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

AUGMENT Biosimilars
Country fiche SWEDEN

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augment biosimilars

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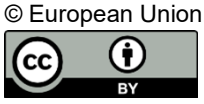

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Annex 7.30

AUGMENT Biosimilars country fiche: Sweden 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 Sweden 2025

Key stakeholders

The **Swedish Medical Products Agency** (MPA) and the **Dental and Pharmaceutical Benefits Agency (TLV)** are – besides the Ministry of Health and Social Affairs who prepares the legislation - the main stakeholders involved in biosimilar policy implementation. TLV serves as the national pricing and reimbursement authority but also conducts the HTA assessment for biosimilars.

The choice of prescribing a reference medicine or a biosimilar rests with the **physician**. The Medical Products Agency has suggested that the exchange of biological medicines in pharmacies should be investigated further (Läkemedelsverket 2024).

Major biosimilar policies and practices

Neither a biosimilar price link nor external price referencing is applied for biosimilars.

Tendering for biosimilars is only applied in the inpatient sector. Tendering takes place at the **hospital or regional level** (multiple hospitals together). Tenders are usually conducted every 2-3 years (but may be done in shorter intervals) often with an option to extend the contract for another year; multi-winner contracts are also used. Tendering-like procedures in the outpatient sector, as known for generics, are not applied for biosimilars.

Switching is a policy used in Sweden, where doctors decide on a case-by-case basis on the switch from originator to biosimilar(s). Managed-switch programs for biologics have also been implemented at the regional level.

Local gain-sharing agreements also take place at the level of counties (regions that fund), where the cost savings generated through the switching process have been reallocated to local hospitals.

No reference price system is in place – neither for biosimilars nor for medicines in general. There are no special regulations for biosimilars. To be included in the reimbursement system, biosimilars require a positive reimbursement decision from TLV. The comparator should be the most cost-effective of the available and clinically relevant treatment alternatives in Sweden. The most relevant comparator to a biosimilar is often other medicines with the same active substance. If there are several biosimilars in addition to the reference product, the price comparison is made against the product with the lowest price. If there is uncertainty as to whether the use of the reference product is cost-effective, it may be appropriate to choose a comparator other than the reference product. Sometimes a cost minimization analysis may be sufficient and if equivalent packaging already exists within the benefits and where nothing else significantly differs it may be sufficient to compare only the packaging prices. TLV accepts the requested price if it is equal to or lower

than the price of the comparator. INN prescribing or biosimilar substitution are **not allowed**.

Impact assessment

For the impact of biosimilars in Sweden, mostly switching practices have been evaluated, showing positive impact of the policy on **public savings, utilisation of certain biosimilars** and **patient access**. Moreover, studies have shown **high acceptance** of biosimilar use in the country.

According to literature, tendering policies in Sweden, which take place at the county/hospital level, **autonomy**, **market sustainability** as well as **acceptability of biosimilars** among stakeholders.

Barriers, facilitators and good practice examples

Literature shows **high acceptance** in the use of biosimilars in Sweden in comparison to other European countries.

One study also assessed the feasibility of **switching** in Sweden, where authors found **no difference in treatment efficacy** through biosimilar use compared to treatment with originators, but substantial **cost savings** associated with switching (Flodmark et al. 2013).

Sweden currently has gain-sharing models and prescribing quota in place in the inpatient sector.

Literature found that there are **geographical differences between the Swedish regions** in Biosimilar uptake. For instance, the implementation of policies such as local gain-sharing arrangements may result in a difference in uptake and eventually, also patient access (Moorkens et al. 2019b).

Recent developments

The Swedish Medical Products Agency (MPA) has analyzed **evidence for single and multiple switches** in 2024. From the resulting analysis they evaluated the possibility of automatic substitution of biological medicinal products at pharmacy level. MPA concludes that the current system for determining substitution at pharmacies could legally be applied to biological medicinal products at **pharmacy level.** However, there are **several important factors that need to be** taken into account in order for a substitution to be made safely for patients, if such a change becomes relevant. MPA therefore considers that a next step, if the evaluation of automatic substitution of biological medicinal products is to be taken further shall be, among other things, an economic analysis.

