European Commission

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

## AUGMENT Biosimilars
## Country fiche CZECH REPUBLIC

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augment biosimilars

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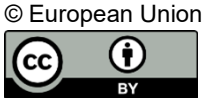

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Annex 7.6

# AUGMENT Biosimilars country fiche: Czech Republic 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:

Ondrej Nemecek, Státní ústav pro kontrolu léčiv (SUKL) / State Institute for Drug Control, Czech Republic

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# 1 Summary of biosimilar policies and practice in the Czech Republic 2025

**Key stakeholders**

In the Czech Republic, the key stakeholder in designing and implementing biosimilar policies is the State Institute for Drug Control (SÚKL).

**Major biosimilar policies and practices**

Pricing and procurement policies in the Czech Republic include a biosimilar price link for the first biosimilar entering the market, external price referencing, as well as tendering (inpatient and outpatient sectors).

Biological medicines are clustered on the basis of therapeutic interchangeability, using reference price system that is paired with reimbursement price and conditions.

Demand-side measures regarding biosimilar medicines includes INN prescribing, also for biologicals (at physician's discretion). Furthermore, switching to and between biosimilars is possible.

**Impact analysis**

While there is some information on the development on biosimilar sales (e.g. in 2024 the biosimilar sales reached CZK 3. billion / €12.4 million, representing a four-year Compound annual growth rate (CAGR) of 22,1%), no evidence was found on the impact of specific biosimilar policies in the Czech Republic.

**Barriers, facilitators and good practice examples**

Low prices of biosimilar medicines can lead to re-export and several operational challenges (i.e. when introducing them to the market). Furthermore, pricing requirements put additional pressure on manufacturers who may prefer delayed or no entry to the Czech market (not to be generalized for all biosimilars).

There can be hesitancy among physicians and patients to switch from reference biological medicines to biosimilars due to concerns to efficacy and safety.

A reference price system which quickly includes biosimilars is, in general, considered as a facilitator for biosimilar uptake, and such a reference price system is in place in the Czech Republic (Vogler et al. 2021).

Furthermore, the State Institute for Drug Control (SÚKL) can set specific reimbursement conditions, such as prescription or indication restrictions.

Additionally, whilst pricing requirements can act as a barrier to biosimilar implementation on the market, such requirements make drug prices more affordable (Czech Republic employs a policy which requires the first biosimilar medicine to be priced 30% below the price of the reference medicine).

**Recent developments**

No information on recent developments.

**Highlights and learnings**

The Czech Republic has implemented several policies to manage biosimilars effectively. These include: biosimilar price link, reference pricing system and tendering in both inpatient (primarily) and outpatient sectors. Biosimilar medicines are also grouped into clusters, paired with reimbursement price and conditions.. The Czech Republic introduces crucial demand-side measures, which enable to switch and prescribe biosimilars with the use of INN.

# 2 Key data regarding biosimilars in the Czech Republic

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

Number of the **biosimilars marketed**:
17 molecules with biosimilars available, as of September 2025
45 biosimilars (per trade name), as of September Source: SUKL 2025

**Biosimilar market shares in 2022:**

0,2% **in volume** in 2022
Volume is defined as **units sold**

2,9% **in value** in year 2022
Value is defined as **share of total pharmaceutical**

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**

**List of reimbursed medicines (including biosimilars)**
https://sukl.gov.cz/ceny-a-uhrady-leciv/prehledy-cen-a-uhrad-leciv/seznam-leciv-a-pzlu-hrazenych-ze-zdravotniho-pojisteni/?%3Ar1%3A-page=1

