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

AUGMENT Biosimilars
Country fiche GERMANY

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augment biosimilars

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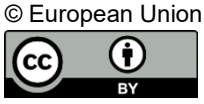

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Annex 7.11

AUGMENT Biosimilars country fiche: Germany 2025

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

The AUGMENT Consortium produced this country fiche as part of the project "Capacity building to support the uptake of biosimilars in a multistakeholder approach (HADEA/2023/OP/0040)" commissioned by the European Health and Digital Executive Agency (HaDEA). The AUGMENT Consortium consists of the Austrian National Public Health Institute (Gesundheit Österreich Forschungs- und Planungs GmbH / GÖ FP), as consortium lead; the Polish Agency for Health Technology Assessment and Tariff System (Agencja Oceny Technologii Medycznych i Taryfikacji / AOTMiT), the Medical University Sofia (MUS), and the NOVA National School of Public Health in Lisbon.

In this project (abbreviated AUGMENT Biosimilars project), the AUGMENT Consortium performed a **comprehensive study** which aimed to offer a **mapping and** an **analysis of existing policies and practices** to encourage biosimilar uptake and competition in 32 European countries (all European Union (EU) and European Free Trade Association (EFTA) Member States, and the United Kingdom). In the analysis, the impact of biosimilar policies on improving patient access to medicines as well as barriers and facilitators in the policy implementation will be studied. For further information see biosimilars.goeg.at.

Key terms related to biosimilar policies can be found in the project's Glossary.

Contributors

This country fiche was produced by GÖ FP based on information the PPRI network was used, and findings from systematic and narrative literature reviews.

We gratefully acknowledge the validation of this country fiche by:

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1 Summary of biosimilar policies and practice in Germany 2025

Key stakeholders

Major institutions in the public sector with regard to biosimilars are the **Medicines Agency BfArM** and the **Paul Ehrlich Institute PEI**, which publish regularly updated lists of biosimilars that are included in Germany's internal reference price system. The higher HTA body, the **Joint Federal Committee** (Gemeinsamer Bundesausschuss / G-BA), is tasked with updating the pharmaceutical guideline targeting both doctors for economic prescribing as well as community pharmacists regarding the provisions for biosimilar substitution. In Germany's fragmented health care sector, the (regional) **sickness funds** act as public payers (and procurers) and also steer prescribing behaviour. Among the doctors, the Drug Commission **of the German Medical Association** has been active on informing prescribers. The generic (and biosimilar) medicine industry association has a working group dedicated to biosimilars (**ProBiosimilars**).

Major biosimilar policies and practices

Germany has **no biosimilar price link**. Biosimilars for inpatient use are **procured by hospitals**, frequently through hospital purchasing groups, whereas biosimilars for outpatient use are often procured through **tendering-like procedures by the sickness funds**. In these tendering-like procedures, called "**Rabattverträge**" (discount agreements), the winning active ingredient is granted the contract with the respective sickness fund (each sickness funds manages its own discount agreements). For biosimilars, the less competitive variant of "**open house contracts**" is also applied, whereby sickness funds define and publish the discount rate in advance and the companies are invited to join the contract if they accept that rate. Aligned with the regional Associations of Statutory Health Insurance Physicians, regional associations of the sickness funds set **prescribing targets**, including for biosimilars, but there is high variation across sickness funds in the scope of biosimilars under these targets and the extent of discounts. Overall, doctors are mandated to prescribe economically, and this also includes starting a treatment with a biosimilar should it be less expensive and switching to a less expensive biosimilar. Some sickness funds incentivize doctors through **gain-sharing** models. Prescribing by International Non-Proprietary Name is not allowed. Biosimilars may be included in the internal **reference price system**, and in these cases patients have to co-pay the price difference up to a higher priced biological if they insist on being dispensed that medicine. In general, all pharmaceutical companies lower the prices to the level of the reference price. **Biosimilar substitution** at community pharmacy level is allowed for a few defined medicines for parental use.

Impact analysis

Several studies and analyses show the **achieved savings for public payers** through biosimilars and expected savings in case of increased uptake, but these estimates are not always linked to specific policies. Some studies analysed savings

which could be gained if some policies (e.g., biosimilar substitution) had been introduced at an earlier stage or in a different design.

