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

AUGMENT Biosimilars
Country fiche AUSTRIA

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augment biosimilars

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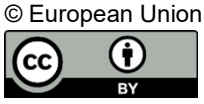

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Annex 7.1

AUGMENT Biosimilars country fiche: Austria 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:

Sarah Mörtenhuber, Bundesministerium für Arbeit, Soziales, Gesundheit, Pflege und Konsumentenschutz (BMASGPK) / Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection

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1 Summary of biosimilar policies and practice in Austria 2025

Key stakeholders

Key stakeholders involved in designing and implementing biosimilar policies include the Federal **Ministry of Labour, Social Affairs, Health, Care and Consumer Protection** (BMASGPK), which is in charge of the legal framework, and the **Austrian Social Insurance**, which decides on reimbursement for outpatient medicines and their reimbursement prices. **Hospital** owner associations (and sometimes individual hospitals) procure biosimilars for inpatient use, and negotiate their prices. Regarding the private sector, Austria has a biosimilar trade association.

Major biosimilar policies and practices

Austria employs a **biosimilar price link policy** for medicines included in the outpatient reimbursement list, where the price of biosimilars is set at a defined percentage lower than the reference product. The first biosimilar must be priced 38% lower than the originator, with subsequent biosimilars priced progressively lower. As for generics (where a generic price link is in place), the originator medicine must also reduce its price (by 30%) three months after the inclusion of the first biosimilar in the outpatient reimbursement list. For biosimilars, a simpler process (fewer requirements) is applied for inclusion into outpatient reimbursement compared to medicines with added therapeutic benefits.

Tendering practices are used primarily in the inpatient sector, with multiple-winner tenders in some cases to support supply security. In the inpatient sector, biosimilars are included in hospital formularies.

Doctors are requested to **prescribe** rationally (i.e., the **most economical alternative**), which implies biosimilar prescribing and switching. Austria has low implementation level of generic promotion policies (no reference price system, no prescribing by the International Non-Proprietary Name and no substitution in community pharmacy), so these measures are equally not applied for biosimilars.

Impact analysis

No study that analysed the impact of biosimilar policies was identified.

Barriers, facilitators and good practice examples

A key barrier to biosimilar uptake in Austria is the **fragmented healthcare system** with different organisation, funding and policy implementation for outpatient and inpatient sectors and no "interface measure" to bridge across sectors. Furthermore, Austria is one of the countries with **low levels of policy implementation for offpatent medicines**, and this lack of generic policies may also explain the few initiatives for biosimilar promotion. While Austria has implemented some pricing and

reimbursement policies targeted at biosimilars (e.g., defined rates for the biosimilar price link compared to the generic price link), some legal provisions have been introduced only on a temporary basis, which may create uncertainty for targeted stakeholders. The low implementation level of demand-side policies for off-patent medicines, including biosimilars, may also be one explanatory factor for **low biosimilar literacy** and **hesitancy towards biosimilar prescribing and switching**. Even the generic and biosimilar trade associations oppose demand-side measures such as INN prescribing or substitution. On the positive side, the Austrian Medicines Agency has in-depth knowledge on biosimilar marketing authorisation, since Austria frequently takes the role as reference member state in biosimilar approval in the decentralised procedure of the European Medicines Agency.

Recent developments

Until some years ago, Austria's price link policy requested the same amount of discounts for all off-patent medicines. In 2017, as part of a reform of the General Social Health Insurance Law, **specific (lower) price reductions for first and subsequent biosimilars** applying for inclusion in the outpatient reimbursement list were introduced, while the requested price reductions for generics were increased compared to the previous situation. This provision was only introduced on a temporary basis and prolonged twice, now valid until end of 2025. As of 2025, it is part of the current government plan to extend this temporary provision till end of the current government term.

Highlights and learnings

Austria showcases the importance of learnings and progresses made on generic policies, in particular related to demand-side measures. Since Austria has a low implementation of demand-side measures to encourage generic uptake, there is also limited leverage to expand generic policies to the field of biosimilars.

2 Key data regarding biosimilars in Austria in 2025

First biosimilar medicine launched (i.e. brought on the market):

To note that the first biosimilar approved by the European Medicines Agency (EMA), Somatropin (Omnitrope®) in 2006, was produced by Sandoz in Kundl (Austria) (Schiestl et al. 2018).