Highlights and learnings

Overall, Sweden is **advanced** in their implementation of Biosimilars policies compared to other countries in Europe. Several **demand-side measures** have been

implemented, which resulted in a **positive uptake of biosimilars**. Despite differences in the uptake between counties, Sweden has generally high acceptance of biosimilars by stakeholders and patients.

2 Key data regarding biosimilars in Sweden

First biosimilar medicine approved:
Epoetin teta (B03XA01) in 2007
Somatropin in 2011
Source: TLV

Number of the **biosimilars marketed**:
20 molecules with biosimilars available, as of March 2025
average 2.65 biosimilars (per trade name) or 1-6 per substance, as of March 2025
Source: EMA, Läkemedelsverket

Biosimilar market shares in 2024:

72% **in volume** in 2024
Note: Volume is defined as as share of volume total for ATCs (A10AB04, A10AB05, A10AE04, B03XA01, G03GA05, H01AC01, H05AA02, L01FA01, L01FD01, L01FG01, L03AA02, L03AA13, L04AB01, L04AB02, L04AB04, L04AC05, L04AC07, L04AG03, L04AJ01, S01LA04)

62 % **in value** in 2024
Value is defined as share of total pharmaceutical expenditure. Biosimilar market shares data relate to the total market (outpatient and hospital, public and private sectors).

Note: Value of biosimilars as share of total value for ATCs (A10AB04, A10AB05, A10AE04, B03XA01, G03GA05, H01AC01, H05AA02, L01FA01, L01FD01, L01FG01, L03AA02, L03AA13, L04AB01, L04AB02, L04AB04, L04AC05, L04AC07, L04AG03, L04AJ01, S01LA04).

