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

AUGMENT Biosimilars
Country fiche POLAND

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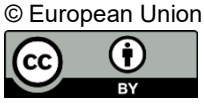

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Annex 7.24

AUGMENT Biosimilars country fiche: Poland 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 national experts.

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1 Summary of biosimilar policies and practice in Poland 2025

Key stakeholders

In Poland, the **Ministry of Health** (MoH) is the main regulatory authorities with regard to all medicines.

The key policy maker and regulator in the system (the Ministry of Health) is supported by the Polish Agency for Health Technology Assessment and Tariff System (AOTMiT), responsible for HTA, and the Economic Commission, responsible for price and MEA negotiations. Biosimilars usually do not undergo HTA assessment and follow the fast-track reimbursement process.

The Reimbursement Act (from 2012 year) implemented a reimbursement policy and rationalize the activity of the public payer (the National Health Fund).

There is a clear separation of health care financing and provision: the NHF—the main payer in the system — is in charge of health care financing and contracts with public and non-public health care providers.

Major biosimilar policies and practices

The Reimbursement Act does not distinguish between generic medicines and biosimilars, the same rules apply for both. In 2014 MoH published a statement addressed to pharmacists, clinicians, industry, and NHF, and informed that biosimilars should be treated as equivalents (MZ 2014). Biosimilars approved for marketing, with the same active substance, therapeutic indications, safety profile, dosage and pharmaceutical form, were approved for switching and substitution in terms of reimbursement.

Biosimilars are reimbursed outpatient (positive reimbursement list with up to 100% of reimbursement) and inpatient (positive reimbursement list, free of charge for patients). Substitution is possible in both the outpatient and inpatient sectors, but not mandatory.

Mandatory price reduction is imposed for the first biosimilar entering the market (biosimilar price link of minus 25%).The price od second and third biosimilar cannot exceed the pricing of already reimbursed biosimilars. Reimbursement list clusters biosimilars into reference price systems. INN prescribing, switching, and substitutions are allowed.

Impact analysis

The number of biosimilars reimbursed and market share of biosimilars in Poland increases over time (Grieco and Bodin 2024). Introduction of biosimilars is strongly associated with containment of reimbursement expenses in Poland (Barszczewska 2013, Stajszczyk 2023, Brodszky 2015, Zielinska and Bialik 2016). Furthermore, a biosimilar link is in place (Kawalec 2017).

Barriers, facilitators and good practice examples

Poland has no major legal obstacles to biosimilar medicines – which are considered equivalent to originator biologics under the Reimbursement Act. However, restrictions on treatment settings, strict reimbursement criteria of biosimilars reimbursed within drug programs, and the absence of an implementation plan limit their overall uptake. Currently, there are no financial incentives for healthcare providers, or hospitals, consequently – hospitals often lack the motivation to negotiate for reduced prices. RPS induced patient's co-payments are effective only for pharmacy dispensed biosimilars (e.g. insulins).

Additionally, insufficient education and awareness among patients (but also physicians) hinder acceptance and strategic procurement.

As mentioned above – Reimbursement Act defines biosimilar medicines as equal to originators and other biosimilars and thus, they are not subject to separate legal regulations. Poland is one of the countries, where INN prescribing and biosimilar substitution are possible. Furthermore, reference pricing system allows to contain therapy-related expenses and increase market competition.

Recent developments

No recent developments.

Highlights and learnings

A Reimbursement Act stipulates that biosimilars are considered equivalent to originator and among each other in Poland. This is a basis for developing biosimilar-related policies. For instance, switching and substitution are allowed.