Number of the **biosimilars marketed**:
16 molecules with biosimilars available, as of 2021
46 biosimilars (per trade name), as of 2021
Source: Sandoz 2022

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

4.2% **in volume of total market** and in 2021
Volume is defined as units dispensed

0.5% **in value** of total market in 2021. **30% (outpatient) and 87% (inpatient)** market share in the biological market in 2021
Value is defined as x share of total pharmaceutical expenditure

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

2021 data: 35.6% of sales go to biologics, and among this group, the biosimilar shares amounted to slightly below 30% in the outpatient sector and 87% in the hospital sector.

Source: Sandoz 2022

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)*:

- Sandoz 2022 (Biosimilar-Barometer: https://austrianhealthreport.at/fachkreise)

3 Stakeholders involved in and targeted by biosimilar policies in Austria

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group related to biosimilars
Legislator	Bundesministerium für Arbeit Soziales, Gesundheit, Pflege und Konsumentenschutz (BMASGPK) / Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection	Legislative framework for policies related to price, reimbursement and use of biosimilars.	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group related to biosimilars
National regulatory authority	AGES Medizinmarktaufsicht / AGES Medicines & Medical Devices business segment	Regulatory authority, involved in marketing authorisation, quality assurance and pharmacovigilance	Website: BASG www.basg.gv.at/en/consumers/facts-worth-knowing-about-medicines/medicinal-products/biosimilars
Pharmaceu-tical pricing commission	Bundesministerium für Arbeit Soziales, Gesundheit, Pflege und Konsumentenschutz (BMASGPK) / Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection	Implements pricing policies. Monitoring the market to ensure that the prices of biosimilars remain fair.	
Pharmaceuti-cal reimburse-ment authority	Dachverband der österreichischen Sozialversicherungsträger / Austrian Social Health Insurance	Decides on inclusion of biosimilars into outpatient reimbursement list and their reimbursement price. Published a prescribing guideline (RöV) in 2005, which is also appliable for biosimilars	Richtlinie über ökonomische Verschreibweise: HVB 2005
Sickness funds		Fund outpatient medicines, disbursement, oversees rational prescribing	
Procurement agency	Bundesbeschaffungs GmbH (BBG) / Austrian Federal Procurement Agency	Involved in tenders and procurement procedures, but no role in biosimilar tenders	
HTA agency / body	Austrian Institute for Health Technology Assessment (AIHTA)	No role with regard to biosimilars	
National competition authority	Bundeswettbewerbsbehörde / Federal Competition Authority of Austria	Enforcement of the competition law, anti-trust cases. By now, no role with biosimilars	
National patent office	Österreichisches Patentamt / Austrian Patent Office	Granting and managing patents on biologic medicines	
Doctors	Österreichische Ärztekammer (ÖÄK) / Austrian Chamber of Physicians Medical societies related to disease with biological use: Österreichische Diabetes Gesellschaft (ÖDG) / Austrian Diabetes Association for Healthcare Professionals Österreichische Gesellschaft für Gastroenterologie und Hepatologie (ÖGGH) / Austrian Society of Gastroenterology and Hepatology Österreichische Gesellschaft für Hämatologie & Medizinische Onkologie (OeGHO) / Austrian Society for Hematology and Medical Oncology Österreichische Gesellschaft für Rheumatologie (ÖGR) / Austrian Society of Rheumatology	Doctors prescribe biosimilars in line with the guidelines	Hesitancy towards demand-side measures (generic substitution, INN prescribing) for generics: apm 2020

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group related to biosimilars
Nurses	Österreichischer Gesundheits- und Krankenpflegeverband (ÖGKV) / Austrian Nurses Association	No role with regard to biosimilars	
Community pharmacists	Österreichische Apothekerkammer/Austrian Chamber of Pharmacists Österreichischer Apothekerverband/Austrian Pharmacy Owners Association	Dispense medicines, inform patients	
Hospital pharmacists	Arbeitergemeinschaft Österreichischer Krankenhäuser / Austrian Association of Hospital Pharmacists (AAHP)	Support procuring medicines, inform patients / health professionals / procurers	
Patient organisations	Patienten- und Pflegeanwaltschaft / Patient and Care Advocacy Disease-specific patient organisations: Österreichische Diabetes Gesellschaft (ÖDG) / Austrian Diabetes Association Österreichische Morbus Crohn/Colitis ulcerosa Vereinigung / Austrian Crohn's and Colitis Association Österreichische Hämophilie Gesellschaft (ÖHG) Österreichische Krebshilfe / Austrian Cancer Aid Österreichische Rheumaliga / Austrian Rheumatology League Pro Rare Austria, Allianz für seltenen Erkrankungen	Patient organisations in diseases with particular biologics use a/o organisations with specific advocacy or education work on biosimilars	
Consumer organisations	Verein für Konsumenteninformation (VKI) / Austrian Consumers' Association		
Biosimilar industry	Biosimilarverband Österreich / Austrian Association of Biosimilar Medicine	Trade association to promote biosimilars	Information about biosimilars on its website, and information materials for patients (link to the EC publication, leaflet on rheuma and biosimilars, BIVÖ 2022) and for doctors (link to the doctors guideline by the Germany medical association): Biosimilarverband Opposition to introduction of INN prescribing: Generikaverband ÖGV 2020
Generic industry	Österreichischer Generikaverband (OEGV) / Austrian Association of Generic medicines	Previously host of the biosimilar association (same website).	Hesitancy towards specific demand-side measures for generic (and biosimilars), e.g. Austria aimed to introduced INN prescribing (in general) – this was opposed