Source: TLV, based on data from the Swedish eHealth Agency

3 Stakeholders involved in and targeted by biosimilar policies in Sweden

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Socialdepartementet / Ministry of Health and Social Affairs	Prepares legislation	
National regulatory authority	Läkemedelsverket / Swedish Medical Products Agency (MPA)	Implements regulatory provision regarding all medicines (incl. biosimilars), quality assurance and pharmacovigilance. In charge of market authorisation, classification, vigilance and monitoring of clinical trials.	Analysera switch och i förlängningen utbytbarhet av biologiska läkemedel på apotek
Pharmaceutical pricing authority	Tandvårds- och läkemedelsförmånsverket (TLV) / Dental and Pharmaceutical Benefits Agency	Implements pricing legislation regarding all medicines (incl. biosimilars). The Board for Pharmaceutical Benefits decides on pricing and reimbursement for new medicines and other products which are part of the benefits scheme for out-patient care/ products dispensed at pharmacies.	Analys av marknaden för biologiska läkemedel med konkurrens av biosimilarer Biosimilarer i den svenska sjukvården - en beskrivning av användning och kostnader
Pharmaceutical reimbursement authority	Tandvårds- och läkemedelsförmånsverket (TLV) / Dental and Pharmaceutical Benefits Agency	Decides on inclusion into reimbursement for biosimilars and their price, including HTA. The Board for Pharmaceutical Benefits decides on reimbursement for new medicines and other products which are part of the reimbursement system for out-patient care/ products dispensed at pharmacies.	*See above*
Procurement agency	Regionerna / The regions	The regions procure medicines used in hospitals. The regions' Pharmaceutical Committees produce, for example, lists of medicines recommended as the first choice treatment for a range of common diseases.	
HTA agency / body	Tandvårds- och läkemedelsförmånsverket (TLV) / Dental and Pharmaceutical Benefits Agency Statens beredning för medicinsk och social utvärdering (SBU) / Swedish Agency for Health Technology Assessment and Assessment of Social Services	To be included in the reimbursement system, biosimilars require a positive reimbursement decision from TLV. The comparator should be the most cost-effective of the available and clinically relevant treatment alternatives in Sweden SBU provides systematic reviews and meta-analysis, but does not have a decision-making role.	
National competition authority	Konkurrensverket / Swedish Competition Authority	Enforcement of the competition law, anti-trust cases	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
National patent office	Patent Och registreringsverket / Swedish Intellectual Property Office	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Sveriges Läkarförbund / Swedish Medical Association[1] *Medical societies*: Svensk Förening för Diabetologi (SFD) / Swedish Diabetes Society ; Svenska Gastroenterologisk Förening (SGF) / Swedish Gastroenterology Society Svensk Förening för Hematologi (SFH) / Swedish Society of Hematology; Svensk Reumatologisk Förening (SRF) / Swedish Rheumatology Association	Prescribe biosimilars (INN prescribing is NOT allowed). Inform patients Medical societies in disease areas with biologics use	
Nurses	*Represented by:* Vårdförbundet / Swedish Association of Health Professionals		
Community pharmacists	*Represented by:* Sveriges Apoteksförening / Swedish Pharmacy Association[2]	Dispense medicines, inform patients	
Hospital pharmacists	*Represented by:* Apotekarsocieteten / Section for Hospital Pharmacy of the Swedish Pharmaceutical Society[3]	Support procuring medicines, inform patients / health professionals / procurers	
Patient organisations	*Represented by:* Svenska Diabetesförbundet / Swedish Diabetes Association Mag- och tarmförbundet / Swedish Gastrointestinal Association Förbundet Blödarsjuka i Sverige / The Association of Hemophilia in Sweden Cancerfonden / Swedish Cancer Society Reumatikerförbundet / Swedish Rheumatism Association	Patient organisations in diseases with particular biologics use	
Consumer organisations	Sveriges Konsumenter	-	
Biosimilar industry	*Represented by:* Föreningen för Generiska läkemedel och Biosimilarer (FGL) / Swedish Association of Manufacturers of Generics and Biosimilars[3]	Produces and supplies biosimilars	
Generic industry	*Represented by:* Föreningen för Generiska läkemedel och Biosimilarer (FGL) / Swedish Association of Manufacturers of Generics and Biosimilars[3]	Same association as for biosimilars	
Pharmaceutical industry in general	*Represented by:* Läkemedelsindustriföreningen (LIF) / Trade association for the research-based pharmaceutical industry in Sweden[1]	Represents the producers of originator products	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Pharmaceutical industry for new biological medicines	*Represented by:* Läkemedelsindustriföreningen (LIF) / Trade association for the research-based pharmaceutical industry in Sweden[1]		

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium); Medicines for Europe 2023

4 Biosimilar policies and practices in Sweden 2025

Note that the information relates to the year 2025, to the national level and to outpatient and inpatient sectors, unless specified differently.

4.1 Pricing and procurement policies

Biosimilar price link

A **biosimilar price link** is in place.	No (TLV accepts the requested price if it is equal to or lower than the price of the comparator)
It applies for the following situations:	n.a.
Price reduction of the first biosimilar compared to the reference product	n.a.
Price reduction of the second, third and further biosimilars	n.a.
Price reduction for the reference product	n.a.
Any further specificities	
Generic price link	Yes, generic price link in the form that, while there are no percentage cuts for the 2nd, 3rd product on the market, the price of any generic or originator has to be lower than the "ceiling price" (35%) of the originator price) when generic competition is established (defined as there is sustainable competition below 30% of the originators price).

