European Commission

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

AUGMENT Biosimilars
Country fiche HUNGARY

Excerpt from:

European Commission: European Health and Digital Executive Agency, Vogler, S., Habimana, K., Helter, T., Knoll, V. et al., Capacity building to support the uptake of biosimilars in a multistakeholder approach – Final study report. Annex 7, AUGMENT, Country fiches, Publications Office of the European Union, 2025

Vogler S, Walter M, Knoll V, Habimana K, Helter T

augment biosimilars

EUROPEAN COMMISSION

Directorate-General for Health & Food Safety
Unit: SANTE-D2 (Medical products: quality, safety, innovation)

Contact: François Janssens

E-mail: sant-atf@ec.europa.eu

European Commission
B-1049 Brussels

Disclaimer

This Country fiche was produced under the EU4H 2023 Programme under a service contract with the European Health and Digital Executive Agency acting under the mandate from t he European Commission. The information and views set out in this study are those of the author(s) and do not necessarily reflect the official opinion of the Commission/ Executive Agency. The Commission/ Executive Agency do not guarantee the accuracy of the data included in this study. Neither the Commission /Executive Agency nor any person acting on the Commission's / Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.

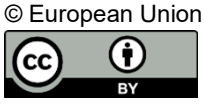
Manuscript completed in November 2025

First edition

This document has been prepared for the European Commission however it reflects the views only of the authors, and the European Commission is not liable for any consequence stemming from the reuse of this publication.

Luxembourg: Publications Office of the European Union, 2025

© European Union, 2025



The reuse policy of European Commission documents is implemented by Commission Decision 2011/833/EU of 12 December 2011 on the reuse of Commission documents (OJ L 330, 14.12.2011, p. 39). Unless otherwise noted, the reuse of this document is authorised under a Creative Commons Attribution 4.0 International (CC BY 4.0) licence (https://creativecommons.org/licenses/by/4.0/). This means that reuse is allowed provided appropriate credit is given and any changes are indicated.

For any use or reproduction of elements that are not owned by the European Union, permission may need to be sought directly from the respective rightholders.

PDF ISBN 978-92-95239-98-2 doi: 10.2925/9409811 HW-01-25-049-EN-N

Annex 7.13

AUGMENT Biosimilars country fiche: Hungary 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.

This country fiche has not been validated by national experts.

How to quote: Helter T, Walter M, Vogler S: AUGMENT Biosimilars country fiche: Hungary 2025. Annex to the study on "Capacity building to support the uptake of biosimilars in a multistakeholder approach", AUGMENT, 2025. Commissioned by the European Health and Digital Executive Agency (HaDEA)

1 Summary of biosimilar policies and practice in Hungary 2025

Key stakeholders

In Hungary, key stakeholders in biosimilar policy design include the State Secretary for Health, Ministry of Economy, National Centre for Public Health and Pharmacy (NCPHP), National Institute of Health Insurance Fund Management (NEAK), and the Hungarian Medical Chamber (MOK). These groups, along with others, publish guidelines and position papers to support biosimilar use.

Major biosimilar policies and practices

Hungary has implemented several policies to encourage the uptake of biosimilars. These include a biosimilar price link policy, which mandates a 30% price reduction for the first biosimilar compared to the reference product, and further reductions for subsequent biosimilars. Tendering processes are used for both inpatient and outpatient sectors to procure biosimilars, ensuring competitive pricing. Additionally, biosimilars are included in the reference price system and in prescribing quotas for doctors. Biologics may be prescribed by the international non-proprietary name.

Impact assessment

The introduction of biosimilar policies in Hungary has led to significant cost savings for the healthcare system. For example, tendering- reduced the prices of granulocyte colony-stimulating factor (GCSF) and erythropoietin (EPO) products, increasing their accessibility and resulting in substantial savings. However, the overall utilisation of biosimilars like infliximab has not significantly increased, as patients sometimes insist on being treated with the originator biologic. Moreover, tenders are now stopped for these substances, they were moved back to the general reimbursement scheme and the significant savings are not any more achieved.

Barriers, facilitators and good practice examples

Barriers include unclear regulations and limited incentives for healthcare professionals to prescribe or dispense biosimilars. Facilitators include Hungary's quick market entry for biosimilars, supported by national guidelines, education programs, prescription quotas, and international collaboration, promotes their use and acceptance among healthcare providers and patients. Good practice examples include financial incentives for providers and a comparably short time from EMA approval to market entry.