**Online database of medicines**
https://prehledy.sukl.cz/prehled_leciv.html#/

# 3 Stakeholders involved in and targeted by biosimilar policies in the Czech Republic

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| Goverment | Vláda České republiky/ The Government of the Czech Republic | The supreme body of state administration and legislative proposals | https://vlada.gov.cz/ |
| Ministry | Ministerstvo zdravotnictví České republiky/ Ministry of Health of the Czech Republic | key role in health policy and the regulation of healthcare services | https://mzd.gov.cz/ |
| Legislator | Poslanecká sněmovna / Chamber of Deputies Senát / Senate | Approves, repares legislation | https://www.psp.cz/sqw/hp.sqw |
| National regulatory authority | Státní ústav pro kontrolu léčiv (SUKL) / State Institute for Drug Control | State Institute for Drug Control (SÚKL) is the national regulatory authority (Medicines Agency) responsible for overseeing pharmaceuticals, including biosimilars | SUKL 2022 |
| Pharmaceutical pricing authority | Státní ústav pro kontrolu léčiv (SUKL) / State Institute for Drug Control | Evaluates cost-effectiveness, safety, and therapeutic value to determine pricing and reimbursement amounts. Pricing is guided by national and international reference pricing systems, and reimbursement decisions incorporate health economic assessments and budget impact analyses. The Ministry of Health oversees the overall framework | https://sukl.gov.cz/nezarazene-cs/generika-a-biosimilars-spolu-se-sukl-setri-miliardy-a-pomahaji-lecit-vice-pacientu/ |
| Pharmaceutical reimbursement authority | Státní ústav pro kontrolu léčiv (SUKL) / State Institute for Drug Control | State Institute for Drug Control (SÚKL) is responsible for pharmaceutical reimbursement decisions. It evaluates the therapeutic and economic value of medications to determine whether they are eligible for reimbursement under the national health insurance system. This involves health technology assessments and cost-effectiveness analyses. | https://sukl.gov.cz/nezarazene-cs/generika-a-biosimilars-spolu-se-sukl-setri-miliardy-a-pomahaji-lecit-vice-pacientu/ |

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| Procurement agency | Úřad pro ochranu hospodářské soutěže (ÚOHS) / Office for the Protection of Competition (Czech Public Procurement Office) | The main agency responsible for public procurement, including the procurement of pharmaceuticals and medical supplies, is the Czech Public Procurement Office (Úřad pro ochranu hospodářské soutěže - ÚOHS). This body oversees the legal framework for procurement processes, ensuring transparency and competition. Additionally, hospitals and healthcare systems may also handle procurement at the regional level | |
| HTA agency / body | Státní ústav pro kontrolu léčiv (SUKL) / State Institute for Drug Control | Evaluation of Cost-Effectiveness, Clinical Effectiveness and Safety Review, Budget Impact Analysis, Guidance on Implementation - provides frameworks for integrating biosimilars into clinical practice, including guidelines for prescribing and patient monitoring | |
| National competition authority | Úřad pro ochranu hospodářské soutěže (ÚOHS) / Office for the Protection of Competition | Primarily focused on ensuring fair competition in the pharmaceutical market, promoting accessibility, and preventing anti-competitive practices by manufacturers of originator biologics or biosimilars | |
| National patent office | Úřad průmyslového vlastnictví / Industrial Property Office of the Czech Republic | Granting and managing patents on biologic medicines | |
| Payers | Všeobecná zdravotní pojišťovna (VZP) /The General Health Insurance Company; Svaz zdravotních pojišťoven/ The Association of Health Insurance Companies | 7 health insurance funds (VZP with 60 % share, 6 smaller ones acting usually together under the association) | https://www.vzp.cz/<br><br>https://szpcr.cz/ |
| Doctors | *Represented by:* Česká lékařská komora (ČLK) / Czech Medical Chamber<br><br>*Medical societies:* Lékařský odborový klub – Svaz českých lékařů, (LOK-SČL) / Medical Trade Union Club – Union of Czech Physicians<br><br>Česká diabetologická | Prescribing Biosimilars: Informed Decision-Making Switching Patients Substitution Practices | |