Source: PPRI 2025, Rönnholm and Skiöld 2023

External price referencing

External price referencing is applied for biosimilars.	No
If yes, it is applied for the following situations:	n.a.
Any specificities	n.a.
External price pricing is in place for other medicines than biosimilars.	No

Source: PPRI 2025, Rönnholm and Skiöld 2023

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, on the regional level

Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All biological medicines
Institutional framework	Conducted by regions
Information available on procurement procedures and practices	The key award criterion for biosimilar tenders is price, since there is no difference in product characteristics. Tenders are usually conducted every 2 years but may be done in shorter intervals if a new product is expected to enter the market. Tenders for biological medicines use a "winner-takes-it-all" approach. Tenders are conducted at WHO ATC-5 level (i.e. at the level of substances). Multiple-winner contracts are also used. The average contract duration of the tender is 48 months.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	No, this tendering-like "Product of the Month" system do only relate to generics
Institutional framework	
Information available on procurement procedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes, all pharmaceuticals in the inpatient sector are procured through tenders. Outpatient: Yes, a tendering-like system ("Product of the Month")

Source: PPRI 2025; Vogler et al. 2022; Rönnholm and Skiöld 2023

4.2 Reimbursement policies

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	n.a.
If publicly accessible, indicate URL of RPS list	n.a.
When were first biosimilars included in the reference price system?	n.a.
Any further specificities	
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	No (however, similar mechanism due to mandatory generic substitution and "Product of the Month" scheme). More information: Information about product of the month: Product of the month - Tandvårds- och läkemedelsförmånsverket TLV Product of the month list: Periodens varor - Tandvårds- och läkemedelsförmånsverket TLV

Source: PPRI 2025, Rönnholm and Skiöld 2023

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. To be included in the reimbursement system, medicines require a positive reimbursement decision from the TLV.

If yes, how many and date of inclusion into reimbursement, if known)	Inclusion of outpatient reimbursement for 29 products. In the following, the products (by trade name) as well as the date of their first reimbursement approval (in brackets) are listed: • Omnitrope® (2006-06-16) • Retacrit (2008-04-15) • Nivestim (2010-11-02) • Omnitrope (SurePal) (2013-12-05) • Inflectra (2014-03-28) • Bemfola (2014-06-19) • Accofil (2015-06-11) • Benepali (2016-03-18) • Erelzi (2017-09-28) • Insulin lispro Sanofi (2017-10-26) • Hulio (2018-11-23) • Imraldi (2018-11-23) • AMGEVITA (2018-11-23) • Hyrimoz (2018-11-23) • Flixabi (2018-12-13) • Fulphila (2019-02-21) • Ziextenzo (2019-05-23) • Movymia(2019-08-29) • Idacio (2019-09-26) • Ovaleap (2020-03-19) • Insulin aspart Sanofi (2020-08-27) • Hukyndra (2022-04-22) • Sondelbay (2022-12-15) • Tyenne (2024-02-20) • Remsima (2024-02-22) • Uzpruvo (2024-05-16) • Pyzchiva (2024-08-22) • Wezenla (2024-09-19) • Steqeyma (2024-11-14)
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	Percentage co-payment given the current deductible scheme (more information available here).
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	There is no difference compared to other reimbursed medicines. Savings are shared between the government and the regions for reimbursed medicines that the regions and the pharmaceutical company has entered an MEA.
Indicate URL of outpatient positive list	Link to national database: https://www.tlv.se/beslut/sok-priser-och-beslut-i-databasen.html
Co-payments for biosimilars for outpatient use	Yes
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	Positive list Percentage co-payments are in place. The amount decreases and becomes zero, upon reaching a specific threshold within a year (more information available here).
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes. Prescribers are often advised to choose the one with the lowest cost, the original biological or the biosimilar. It is also dependent to the region that is procuring the biosimilars to choose.
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	n.a.
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	URL of national hospital pharmaceutical formulary is not publicly available

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	Hospital pharmaceutical formularies at (hospital) level. No co-payments for medicines for inpatient use.

