatology	Prescribe biosimilars, ~~a/o by INN~~ (INN prescriptions is used only for generics in Slovakia), patient education	Mlynáriková and Mičeková 2023
Nurses	*Represented by:* Slovenská komora sestier a pôrodných asistentiek / Slovak Chamber of Nurses and Midwives		
Community pharmacists	*Represented by:* Slovenská ~~Ł~~lekárnická komora / Slovak Chamber of Pharmacists	Dispense medicines, inform patients	
Hospital pharmacists	*Represented by:* Slovenská ~~Ł~~lekárnická komora - Sekcia nemocničných lekárnikov / Slovak Chamber of Pharmacists - Section of Hospital Pharmacists	Support to inform patients / health professionals / procurers	Vogler, Salcher-Konrad and Habimana 2022

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant publications by this stakeholder group
Patient organisations	Represented by: Asociácia na ochranu práv pacientov / Association for the Protection of Patients' Rights (AOPP) Patient organisations: - Diabetes: Zväz diabetikov Slovenska / Slovak Diabetes Association, - Gastroenterology: Slovenská organizácia pre Crohnovu chorobu a ulceróznu kolitídu (SOCC) / Slovak Crohn's and Colitis Association - Hematology: Slovenské hemofilické združenie (SHZ) / Slovak Hemophilia Association - Oncology: Liga proti rakovine SR / Slovak Cancer League, - Rheumatology: Liga proti reumatizmu na Slovensku / Slovak League Against Rheumatism - Other: Slovenská aliancia zriedkavých chorôb / Slovak Alliance of Rare Diseases	Patient organisations in diseases with particular biologics use a/o organisations with specific advocacy or education work on biosimilars	Crohnika 2025
Consumer organisations	-	-	-
Biosimilar industry	*Represented by:* Asociácia pre generické a biosimilárne lieky (GENAS) / Association for Generics and Biosimilars	Produces and supplies biosimilars	
Generic industry	*Represented by:* Asociácia pre generické a biosimilárne lieky (GENAS) / Association for Generics and Biosimilars	Same association as for biosimilars	
Pharmaceutical industry in general	*Represented by:* Zväz chemického a farmaceutického priemyslu Slovenskej republiky / Association of the Chemical and Pharmaceutical Industry of the Slovak Republic		
Pharmaceutical industry for new OR biological medicines	*Represented by:* Asociácia ~~I~~inovatívneho ~~F~~farmaceutického ~~P~~priemyslu (AIFP) / Innovative Pharmaceutical Industry Association)		

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium); MZ SR 2021; Act No. 363/2011 Coll.; Mlynáriková a Mičeková 2023; EC 2022; Crohnika 2025

4 Biosimilar policies and practices in Slovakia 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:	For biosimilar medicines in the outpatient and inpatient sectors entering the market
Price reduction of the first biosimilar compared to the reference product	-25% (Since 1st August 2022: A medicinal product cannot be included in the Reimbursement list of medicinal products if: it is the first biosimilar medicinal product that, by its characteristics, belongs to the reference group or reference subgroup included in the list of categorized medicinal products and the proposed maximum price of this medicinal product in a public pharmacy, converted to a standard dose of the medicinal product, is higher than 75% of the lowest maximum price of the medicinal product in a public pharmacy valid on the date of submission of the application, converted to a standard dose of the medicinal product included in the reference group or reference subgroup.)
Price reduction of the second, third and further biosimilars	None
Price reduction for the reference product	The ex-factory prices of the reference products approved for the Slovak reimbursement list may not exceed the average of the three lowest prices of the same reference products available on pharmaceutical markets across the European Union.
Any further specificities	
Generic price link	Since 1st August 2022: A medicinal product cannot be included in the Reimbursement list of medicinal products if: it is the first generic medicinal product which, by its characteristics, belongs to the reference group or reference subgroup included in the list of categorized medicinal products and the proposed maximum price of this medicinal product in a public pharmacy, converted to a standard dose of the medicinal product, is higher than 51% of the lowest maximum price of the medicinal product in a public pharmacy valid on the date of submission of the application, converted to a standard dose of the medicinal product included in the reference group or reference subgroup.