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| | společnost (ČDS) / Czech Diabetes Society<br><br>Česká gastroenterologická společnost / Czech Gastroenterological Society<br><br>Česká hematologická společnost (ČHS) / Czech Society of Hematology<br><br>Česká onkologická společnost (COS) / Czech Society of Oncology<br><br>Česká revmatologická společnost (ČRS) / Czech Society of Rheumatology | | |
| Nurses | *Represented by:* Czech Association of Nurses (Česká asociace sester, ČAS) | - | |
| Community pharmacists | Česká farmaceutická společnost / Czech Pharmaceutical Society | Patient education, medication management | https://www.cfs-cls.cz/ |
| Hospital pharmacists | *Represented by:* Czech Pharmaceutical Society / Česká farmaceutická společnost | Support procuring medicines, inform patients / health professionals / procurers | https://nemfarm.cz/ |
| Patient organisations | *Represented by:* Svaz pacientů České republiky / Czech Patients' Union<br><br>*Patient associations organisations in diseases with particular biologics use:*<br><br>Svaz diabetiků České republiky / Czech Diabetes Association<br><br>Klub pacientů s idiopatickými střevními záněty / Czech Crohn's and Colitis Association<br><br>Český svaz hemofiliků / Czech | Patient organisations in diseases with particular biologics use a | https://www.crohn.cz/dotaz/godnoceni-zmeny-originalniho-pripravku-za-biosimilarni<br><br>https://www.crohn.cz/zaznam-z-webinare-na-tema-novinky-v-lecbe-ibd<br><br>https://www.crohn.cz/efcca-biologics-biosimilars-patient-access-advocacy-workshop |

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| | Society of Hemophilia (CSH)<br><br>Diagnoza CML / Patient organizsation for CML patients<br><br>Liga proti rakovině Praha / Czech League Against Cancer | | |
| Consumer organisations | - | - | - |
| Biosimilar industry | *Represented by:* Česká asociace farmaceutických firem (ČAFF) / Association of Pharmaceutical Industry | Education on biosimilars | https://www.caff.eu/en/co-delame/biosimilarni-leky |
| Generic industry | *Represented by:* Česká asociace farmaceutických firem (ČAFF) / Association of Pharmaceutical Industry | Education on generic medicines | https://www.caff.eu/co-delame/genericke-leky |
| Pharmaceutical industry in general | *Represented by:* Česká asociace farmaceutických firem (ČAFF) / Association of Pharmaceutical Industry | Education | https://www.caff.eu/en/co-delame/biosimilarni-leky |
| Pharmaceutical industry for new biological medicines | *Represented by:* Asociace inovativního farmaceutického průmyslu/ The Association of Innovative Pharmaceutical Industry | Represents the innovative industry | https://aifp.cz/en/ |

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium); Act No. 378/2007 Coll.; Act No. 48/1997 Coll.; ČAFF 2025; Decree No. 228/2008 Coll.; Decree No. 376/2011 Coll.; Mitrová 2024; Pacienti IBD (2017, 2020); SÚKL (2022, 2023, 2025); ÚOHS 2022.

# 4 Biosimilar policies and practices in the Czech Republic 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 2025

### Biosimilar price link

| | |
|---|---|
| A **biosimilar price link** is in place. | Yes |
| It applies for the following situations: | For biosimilar medicines in the outpatient sectors entering the market |

| | |
|---|---|
| Price reduction of the first biosimilar compared to the reference product | 30% |
| Price reduction of the second, third and further biosimilars | NO |
| Price reduction for the reference product | No price reduction for the reference product |
| Any further specificities | Reduction of reimbursement price of reference product after the biosimilar product is reimbursed and enters the market. |
| Generic price link | Yes, the price of the first generic must be at least 40% lower than the original medicine |

Source: PPRI 2025, Vogler et al. 2025

### External price referencing

| | |
|---|---|
| External price referencing is applied for biosimilars. | Yes |
| If yes, it is applied for the following situations: | The State Institute for Drug Control (SÚKL), utilizes EPR by comparing the prices of biosimilars using prices from the reference basket (all EU countries with 9 exceptions), using average of the three lowest prices as a reference |
| Any specificities | |
| External price pricing is in place for other medicines than biosimilars. | Yes, for all medicines |

Source: PPRI 2025, Decree No 92/2008 Coll.

### Tendering

| | |
|---|---|
| Some (or all) biosimilars are procured through tendering (or tendering-like) processes. | Yes |
| If yes, the scope with regard to the care sector: | Primarily inpatient, but also outpatient sector |
| **Tendering biosimilars in the inpatient sector** | |
| Scope of biological medicines tendered | All |
| Institutional framework | Conducted by on hospital level |
| Information available on procurement procedures and practices | Open and restricted tenders are commonly used to invite suppliers to bid for contracts. |
| **Tendering biosimilars in the outpatient sector (or tendering-like policies)** | |
| Scope of biological medicines tendered | Some off-patent biological medicines |
| Institutional framework | Health care providers (hospitals) organize tenders for the supply of medicines to ensure the efficient use of funds and the availability of necessary medicines for patients. |
| Information available on procurement procedures and practices | Main criteria: price, quality, and supply reliability |
| Generics are tendered (or procured through competitive tendering-like policies). | Inpatient: Yes (mainly)<br>Outpatient: Yes |