Recent developments

Hungary has made the process from EMA approval to market entry for biosimilars faster and more efficient. Major Hungarian pharmaceutical companies like Egis Pharmaceuticals and Gedeon Richter expanded their biosimilar portfolios in 2024.

Highlights and learnings

Key learnings from Hungary's experience with biosimilars include the importance of competitive pricing policies and tendering processes in achieving cost savings. The need for education and training programs in increasing awareness and acceptance of biosimilars among healthcare providers and patients is also highlighted.

2 Key data regarding biosimilars in Hungary

First biosimilar medicine launched (i.e. brought on the market):
infliximab (Remsima ®) in 2013
Source: https://bse.hu/newkibdata/115250544/EGI130913ER01E.pdf

Number of the **biosimilars marketed**:
14 molecules with biosimilars available, as of September 2024
53 biosimilars (per trade name), as of September 2024 *Source*: Arzneiverordnungs-Report 2023

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

20% **in volume** in 2023
Volume is defined as units dispensed or

10% **in value** in 2023
Value is defined as share of total pharmaceutical expenditure or

Please indicate the market to which the biosimilar market shares data relate to:
total public market (outpatient and hospital, public sector only)

3 Stakeholders involved in and targeted by biosimilar policies in Hungary

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Belügyminisztérium Egészségügyi Államtitkárság / State Secretariat for Health within the Ministry of Interior	Prepares legislation and	Health bulletin: https://www.kozlonyok.hu/kozlonyok/index.php?m=1&p=0100&k=6
National regulatory authority	Nemzeti Népegészségügyi és Gyógyszerészeti Központ (NNGYK) / National Centre for Public Health and Pharmacy (NCPHP)	Responsible for marketing authorisation of medicines	Medicine database: https://ogyei.gov.hu/gyogyszeradatbazis
Pharmaceutical pricing authority	Nemzeti Egészségbiztosítási Alapkezelő (NEAK) / National Institute of Health Insurance Fund Management	Implement reimbursement policies Involved in the pricing of medicines, including tenders and the operation of a tendering-like system for off-patent medicines	Annual reports
Pharmaceutical reimbursement authority	Nemzeti Egészségbiztosítási Alapkezelő (NEAK) / National Health Insurance Fund Management	Manages the positive list of reimbursed medicines and conducts centralised tenders for high-cost inpatient medicines	Annual reports
Procurement agency	Közbeszerzési és Ellátási Főigazgatóság (KEF) / Directorate-General for Public Procurement and Supply Procurement department at NEAK		
HTA agency / body	NNGYK Technológia-értékelő Főosztályája / HTA Department at NNGYK	Conducts health technology assessments for new medicines, new indications, and new routes of administration	
National competition authority	Gazdasági Versenyhivatal (GVH) / Hungarian Competition Authority	Ensures fair competition in the pharmaceutical market, including oversight of procurement practices to prevent cartel formation and corruption	
National patent office	Szellemi Tulajdon Nemzeti Hivatala / Hungarian Intellectual Property Office	Granting and managing patents on biologic medicines	
Doctors	Represented by: Magyar Orvosi Kamara (MOK) / Hungarian Medical Chamber Medical societies: Hungarian Society of Hospital Pharmacists, Professional College of Health Care, Hungarian Society of Rheumatology, Hungarian Society of Gastroenterology, Hungarian Society of Oncology, Hungarian Society of Dermatology, Hungarian Society of Hematology and Transfusion, etc.	MOK and the societies provide guidelines, support research, and educate both healthcare professionals and patients about the use of biologics and biosimilars.	https://mok.hu/orvosoklapja/alaprol
Nurses	Represented by: Magyar Egészségügyi Szakdolgozói	MESZK plays a role in educating and training	https://meszk.hu/kiadvanyok/hirlevel/