Source: PPRI 2025, Vogler et al. 2025, Vogler et al. 2021, Tesar et al. 2019

External price referencing

External price referencing is applied for biosimilars.	Yes
If yes, it is applied for the following situations:	For biosimilar medicines aiming to be included into the outpatient reimbursement list
Any specificities	European reference price for a medicine is defined by Act No. 363/2011 as "the average of the three lowest prices among the official prices of a medicinal product in other Member States" (10.3389/fphar.2021.795002)

External price referencing is in place for other medicines than biosimilars.	Yes, for new medicines (originals and biologics) and generics and there are regular re-evaluations of prices based on external price referencing for already included medicinal product into the Slovak reimbursement list.

Source: PPRI 2025, CR (EU) No 363/2011

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 and outpatient sectors
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All biological medicines
Institutional framework	Tendering is used for procurement of biosimilar medicines by health insurance funds (at the national level) and in the hospital setting (at the hospital level)
Information available on procurement procedures and practices	Award criteria applied in SK: quality / safety of product, added therapeutic value and the lowest price in the reference group.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	Tendering-like practices, conducted for some ~~(all?)~~ biosimilar medicines
Institutional framework	Conducted at national level. Tendering is used for procurement of biosimilar medicines by health insurance funds (at the national level).
Information available on procurement procedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes, in the hospital setting (at the hospital level). Outpatient: tendering-like system for some generics, by health insurance funds (at the national level).

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Vogler et al. 2025

4.2 Reimbursement policies

Reference price system

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	Yes
If yes, how many and under which specifications	A reference-pricing system groups biologic and biosimilar medicines based on the same active substance and administration form. Health insurance funds reimburse biologic and biosimilar medicines at the price of the least expensive option in a reference group. Patients pay the price difference for costlier alternatives (though physicians retain the decision on treatment). Reimbursement levels are equal for a standard daily dose of biosimilars and original biologics in the same group.
If publicly accessible, indicate URL of RPS list	No separate file with grouping, but RPS based on ATC coding is listed within the reimbursement list: https://www.sukl.sk/hlavna-stranka-1/english-version/databases-and-services/database-of-medicinal-products/database-of-medicinal-products?page_id=410
When were first biosimilars included in the reference price system?	

Any further specificities	
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	Yes ATC 5 cluster

Source: PPRI 2025, Simoens et al. 2021, Tesar et al. 2019

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
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	100 % reimbursement of the cheapest drug in the reference group. A reference-pricing system groups biologic and biosimilar medicines based on the same active substance and administration form. Health insurance funds reimburse biologic and biosimilar medicines at the price of the least expensive option in a reference group. Patients pay the price difference for costlier alternatives. Reimbursement levels are equal for a standard daily dose of biosimilars and original biologics in the same group.
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	No, the same time limit 180 days for all medicinal products, for the decision of MoH
Indicate URL of outpatient positive list	
Co-payments for biosimilars for outpatient use	100 % reimbursement of the cheapest drug in the reference group. Patients pay the price difference for costlier alternatives.
<u>For medicines for outpatient use in general (other medicines than biosimilars)</u> Positive list for medicines in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	For medicines in general for outpatient use: - Positive list - Percentage reimbursement rates are in place (there is no prescription fee for e-prescriptions in Slovakia) percentage co-payments - 100 % reimbursement of the cheapest drug in the reference group. Patients pay the price difference for costlier alternatives.
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~~ regional and/or facility level) Main facilitators and good practice examples include implementation publication of prescribing guidelines for switching from the Slovak Ministry of Health. On the other hand, there are no sanctions for failure to comply with the prescribing guidelines for switching, so implementation is very limited in reality.
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	Shorter timelines
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	URL of national hospital pharmaceutical formulary: Not publicly available
Co-payments for biosimilars for inpatient use	No