2 Key data regarding biosimilars in Poland

First biosimilar medicine launched (i.e. brought on the market):
somatropin (Omnitrope®) in 2007
Source: MoH (Polish Ministry of Health)

Number of the **biosimilars marketed**:
17 molecules with biosimilars available, as of -October 2024
37 biosimilars (per trade name), as of October 2024
Source: National reimbursement list, October 2024 List

Biosimilar market shares in 2023 (or latest available data):

99% % **in value** in 2022
Value is defined as **share of total pharmaceutical expenditure** or

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

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)*:

No publicly available reports or databases. General information may be found at:

- National Health Fund (NHF; https://www.nfz.gov.pl/) - total public market (outpatient and hospital, public sector only);
- Center e-Health (CeZ; https://www.cez.gov.pl/pl) – outpatient market; public and private Rx sectors (database e-recepta);
- Ministry of Health (MoH; https://www.gov.pl/web/zdrowie/obwieszczenia-ministra-zdrowia-lista-lekow-refundowanych) – the reimbursement list

3 Stakeholders involved in and targeted by biosimilar policies in Poland

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Ministerstwo Zdrowia / Ministry of Health	Prepares legislation	
National regulatory authority	Ministerstwo Zdrowia / Ministry of Health	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance	https://archiwum.mz.gov.pl/aktualnosci/komunikat-w-sprawie-stosowania-lekow-generycznych/
Pharmaceutical pricing authority	Ministerstwo Zdrowia / Ministry of Health	Implements pricing legislation regarding biosimilars, decides on the prices	
Pharmaceutical reimbursement authority	Ministerstwo Zdrowia / Ministry of Health	Decides on inclusion into reimbursement for biosimilars and their price. Produces prescribing guidelines for biosimilars, responsible for prescription quotas	
Procurement agency	Hospitals, Zakład Zamówień Publicznych przy Ministrze Zdrowia / Central public procurement - ZZP	Involved in tenders and procurement procedures	
HTA agency / body	Agencja Oceny Technologii Medycznych i Taryfikacji / Agency for Health Technology Assessment and Tariff System	Rarely involved, only if biosimilar is part of medical procedure (i.e. some eye-related indications, but not all)	
National competition authority	Urząd Ochrony Konkurencji I Konsumentów/Office of Competition and Consumer Protection	Enforcement of the competition law, anti-trust cases	
National patent office	Urząd Patentowy Rzeczypospolitej Polskiej / Patent Office of the Republic of Poland	Granting and managing patents on biologic medicines	
Doctors	Naczelna Izba Lekarska / Supreme Chamber of Physicians	Prescribe biosimilars a/o by INN. Inform patients Medical societies in disease areas with biologics use	
Nurses	Naczelna Izba Pielęgniarek i Położnych /Supreme Chamber of Nurses and Midwives	Not involved	
Community pharmacists	Naczelna Izba Aptekarska / Supreme Pharmacy Chamber	Dispense medicines, inform patients	
Hospital pharmacists	Naczelna Izba Aptekarska / Supreme Pharmacy Chamber	Support procuring medicines, inform patients / health professionals	

Patient organisations	Federacja Pacjentów Polskich (FPP) / Federation of Polish Patients Instytut Praw Pacjenta i Edukacji Zdrowotnej / Institute for Patient Rights and Health Education oncological diseases Stowarzyszenie Pacjentów i Osób Wspierających Chorych Na Guzy Neuroendokrynne Fundacji Rak'n'Roll Fundacja OmeaLive Rak piersi nie ogranicza Polskie Amazonki Ruch Społeczny Alivia - Fundacja Onkologiczna Fundacja Glioma-Center im. Hani Magiery Fundacja "Pokonaj raka" Fundacja ISKIERKA Ogólnokrajowe Stowarzyszenie Pomocy Chorym Na Przewlekłą Białaczkę Szpikową Stowarzyszenia Walki z Chorobami Nowotworowymi SANITAS Fundacja Onkologiczna Różowa Konwalia Stowarzyszenie Walki z Rakiem Płuca Oddział Szczecin Ogólnopolska Federacja Onkologiczna Fundacja OnkoCafe-Razem Lepiej Stowarzyszenie UNICORN Fundacja Razem w Chorobie Fundacja Na Ratunek Dzieciom z Chorobą Nowotworową Fundacja Kierunek Zdrowie Stowarzyszenie Pomocy Chorym na Nowotwory Krwi w Zamościu Fundacja Carita im. Wiesławy Adamiec Autoimmune diseases Polskie Towarzystwo Chorób Atopowych AMICUS Fundacja Łuszczycy i ŁZS Ogólnopolskie Stowarzyszenie Młodych z Zapalnymi Chorobami Tkanki Łącznej "3majmy się razem" Polskie Towarzystwo Chorób Nerwowo Mięśniowych Diabetes: Fundacja Diabeciaki Polskie Stowarzyszenie Diabetyków Ogólnopolska Federacja Organizacji Pomocy Dzieciom i Młodzieży Chorym na Cukrzycę Other: Retina AMD Polska Fundacja "Gwiazda Nadziei"	Patient organisations in diseases with particular biologics use. Patient education.	https://federacjadiabetykow.pl/wp-content/uploads/Raport2.pdf https://ippez.pl/wp-content/uploads/2019/03/Leczenie-biologiczne-wazne-informacje-raport.pdf