Some studies analysed **biosimilar uptake across German regions**. **Large variation** was observed, and this was attributed to different approaches of the regional sickness funds, in particular regarding demand-side measures.

Barriers, facilitators and good practice examples

Overall, biosimilar policies are **quite advanced** in Germany, and this may facilitate uptake. However, there is **fragmentation in the health care system**, with a variety of sickness funds with different procurement and demand-side policies regarding biosimilars.

Despite information and capacity-building measures, **gaps in knowledge** about biosimilars were identified with doctors and pharmacists.

Recent developments

After a long preparatory time and delays in implementation due to stakeholder opposition, biosimilar substitution was introduced in March 2024.

Highlights and learnings

While Germany has an **advanced biosimilar policy landscape**, also resulting in high uptake, **regional variation** in policy implementation also impact to biosimilar uptake.

2 Key data regarding biosimilars in Germany

First biosimilar medicine launched (i.e. brought on the market): Somatropin in January 2006
Source: Medicines for Europe 2023

Number of the **biosimilars marketed**:
70 biosimilars (of 20 active ingredient), as of April 2023
Source: Probiosimilars 2024

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

Biosimilar market shares in volume (expressed in DDD) 2023:
16.1% of biological market (excl. insulins and vaccines) and 7.64% of biological market (incl. insulins and vaccines)
0.25% of total reimbursement market (GKV)

Biosimilar market shares in value (expressed in euro) 2023:
16.1% of biological market (excl. insulins and vaccines) and 13.2% of biological market (incl. insulins and vaccines)
4.47% of total reimbursement market (GKV)

On average, 72% in volume (in DDD) for these biological active substances where biosimilar competition exists (however, variation across molecules and across German regions)

Source: Probiosimilars 2024

Key national publicly accessible sources reporting data on biosimilars

- Biosimilar medicines included in the internal reference price system ("Festbetragssystem"): https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/...node.html (latest update: 15 January 2025: https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/amInformationen/Festbetraege/2025/....)
- Anlage VIIa zum Abschnitt M der Arzneimittel-Richtlinie Biotechnologisch hergestellte biologische Referenzarzneimittel und im Wesentlichen gleiche biotechnologisch hergestellte biologische Arzneimittel nach § 129 Absatz 1a Satz 3, 5 und 6 SGB V : https://www.g-ba.de/richtlinien/anlage/290/

3 Stakeholders involved in and targeted by biosimilar policies in Germany

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Bundesministerium für Gesundheit (BMG) / Ministry of Health	Prepares legislation, including the legal mandate for biosimilar substitution	-
National regulatory authority	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) / Federal Institute for Drugs and Medical Devices; Paul Ehrlich Institute (PEI) / Federal Institute for Vaccines and Biomedicines	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance. BfArM to maintain the list of biosimilars include in the internal reference price system. Information material on biosimilars. PEI responsible for for vaccines and some biological medicines.	Interchangeability (BfArm 2022a) Biosimilars marketing authorisation (BfarM 2022b) Biosimilar workshop Biosimilar conference Biosimilar fellows
Pharmaceutical pricing authority	Gemeinsamer Bundesausschuss (GBA) / Federal Joint Committee	Establishes the reference groups ("Festbetragsgruppen") and decides on which biosimilars to include into a reference group. Maintains and updates the Pharmaceutical Guideline, containing provision for prescribing and dispensing (substitution)	Pharmaceutical Guideline for prescribing medicines in the provision by contract doctors
Pharmaceutical reimbursement authority	GKV Spitzenverband / National Association of Statutory Health Insurance Funds		
Public payers	Sickness Funds	Run tendering-like procedures ("Rabattverträge") with biosimilar manufacturers	
Procurement agency	Not applicable. There are four federal centralised procurement bodies, but none for the procurement of medicines.		
HTA agency / body	Lower HTA body: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) / Institute for Quality and Efficiency in Health Care; Higer HTA body: Gemeinsamer Bundesausschuss (GBA) / Federal Joint Committee	IQWIG conducts HTA (not relevant, no HTA for biosimilars). For G-BA see above.	Pharmaceutical Guideline for prescribing medicines in the provision by contract doctors Biologicals and biosimilars: Interchangeability of biotechnologically produced medicines
National competition authority	Bundeskartellamt	Enforces anti-trust legislation, including mergers that could prevent biosimilar competition.	Approval of a merger
National patent office	Deutsches Patent- und Markenamt / German Patent and Trade Mark Office	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Bundesärztekammer (BÄK), hosting its scientific committee: Arzneimittelkommission der deutschen Ärzteschaft (AkdÄ) / Drug Commission of the German Medical Association *Medical societies:* • Deutsche Diabetes Gesellschaft (DDG) / German Diabetes Society • Deutsche Gesellschaft für Gastroenterologie,	Prescribe biosimilars. Inform patients about biosimilars. Several medical societies in disease areas with biologics use identified (see left) Drug Commission of the German Medical Association has been commented on the biosimilar policies and producing information materials (guideline).	Guideline of the Drug Commission of the German Medical Association, 2nd edition of January 2021 (1st edition of 2017) At their website patient information by ÄZQ (ÄZQ 2024)