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, Vogler et al. 2025

4.3 Specific pricing, procurement and funding policies

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	No
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Solely financial MEAs

Source: PPRI 2025

4.4 Supportive tools and practices for policy-makers

Horizon scanning

Public authorities or public payers use a horizon scanning system to identify loss of exclusivity (patent expiry) of biologics	Yes, systematically
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	https://ihsi-health.org/

Source: Vogler, Salcher-Konrad and Habimana 2022

Health technology assessment

HTA is applied for biosimilar medicines	In general no. Only, in the case of a new reference group, where cost effectiveness is necessary to prove.
If yes, in which situations and settings (outpatient and inpatient)	For biosimilar medicines aiming to be included into the reimbursement list, in the case that a reference product is not available in the Slovak reimbursement list and there are not any biosimilars with the same active substance in the Slovak reimbursement list (it is a new reference group, where cost effectiveness is necessary to prove).
Differences in criteria and processes of HTA for biosimilars compared to other medicines	No
Any specificities	

Source: Roediger 2017

4.5 Demand-side measures

Doctors (and further prescribers)

Country context: Only doctors may prescribe

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes
If yes, what is recommended for naïve patients?	Recommendation to prescribe biosimilars for naïve patients
If yes, what is recommended for patients already on biologic treatment	Recommendation to switch patients for economic reasons
Prescription guidelines (including switching guidelines) were issued by	The Slovak Ministry of Health
URL of prescription & switching guidelines	
Prescribing quotas	
Prescribing quotas for doctors with regard to prescription of biosimilars exist	Yes
If yes, which quotas are defined for biosimilars	In the case of newly diagnosed patients, the healthcare provider is obliged to start administering the centrally purchased medicine (biosimilar) while adhering to the indication and prescription restrictions in at least 80 percent of newly enrolled patients during the duration of the central purchase of the relevant medicine (biosimilar). In the case of patients who are already set up for treatment (chronically ill patients) before the central purchase of the relevant medicine (biosimilar) became valid, the provider is obliged to set up 40 percent of chronically ill patients on the centrally purchased medicine (biosimilar) during the first 12 months from the validity of the central purchase of the relevant medicine (biosimilar), and another 40 percent of chronically ill patients on the centrally purchased medicine (biosimilar) within 24 months from the validity of the central purchase of the relevant medicine (biosimilar).
Any exemptions	
Any sanctions in case of non-achievement	No
Any (financial) incentives for achieving the quota	No
Prescribing quota were issued by	The Slovak Ministry of Health
URL of prescribing quota	
Prescribing quota for other non-biosimilar medicines exists	No
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	No
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	
Publicly accessible information	No
INN prescribing	
In general, prescribing by INN is place (information not focused on biologics)	Yes, but only mandatory for defined groups of generics.

If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	Biologics and biosimilars may not be prescribed by INN
Further measures targeted at doctors	
Information materials for doctors	Yes, issued by INEKO. URL: https://www.ineko.sk/file_download/1689/Anal%C3%BDza+stavu+a+mo%C5%BEnost%C3%AD+%C5%A1ir%C5%A1ieho+vyu%C5%BE%C3%ADvania+generick%C3%BDch+a+biosimil%C3%A1rnych+liekov+na+Slovensku+2021.pdf Yes, URL: https://www.sciencedirect.com/science/article/pii/S2211883719300577?via%3Dihub
Information events for doctors (e.g., seminars, trainings)	No
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	No

Source: PPRI 2025, INEKO 2021

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense

Substitution policies	
(Automatic) substitution for biosimilars	No
If yes, for which biologic substances and under which prerequisites?	
If yes, since when, and when was it extended? (process of implementation)	
Any specificities	
URL of underlying law	
Generic substitution in place	Yes
Gain-sharing models	
Gain-sharing models for pharmacists	No
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	
Publicly accessible information	No
Further measures targeted at pharmacists	
Information materials for pharmacists	Yes, issued by INEKO. URL: https://www.ineko.sk/file_download/1689/Anal%C3%BDza+stavu+a+mo%C5%BEnost%C3%AD+%C5%A1ir%C5%A1ieho+vyu%C5%BE%C3%ADvania+generick%C3%BDch+a+biosimil%C3%A1rnych+liekov+na+Slovensku+2021.pdf Yes, URL: https://www.sciencedirect.com/science/article/pii/S2211883719300577?via%3Dihub
Information events for pharmacists (e.g., seminars, trainings)	No