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group related to biosimilars
Pharmaceutical industry in general	Vereinigung Pharmazeutischer Unternehmen (PHARMIG) / Austrian Association of Pharmaceutical Companies Fachverband der Chemischen Industrie Österreich (FICO)	Umbrella trade association for pharmaceutical industry in general. PHARMIG also includes biosimilar companies	Same hesitancy against INN prescribing or biosimilar substitution as the generic industry: Pharmig Pharmig 2022
Pharmaceutical industry for new biological medicines	Forum der forschenden pharmazeutischen Industrie in Österreich (FOPI) / The Association of the Research & Development based Pharmaceutical Industry in Austria	Some member companies (mainly originator companies) are also involved in biosimilar production	

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

4 Biosimilar policies and practices in Austria

Below, information on different biosimilar policies and practices is provided (and in some cases, also on further medicines, e.g., on generics or other biosimilars – presented in the grey shaded lines in the tables). 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 which apply for inclusion in the outpatient reimbursement list
Price reduction of the first biosimilar compared to the reference product	38%
Price reduction of the second, third and further biosimilars	The second biosimilar must be priced at least 15% lower than the first biosimilar that was included into outpatient reimbursement. The third biosimilar must be priced at least 10% below the previous biosimilars. Additional biosimilars must be priced 10 cents below the lowest priced medicine of that substance.
Price reduction for the reference product	Yes, the reference product must reduce its price by 30% three months after the first biosimilar has been included in the outpatient reimbursement list and it must lower the price to that of the cheapest included biosimilar 3 months after the inclusion of the third biosimilar in the list.
Any further specificities	The differentiated price reductions for generics and biosimilars were implemented in 2017 as a temporary measure, initially set to expire at the end of 2021, then extended until the end of 2023 and now until end of 2025.

Generic price link	Yes, in place, for generics which apply to be included in the outpatient reimbursement list The price of the first generic must be at least 50% lower than the price of the originator and the price of the second generic must be at least 18% lower than of the first generic (different rates than for biosimilars). The price of the third generic must be at least 15% lower than the lowest priced generic. Additional generics must be priced 10 cents below the lowest-priced medicine of that substance (same as for biosimilars). The originator must reduce its price by 30% three months after the first generic is included in the outpatient reimbursement list and it must lower the price to that of the cheapest included generic 3 months after the inclusion of the third generic in the list. (same as for biosimilars)

Source: PPRI 2025

External price referencing

External price referencing is applied for biosimilars.	No
If yes, it is applied for the following situations:	Not applicable
Any specificities	
External price referencing is in place for other medicines than biosimilars.	Yes, for new medicines in the outpatient sector for which reimbursement is sought

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 sector only Current legal situation does not allow tendering or tendering-loke processes in the outpatient sector
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	Several off-patent biological medicines
Institutional framework	Hospitals, hospital procurement groups, regional procurement bodies (e.g., provincial hospital funds), religious order hospitals with central procurement units
Information available on procurement procedures and practices	Primary award criterion is typically the price. Multiple-winner tenders are often used, especially for products where shortages have a severe impact (e.g., antibiotics, immunoglobulins).
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	No, not applicable
Institutional framework	No Tendering by the Austrian Social Insurance is not allowed
Information available on procurement procedures and practices	No
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes Outpatient: No

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

4.2 Reimbursement policies 2025

Reference price system

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	No RPS in place
If yes, how many and under which specifications	*Not applicable*
If publicly accessible, indicate URL of RPS list	*Not applicable*
When were first biosimilars included in the reference price system?	*Not applicable*
Any further specificities	*Not applicable*
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	No