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Vogler et al. 2025, IQVIA 2022, ÚOHS 2023

## 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 | |
| If publicly accessible, indicate URL of RPS list | SCAU |
| When were first biosimilars included in the reference price system? | 2015 |
| Any further specificities | Therapeutic equivalence to the reference biologic |
| In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered? | Yes<br>Broader clusters than ATC 5 |

Source: PPRI 2025

| **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 | |
| Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use | Same as for generic drugs |
| Indicate URL of outpatient positive list | https://www.vzp.cz/; https://szpcr.cz/ |
| Co-payments for biosimilars for outpatient use | SCAU |
| For medicines for outpatient use in general (other medicines than biosimilars)<br>Positive list for medicines in general<br>Percentage reimbursement rates are in place<br>Co-payments for reimbursable outpatient medicines | For medicines in general for outpatient use:<br>- Positive list<br>- No fixed percentage rate, but resulting from the setting of the reimbursement price and the maximum price for each medicine.<br>- Co-payment: Difference between maximum reimbursement price and pharmacy retail price |
| **Reimbursement in the inpatient sector** | |
| Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level | Yes, additionally to the originator biological (and doctors are recommended to switch) |
| Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use | E.g. |
| Indicate URLs of hospital pharmaceutical formularies, if publicly accessible | - |
| Co-payments for biosimilars for inpatient use | No |

| | |
|---|---|
| For medicines for inpatient use in general (other medicines than biosimilars):<br>Hospital pharmaceutical formularies<br>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 2025

| | |
|---|---|
| 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 | |
| Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines | Predominantly financial but also some performance-based MEAs |

Source: PPRI 2025

## 4.4 Supportive tools and practices for policy-makers 2025

### Horizon scanning

| | |
|---|---|
| Public authorities or public payers use a horizon scanning system to identify loss of exclusivity (patent expiry) of biologics | Not in place |
| If yes, describe the process and the tools (e.g. regular consultation of a database, horizon scanning scoping meeting with stakeholders), including who use horizon scanning | |

Source: PPRI 2025

### Health technology assessment

| | |
|---|---|
| HTA is applied for biosimilar medicines | Yes, when originator medicine is not reimbursed |
| If yes, in which situations and settings (outpatient and inpatient) | - |
| Differences in criteria and processes of HTA for biosimilars compared to other medicines | No |
| Any specificities | |

Source: PPRI 2025

## 4.5 Demand-side measures 2025

| **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 naive patients |

| | |
|---|---|
| If yes, what is recommended for patients already on biologic treatment | Rcommendation to switch patients for economic reasons |
| Prescription guidelines (including switching guidelines) were issued by | Professional societies |
| URL of prescription & switching guidelines | |
| **Prescribing quotas** | |
| Prescribing quotas for doctors with regard to prescription of biosimilars exist | No |
| If yes, which quotas are defined for biosimilars | |
| Any exemptions | |
| Any sanctions in case of non-achievement | No |
| Any (financial) incentives for achieving the quota | |
| Prescribing quota were issued by | |
| URL of prescribing quotas | |
| Prescribing quotas 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 | |
| **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, |
| Information events for doctors (e.g., seminars, trainings) | yes |
| Involvement of doctors in switching studies that evaluate clinical outcomes of a switch | |

Source: PPRI 2025; EMA and HMA 2022

## Pharmacists (and further dispensers)

| | |
|---|---|
| **Substitution policies** | |
| (Automatic) substitution for biosimilars | |
| 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 | |
| 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 | |
| Information events for pharmacists (e.g., seminars, trainings) | |

Source: PPRI 2025

**Patients**

| **Information and educational measures** | |
|---|---|
| Information materials for patients | Yes |
| If yes, provide URL of most common materials | www.sukl.cz, www.caff.eu |
| If yes, key producers of education measures | |
| Information events for patients (e.g., seminars, trainings) | Yes |
| If yes, key providers of educational events | HTA body, industry, patient organizations |
| **Gain-sharing models** | |
| Gain-sharing models for patients | No |
| If yes, pls. describe | |
| Publicly accessible information | No |

Source: PPRI 2025, Barbier et al. 2022

# 5 Impact of biosimilar policies and practices in Czech Republic

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.