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
	Verdauungs- und Stoffwechselkrankheiten (DGVS) / German Society of Gastroentero-logy • Deutsche Gesellschaft für Hämatologie und Medizinische Onkologie (DGHO) / German Society for Hematology and Medical Oncology • Deutsche Gesellschaft für Rheumatologie (DGRh) / German Society for Rheumatology • Seltene Erkrankungen (Nationale Allianzen) / National Alliance for Rare Diseases		
Nurses	*Represented by:* Deutscher Berufsverband für Pflegeberufe (DBfK) / German Nurses Association		
Community pharmacists	*Represented by:* Bundesvereinigung Deutscher Apothekerverbände (ABDA) / Federal Union of German Pharmacists Associations	Dispense medicines (according to "discount agreement" of the respective sickness funds), inform patients, may substitute biosimilars (defined cases)	Negative statements on planned biosimilar substitution (latest published statement of 2022)
Hospital pharmacists	*Represented by:* Bundesverband Deutscher Krankenhausapotheker (ADKA) / German Society of Hospital Pharmacists	Involved in the procurement of biosimilars for the inpatient sector via tendering, inform patients.	Statement of the relevance of hospital pharmacists with regard to biosimilars
Patient organisations	*Represented by:* BundesArbeitsGemeinschaft der PatientInnenstellen (BAGP) Deutsche Arbeitsgemeinschaft Selbsthilfegruppen e.V. *Represented by disease specific associations:* • Deutsche Diabetes-Hilfe / German Diabetes Association • Deutsche Morbus Crohn / Colitis ulcerosa Vereinigung e.V. (DCCV) / German Crohn's and Colitis Association • Deutsche Leukämie- und Lymphomhilfe e.V. • Deutsche Hämophilie Gesellschaft (DHG) / German Hemophilia Society • Deutsche Krebshilfe / German Cancer Aid • Deutsche Rheuma-Liga Bundesverband e.V. / German Rheumatism League • BAG Selbsthilfe / Federal Association of Self-Help Organisations for people with disabilities and chronic diseases and their relatives	Patient organisations in diseases with particular biologics use and organisations with specific advocacy or education work on biosimilars identified (see left).	
Consumer organisations	*Represented by:* Verbraucherzentrale Bundesverband – vzbv Stiftung Warentest		
Biosimilar	*Represented by:*	Produces market data,	Biosimilars in figure

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
industry	AG Pro Biosimilars (a working group of Pro Generika)	information activities on biosimilars, publishes statements on biosimilar policies	2023 (Probiosimilars 2024) Statement against biosimilar substitution (2014)
Generic industry	*Represented by:* Pro Generika	Association of manufacturers of generics and biosimilars (biosimilar manufacturers are represented in a specific working group)	See above
Pharmaceutical industry in general	*Represented by:* Pharma Deutschland (till 3/2024 called Bundesverband der Arzneimittel-Hersteller (BAH) Bundesverband der Pharmazeutischen Industrie e.V (BPI) / Federal Association of the Pharmaceutical Industry Verband Forschender Arzneimittelhersteller e.V. (VFA) / German Association of Research-Based Pharmaceutical Companies		
Pharmaceutical industry for new biological medicines	*Several represenations:* • BIO Deutschland • BIO.NRW / Network of the Biotechnology in North Rhine-Westphalia • Verband der Chemischen Industrie e.V. (VCI)		

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

4 Biosimilar policies and practices in Germany 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.	No, not in place.
It applies for the following situations:	Not applicable as not in place.
Price reduction of the first biosimilar compared to the reference product	
Price reduction of the second, third and further biosimilars	
Price reduction for the reference product	
Any further specificities	
Generic price link	No, not in place.