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
	Krajowe Forum Na Rzecz Terapii Chorób Rzadkich ORPHAN Polskie Stowarzyszenie Chorych na Hemofilię / Polish Association of Patients with Hemophilia Multispecialties: Fundacja To się leczy Fundacja My Pacjenci Fundacja "Z sercem do Pacjenta" Fundacja Zdrowie i Opieka		
Consumer organisations	no dedicated representation	not involved	
Biosimilar industry	no dedicated representation		
Generic industry	Polski Związek Pracodawców Przemysłu Farmaceutycznego (PZPPF) / Polish Association of Pharma Industry Employers Polska Izba Przemyslu Farmaceutycznego i Wyrobów medycznych (POLFARMED) / Polish Chamber of Pharmaceutical Industry and Medical Equipment		
Pharmaceutical industry in general	Izba Gospodarcza "Farmacja Polska" / Chamber of Commerce PHARMACY POLAND PharmaNET - Związek Pracodawców Aptecznych / The Association of Pharmaceutical Employers		
Pharmaceutical industry for new biological medicines	Związek Pracodawców Innowacyjnych Firm Farmaceutycznych INFARMA / The Employers' Union of Innovative Pharmaceutical Companies INFARMA		

Source: Czupryniak 2025; Stakeholder mapping done by GÖ FP (AUGMENT Consortium)

4 Biosimilar policies and practices in Poland

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 2025

Biosimilar price link

A **biosimilar price link** is in place.	Yes
It applies for the following situations:	For biosimilar medicines aiming to be included into the outpatient reimbursement list (community pharmacy market) and hospital reimbursement list (only chemotherapy and Drug Programs)
Price reduction of the first biosimilar compared to the reference product	Mandatory reduction of minus 25% of the originator biological medicine for the first biosimilar when included in the respective reimbursement lists

Price reduction of the second, third and further biosimilars	There is no mandatory price reduction, but a new biosimilar price cannot exceed the price of the lowest-price reference product accounting for at least 25% market share.
Price reduction for the reference product	No mandatory price reduction
Any further specificities	Pricing policy (including biosimilar price link) was introduced in 2012 - Reimbursement Act
Generic price link	In place: yes, the same rules as per biosimilars, same extent of price reductions (minus 25% for the first generic)

Source: PPRI 2025, Vogler et al. 2025, Ustawa o refundacji Dz. U. 2011 Nr 122 poz. 696

External price referencing.

External price referencing is applied for biosimilars.	Yes, as a supplementary policy
If yes, it is applied for the following situations:	For biosimilar medicines aiming to be included into the outpatient reimbursement list (community pharmacy market) and hospital reimbursement list (only chemotherapy and Drug Programs)
Any specificities	
External price referencing is in place for other medicines than biosimilars.	Yes, for all medicines aiming to be included into the outpatient reimbursement list (community pharmacy market) and hospital reimbursement list (only chemotherapy and Drug Programs)