Source: PPRI 2025, Moorkens et al. 2019a; Moorkens et al. 2019b, TLV

4.3 Specific pricing, procurement and funding policies

Application of special pricing, procurement and reimbursement models for biosimilars (e.g. delinkage / subscription-model, managed-entry agreements (MEA))	No. There are no special regulations for biosimilars.
Enforcement of anti-trust policies	No
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	There is a system for MEAs

Source: PPRI 2025, Moorkens et al. 2020

4.4 Supportive tools and practices for policy-makers

Horizon scanning

Public authorities or public payers use a horizon scanning system to identify loss of exclusivity (patent expiry) of biologics	Yes, sometimes
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	The Regions as well as TLV conduct horizon scanning activities.

Source: PPRI 2025; Moorkens et al. 2019a

Health technology assessment

HTA is applied for biosimilar medicines	Yes
If yes, in which situations and settings (outpatient and inpatient)	Outpatient: TLV publishes guidance for manufacturers to prepare reimbursement applications. Biosimilars are classified as "new medicines". To be included in the benefits scheme, medicines require a positive reimbursement decision from TLV. TLV accepts the requested price if it is equal to or lower than the comparator's price. The Board for Pharmaceutical Benefits emits the final pricing/reimbursement decision.
Differences in criteria and processes of HTA for biosimilars compared to other medicines	Biosimilars reimbursement price is expected to be equal or lower than the comparator's price. Reimbursement restrictions have not applied to originators following the availability of less costly biosimilar alternatives. In some cases, TLV may start a reassessment of all medicines within a reference group. Those medicines with a price above an acceptable level are excluded from the reimbursement system unless the company voluntarily lowers its price to the accepted level (or lower).

Any specificities	Biosimilars are not interchangeable at the pharmacy level. Although TLV classifies biosimilars as 'new medicines', their assessment can often be simplified in relation to the originator's assessment. In addition to clinical evaluation data such as the assessment report from the EMA, TLV needs medical economic evaluation data where the comparator should be the most cost-effective of the available and clinically relevant treatment alternatives in Sweden.

Source: PPRI 2025, Barcina Lacosta et al. 2024

4.5 Demand-side measures

Doctors (and further prescribers)

Country context: Only doctors may prescribe biosimilars.

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 the lowest cost option
If yes, what is recommended for patients already on biologic treatment	Doctors are asked to decide on a case-by-case basis. The choice between reference medicine or biosimilar(s) rests with the physician. Physicians are urged to consider all factors including safety, effectiveness, and price difference. Managed-switch programs for some biologics have been implemented at the regional level
Prescription guidelines (including switching guidelines) were issued by	The regions
URL of prescription & switching guidelines	
Prescribing quota	
Prescribing quota for doctors with regard to prescription of biosimilars exist	Yes
If yes, which quota are defined for biosimilars	
Any exemptions	
Any sanctions in case of non-achievement	
Any (financial) incentives for achieving the quota	
Prescribing quota were issued by	
URL of prescribing quota	
Prescribing quota for other non-biosimilar medicines exists	
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	Yes
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	Local gain share agreements also take place at the level of the regions (inpatient funders), where the cost savings generated through the switching process have been reallocated to local hospitals.
Publicly accessible information	

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	n.a.
Further measures targeted at doctors	
Information materials for doctors	Yes TLV has gathered its information here: Biosimilarer - Tandvårds- och läkemedelsförmånsverket TLV
Information events for doctors (e.g., seminars, trainings)	
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	

Source: PPRI 2025; Machado et al. 2024; Mestre-Ferandiz et al. 2024 ; Barcina Lacosta 2024

Pharmacists (and further dispensers)

Country context: The main rule is that only pharmacists may dispense medicines.