Source: PPRI 2025, Vogler et al. 2023, INEKO 2021

Patients

Information and educational measures	
Information materials for patients	Yes. Issued by EMA. URL: https://www.sukl.sk/buxus/docs/Media/2018/SK_Patient_QA_on_Biosimilars_Nov_2017_FINAL_for_publication_rev.pdf
If yes, provide URL of most common materials	https://www.sukl.sk/buxus/docs/Media/2018/SK_Patient_QA_on_Biosimilars_Nov_2017_FINAL_for_publication_rev.pdf
If yes, key producers of education measures	
Information events for patients (e.g., seminars, trainings)	No
If yes, key providers of educational events	
Gain-sharing models	
Gain-sharing models for patients	No
If yes, pls. describe	
Publicly accessible information	No

Source: PPRI 2025, EMA 2017

5 Impact of biosimilar policies and practices in Slovakia

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 Slovakia

Outcome indicator	Caused by (specify policy, if applicable)	Findings	Publication (citation or URL)
Savings for the public payer	No policy specified	Central and Eastern European countries with low levels of access to biologic medicines have seen a reduction of 1.5%–2.5% on their total drug spendings (Slovakia – approx. 1.56%), that may be explained by the introduction of biosimilars.	IQVIA 2021
Savings for the public payer	Mix of policies	Only 14 reimbursement dossiers were submitted for biosimilars between 2006 and 2018 in Slovakia. In 2016 and 2017, no reimbursement dossiers were submitted. The results, based on data provided by wholesalers who are legally obliged to deliver information to the State Institute for Drug Control, showed that the Slovak health budget could save €28.26M-€39.56M per year if biosimilars with marketing authorisations were available in the Slovak market, and a 25–35% decrease in price compared with that of biological medicinal products. This outcome was attributed to several policies, including biosimilar price link.	Tesar et al. 2019
Savings for patients	Reference price system	In Slovakia, all biologic and biosimilar medicines in a given reference group have the same level of reimbursement from the health insurance funds, which is equal to the price of the least expensive alternative in the internal reference group. The co-payments for all medicines except the least expensive alternative equal the difference between the reimbursement level of the least expensive alternative and the real prices of medicines in the internal reference group. Therefore, although it is the physician's decision to choose the right treatment for a patient, health insurance funds provide the same reimbursement level (in absolute terms) for a standard daily dose of biosimilars or the original biologic in the same internal reference group.	Tesar et al. 2019
Savings for the public payer, overall access	Reimbursement policies	The analysis of the opportunity cost carried out by the authors, indicated that the lost opportunity for savings (due to delayed market entry of biosimilars in Slovakia) amounted to €28.26-€39.56 million per year	Tesar et al. 2019
Savings for the public payer	Tendering policies	In 2018, Slovakia's General Health Insurance Company held its first tender for infliximab, achieving a 57% price reduction compared to the official reimbursement level. A 2019 tender for rituximab achieved only a 25% reduction, as companies anticipated no volume-based agreements, leading to less aggressive pricing strategies.	Tesar et al. 2019
Overall access	Biosimilar price link	Despite of the underuse of biosimilar medicines, in 2019 legislative amendment Slovakia has increased entry barriers for biosimilars by requiring significant initial price reductions. No biosimilars entered the market in 2016 and 2017; this was attributed to an existing biosimilar price link; the increase in the percentage rate of the price link in 2018 was met with the concern about continuing limited availability (no marketing) of biosimilars (but no data available at the time of the study).	Tesar et al. 2019
Overall access	Mix of policies	Of the 47 biosimilars registered by the EMA, 9 medicines (19%) were available on	Tesar et al. 2021