Currently, several factors present both opportunities and challenges for the advancement of biosimilars in Czech Republic. The country's strict pricing policy, embedded in its legal framework, regulates prices, providing stability but also limiting flexibility in a competitive market. Additionally, the multi-faceted tendering system fosters competition (though it increases operational complexity and reduces transparency). Overall, the biosimilar market in the Czech Republic is fragmented, with many direct and indirect influences shaping the competitive environment.

The current environment in the Czech Republic has both supportive and hindering elements with regard to fostering biosimilar uptake. while individual tenders support the competitive environment and desired long-term innovation and prescribing freedom helps healthcare professionals gain experience with multiple biosimilar alternatives, the complexity of the entire system the market difficult.

**Evidence from the literature on impacts of biosimilar policies and practices in Czech Republic**

| Outcome indicator | Caused by | Findings | Publication |
|---|---|---|---|
| Improved uptake | No specific policy analysed | According to IQVIA sell-in data, as of MAT/06/2021, biosimilars sales reached CZK 1.68 billion (€67.4 million), representing a four- year Compound annual growth rate (CAGR) of 26%. | IQVIA 2022, https://www.iqvia.com/-/media/iqvia/pdfs/czech/library/white-papers/advancing-biosimilars-in-the-czech-republic.pdf |
| Improved uptake | No specific policy analysed | Regarding three anti-TNF-α biosimilars (adalimumab, etanercept, and infliximab), the market share increased from 36% to 68% (2018 to 2023). | ISPOR conference poster<br>Grieco and Bodin 2024: https://www.ispor.org/docs/default-source/euro2024/isporeurope24griecohpr25poster142729-pdf.pdf?sfvrsn=8228559c_0 |

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 Czech Republic

### Legal barriers

Not identified.

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

The possibility of re-export of biosimilars (caused by low prices) leading to insufficient medicines supply at times, limit the number of biosimilars available on the market and subsequently limit patient access to new innovative treatments.

### Financial barriers

Requiring medicines prices in the Czech Republic to be the equivalent of the three lowest prices in the EU reference basket, such as pricing requirements put additional pressure on manufacturers who may prefer delayed or no entry to the Czech market. This applies only for reimbursed medicines.

### Evidence and communication-related barriers

Not identified.

### Policy-related barriers

The system supports strong prescription freedom for healthcare professionals, however it’s complexity can result in operational difficulties (as well as transparency problems)

Bidding at multiple regional levels and negotiating discounts and rebates

Single-winner tendering

### Stakeholder-related barriers

There can be hesitancy among physicians and patients to switch from reference biological medicines to biosimilars due to concerns to efficacy and safety.

**Any other barriers**

Not identified.

# 7 Facilitators and good practice examples in the Czech Republic

For payers, the presence of biosimilars means a broader portfolio of biologic treatments and lower prices, relieving the often-stretched healthcare system's budget.

Rules set out in the Regulation 726/2004 ("MPA Regulation") apply to the marketing authorisation of biosimilars.