Source: PPRI 2025

External price referencing

External price referencing is applied for biosimilars.	No, not in place
If yes, it is applied for the following situations:	Not applicable as not in place.
Any specificities	

External price pricing is in place for other medicines than biosimilars.	No, not as a rule, but for new medicines with added therapeutic benefit in case of the arbitration procedure process if the negotiation between reimbursement authorities (GKV-Spitzenverband) and company has failed

Source: PPRI 20255 Vogler 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: Tendering at facility level (i.e. performed by hospitals or hospital purchasing groups). Outpatient sector: Tendering-like with open house contracts.
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	Depending on facility.
Institutional framework	On the level of individual facilities, frequently supported by purchasing groups
Information available on procurement procedures and practices	-
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	Some but not all biosimilars are tendered by sickness funds (so-called "discount contracts" / "Rabattverträge), variation in the scope of biosimilars tendered between sickness funds
Institutional framework	A system of tendering for off-patent medicines in the outpatient sector: so-called discount contracts ("Rabattverträge"), they started for generics more than a decade ago and were then extended to biosimilars. Sickness funds launch a tender for an active ingredient, and the winning company is granted a "**discount contract**". In return for granting discounts on their products, manufacturers can benefit from exclusive dispensing of their medicines. In the community pharmacy, the medicines which won the tender must be supplied for the customers of the respec-tive sickness funds. However, it should be noted that, by law, sickness funds (both public and private) under the statutory health insurance are requested to compete; thus, each sickness fund launches its own tenders, and companies may be winners with the different procurers. Thus, a community pharmacy will be obliged to supply different medicines of the same active ingredients to customers of different sickness funds. For biological substances, some sickness funds perform less competitive procedures in the form of "open house contracts": Under this tendering procedure, a sickness fund specifies in advance and published the discount rate and to a contract at this discount rate to all competing suppliers that are willing to join this contract, and no individual negotiations are concluded.
Information available on procurement procedures and practices	Award by active substance, winning prices are visible for competitors in the open house system. Price is the sole award criterion
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes. Outpatient: Yes

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

4.2 Reimbursement policies 2025

Reference price system

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	Yes, RPS includes generics and biosimilar medicines.
If yes, how many and under which specifications	Some but only not all biosimilar medicines
If publicly accessible, indicate URL of RPS list	BfArM - Arzneimittel-Festbeträge: https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Festbetraege-und-Zuzahlungen/Festbetraege/_node.html
When were first biosimilars included in the reference price system?	Since 2009
Any further specificities	Same specificities as for the RPS in general, with broader clusters than ATC-5 (see below). Internal reference price is established on the basis of the average price of biosimilar medicines.
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	Yes, RPS in place, broader clusters than ATC-5. There are three types of reference price groups: a reference group is established to include medicines of 1) the same active ingredients (reference group type 1), 2) of comparable pharmacological-therapeutical ingredients (reference group type 2), or 3) of therapeutically comparable effect (reference group type 3)

Source: PPRI 2025, BfArM 2025, Vogler et al. 2021, Vogler et al. 2021, Vogler et al. 2025, Vogler 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).	Germany has no positive list. In principle, all medicines are reimbursed except those included in the negative list. This applies to biosimilars.
If yes, how many and date of inclusion into reimbursement, if known)	
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	100% coverage for reimbursable medicines, unless those included in the reference price system
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	No
Indicate URL of outpatient positive list	https://www.g-ba.de/richtlinien/anlage/9/ (negative list)
Co-payments for biosimilars for outpatient use	Yes, fixed amount per prescription/pack (co-payment of 10%, max. 10 euro, min. 5 euro). No difference in co-payment compared to reference product.
For medicines for outpatient use in general (other medicines than biosimilars) Positive list for medicines in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	A national negative list is in place. Full (100%) coverage for all medicines in reimbursement. Co-payments are charged for funded medicines in the outpatient sector (see above).
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes, they may be included.

Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	No
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	Not publicly accessible.
Co-payments for biosimilars for inpatient use	No
For medicines for inpatient use in general (other medicines than biosimilars): Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	No national and/or regional /list list(s), but hospital pharmaceutical formularies at hospital level. No co-payments for medicines for inpatient use.

Source: PPRI 2025, Vogler 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))	Tendering-like procedures for off-patent biological medicines, like for other off-patent medicines (> 90% of biosimilar prescriptions in 2023 were under a "discount contract"))
Enforcement of anti-trust policies	No cases known, but consideration of competitive action (e.g., during approval of a merger)
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Tendering-like procedures for off-patent medicines (see above)

Source: PPRI 2025, Probiosimilars 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, 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	Not applicable as not in place.

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

Health technology assessment

HTA is applied for biosimilar medicines	No, no HTA for biosimilars
If yes, in which situations and settings (outpatient and inpatient)	Not applicable as not used.
Differences in criteria and processes of HTA for biosimilars compared to other medicines	
Any specificities	

Source: PPRI 2025, Craddy 2022

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Country context: Only doctors may prescribe medicines.

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes, in place. Use and switching are recommended, but physicians and patients can opt out. Switching is recommended when done in conjunction with continuous monitoring. In line with the Pharmaceutical Guideline by the G-BA (see below).
If yes, what is recommended for naïve patients?	In line with Pharmaceutical Guideline by the G-BA, which requests economic prescribing, thus treatment should be started with a biosimilar if less expensive is recommended.
If yes, what is recommended for patients already on biologic treatment	In line with Pharmaceutical Guideline by the G-BA, which requests economic prescribing, thus switching the prescription to a biosimilar if less expensive.
Prescription guidelines (including switching guidelines) were issued by	Pharmaceutical Guideline for prescribing medicines in the provision by contract doctors issued (and updated) by the Joint Federal Committee (G-BA) request economical prescription of biotechnologically manufactured biological medicines.
URL of prescription & switching guidelines	Pharmaceutical Guideline by the Joint Federal Committee (§ 40a)
Prescribing quotas	
Prescribing quotas for doctors regarding prescription of biosimilars exist	Yes, pharmaceutical agreements with prescription quotas and selective contracts (integrated contracts) in place.
If yes, which quotas are defined for biosimilars	Medicines under prescription quota and the extent of the target differ considerably per per regional Associations of Statutory Health Insurance Physicians. The biologicals most commonly subject to regional prescription targets are epoetins, infliximab, and etanercept, as well as oncologic biosimilars for rituximab and trastuzumab.
Any exemptions	-
Any sanctions in case of non-achievement	-
Any (financial) incentives for achieving the quotas	"Integrated care contracts" between individual sickness funds and individual providers, their networks or professional bodies (so-called selective contracts). Patients enrolled in such contracts have to use participating providers, who are in turn expected to prescribe biosimilars as a preferred option. Rheumatologists working under the 2018 specialist contract with the "Techniker Krankenkasse," one of Germany's largest sickness funds, have a 60% biosimilar prescribing target for etanercept and 80% for infliximab and rituximab infusions.
Prescribing quotas were issued by	Large variations among regional Associations of Statutory Health Insurance Physicians
URL of prescribing quotas	-
Prescribing quotas for other non-biosimilar medicines exists	Yes, for generics
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	Yes, they have been implemented by some sickness funds.

If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced) Publicly accessible information	E.g. BioLike initiative, launched by the insurer company Barmer GEK for gastroenterologists and rheumatologists in different regions (e.g., Hamburg, Saarland, Saxony, Schleswig-Holstein, Thuringia, Westphalia-Lippe). This initiative has led to an increased use of TNFα inhibitor biosimilars and has allowed sharing the realized savings through biosimilar prescriptions between groups of prescribers and the insurer companies. Another example concerned benefit-sharing contracts between the Professional Association of German Rheumatologists (BDRh) and several health insurance companies, resulting in an enrolment of 12,000 patients, data of 2017). The gain-sharing model aimed in involved multiple sickness funds and to be rolled out country-wide.
INN prescribing	
In general, prescribing by **INN is in place** (information not focused on biologics)	Yes, in place.
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	Not permitted for biologics. Biosimilars are prescribed by trade name.
Further measures targeted at doctors	
Information materials for doctors	Guideline of the Drug Commission of the German Medical Association, 2nd edition of January 2021 (1st edition of 2017) to support prescribers.
Information events for doctors (e.g., seminars, trainings)	Trainings and seminars for physicians by the regional medical associations (Landesärztekammern)
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	