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), 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	Not applicable since no percentage reimbursement rates
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	The process for including biosimilars in the outpatient reimbursement list involves a three-step evaluation by the Austrian Social Insurance: pharmacological evaluation, a medical-therapeutic evaluation and a health-economic evaluation. For biosimilar medicines aiming to be included into the reimbursement list, the standard evaluation processes apply but for biosimilar there is no health-economic evaluation but biosimilars need to be priced in relation to the originator price (biosimilar price link regulations) to be included in the reimbursement list.
Indicate URL of outpatient positive list	https://www.sozialversicherung.at/cdscontent/?contentid=10007.844481
Co-payments for biosimilars for outpatient use	Same as for any other medicines
<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	Positive list (Erstattungskodex, EKO) Percentage reimbursement rates are not applied Fixed prescription fee of €7.55 (as of 2025), no percentage co-payment or deductibles

Co-payments for reimbursable outpatient medicines	
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	There are no specific shorter timelines or less tightened criteria for biosimilars compared to other medicines.
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	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	No co-payments for medicines for inpatient use

Source: PPRI 2025, Vogler 2022, Vogler, Haasis and Zimmermann 2024

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 special pricing, procurement and reimbursement models for biosimilars (e.g., delinkage / subscription-model, management-entry agreements (MEA))	No
Enforcement of anti-trust policies	No specific examples known
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Pre-dominantly financial MEAs and some performance-based MEAs

Source: PPRI 2025, DG Competition 2024

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, sometimes Validation with Social Insurance and hospital payers ongoing
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	While Austria's current horizon scanning system (done by the Austrian HTA Institute, AIHTA) is focused on new medicines in oncology, Austrian authorities are part of IHSI (International Horizon Scanning Initiative) which allows also for scanning for loss of exclusivity.

Source: PPRI 2025

Health technology assessment

HTA is applied for biosimilar medicines	No, no full HTA process
If yes, in which situations and settings (outpatient and inpatient)	Outpatient: In principle, the HTA process of the outpatient process involves three steps: a pharmacological evaluation, a medical-therapeutic evaluation and a health-economic evaluation. For biosimilar medicines aiming to be included into the reimbursement list, the standard evaluation processes apply but for biosimilars there is no health-economic evaluation but biosimilars need to be priced in relation to the originator price (biosimilar price link regulations) to be included in the reimbursement list.
Differences in criteria and processes of HTA for biosimilars compared to other medicines	Outpatient: see above Inpatient: no full national-wide HTA process for medicines, including biosimilars (only high-cost medicines in hospitals and at the interface are subject to a new HTA process labelled as "Appraisal Board")
Any specificities	

Source: PPRI 2025, Vogler 2022

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Country context: Only doctors may prescribe

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes Austrian prescribing guidelines do not address specifically biosimilars but request rational (economic) prescription by the doctors. They were issued by the Austrian Social Insurance in 2005 (before the first biosimilar was marketed) and are targeted at doctors in the outpatient sector, but it has also been argued that these guidelines (RöV) are also relevant for the inpatient sector (however, different rules with regard to hospital pharmaceutical formularies exist). These RöV guidelines request that doctors prescribe the most economical medicine out of several therapeutically similar alternatives. Biosimilars are not explicitly mentioned, but due to the pricing and reimbursement policies these medicines will likely be the lowest-priced medicines per substance. In addition, the Medicines Agency published a statement on prescribing and switching in 2017: "Biosimilars are hightech