# 8 Bibliography


| | |
|---|---|
| Acha et al. 2015 | Acha V, Allin P, Bergunde S, Bisordi F, Roediger A. (2015). What pricing and reimbursement policies to use for off-patent biologicals? - Results from the EBE 2014 biological medicines policy survey. Gabi Journal. 4(1), 17-24. https://doi.org/10.5639/gabij.2015.0401.006 |
| Barbier et al. 2022 | Barbier L, Mbuaki A, Simoens S, Declerck P, Vulto AG, Huys I. Regulatory Information and Guidance on Biosimilars and Their Use Across Europe: A Call for Strengthened One Voice Messaging. Front Med (Lausanne). 2022 Mar 9;9:820755. doi: 10.3389/fmed.2022.820755. |
| Blackstone et al. 2013 | Blackstone EA, Joseph PF. The economics of biosimilars. Am Health Drug Benefits. 2013 Sep;6(8):469-78. PMID: 24991376; PMCID: PMC4031732. |
| ČAFF 2025 | Biosimilar medical drugs. Accessible from: https://www.caff.eu/en/co-delame/biosimilarni-leky (accessed 27 January 2025) |
| ČAFF 2025 | Generic drugs. Accessible from: https://www.caff.eu/co-delame/genericke-leky (accessed 27 January 2025) |
| EMA 2019 | EMA. Biosimilars in the EU. Information guide for healthcare professionals. 2019. Accessible from: https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf?bcgovtm=stua2019 (accessed 23 January 2025) |
| EMA and HMA 2022 | EMA and HMA. Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. 2022. Accessible from: https://sukl.gov.cz/reg-biosimilars/prohlaseni-o-odbornych-duvodech-podporujicich-zamenitelnost-biologicky-podobnych-lecivych-pripravku-biosimilars-v-eu/ (accessed 27 January 2025) |
| EMA and HMA 2023 | EMA and HMA. Q&A on the Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. EMA/93740/2023 Rev. 1. Accessible from: https://www.ema.europa.eu/en/documents/other/qa-statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf (accessed 27 January 2025) |
| Grieco and Bodin 2024 | Grieco and Bodin. ISPOR conference poster: Assessing Sustainable Biosimilar Competition: Current Trends and Impacts of Anti-TNF Biosimilar Competition in Europe. Accessible from: https://www.ispor.org/docs/default-source/euro2024/isporeurope24griecohpr25poster142729-pdf.pdf?sfvrsn=8228559c_0 (accessed 27 January 2025) |
| IQVIA 2022 | Advancing Biosimilars in the Czech Republic Challenges and Opportunities. IQVIA report (2022). Accessible from: https://www.iqvia.com/locations/czech/library/white-papers/advancing-biosimilars-in-the-czech-republic (accessed 23 January 2025) |
| IQVIA 2023 | The Impact of Biosimilar Competition in Europe 2023. Accessible from: https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2023 (accessed 27 January 2025) |
| IQVIA 2024 | IQVIA. The Impact of Biosimilar Competition in Europe 2023. Accessible from: https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2023.pdf (accessed 27 January 2025) |

| | |
|---|---|
| Kawalec et al. 2017 | Kawalec P, Stawowczyk E, Tesar T, Skoupa J, Turcu-Stiolica A, Dimitrova M et al. Pricing and Reimbursement of Biosimilars in Central and Eastern European Countries. Front Pharmacol. 2017 Jun 8;8:288. doi: 10.3389/fphar.2017.00288. |
| Medicines for Europe 2023 | Biosimilar medicines. Market review – European biosimilar medicine markets. Accessible from: https://www.medicinesforeurope.com/wp-content/uploads/2023/09/Biosimilars-Market-Review-2023-final-06-09-2023.pdf (accessed 27 January 2025) |
| Mestre-Ferrandiz et al. 2023 | Mestre-Ferrandiz J, Czech M, Smolen JS, Cornes P, Aapro MS, Danese S et al. Capturing the holistic value of biosimilars in Europe - part 1: a historical perspective. Expert Rev Pharmacoecon Outcomes Res. 2024 Feb;24(2):237-250. doi: 10.1080/14737167.2023.2297926. |
| Mestre-Ferrandiz et al. 2024 | Mestre-Ferrandiz J, Czech M, Smolen JS, Cornes P, Aapro MS, Danese S et al. Leveraging the holistic benefits of biosimilars in Europe – part 2: how payers can safeguard the future of a healthy biosimilar market environment. Expert Review of Pharmacoeconomics & Outcomes Research 24, no. 4 (20 April 2024): 509–19. https://doi.org/10.1080/14737167.2024.2310684. |
| Mitrová 2024 | Mitrová K. Evaluation of the change from the original product to a biosimilar. 2024. Accessible from: https://www.crohn.cz/dotaz/godnoceni-zmeny-originalniho-pripravku-za-biosimilarni (accessed 27 January 2025) |
| Pacienti IBD 2017 | Information on Biologics & Biosimilars Patient Access and Advocacy Workshop. Accessible from: https://www.crohn.cz/efcca-biologics-biosimilars-patient-access-advocacy-workshop (accessed 27 January 2025) |
| Pacienti IBD 2020 | Information on webinar recording: News in IBD treatment. Accessible from: https://www.crohn.cz/zaznam-z-webinare-na-tema-novinky-v-lecbe-ibd (accessed 27 January 2025) |
| Pharma Boardroom 2024 | The Pharma Legal Handbook: Czech Republic. Accessible from: https://pharmaboardroom.com/legal-reports/the-pharma-legal-handbook-czech-republic/. (accessed 27 January 2025) |
| PPRI 2025 | PPRI. PPRI Indicators 2025 (yet unpublished dashboard) |
| SÚKL 2022 | SUKL. Generika a biosimilars spolu se SÚKL šetří miliardy a pomáhají léčit více pacientů. 2022. Accessible from: https://sukl.gov.cz/media/tiskove-zpravy/generika-a-biosimilars-spolu-se-sukl-setri-miliardy-a-pomahaji-lecit-vice-pacientu/ (accessed at 27 January 2025) |
| SÚKL 2023 | SUKL. Otázky a odpovědi k zaměnitelnosti biosimilars v EU. 2022. Accessible from: https://sukl.gov.cz/reg-biosimilars/otazky-a-odpovedi-k-zamenitelnosti-biosimilars-v-eu/ (accessed 27 January 2025) |
| SUKL 2024 | SUKL. Reimbursement list 2024. Accessinle from: https://prehledy.sukl.cz/prehled_leciv.html#/ (accessed 27 January 2025) |
| SÚKL 2025 | SUKL. Overview of the most important legal regulations - prices and reimbursements of medicinal products and Foods for special medical purposes. 2024. Accessible from: https://sukl.gov.cz/en/overview-of-the-most-important-legal-regulations/prices-and-reimbursements-of-medicinal-products-and-foods-for-special-medical-purposes/ (accessed 27 January 2025) |