Outcome indicator	Caused by (specify policy, if applicable)	Findings	Publication (citation or URL)
		the Slovak market as of August 1, 2018. Of the 54 biosimilars registered by the EMA, 24 medicines (44%) were available on the Slovak market as of August 1, 2019. Of the 58 biosimilars registered by the EMA, 31 medicines (53%) were available on the Slovak market as of August 1, 2020. Of the 66 biosimilars registered by the EMA, 38 medicines (58%) were available on the Slovak market as of August 1, 2021. In financial terms, the sales of biosimilars in Slovakia increased from 0.94% in 2015 to 2.00% in 2020. In terms of the DDD, sales of biosimilars in Slovakia increased from 0.10% in 2015 to 0.22% in 2020. Sales of biosimilars in Slovakia increased from 0.94% in 2015 to 2.00% in 2020. In Slovakia biosimilars are included in an internal reference pricing system, where reimbursement levels are tied to the lowest-priced alternative within the reference group. Biosimilar price link fosters competition on the market and ensures affordability (for patients). Altogether with health insurance funding, these drive competition and enable access to biosimilar medicines.	

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 Slovakia

Legal barriers

Some entry barriers result from the biosimilar price reduction requirements. Despite of the underuse of biosimilar medicines, in 2018 legislative amendment Slovakia has increased entry barriers for biosimilars by requiring significant initial price reductions and subsequent price decreases for the second and third biosimilars coming to the Slovak market. The legislative amendment, which came into force 2022, was not sufficient for supporting availability of biosimilars in Slovakia.

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

Off-patent medicines not being a political focus; there are no sanctions for failure to comply with the prescribing guidelines for switching of biosimilars, so implementation is very limited in reality.

Financial barriers

Despite higher cost-effectiveness thresholds that give easier market access to "innovative" medicines, increased hurdles to market entry for biosimilars mean that the biologic arena is less competitive and price erosion is not suficient. Off-patent biopharmaceuticals therefore may not be able to deliver the expected savings for the pharmaceutical budget.

Evidence and communication-related barriers

Lack of guidance of the national regulatory authority, procurers or payers on prescribing, switching and use of biosimilars. There are no sanctions for failure to comply with the prescribing guidelines for switching of biosimilars prepared by the Slovak Ministry of Health, so implementation is very limited in reality.

Policy-related barriers

Price lowering policies for biosimilar medicines such as External Reference Pricing, may restrict the availability of biosimilars in the market. There are no sanctions for failure to comply with the prescribing guidelines for switching of biosimilars prepared by the Slovak Ministry of Health, so implementation is very limited in reality.

Stakeholder-related barriers

Limited knowledge of some health professionals, such as doctors or pharmacists about biosimilars, mistrust.

Any other barriers

External factors surrounding the availability of medicines in CEE region (including biosimilars).

Medicines for Europe calls the Slovakian government to expand demand side policy incentives that have proven to encourage competition and greater use of generic and biosimilar medicines.

7 Facilitators and good practice examples in Slovakia

Prescribing recommendations on switching and using biosimilars in treatment naïve patients and chronic patients (already used biologics, switching due to economic reasons).

Internal reference pricing system including biosimilar

The current financial pressures serve as a driving force to encourage greater uptake of biosimilar medicines

8 Developments in Slovakia

Recent changes

Since 1st August 2022: A medicinal product cannot be included in the Reimbursement list of medicinal products if:

it is the first biosimilar medicinal product that, by its characteristics, belongs to the reference group or reference subgroup included in the list of categorized medicinal products and the proposed maximum price of this medicinal product in a public pharmacy, converted to a standard dose of the medicinal product, is higher than 75% of the lowest maximum price of the medicinal product in a public pharmacy valid on the date of submission of the application, converted to a standard dose of the medicinal product included in the reference group or reference subgroup.

Plans or under discussion

Significant changes in the Slovak legislation are expected in 2025-2026 with the aim to increase availability of off-patent medicinal products.

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