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
	Kamara (MESZK) / Hungarian Chamber of Health Care Professionals, (Magyar Ápolási Egyesület (MAE) / Hungarian Nurses Association	nurses about biosimilars. This includes providing information on the safe administration of biosimilars, understanding their benefits, and addressing any concerns related to their use.	
Community pharmacists	Represented by: Magyar Gyógyszerész Kamara (MGYK) / Hungarian Chamber of Pharmacists	Dispensing biosimilars and providing counseling to patients about their use	
Hospital pharmacists	Represented by: Magyar Gyógyszerésztudományi Társaság Kórházi Gyógyszerészeti Szervezete (MGYT-KGYSZ) / Hungarian Society of Hospital Pharmacists	Optimisation of inpatient medication management, including the use of biosimilars, and procurement and management of biosimilars within hospital settings	
Patient organisations	Represented by: Betegszervezetek Magyarországi Szövetsége (EMOSZ) / Hungarian Alliance of Patients' Organisations	A national coalition representing various patient organisations.	https://www.bemosz.hu/kik-vagyunk/hivatalos-dokumentumok
Consumer organisations	Fogyasztóvédelmi Egyesületek Országos Szövetsége – (NFACPH) / National Federation of Associations for Consumer Protection in Hungary		https://feosz.hu/tudastar/
Biosimilar industry	Represented by: Generikus Gyógyszergyártók és Forgalmazók Magyarországi Érdekvédelmi Egyesülete / Hungarian Association for the Protection of Interests of Generic Drug Manufacturers and Distributors	No specific biosimilar medicines assocation but involved as part of the generics medicines association	
Generic industry	Represented by: Generikus Gyógyszergyártók és Forgalmazók Magyarországi Érdekvédelmi Egyesülete / Hungarian Association for the Protection of Interests of Generic Drug Manufacturers and Distributors	Generic medicines association which also includes the biosimilar manufacturers	
Pharmaceutical industry in general	Represented by: Magyarországi Gyógyszergyártók Országos Szövetsége (MAGYOSZ) / Association of Hungarian Pharmaceutical Manufacturers	Represents the interests of national pharmaceutical companies involved in the development, production, and distribution of medicines, including some biosimilars.	
Pharmaceutical industry for new biological medicines	Represented by: Innovatív Gyógyszergyártók Egyesülete / Association of Innovative Pharmaceutical Manufacturers (AIPM)	AIPM aim to promote the use of advanced therapies, to improve patient access to effective treatments.	

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

4 Biosimilar policies and practices in Hungary 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 aiming to be included into the outpatient reimbursement list
Price reduction of the first biosimilar compared to the reference product	30%
Price reduction of the second, third and further biosimilars	10% reduction for each subsequent competitor compared to the previous medicine
Price reduction for the reference product	
Any further specificities	The price reduction policy for biosimilars in Hungary was introduced in 2011.
Generic price link	Yes The initial generic entering the market must be priced at least 40% lower than the reference drug. Subsequent generics must be priced at least 20%-10%-10% lower than the previous generic.

Source: PPRI 2025

External price referencing

External price referencing is applied for biosimilars.	No
If yes, it is applied for the following situations:	
Any specificities	
External price referencing is in place for other medicines than biosimilars.	Yes, for new medicines and for generics

Source: PPRI 2025

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 off-patent biological medicines
Institutional framework	Individual hospitals may conduct their own procurement processes. Hospital procurement groups may collaborate to conduct joint procurement to leverage better pricing and terms. Centralised procurement is managed by the National Health Insurance Fund Management (NEAK).

Information available on procurement procedures and practices	Multiple criteria, including price, quality, supply reliability, compliance with regulatory standards, past performance. There are both single and multiple-winner tenders.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	All off-patent biological medicines
Institutional framework	Conducted at national level by National Health Insurance Fund Management (NEAK)
Information available on procurement procedures and practices	A tendering-like process, the biolicit process was introduced by the Hungarian National Health Insurance Fund Administration (NEAK) in 2012 to manage the costs of biosimilars. This process involves annual price bidding for biosimilars, where the lowest bid and bids within 10% of the lowest price are awarded preferred status. These preferred products receive 100% reimbursement, with a minimal co-payment from patients.
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes, the procurement process is similar to that of biosimilars, involving centralised tenders conducted by hospitals, hospital procurement groups, or procurement agencies. Outpatient: Yes, Also managed at a central level at NEAK.