Substitution policies	
(Automatic) substitution for biosimilars	Not, not allowed
If yes, for which biologic substances and under which prerequisites?	n.a.
If yes, since when, and when was it extended? (process of implementation)	n.a.
Any specificities	Biosimilars are not assessed by the Swedish Medical Products Agency as substitutable on a pharmacy level in Sweden. Instead, they are treated as their own separate substances and are not included in the "Product-of-the-Month" system that applies for generic substitution.
URL of underlying law	n.a.
Generic substitution in place	Yes, mandatory Exemptions can be made due to medical reasons (e.g. allergies). The patient can oppose substitution if he/she wants to but has to pay the difference. Prescribers and pharmacists at pharmacies can also object to a substitution (under special circumstances).
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)	n.a.
Publicly accessible information	n.a.

Further measures targeted at pharmacists	
Information materials for pharmacists	Yes TLV and MPA have produced information material regarding generic substitution specifically targeted at patients, prescribers and pharmacists. The material comprises of a patient folder, posters, fact sheets and other in-depth material to pharmacists and prescribers. All the material has been developed in consultation with patient organisations, pensioners' associations, regions, and other pharmacy associations. The information is based on current regulations and guidelines, research findings and other studies and reports as well as interviews.
Information events for pharmacists (e.g., seminars, trainings)	Yes, see: Informationsmaterial om det generiska utbytet - Tandvårds- och läkemedelsförmånsverket TLV

Source: PPRI 2025

Patients

Information and educational measures	
Information materials for patients	Yes
If yes, provide URL of most common materials	What are biosimilars: Biosimilarer | Läkemedelsverket Switch and interchangeability of biological medicines in pharmacies: Analysera switch och i förlängningen utbytbarhet av biologiska läkemedel på apotek | Läkemedelsverket Generic substitution: Generiskt utbyte - Tandvårds- och läkemedelsförmånsverket TLV Biosimilars: Biosimilarer - Tandvårds- och läkemedelsförmånsverket TLV
If yes, key producers of education measures	Authorities
Information events for patients (e.g., seminars, trainings)	n.a.
If yes, key providers of educational events	
Gain-sharing models	
Gain-sharing models for patients	No
If yes, pls. describe	
Publicly accessible information	