Source: PPRI 2025

Tendering

Some (or all) biosimilars are procured through tendering (or tendering-like) processes.	Yes, all
If yes, the scope with regard to the care sector:	Tendering performed by hospitals (inpatient sector) or national procurement (only for very low volume medicines) for biosimilars used inpatient and outpatient
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All off-patent biological medicines
Institutional framework	Conducted by hospitals or national procurement for very low volume medicines
Information available on procurement procedures and practices	Information available on the public sites of respective hospitals. One winner with the lowest price. Hospital covers the difference in cost if more expensive medicine is used.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	Only for off-patent biological medicines available through drug programs (programy lekowe) and chemotherapy
Institutional framework	Conducted by hospitals or national procurement for very low volume medicines
Information available on procurement procedures and practices	Information available on the public sites of respective hospitals. One winner with the lowest price. For drug programs medicines and chemotherapy, outpatient treatment provided only by outpatient clinics within hospitals. Hospital covers the difference in cost if more expensive medicine is used.
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Tendering performed by hospitals (inpatient sector) Outpatient: No tendering or procurement, only price negotiations by the Ministry of Health

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Vogler 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
If yes, how many and under which specifications	All
If publicly accessible, indicate URL of RPS list	https://www.gov.pl/web/zdrowie/obwieszczenia-ministra-zdrowia-lista-lekow-refundowanych
When were first biosimilars included in the reference price system?	In 2012 – Reimbursement Act
Any further specificities	RPS involves grouping of medicines with the same INN, similar therapeutic effect, or similar mechanism of action into one group
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	Yes RPS involves grouping of medicines with the same INN, similar therapeutic effect, or similar mechanism of action into one group

Source: PPRI 2025, Ustawa o refundacji Dz. U. 2011 Nr 122 poz. 696

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, once the medicine is included into reimbursement list it is automatically clustered into RPS.
If yes, how many and date of inclusion into reimbursement, if known)	21 biosimilars may be used outpatient - 12 biosimilar outpatient only, 9 both outpatient and inpatient.
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	100%, 70% and 50% reimbursement rates Percentage reimbursement and deductible (3.40 PLN, <1 EUR)
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	Shorter timelines, no HTA required
Indicate URL of outpatient positive list	https://www.gov.pl/web/zdrowie/obwieszczenia-ministra-zdrowia-lista-lekow-refundowanych
Co-payments for biosimilars for outpatient use	Percentage co-payments and deductible
<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	Positive list Percentage reimbursement rates are in place (100%, 70%, 50%) Percentage reimbursement and deductible (3.40 PLN, <1 EUR)
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level)	Yes
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	Inclusion based on national positive list and tendering timelines

Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	https://www.gov.pl/web/zdrowie/obwieszczenia-ministra-zdrowia-lista-lekow-refundowanych
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, Ustawa o refundacji Dz. U. 2011 Nr 122 poz. 696

4.3 Specific pricing, procurement and funding policies 2024

Application of special pricing, procurement and reimbursement models for biosimilars (e.g., delinkage / subscription-model, management-entry agreements (MEA))	Yes, MEA available for originator biological medicines and for biosimilars (inpatient and outpatient sector)
Enforcement of anti-trust policies	No
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Mostly financial MEAs

Source: PPRI 2025, Ustawa o refundacji Dz. U. 2011 Nr 122 poz. 696

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	Yes.
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	Horizon scanning is used in procedures like TLI (list of highly innovative drug technologies) or list of drugs with well-established effectiveness. These procedures allow to faster reimbursement due to the lack of requirement for the submission of HTA analysis. The Ministry of Health also uses Horizon scanning when analysing of the reimbursement plans for generic and innovative companies. This helps to predict in which sector the public payer is expected to see savings due to the introduction of the first biosimilars to the market which can replace the original ones. Requirement to inform the Ministry of Health about reimbursement plans by pharmaceutical companies was taken into account in processed amendment of the Reimbursement Act.

Source: PPRI 2025, Ustawa o refundacji (Dz. U. 2011 Nr 122 poz. 696, Art. 30a, 40a).

Health technology assessment

HTA is applied for biosimilar medicines	Yes (extremely rarely in some cases)
If yes, in which situations and settings (outpatient and inpatient)	Outpatient and inpatient HTA may be considered for biosimilars if a biosimilar is entering the market before the original biological medicine HTA may be considered rarely for biosimilars used within medical procedures (e.g. eye related indications)
Differences in criteria and processes of HTA for biosimilars compared to other medicines	If HTA is performed, there are no differences to standard procedures
Any specificities	-

Source: PPRI 2025, Ustawa o refundacji Dz. U. 2011 Nr 122 poz. 696, Ustawa o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych Dz. U. 2004 nr 210 poz. 2135

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Country context: Doctors, nurses, pharmacists and feldshers may prescribe.