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Hornyak et al. 2021

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	Multiple biosimilars are included in the RPS that are typically grouped with their reference products and other therapeutically equivalent biosimilars (ATC 5 and ATC 4 cluster). The reference price is set based on the lowest-priced product within the group.
If publicly accessible, indicate URL of RPS list	https://www.neak.gov.hu/felso_menu/szakmai_oldalak/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/pupha/Vegleges_PUPHA https://www.neak.gov.hu/felso_menu/szakmai_oldalak/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/gyartok_forgalomba_hozok/dipc
When were first biosimilars included in the reference price system?	2013
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 and by broader cluster (ATC 4)

Source: PPRI 2025

Inclusion into reimbursement and co-payments

Reimbursement in the outpatient sector	
Apart from their potential inclusion into the reference price system (see above),	Yes

biosimilars are included in outpatient reimbursement (positive list).	
If yes, how many and date of inclusion into reimbursement, if known)	53
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	Biosimilars included in the outpatient positive list are typically reimbursed at rates of 100% for certain chronic conditions, with a symbolic co-payment of 300 HUF (~1 EUR) per package. For other conditions, the reimbursement rates can vary and may be set at 90%, 70%, 50%, or 25%, depending on the specific therapeutic indication and patient eligibility.
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	A decision is made by the NEAK, often involving consultations with the Technology Assessment Committee (TAC).
Indicate URL of outpatient positive list	https://www.neak.gov.hu/felso_menu/szakmai_oldalak/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/pupha/Vegleges_PUPHA
Co-payments for biosimilars for outpatient use	A symbolic fixed co-payment of 300 HUF (~1 EUR) per package is applied for biosimilars with 100% reimbursement. For other reimbursement categories, patients may need to pay a percentage of the cost, which can be 10%, 30%, 50%, or 75%, depending on the reimbursement rate (90%, 70%, 50%, or 25% respectively).
<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 The reimbursement rates for medicines can be 100%, 90%, 70%, 50%, 25%, or 0%, depending on the therapeutic indication and patient eligibility. Co-payments: Patients are required to pay the difference between the gross retail price and the reimbursement amount. For 100% reimbursed medicines, the co-payment is a prescription fee of 300 HUF (~1 EUR).
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes, alongside or instead of the originator biological, depending on the specific hospital's procurement and treatment protocols.
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	Pharmaceuticals in the inpatient sector are covered under the DRG system. Biosimilars are evaluated by the TAC based on their similarity to already approved reference products, which simplifies the assessment process.
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
<u>For medicines for inpatient use in general (other medicines than biosimilars):</u> Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	Hospital pharmaceutical formularies at national, regional and/or facility (hospital) level No co-payments for medicines for inpatient use

Source: PPRI 2025

4.3 Specific pricing, procurement and funding policies 2025

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 pricing and reimbursement models which apply delinkage for biosimilars	No
Application of financial managed-entry agreements (e.g., price-volume agreements, caps) for biosimilars	No
Application of performance-based managed-entry agreements (e.g., risk-sharing agreements, pay-for-performance) for biosimilars	No
Any other relevant pricing and funding models for biosimilars	Yes (e.g. confidential discounts and paybacks) Indicate sector: inpatient and outpatient sectors
Enforcement of anti-trust policies	Yes (policies include measures to prevent cartel formation and corruption in procurement practices and is overseen by the Hungarian Competition Authority (GVH)
Specific pricing and funding (e.g., subscription models, MEA, …) for other medicines	Predominantly financial MEAs and some performance-based MEAs

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022; Hornyak et al. 2021; EC DG Competition 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
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	

Source: PPRI 2025,

Health technology assessment

Definition: HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

HTA is applied for biosimilar medicines	
If yes, in which situations and settings (outpatient and inpatient)	If a biosimilar applies for a new indication (has not yet ever happened).
Differences in criteria and processes of HTA for biosimilars compared to other medicines	No
Any specificities	No