ÚOHS 2022 — Metodické doporučení Úřadu pro ochranu hospodářské soutěže pro nákup léčivých přípravků v režimu zákona o zadávání veřejných zakázek. Accessible from: https://www.uohs.cz/download/Sekce_VZ/Metodiky/Metodika-leky_final.pdf (accessed 27 January 2025)

ÚOHS 2023 — Zpráva ze sektorového šetření v oblasti distribuce léčiv. Accessible from: https://uohs.gov.cz/cs/informacni-centrum/tiskove-zpravy/hospodarska-soutez/3526-urad-vydal-uplnou-verzi-zaverecne-zpravy-ze-sektoroveho-setreni-ve-farmacii.html (accessed 27 January 2025)

Vogler et al. 2021 — Vogler S, Schneider P, Zuba M, Busse R, Panteli D. Policies to Encourage the Use of Biosimilars in European Countries and Their Potential Impact on Pharmaceutical Expenditure. Front Pharmacol. 2021 Jun 25;12:625296. doi: 10.3389/fphar.2021.625296.

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, Salcher-Konrad and Habimana 2022 — Vogler, Salcher-Konrad and Habimana 2022. Study on best practices in the public procurement of medicines. Accessible from: https://op.europa.eu/en/publication-detail/-/publication/ca856a7f-7c37-11ed-9887-01aa75ed71a1 (accessed 27 January 2025)

## LEGAL ACTS:

Act No. 378/2007 Coll. — Act on Pharmaceuticals and Amendments to Certain Related Acts (Pharmaceuticals Act). Accessible from: https://www.zakonyprolidi.cz/cs/2007-378 (accessed 27 January 2025)

Act No. 48/1997 Coll. — Act on Public Health Insurance. Accessible from: https://natlex.ilo.org/dyn/natlex2/r/natlex/fe/details?p3_isn=63369 (accessed 27 January 2025)

Decree No. 228/2008 Coll. — Decree on the registration of medicinal products. Accessible from: https://www.zakonyprolidi.cz/cs/2008-228 (accessed 27 January 2025)

Decree No. 376/2011 Coll. — Decree implementing some provisions of the Act on Public Health Insurance. Accessible from: https://app.beck-online.cz/bo/chapterview-document.seam?documentId=onrf6mrqgeyv6mzxgywta (accessed 27 January 2025)

Regulation (EC) No. 726/2004 — Regulation (EC) No 726/2004 of the European Parliament and of the Council

of 31 March 2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. Accessible from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0726 (accessed: 27 January 2025)



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