Source: PPRI 2025, Barcina Lacosta et al. 2022, G-BA 2025a, AkdÄ 2021, Luley and Pieloth 2018, Moorkens et al 2022 Vogler, Habimana, Salcher-Konrad 2022,

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense.

Substitution policies	
(Automatic) substitution for biosimilars	Allowed for defined biosimilars
If yes, for which biologic substances and under which prerequisites?	Based on a G-BA guideline which, for the time being, addresses those medicines that are prepared by community pharmacies upon medical prescription and which are administered parenterally (e.g., infusion, injection) by the doctors. It concerns both biological originators as well as biosimilars: namely for the active substances of bevacizumab, eculizumab, infliximab, rituximab, tocilizumab and trastuzumab.

If yes, since when, and when was it extended? (process of implementation)	The underlying law was implemented on 15 March 2024. Long preparatory process: The underlying legal mandate to allow biosimilar substitution in community pharmacy was passed in 2019, and implementation was planned for beginning in 2022. A prerequisite for implementation was that the Federal Joint Committee (G-BA) would have determined the interchangeability of the respective medicines (and that the prescribing physician would not explicitly biosimilar substitution). However, another law (GKV Financial Stability Law, July 2022) decided to postpone implementation by another year (2023).
Any specificities	In principle, substitution for a lower-priced medicine. The substituting medicine must comply at least for the modes of and at least for the indications of the prescribed medicine. If a biological medicine (biological originator or biosimilar) is subject to a "discount contract", then it is automatically assumed to the most economic prescription, and will be dispensed. In addition to the prescriber (exclusion for medical-therapeutical reasons), the pharmacy may also exclude substitution (acknowledging patient relevant aspects, e.g., adverse reactions in the past, allergies). To note that this legal mandate for biosimilars adds to the possibility of substituting "bioidentical biologicals "(e.g., same manufacturing site but marketed as different medicines existed for years).
URL of underlying law	Gesetz für mehr Sicherheit in der Arzneimittelversorgung (GSAV) 2018
Generic substitution in place	Yes, mandatory.
Gain-sharing models	
Gain-sharing models for pharmacists	No, not in place.
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	Not applicable as not in place.
Publicly accessible information	
Further measures targeted at pharmacists	
Information materials for pharmacists	
Information events for pharmacists (e.g., seminars, trainings)	

Source: PPRI 2025, G-BA 2024a, G-BA 2024b, Sucker-Sket 2025, Vogler et al. 2021, Vogler et al. 2025

Patients

Information and educational measures	
Information materials for patients	Information materials by BfArM (general information) and ÄZQ (patient information)
If yes, provide URL of most common materials	BfarM 2022a, BfArM 2022b ÄZQ 2024
If yes, key producers of education measures	
Information events for patients (e.g., seminars, trainings)	
If yes, key providers of educational events	

Gain-sharing models	
Gain-sharing models for patients	No, not in place. But the inclusion of biosimilar medicines in the "Festbetragssystem" (reference price system) offers financial advantages for patients using the lower-priced medicines (relevant for the outpatient sector only)
If yes, pls. describe	Not applicable as not in place.
Publicly accessible information	