Source: PPRI 2025

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Country context: Only doctors are allowed to 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	Doctors are asked to decide on a case-by-case basis
Prescription guidelines (including switching guidelines) were issued by	National Health Insurance Fund Management (NEAK) and Hungarian Medical Chamber (MOK)
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	Specific quotas are set for the prescription of biosimilars to ensure their uptake and utilisation. These quotas are typically defined as a percentage of total prescriptions for certain therapeutic areas, such as oncology and rheumatology.
Any exemptions	Case-by-case basis
Any sanctions in case of non-achievement	Yes, sanctions can include financial penalties or other administrative measures to ensure compliance with the quotas.
Any (financial) incentives for achieving the quota	Incentives can include bonuses or additional funding for their practice.
Prescribing quotas were issued by	National Health Insurance Fund Management (NEAK) in collaboration with the Hungarian Medical Chamber (MOK).
URL of prescribing quotas	
Prescribing quotas for other non-biosimilar medicines exists	Yes
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	Yes
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	Both outpatient and inpatient Contract parties: agreements between the National Health Insurance Fund Management (NEAK), healthcare providers (hospitals and clinics), and pharmaceutical companies Content and incentives: financial bonuses, shared savings, and additional funding Introduced over the last decade
Publicly accessible information	

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 exemptions for biologicals: biologics and biosimilars may be prescribed by INN
Further measures targeted at doctors	
Information materials for doctors	Yes, pls. specify (e.g., guidelines on the clinical use of biosimilars, safety and efficacy data, and economic benefits issued by NEAK or MOK)
Information events for doctors (e.g., seminars, trainings)	Yes, mainly about the benefits and use of biosimilars, address any concerns, and provide updates on the latest clinical data, issued by NEAK, MOK or other relevant healthcare organisations.
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	Yes

Source: PPRI 2025, Kun 2019, Kawalec 2017, IQVIA 2020

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense

Substitution policies	
(Automatic) substitution for biosimilars	No, not allowed
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, indicative
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	
Further measures targeted at pharmacists	
Information materials for pharmacists	Yes, the National Institute of Pharmacy and Nutrition (NNGYK) provides guidelines on the use of biosimilars, updates on regulatory changes, and best practices for patient counseling.
Information events for pharmacists (e.g., seminars, trainings)	Yes, e.g. Congressus Pharmaceuticus Hungaricus (CPH) and EUFEPS Annual Meeting

Source: PPRI 2025

Patients

Information and educational measures	
Information materials for patients	Yes
If yes, provide URL of most common materials	
If yes, key producers of education measures	National Institute of Pharmacy and Nutrition (NNGYK) provides information on the benefits and safety of biosimilars, guidelines for their use, and answers to common patient questions
Information events for patients (e.g., seminars, trainings)	Yes

If yes, key providers of educational events	National Public Health Centre (NNK) and patient organisations such as the Hungarian League of Patients with Rheumatic Diseases and the Hungarian Coeliac Society
Gain-sharing models	
Gain-sharing models for patients	No
If yes, pls. describe	
Publicly accessible information	

Source: PPRI 2025

5 Impact of biosimilar policies and practices in Hungary

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 Hungary

Outcome indicator	Caused by	Findings	Publication
Biosimilar uptake	Not specific policy as causal factor studied, but prescribing including switching pattern of doctor following biosimilar launch was analysed	The launch of biosimilar infliximab did not lead to a significant increase in the overall utilisation of multisource infliximab. Instead, patients previously treated with originator biologicals were often switched to other originator biologicals with similar therapeutic effects rather than the more affordable biosimilar alternatives. This could be due to physician preferences, perceived efficacy, or safety concerns regarding biosimilars. Although some treatment-naive patients were initiated on the biosimilar due to its lower cost, the majority were prescribed an originator biologic from the outset.	Harsanyi et al. 2020 10.1080/14737167.2019.1667232
Savings for the public payer	Tendering-like procedure	A price competition measure (biosimilar bid) for biosimilars in Hungary was introduced by the Hungarian National Health Insurance Fund Administration (NEAK). The goal was to reduce the costs of biosimilars and increase their market share through tenders and price negotiations. This measure specifically targeted measure like erythropoietin and colony-stimulating factors (CSF). It led to a significant reduction in the prices of biosimilars. The market share of biosimilars increased as the lower prices made them more attractive to patients and the healthcare system. The number of patients treated with erythropoietin increased slightly by 1.4% in the first year and 3.6% in the second year after the measure was implemented. Health insurance reimbursements for these medicines decreased by 47% in the first year, resulting in significant cost savings for the healthcare system.	Hornyak et al. 2014 10.1016/j.jval.2017.08.355
Savings for the public payer	Tendering-like procedure	The tendering-like Biolicit procedure, introduced by the Hungarian National Health Insurance Fund Administration (NEAK), aimed to reduce the costs of originator and biosimilar granulocyte colony-stimulating factor (GCSF) and erythropoietin (EPO) products through competitive bidding. This process encouraged price competition among manufacturers, leading to lower prices and increased accessibility of these medicines. The Biolicit procedure led to a significant decrease in the prices of GCSF and EPO products. The number of treatment days for GCSF increased by 59% and 72% in the two years following the bid. For EPO, the number of treatment days increased by 52% and 50%. More patients were treated with these medicines as their affordability improved. The healthcare system saved significant amount of money, with reimbursements for these medicines decreasing by around 70%.	Hornyak et al. 2021 10.33892/aph.2021.91.21-28