	and high quality products. They are authorized within the framework of European centralized procedures, tested according to highest state-of-the-art knowledge and are assessed to strictest and up-to-date points of view. Prescribing biosimilars to treatment-naïve patients as well as even an exchange of the biosimilar or an originator biological is appropriate, provided that this is done under supervision of the prescribing physician. Data from recent studies, and from safety monitoring and pharmacovigilance trials, are already leading us in a positive direction towards increased biosimilar uptake and interchangeability as well. We expect pronounced evidence to increase even further in the months and years to come." (quoted in Baumgärtel 2017).
If yes, what is recommended for naïve patients?	See above. Social Insurance: There is no explicit recommendation to prescribe biosimilars for naïve patients, but if biosimilars are the most economical alternative (which they will mostly be), then they are requested to do so. Medicines Agency: Prescribing biosimilars for naïve patients is appropriate.
If yes, what is recommended for patients already on biologic treatment	See above. Social Insurance: There is no explicit recommendation to switch, but if biosimilars are the most economical alternative (which they will mostly be), then doctors are requested to switch (for economic reasons). However, doctors are asked to decide on a case-by-case basis. Medicines Agency: Switching is appropriate if it is done under the supervision of a doctor.
Prescription guidelines (including switching guidelines) were issued by	Austrian Social Insurance Medicines Agency
URL of prescription & switching guidelines	Guidelines on the economic prescription of medicines and therapeutic aids [Richtlinien über die ökonomische Verschreibweise von Heilmitteln und Heilbehelfen (RöV 2005)] www.ris.bka.gv.at/Dokumente/Avsv/AVSV_2005_0005/AVSV_2005_0005.html Medicines Agency statement – quoted in Baumgärtel 2017
Prescribing quotas	
Prescribing quotas for doctors with regard to prescription of biosimilars exist	No While the prescribing behaviour of doctors is monitored by the sickness funds (whether the prescriber adheres to the guidelines to prescribe economically), there are no quotas.
If yes, which quotas are defined for biosimilars	*Not applicable*
Any exemptions	*Not applicable*
Any sanctions in case of non-achievement	*Not applicable* In case of non-compliance with prescribing guidelines, the sickness funds may get in contact with the respective doctors and issue a reprimand.
Any (financial) incentives for achieving the quotas	*Not applicable*
Prescribing quotas were issued by	*Not applicable*
URL of prescribing quotas	*Not applicable*
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)	*Not applicable*
Publicly accessible information	*Not applicable*

INN prescribing	
In general, prescribing by INN is place (information not focused on biologics)	No, not allowed
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	*Not applicable since INN prescribing is not allowed.*
Further measures targeted at doctors	
Information materials for doctors	Mainly from the Austrian Social Insurance, particular from sickness funds. A working group of departments in the sickness funds collaborating on responsible use have been issuing for years a newsletter of their doctor ("Konsenus Heilmittelökonomie"), in which they report about spending development and savings due to loss of exclusivity. Information on biosimilars is also available in some cases (see https://www.gesundheitskasse.at/aussendungen). Some information is available at the website of the Biosimilars Association Austria (BiVÖ). Particularly for doctors, the BIVÖ refers to the guideline of the German medical association.
Information events for doctors (e.g., seminars, trainings)	Yes. In the literature, an information event organised by the Austrian Social insurance and the Medicines Agency for outpatient and hospital doctors on biosimilars in 2012 was reported.
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	No switching studies known for Austria

Source: PPRI 2025, HVB 2005, Vogler, Haasis and Zimmermann 2024, Baumgärtel 2013, Baumgärtel 2017

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense.

Substitution policies	
(Automatic) substitution for biosimilars	Not, not allowed
If yes, for which biologic substances and under which prerequisites?	Not applicable
If yes, since when, and when was it extended? (process of implementation)	Not applicable
Any specificities	Not applicable
URL of underlying law	Not applicable
Generic substitution in place	No, not allowed
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)	Not applicable
Publicly accessible information	Not applicable
Further measures targeted at pharmacists	
Information materials for pharmacists	Yes, the materials are issued by the Federal Office for Safety in Health Care (BASG), the Austrian Chamber of Pharmacists, and the Biosimilars Association Austria (BiVÖ).
Information events for pharmacists (e.g., seminars, trainings)	Yes, the Biosimilars Association Austria (BiVÖ) and other stakeholders organise events to raise awareness and educate healthcare professionals about biosimilars.

Source: PPRI 2025

Patients

Information and educational measures	
Information materials for patients	Yes
If yes, provide URL of most common materials	Medicines Agency – general information: www.basg.gv.at/en/consumers/facts-worth-knowing-about-medicines/medicinal-products/biosimilars Information leaflet: https://www.basg.gv.at/fileadmin/redakteure/05_KonsumentInnen/Generika_und_Biosimilars/Patienteninfo_Biosimilars.pdf BIVÖ: https://biosimilarsverband.at/biosimilars/infos/
If yes, key producers of education measures	Some information provided by the Austrian Social insurance and its sickness fund, the Federal Office for Safety in Health Care (BASG) and the Biosimilars Association Austria (BiVÖ), e.g., with reference to materials of the EC for patient information
Information events for patients (e.g., seminars, trainings)	No (no information events are known)
If yes, key providers of educational events	Not known
Gain-sharing models	
Gain-sharing models for patients	No
If yes, pls. describe	*Not applicable*
Publicly accessible information	*Not applicable*

Source: PPRI 2025, website of the institutions

5 Impact of biosimilar policies and practices in Austria

This section aims to inform 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.