Source: PPRI 2025, BfarM 2022a, BfArM 2022b, ÄZQ 2025

5 Impact of biosimilar policies and practices in Germany

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 Germany

Outcome indicator	Caused by	Findings	Publication
Realisation of potential savings for Germany	Introduction of specific biosimilar policies (e.g., biosimilar price link) or change in the design of a policy (reference price system) or use of lowest prices in Europe	The study investigated the savings potential of biologicals for the public expenditure if in the year 2018 certain policies had been in place. The largest savings potential was the assumption of the use of the price of the lowest-priced European country (instead of the German price) = 55.7& price reduction compared to the baseline; followed by a reference price system in which European prices were considered (43.6% price reduction). The other scenarios (reference price system: 18.1% price reduction) and a biosimilar price link (15.6% with leveling of the originator price to the biosimilar level and 4.8% price reduction for 30% price reduction on the biosimilars only) also yielded savings.	Vogler et al. 2021
Realisation of potential savings for Germany	Introduction of specific biosimilar policies (e.g., biosimilar price link), change in the design of a policy (reference price system), increases in prescribing quota (by 40%) and introduction of biosimilar substitution (50%)	The study investigated the savings potential of biologicals for the public expenditure if in the year 2019 certain policies had been in place (similar methodology as Vogler et al. 2021) but partially other policies studied. All policies were found to achieve savings compared to the status quo. The highest savings potential was identified for a biosimilar price link, which also provides for the reduction of the originator biological (on average 12.2% price reduction) and a reference price system that would include all biosimilars (11.7& reduction). Biosimilar substitution was assessed to achieve a reduction of on average 8.1%.	Vogler et al. 2020
Reduction of overall treatment costs	Consequent use of biosimilars	*"The consequent use of biosimilars allows a considerable reduction of overall treatment costs, especially for cost-intensive long-term maintenance treatments and therapies with high incidences. If the option of biosimilar usage is fully exploited, enormous resources could be released within the healthcare system in order to offset financing new innovative therapies."*	Hübel et al. 2020
Uptake of TNF alpha inhibitor biosimilars in German regions	Prescription and budget control measures	*"Variation in market penetration of TNFα inhibitor biosimilars between German regions depends on a complex interplay of multiple factors.* *Experts interviewed for this study have highlighted the influence of prescription and budget control activities (organized at the regional and insurer level) on the variable uptake of infliximab and etanercept biosimilars across Germany. The use of biosimilars has been found to depend on: the regional-level implementation of biosimilar quotas, the presence of an effective monitoring and sanctioning system to regulate adherence to biosimilar quotas, the effectiveness of the communication between regional physician associations and individual prescribers, the different conditions for discount contracts established at the insurer-manufacturer level and the organization of initiatives for gainsharing. The allowance of pharmacy-level automatic substitution for biologics is expected to play a decisive role in the evolution of biosimilar consumption patterns across Germany."*	Moorkens et al. 2020

Outcome indicator	Caused by	Findings	Publication
Cost savings	Increased use of intravenous rituximab and trastuzumab biosimilars	Budget impact analysis emphasizing *"that increased use of intravenous rituximab and trastuzumab biosimilars may result in cost savings from the payer's perspective across the EU-5 countries."*	Jang et al. 2021
Increase in biosimilar share	Prescription targets/quota	*"Prescription targets to alter physician prescribing behavior meet their intended goals by increasing biosimilar share. Physicians partly responded to the policy by decreasing overall prescriptions of the target substance. Prescription targets might be a useful tool, but decision makers need to consider all aspects of potential responses."*	Birkner and Blankart 2022
Biosimilar uptake across regions	Policy measures, including prescription quota	The study found differences in the biosimilar uptake across regions for erythropoiesis-stimulating substances, filgrastim, and somatropin, and numerous policy measures. Explicit prescription quota regulation was found to be more effective than priority prescribing. Biosimilar quotas were found to account for 5.13% to 9.75% of the total average biosimilar share of erythropoiesis-stimulating substances.	Blankart and Arndt 2020
Effectiveness of biosimilar substitution and information by pharmacists	Pharmacist knowledge and attitude towards biosimilars	*"Although the biosimilar market has grown continuously over the last years, there have been only limited changes in Swiss and German pharmacists' knowledge and attitudes. A lack of knowledge and confidence in dealing with biologicals is still present among the pharmacists, especially when it comes to substitution with biosimilars. It is likely that more responsibilities in this field are to be placed on pharmacists in the future, as we currently see in Germany and Norway with an ongoing discussion regarding permission for (automatic) substitution of biosimilars. Thus, issues such as hesitancy and misconception must be overcome. Therefore, actions must be taken such as promoting pharmacists' confidence in dealing with biosimilars through individual training, among others."*	Messner et al. 2023
Comparison of prices, savings and uptake	No specific policies	A comparison of the biosimilar markets in Germany, Switzerland and the United States from 2011 till 2020: The study found that fewer biosimilars entered the market in the US between 2011 and 2020 compared with Germany and Switzerland and on average, the biosimilar market share at launch was highest in Germany yet increased at the fastest rate in the US. Monthly treatment costs of biosimilars were substantially higher in the US compared with Germany and Switzerland.	Carl et al. 2022
Savings through use of biosimilar medicines	No policy identified	Achieved savings through biosimilar medicines from 2014 till 2024 amounted to € 7.6 million (savings of € 1.869 billion euro). Methodology of calculation not described, no policy assessed. Discounts granted by sickness funds are said to account for the savings (91.5% of biosimilar packs dispensed under a "discount contract"	Probiosimilars 2024