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Switching is allowed but not common
If yes, what is recommended for naïve patients?	-
If yes, what is recommended for patients already on biologic treatment	-
Prescription guidelines (including switching guidelines) were issued by	-
URL of prescription & switching guidelines	-
Prescribing quota	
Prescribing quota for doctors with regard to prescription of biosimilars exist	No
If yes, which quota are defined for biosimilars	-
Any exemptions	-
Any sanctions in case of non-achievement	No
Any (financial) incentives for achieving the quota	No
Prescribing quota were issued by	-
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, indicative
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	No exemption for biologicals: biologics and biosimilars may be prescribed by INN but uncommon

Further measures targeted at doctors	
Information materials for doctors	No
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, Polish Ministry of Health (MoH), Ustawa o Zawodzie Lekarza i Lekarza Dentysty, Ustawa o Zawodzie Pielęgniarki i Położnej, Ustawa o Zawodzie Farmaceuty, Ustawa o Zawodzie Felczera

Pharmacists (and further dispensers)

Country context: Pharmacist and pharmacy technician

Substitution policies	
(Automatic) substitution for biosimilars	Yes, indicative
If yes, for which biologic substances and under which prerequisites?	Universal
If yes, since when, and when was it extended? (process of implementation)	
Any specificities	-
URL of underlying law	-
Generic substitution in place	Yes, mandatory
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	No
Information events for pharmacists (e.g., seminars, trainings)	No

Source: PPRI 2025, Ustawa o Zawodzie Farmaceuty, Ustawa o Niektórych Zawodach Medycznych

Patients

Information and educational measures	
Information materials for patients	No official information for patients issued by government. Some information materials were issued by non-governmental organisations: Instytut Praw Pacjenta i Edukacji Zdrowotnej: information on biolgical medicines and biosimilars https://ippez.pl/wp-content/uploads/2019/03/Leczenie-biologiczne-wazne-informacje-raport.pdf
If yes, provide URL of most common materials	-
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	-

Source: PPRI 2025, IPPEZ 2019

Other: nursing staff

Information materials for nurses on biosimilars and switching issued by non-governmental organisation: https://esno.org/assets/files/biosimilar-nurses-guideline-final_pl-PL_LQ.pdf

5 Impact of biosimilar policies and practices in Poland

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.

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

Outcome indicator	Caused by	Findings	Publication
Savings for the public payer	No specific policy analysis but a retrospective budget impact analysis	From a public payer perspective, the estimated total savings amount to over €243 million for TNF inhibitors, with over €166 million attributed to treatment cost reduction in rheumatic musculoskeletal diseases (RMD). Real-life savings were calculated as €133 million and €107 million, respectively. The rheumatology sector generated between 68% and 92% of total savings across models, depending on the adopted scenario. The overall decrease in mean annual cost of treatment ranged between 75% and 89% in the study frame. If all budget savings were spent on reimbursement of additional TNF inhibitors, a hypothetical total of almost 45 000 patients with RMDs could be treated in 2021.	Stajszczyk et al. 2023: Budget impact analysis and treatment availability with biosimilar TNF inhibitors in rheumatic diseases in Poland: real-world evidence using a nationwide database doi: 10.1136/ard-2022-223696
Price decrease	Biosimilar price link	In Poland, biosimilars follow a simplified reimbursement process with strict pricing rules. The official selling price must not exceed 75% of the only reimbursed substitute's price for a given indication. The financing limit is set based on the wholesale price per daily drug dose (DDD) of the first reimbursed substitute, and it cannot increase with successive biosimilars. Introducing biosimilars aims to enhance market competition, lower drug costs, improve public healthcare spending efficiency, and expand patient access to treatment programs. Therefore, the biosimilar price link requires a price reduction of at least 25% of the reference product. Introduction of biosimilar adalimumab, infliximab, and trastuzumab led to significant price reductions over eight years horizon of 64.0%, 62.4%, and 59.0%, respectively.	Barszczewska and Piechota 2021: The Impact of Introducing Successive Biosimilars on Changes in Prices of Adalimumab, Infliximab, and Trastuzumab—Polish Experiences doi: 10.3390/ijerph18136952
Improved uptake	Mix of policies	Regarding three anti-TNF-α biosimilars (adalimumab, etanercept, and infliximab), the market share increased from 44% to 99% (2018 to 2023).	ISPOR conference poster Grieco and Bodin 2024: https://www.ispor.org/docs/default-source/euro2024/isporeurope24griecohpr25poster142729-pdf.pdf?sfvrsn=8228559c_0
Improved uptake	Mix of policies, including biosimilar price link and switching of biosimilars	A regulation applied in Poland (where new patients have to be treated with a biosimilar, and even patients receiving the original drug are forced to switch to biosimilar infliximab as maintenance therapy), leads to improved uptake.	Rencz et al. 2015: Biological therapy in inflammatory bowel diseases: access in Central and Eastern Europe doi: 10.3748/wjg.v21.i6.1728