No literature could be identified for Austria.

6 Barriers for biosimilar uptake and policy implementation in Austria

Legal barriers

In Austria, there is some legal uncertainty because the biosimilar price link was first introduced on a temporary basis and then prolonged twice. At the time of the study, it would expire at the end of 2025, but the current government plan provides that it should run till the end of government term (2029).

According to Austrian law, tendering by the Austrian Social Insurance is not allowed. Thus, tendering-like procedures may not be implemented at the moment by the sickness funds in the outpatient sector.

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

Austria's health care system is fragmented, with different competences and funding responsibilities for outpatient and inpatient sectors (Bachner et al. 2024, BMSGPK 2019; Vogler, Haasis und Zimmermann 2024). This fragmentation can hinder the cohesive implementation of policies, also in the area of biosimilars uptake.

Austria is not a large country, which may constitute a barrier for market entry. In the literature, no empirical data on the availability of medicines in Austria have been published to confirm or contest this assumption.

Financial barriers

No information on potential financial barriers is available. There are no policies with financial incentives (e.g., gainsharing) in place, but this may rather be attributable to other rationale than budgetary consideration.

Evidence and communication-related barriers

Some stakeholder groups (e.g., doctors, and also biosimilar industry) have voiced strong opposition to some demand-side policies to promote the uptake of off-patent medicines (not yet introduced for generics in Austria); see also below stakeholder-related barriers. This heated discussion and communication in the public has not been favourable to improving awareness for potential contributions of biosimilars and policies to encourage their use.

Policy-related barriers

Some demand-side measures, such as INN prescribing or substitution, are not allowed in Austria, not even for generics, which likely makes a long and though way for their implementation for biosimilars. Also, in contrast to other countries, Austria cannot build on learnings from demand-side measures for generic promotion, in case of moving forward in encouraging biosimilar uptake.

Stakeholder-related barriers

There is strong biosimilar hesitancy on behalf of the stakeholders. According to a small survey with the specialist doctors, more than one third of the doctors justify this preference to reference products by pointing to good experience with the originator biologicals, and a quarter of the surveyed doctors stated that for the required active substances no biosimilars have yet been launched (Sandoz 2022).

Another potential barrier is the opposition of biosimilar industry to key demand-side measures such as prescribing by International Non-Proprietary Name and

substitution in community pharmacy. The opposition has been voiced against potential introduction of these measures for generics (BiVÖ 2022, Pharmig 2022), and while it is not yet been publicly discussed for biosimilars, it is likely to be met with even more fierce opposition.

In addition, the doctors' association has also raised strong opposition to these demand-side measures (apm 2020).

7 Facilitators and good practice examples in Austria

Despite a challenging environment for biosimilars, the Austrian Medicines Agency (AGES Medizinmarktaufsicht), which has extensive knowledge about biosimilars, has launched some activities. AGES Medizinmarktaufsicht is also a leading reference member state on approvals for biosimilars in the decentralised marketing authorisation procedure). For instance, the Austrian Medicines Agency published an official statement in 2017 by taking a positive stance towards biosimilar interchangeability. The agency has supported the prescribing of biosimilars to treatment-naïve patients and the switching from originator biologics to biosimilars under physician supervision. This policy is seen as a success factor because it aligns with clinical evidence and provides clear guidance to health care providers, thereby promoting the use of biosimilars (Baumgärtel 2017).

Since early times of biosimilars, Austrian authorities and payers (Austrian Medicines Agency, Austrian Social Insurance) have sought the dialogue with doctors (Baumgärtel 2013).

In addition, the 2017 reform of the Austrian Social Insurance Law to introduce differentiated price reduction rates for biosimilars and generics has been generally acknowledged.

8 Developments in Austria

Recent changes

Until some years ago, Austria's price link policy requested the same extent of discounts for all off-patent medicines. In 2017, as part of a reform of the General Social Health Insurance Law, the rates for price reductions were changed and since then differ between biosimilars and generics. Lower price reductions for first and subsequent biosimilars aiming to be included in the reimbursement list have since then been applied compared to the requested price reductions for generics. This provision was introduced on a temporary basis and was scheduled to expire end of 2021. First prolonged till end of 2023, the legislation was prolonged in 2023 for another two years.

Plans or under discussion

The current government plan, agreed upon in 2025, includes the government goal, to expand the price link legislation until the end of their government term (BKA 2025).

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