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 Germany

Legal barriers

Automatic substitution is solely for defined medicines.

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

Fragmented health system, with several sickness funds responsible for managing their tendering-like system ("Rabattverträge"), differences in prescription quota and gain-sharing models. Studies have shown differences in regional uptake as a result of this fragmentation (Moorkens et al. 2020, Blankart and Arndt 2020).

Financial barriers

The price differences between reference medicinal products and biosimilars are often very small; if reference prices are set, there are hardly any differences between the prices (example: adalimumab); open-house contracts imply that the prescription of all participants – reference medicinal products and biosimilars – is cost-effective, regardless of the actual price.

Evidence and communication-related barriers

Lack of trust in biosimilars was identified, both with policy-makers as well as the general public (van Hugten 2024).

Policy-related barriers

The well-advanced biosimilars policy landscape is undermined by regional differences in implementation (see above).

From the point of public payers, the delays in the implementation of the introduction of biosimilar substitution has resulted in delays in uptake and savings.

Stakeholder-related barriers

Still limited knowledge with pharmacists about biosimilars and biosimilar policies (in particular biosimilar substitution (Messner et al. 2023, Arnet et al. 2021)

Mixed opinions of stakeholders (also within stakeholder groups) on some policies, in particular on biosimilar substitution (opposition by pharmacists, doctors and the biosimilar industry).

7 Facilitators and good practice examples in Germany

Germany is well **advanced in biosimilar policies**. In particular, **demand-side measures targeted at doctors (e.g., prescribing quota, coupled with gain-sharing models** in some regions) were attributed to biosimilar uptake and savings, and were also reported to have been well accepted by doctors (Moorkens et al. 2020, Birner and Blankart 2022, Blankart and Arndt 2020). However, these positive experiences appeared to have been undermined by the different approaches by sickness funds (leading to regional variation, see above).

Biosimilar substitution has been considered as another facilitator, and an earlier introduction could have contributed to more savings (Schröder, Löhmüller and Telschow 2019; Vogler et al. 2021; Vogler et al. 2021). However, opinions about biosimilar substitution as facilitator or barrier are mixed, which has also resulted in the delay of biosimilar substitution, since doctors were concerned about switching problems that could promote nocebo effects and compromise treatment adherence and success and biosimilar industry were concerned about driving prices down and thus leading non-availability of biosimilar medicines.

According to the biosimilar industry, the tendering-like system ("**Rabattverträge**") has an impact on the affordability resulting from biosimilars. The impact was shown in combination with demand-side measures (Moorkens et al. 2020, Birner and Blankart 2022, Blankart and Arndt 2020).

Since 1985, German researchers have been publishing the "**Arzneiverordnungs-report**" (Pharmaceutical Monitoring Report) annually, reporting and analysing the public expenditure and volumes of medicines in Germany at detailed levels. This publication series can be considered as good practice example. In more recent years, the publication was extended by chapters on specific content, such as on biosimilars (including European price comparisons, European policy mapping and calculation of saving potential).

8 Developments in Germany

Recent changes

In 2019, the legal mandate provided for a three-year preparatory phase of biosimilar substitution. The date of introduction was postponed, and in March 2024, restricted biosimilar substitution was introduced.

9 Further information

Relevant stakeholders are:

The National Association of Statutory Health Insurance Physicians and the regional Associations of Statutory Health Insurance Physicians

The German Hospital Federation

The Federal Association of German Hospital Pharmacists

The National Association of Statutory Health Insurance Funds

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