Outcome indicator	Caused by	Findings	Publication
Improved uptake	Mix of policies	If cost savings generated in biosimilar scenarios were reinvested in further treatments of CD patients (with biosimilar – infliximab), 722 and 1530 new patients in the BSc1 and BSc2 models, respectively, could be treated after 3 years. These numbers represent 15 and 32% of the currently treated number of patients, and therefore, clearly highlight the tangible benefits of using biosimilars for patients, physicians as well as for healthcare payers. Consequently, introduction of biosimilar infliximab would enhance the increasing access to biological therapy in CEE countries.	Brodszky et al. 2015: A budget impact model for biosimilar infliximab in Crohn's disease in Bulgaria, the Czech Republic, Hungary, Poland, Romania, and Slovakia http://dx.doi.org/10.1586/14737167.2015.1067142
Improved uptake	Mix of policies	Re-monopolization (even by a biosimilar medicine), significantly escalates healthcare expenditures, imposing financial strain on hospitals, and potentially – restricting patient access to treatment. In Poland, this resulted from a regulatory decision to limit market availability to a single biosimilar (by withdrawing reimbursement for the reference biologic drug). This policy, based on a flawed assumption that biosimilar pricing would remain stable, ultimately undermined the cost effectiveness initially achieved through market competition.	Stajszczyk et al. 2024: Charting the Etanercept Journey: Tracing Cost Dynamics in Poland's Off-Patent Market from Reference Drug Rivalry to Biosimilar Monopoly
Improved uptake	Mix of policies	The most meaningful growth in the whole product class was observed in (…) Poland (474%) – it can be assumed that the high price limited the uptake of G-CSF product in this country. With biosimilar entry on the market, competitive environment allowed fitting the price and effectively reducing the treatment costs. One of the factors, influencing price formation was a cost-sharing system that defined an apparent patient fee. Among others, polish patients paid a lump sum fee or a percentage rate of the full price.	Zielińska and Bialik 2016: Recent changes on the biopharmaceutical market after the introduction of biosimilar G-CSF products doi: 10.5603/OCP.2016.0006
Improved uptake	Mix of policies	Fifty four biosimilars were approved by the European Medicines Agency (EMA) in August 2019. Of the total group of licensed biosimilars on the market, 29 biosimilars (54%) were available in the Czech Republic, 28 biosimilars (52%) were available in Poland (…)	Tesar et. al.: Potential Cost-Savings From the Use of the Biosimilars in Slovakia. doi: 10.3389/fpubh.2020.00431

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 Poland

Legal barriers

There are no major legal barriers in Poland. Biosimilars are considered equivalent to originator biological medicine and other biosimilars (The Reimbursement Act).

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

Lack of implementation plan

Other barriers include restricting treatment mostly to inpatient settings and often tight reimbursement criteria (more narrow to EMA registered indications) for many biological medicines restricting the populations size, and thus scaling down potential savings.