Source: PPRI 2025, Medicines for Europe 2023

5 Impact of biosimilar policies and practices in Sweden

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 Sweden

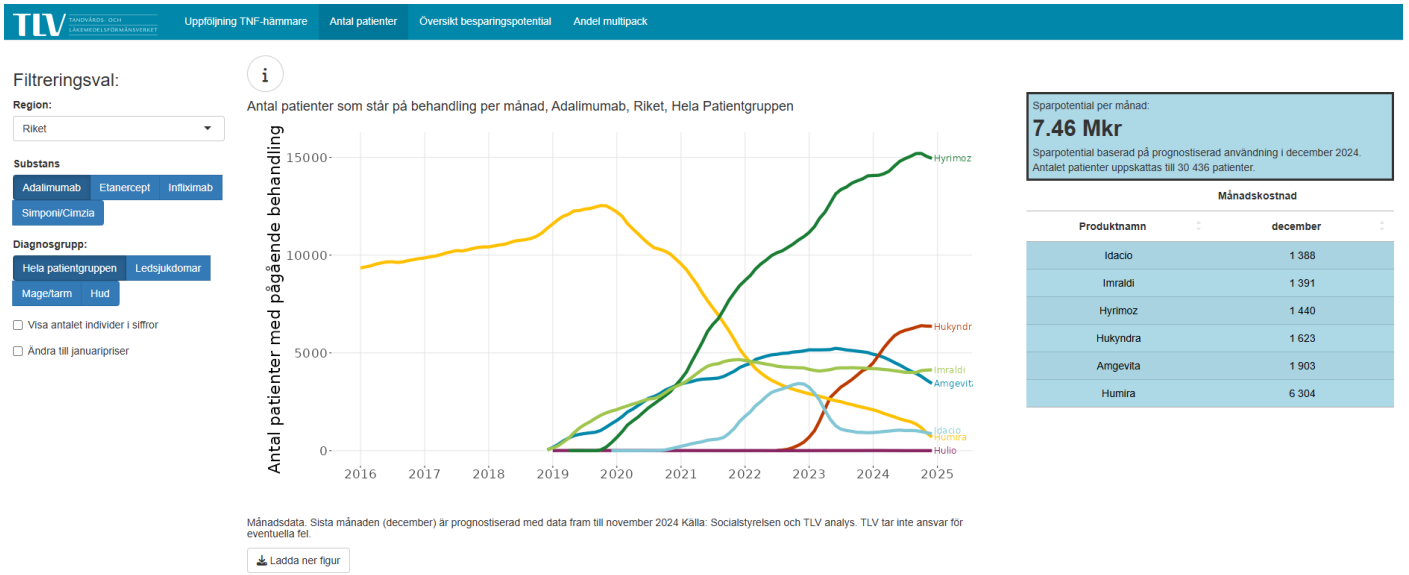
Outcome indicator	Caused by (specify policy, if applicable)	Findings	Publication (citation or URL)
Savings for the public payer	Gain-sharing policies	In Skåne, Stockholm and Västra Götaland, savings that are made via leveraging competition of biosimilars stay within the region medicines budget. As budgets for regions medicines are adjusted every year, it may be that, in the long term, the regions benefit from savings.	Moorkens et al. 2019a
Savings for the public payer	Higher price reductions in tendering	"Both the quantitative and the qualitative study revealed that increasing differences in discounted price between the biosimilar and originator product would favor the use of the least expensive product, indicating that potential savings associated with the biosimilar would incentivize stakeholders to switch from the originator product to the biosimilar."	Moorkens et al. 2019a
Earlier patient access	Introduction of biosimilars on the market (no specific policy studied)	"Overall, we observed a decrease in the discounted price per DDD of infliximab in all counties since the introduction of the biosimilar and a concomitant increase in patients being treated with infliximab. This will benefit patients, as early treatment with biologicals will lead to improved clinical responses."	Moorkens et al. 2019a
More patients treated	Switching	"In a study, including patients starting a first-ever treatment with adalimumab, etanercept, infliximab or rituximab or performing a non-medical switch to a biosimilar of one of these drugs, we found no clinically relevant differences in treatment retention for the biosimilars compared with the originator products."	Di Guiseppe et al. 2022
	Switching, quick & early adoption of biosimilars	Study showed an "increase in utilization of each molecule as indicated by a higher average annual change in volume post-launch of biosimilars in contrast to pre-launch."	Car et al. 2023
More treatment options in the reimbursement list	Tendering on regional level	"The different tender groups in Sweden make the market sustainable for both originator and biosimilar infliximab. (…) Tenders being 541ncentivi at a county level offer an advantage in that a manufacturer who does not win the bid in one county has an incentive to stay on the market by participating in tenders in other counties."	Moorkens et al. 2019a
Increased autonomy	Tendering policies	"An advantage of the Swedish system is the autonomy in making decisions on a new tender, allowing the opinions of all stakeholders on the use of biosimilars and switching from the originator to the biosimilar to be aligned first".	Moorkens et al. 2019b
High acceptance	Information activities	"Sweden has succeeded in achieving widespread acceptance by payers, providers and patients of biosimilars as an integral part of medicine use."	IQVIA 2020
Cost savings	Switching	"Patients were successfully switched from originator to biosimilar rhGH (somatropin), with no negative impact on growth, and no serious or unexpected adverse drug reactions. The switch from originator to biosimilar rhGH is associated with substantial cost savings."	Flodmark et al. 2013
Geographic difference in patient access	Switching	"The association between the likelihood of initiating a biologic (through switching) and the region where patients received care was analyzed. (…) The national switch rate increased marginally over time from 9.7 to 11.0%, though the uptake varied across regions."	Calara et al. 2017
Geographic difference in stakeholder	Local gainsharing arrangements	"Financial streams and local gainsharing arrangements in counties lead to different levels of stakeholder 541ncentivization."	Moorkens et al. 2019b