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 Hungary

Legal barriers

The regulatory framework for biosimilars in Hungary is not always clearly defined, leading to uncertainty among manufacturers and healthcare providers. For example, there are two separate tenders, one for treatment-naïve patients and one for patients already on maintenance biologics (Inotai 2018). This may cause ambiguity regarding the approval process for biosimilars, which can delay their market entry and adoption.

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

The healthcare system in Hungary can be fragmented, with different competences and funding responsibilities for outpatient and inpatient sectors. This fragmentation can complicate the implementation of cohesive biosimilar policies (Harsanyi et al., 2020). Moreover, the bid process requires significant administrative resources from the National Health Insurance Fund Administration (NHIFA), which can be a barrier to efficient implementation (Hornyak et al., 2019).

Financial barriers

The current Hungarian biosimilar policy does not effectively incentivise the uptake of more affordable multisource biologicals.

Evidence and communication-related barriers

There is a lack comprehensive evaluation, communication, and educational efforts to effectively promote the use of biosimilars in Hungary.

Policy-related barriers

Tenders are often awarded based solely on price, and there are calls for more transparent and multi-winner tender systems (IQVIA 2020).

Stakeholder-related barriers

Physicians had limited concerns with switching their patients to other originator biologicals, but they were reluctant to switch their patients to biosimilar infliximab, if there were any other alternative patented biologicals on the reimbursement list (Harsanyi et al. 2020).

7 Facilitators and good practice examples in Hungary

The time from EMA approval to the first sales of biosimilars in Hungary is relatively short, which suggest comparably quick market entry (IQVIA 2020).

National treatment guidelines recommend the use of lower-priced biosimilars for patients starting treatment, which helps in promoting their use (Machado 2024).

Comprehensive training and education programs for both physicians and patients have been implemented to increase awareness and acceptance of biosimilars (IQVIA 2020). These efforts to educate healthcare providers and patients about the safety, efficacy, and benefits of biosimilars have been crucial in building trust and encouraging their use (Mestre-Ferrandiz et al. 2021).

There are prescription quotas and financial incentives for providers that do not restrict physician choice, encouraging the prescription of biosimilars. Biosimilars follow the same prescribing rules as the originator, and products published and listed in the official website of NEAK can be prescribed at the physicians discretion (IQVIA 2020).

Collaboration between healthcare providers, policymakers, and pharmaceutical companies has been essential in creating a supportive environment for biosimilars. In addition, Hungary benefits from participating in international initiatives and sharing best practices with other European countries to enhance biosimilar adoption (Machado et al. 2024).

8 Developments in Hungary

Recent changes

Hungary has streamlined the process from EMA approval to market entry for biosimilars, reducing the time required for these medicines to become available to patients. (Simoens 2024)

Hungary's major pharmaceutical companies, such as Egis Pharmaceuticals and Gedeon Richter, have been expanding their biosimilar portfolios, contributing to the availability of affordable biologic medicines (Egis 2019, Richter Gedeon 2025).

Plans or under discussion

Further incentives are being considered to build physician awareness and acceptance of biosimilars, such as sharing savings with the doctor’s hospital or department.

Initiatives to promote a vibrant start-up environment through science parks and innovation hubs are underway. These hubs aim to foster collaboration between universities, biotech, and pharmaceutical companies, driving further innovation in the biosimilar sector.