Financial barriers

Lack of incentives for health professionals, procurers or patients to prescribe, dispense, use or purchase biosimilars (no gain-sharing) – there are no incentives for hospitals to negotiate prices below maximum price negotiated centrally. NHF reimburses the real cost of treatment & up to maximum price.

Strong requirements for price reductions

Evidence and communication-related barriers

Lack of information materials and educational programs

Lack of guidance of the national regulatory authority, procurers or payers on prescribing, switching and use of biosimilars

The main barriers include insufficient educational and information dissemination activities directed to patients and physicians regarding the effectiveness and safety of biosimilars, but also far-reaching benefits for the medical system and patients resulting from the availability of biosimilar medicines.

Policy-related barriers

Limited experience and knowledge of policy-makers to implement biosimilar policies or of procurers to conduct strategic procurement

Stakeholder-related barriers

Limited knowledge of (some) health professionals, such as doctors or pharmacists about biosimilars and mistrust

Limited knowledge and acceptance about biosimilars on behalf of patients

Any other barriers

Not identified.

7 Facilitators and good practice examples in Poland

Biosimilars are considered equivalent to originator biological medicines and other biosimilars based on Reimbursement Act.

INN prescribing, substitution are possible.

Existence of RPS with inclusion of biologicals

8 Developments in Poland

Recent changes

The Major Amendment to the Reimbursement Act (DNUR) affects the pricing of generic and biosimilar medicines in Poland. The Amendment introduces mandatory price reduction after patent expiry (period specified in Article 11 (3a)), the net ex-factory price cannot exceed 75% of price set in the last reimbursement decision issued before that period.

The Major Amendment to the Reimbursement Act DNUR. **Plans or under discussion**

The Legislative Agenda of the Council of Ministers includes the publication of the draft assumptions for the Act amending the Act on the Reimbursement, as well as certain other acts (project number: UD187). The draft responds to requests submitted to the Minister of Health by pharmaceutical companies, entrepreneurs operating in the pharmaceutical market, beneficiaries, and other social groups affected by the provisions of the reimbursement act. The key objective of the draft is to improve the availability of reimbursed medicines, including biosimilar drugs and medical products, simplify administrative procedures, and better adapt the regulations to the evolving needs of the healthcare system.

Source: Projekt ustawy o zmianie ustawy o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych oraz niektórych innych ustaw - Kancelaria Prezesa Rady Ministrów - Portal Gov.pl

9 Further information

Additional information obtained via consultations with the Polish Ministry of Health (MoH), regarding biosimilar policies and market organization in Poland:

Furthermore, the Department of Drug Policy and Pharmacy of the Ministry of Health provides additional information for justification.

The Ministry of Health plays a key role as the main body responsible for regulating issues related to medicines. The Ministry of Health is supported by AOTMiT (Agency for Health Technology Assessment and Tariff System) and by the Economic Commission, which is responsible for price negotiations, including negotiating risk-sharing instruments.

Biosimilar medicines are usually not subject to HTA (Health Technology Assessment) and undergo an accelerated reimbursement process.

There is a clear distinction between the financing and provision of healthcare services. The National Health Fund (NFZ), as the main payer, is responsible for financing healthcare and contracting services with both public and private healthcare providers.

The reimbursement law does not distinguish between generic and biosimilar medicines; the same rules apply in both cases. In 2014, the Ministry of Health stated that biosimilar medicines should be considered equivalent.

Biosimilar medicines are reimbursed both in outpatient and hospital settings. Substitution is possible in both sectors but is not mandatory.

A mandatory price reduction is applied to the first biosimilar medicine introduced to the market (its price must be at least 25% lower). The price of the second and third biosimilar medicines cannot exceed the price of already reimbursed biosimilars. The reimbursement list groups biosimilar medicines within reference pricing systems. INN (International Nonproprietary Name) prescribing, switching, and substitution are allowed.

Entities associated with biosimilar medicines include the Ministry of Health, hospitals, the Public Procurement Office at the Ministry of Health, AOTMiT, the Office of Competition and Consumer Protection, the Supreme Medical Chamber, the Supreme Pharmaceutical Chamber, patient advocacy organizations, the biosimilar medicine industry, the generic medicine industry, and the pharmaceutical industry

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