Outcome indicator	Caused by (specify policy, if applicable)	Findings	Publication (citation or URL)
incentivization			
Geographic difference in decision to switch	Switching	For Etanercept, "differences in the decision to switch to the biosimilar or wait for lower rebated prices in future agreements seems to purely be affected by the differences in counties' policy and differences in attitudes of key opinion leaders and prescribers towards biosimilars and switching".	Moorkens et al. 2019b

Source: see last column and further details on the full citation in the bibliography at the end of this country fiche

Impact assessment: Theoretical savings by switching TNFs' based on sales data

TLV provides an online app that calculates the potential savings of using the most cost-effective product in the out-patient sector. The saving is calculated by substance, product, patient group, pack-size and region. The app is accessible via this link.



Source: TLV

6 Barriers for biosimilar uptake and policy implementation in Sweden

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

In Sweden, the health care system is highly decentralised, with three independent governmental levels, the national government, regions and municipalities being involved. Even though this results in a fragmentation of the system, all parties work together (Rönnholm and Skiöld 2023).

Financial barriers

The Swedish market is relatively small compared to many other countries in Europe.

Evidence and communication-related barriers

In Sweden, the health care system is highly decentralised. Hence, different actors face different challenges as they are still interconnected in their work. For instance, in the outpatient sector, the regions control prescribers, who then choose which medication the patient receives.

Stakeholder-related barriers

"It seems that some counties are hesitant to switch patients, as it is associated with an increased administrative workload that might not be compensated for by savings associated with a lower priced product" (Moorkens et al. 2019b)

7 Facilitators and good practice examples in Sweden

Moorkens et al. found the following drivers for biosimilar uptake:

- The attitude of key opinion leaders and clinic heads (often part of a county council expert group) – either positive of negative impact;
- Prescribing guidance to physicians offered by the county councils (recommendations);
- Prescription monitoring (to follow up on adherence). (Moorkens et al. 2019a)

Another study by Flodmark et al. assessed the feasibility from switching treatment with an originator to a biosimilar, including its impact on cost and treatment efficacy. Authors found neither negative impact on the treatment nor adverse drug reactions through switching. Moreover, they found a positive association with cost savings through switching (Flodmark et al. 2013).

High acceptance among Swedish stakeholders (payers, providers), in particular also among patients, according to an IQVIA report. Biosimilars are thus viewed as an

essential part of medicine use. One contributing factor to the high acceptance were extensive capacity-building and information activities (IQVIA 2020).

The views of authorities on switching have also evolved over time. Previously, the Swedish Medical Product Agency indicated that limited substitution can be made during an ongoing treatment, but that repeated switches should be avoided (Läkemedelsverket 2017; PPRI 2025). After conducting a report analysing switching of biosimilars in 2023/2024, they concluded that there is currently no evidence indicating that multiple switching between biosimilars and their reference medicines in clinical practice would cause any issues related to effectiveness or safety (Läkemedelsverket 2024).

8 Developments in Sweden

Recent changes

The Swedish Medicines Agency was tasked in the appropriation letter for 2023 to analyze the evidence for single and multiple switching of biological medicines. Based on the analysis carried out, the agency was also to investigate the possibility of switching biological medicines at pharmacies. The report was updated in 2024 (available here: Analysera switch och i förlängningen utbytbarhet av biologiska läkemedel på apotek).

Plans or under discussion

The Swedish eHealth Agency (EHM) is analysing how **INN prescribing** could be introduced in Sweden.

The Swedish MPA concludes that further investigation is needed to be able to substitute/switch biological medicines at pharmacies (April 2024). More information here: Utbyte av biologiska läkemedel på apotek bör utredas vidare | Läkemedelsverket

The Swedish MPA updates their recommendation on the use of biosimilars (September 2023). More information here: Läkemedelsverket uppdaterar rekommendation om biosimilarer | Läkemedelsverket

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