9 Bibliography

EC DG Competition 2024	European Commission Directorate-General for Competition. Update on competition enforcement in the pharmaceutical sector (2018-2022) – European competition authorities working together for affordable and innovative medicines – Report from the Commission to the Council and the European Parliament. Luxembourg: Publications Office of the European Union, 2024
Egis 2091	Egis Pharmaceuticals PLC. Egis Strengthens European Presence in the Biosimilar Area. 2019. Available from https://int.egis.health/a/egis-strengthens-european-presence-in-the-biosimilar-area (accessed on 6 March 2025).
Egis 2013	Egis Pharmaceuticals PLC. Egis is first to launch biosimilar monoclonal antibody within the European Union. Budapest; 13 September 2013. Available from: https://bse.hu/newkibdata/115250544/EGI130913ER01E.pdf (accessed 20 January 2025)
Gedeon Richter 2025	Gedeon Richter Plc. Biotechnology. 2025. Available from https://www.gedeonrichter.com/en/areas-of-expertise/biotechnology (accessed on 6 March 2025)
GÖG 2023	Austrian National Public Health Institute (GÖG). PPRI Indicators 2025. Unpublished
Harsanyi et al. 2020	Harsányi A, Csanádi M, Márky K, Vinczickzki ÁZ, Kaló Z, Inotai A. Influence of biosimilar infliximab launch on the utilization pattern of biological medicines: the case of Hungary. Expert Rev Pharmacoecon Outcomes Res. 2020;20(6):653-660
Hornyak et al. 2014	Hornyák Z, Tálos Z, Ágoston I, Endrei D, Csákvári T, Boncz I. Experiences with price competition of biosimilar drugs in Hungary. Value Health. 2014;17(7):A323-A686
Hornyak et al. 2021	Hornyák L, Nagy Z, Vathy-Fogarassy Á, Endrei D, Csákvári T, Répásy B, Kresz S, Boncz I. The long-term effects of the biolicit procedure for original and biosimilar GCSF and EPO products in Hungary. Acta Pharm Hung. 2021;91:21-28. DOI: 10.33892/aph.2021.91.21-28
Inotai et al. 2018	Inotai A, Csandi M, Petrova G, et al. Patient access, unmet medical need, expected benefits, and concerns related to the utilisation of biosimilars in Eastern European countries: a survey of experts. Biomed Res Int. 2018;2018:9597362.
IQVIA 2020	IQVIA. Bosimilar Scorecard 2020 Hungary. IQVIA Institute. 2020. Available from: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/country-scorecards-for-biosimilar-sustainability/iqvia-biosimilar-scorecard-hungary.pdf (accessed 20 January 2025)
Kun 2019	Kun, J. Hungary's National Champions Betting on Biosimilars, PharmaBoardroom. 2019. Available from https://pharmaboardroom.com/articles/hungarys-national-champions-betting-on-biosimilars/ (accessed on 6 March 2025)
Machado et al. 2024	Machado S, Cruz A, Ferreira PL, Morais C, Pimenta RE. Policy measures and instruments used in European countries to increase biosimilar uptake: a systematic review. Front Public Health. 2024;12:1263472.
Mestre-Ferrandiz et al. 2021	Mestre-Ferrandiz J, et al. Policies to Encourage the Use of Biosimilars in European Countries. Front Pharmacol. 2021;12:625296.
Rieger et al. 2024	Rieger C, Dean JA, Hall L, Vasquez P, Merlo G. Barriers and Enablers Affecting the Uptake of Biosimilar Medicines Viewed

	Through the Lens of Actor Network Theory: A Systematic Review. BioDrugs. 2024;38:541-555.
Simoens et al. 2024	Simoens S, Barcina Lacosta T, Inotai A. Learnings from cross-border biosimilar pricing policies in Europe. Expert Rev Pharmacoecon Outcomes Res. 2024;24(5):585-588.
Vogler et al. 2024	Vogler S, Dicheva-Radev S, Panteli D, Busse R. Überblick über Maßnahmen zur Förderung des Einsatzes von Biosimilars in europäischen Ländern [Overview of measures to encourage the uptake of biosimilars in European countries]. In. Ludwig WD, Mühlbauer B, Seifert R, editors. Arzneiverordnungs-Report 2023 [Medicines Prescription Report 2023]. Berlin Heidelberg: Springer 2023.
Vogler, Sacher-Konrad and Habimana 2022	Vogler S, Salcher-Konrad M, Habimana K. Study on Best Practices in the Public Procurement of Medicines: Final Report. Brussels: European Commission, European Health and Digital Executive Agency, Publications Office of the European Union, 2022



Publications Office
of the European Union