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

AUGMENT Biosimilars
Country fiche FINLAND

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augment biosimilars

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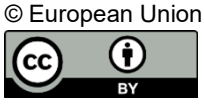

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Annex 7.9

AUGMENT Biosimilars country fiche: Finland 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.

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1 Summary of biosimilar policies and practice in Finland 2025

Key stakeholders

The **Finnish Ministry of Social Affairs and Health** is the main legislator for pharmaceutical policies. The **Pharmaceuticals Pricing Board, subordinated to the Ministry**, is responsible for pharmaceutical pricing and reimbursement decisions on medicines used in outpatient care. The latter reevaluates the prices of reference products after inclusion of biosimilars into reimbursement. The **Finnish Medicines Agency FIMEA** is responsible for developing the list of interchangeable (biological) medicines and is involved in extensive information activities on biosimilars. The **Social Insurance Institution of Finland (SII or KELA)** administers the drug reimbursement system. It is also very active in informing health care professionals and patients on biosimilars, and it monitors biosimilar prescribing and manages outpatient reimbursement.

Health care professions including physicians, nurses and pharmacists are represented in **professional associations**. The **industry is organised in various associations** as well, of which the main is the Pharma Industry Finland (PIF) which appears to be rather reluctant towards some biosimilar policies.

Major biosimilar policies and practices

Finland applies **several biosimilar policies and practices** to support their uptake and use. All biosimilars entering the out-patient market are subject to a **price link** of minus 30% compared to the reference product. Prices of the reference product are reevaluated upon biosimilar inclusion into reimbursement. **Tendering** for biosimilars is performed by the university **hospitals pooling** their demand. Tender contracts must be reopened some months after biosimilar medicines have entered the market. Biosimilars are **included in the positive lists** (national for outpatient sector and hospital formularies in the inpatient sector) and not treated differently from other medicines when it comes to reimbursement. In the outpatient sector different reimbursement rates and co-payments apply, while in the inpatient sector all costs for biosimilars are covered publicly. From 2024, biosimilars have included into the outpatient **reference price system**.

Physicians have to **prescribe the lowest-priced biologic**, and their prescribing behaviour is monitored by KELA. Biologics may also be **prescribed by the International Non-Proprietary Name**. In 2024, **substitution** of biologic medicines by community pharmacists was introduced and is being implemented in a stepwise manner between 2024 and 2026.

Impact analysis

Literature on **uptake and prices of biologics**, and their developments, in Finland have been published and the findings were sometimes interpreted in relation to the existing policy framework. Studies showed sharp decreases in the prices of biological

reference products, and some increases in market shares for biosimilars and lower biosimilar prices, but the data on biosimilars also suggested **room for improvement**.

Barriers, facilitators and good practice examples

Having implemented a **mix of supply-side and demand-side biosimilar policies** and continuing to do so, Finland appears to have several good practice examples. **Policy implementation was frequently based on studies** which had identified room for improvement, and the implementation of new policies was also being **accompanied by evaluations**. In 2019, these analyses highlighted, for example, lower rates of biosimilar prescribing than the position of interviewed physicians suggested. Preliminary findings on the 2023 policy of "steering of prescribing" suggested intended impacts.

Another facilitator appears to be **extensive information** materials and activities by public authorities, in particular the Finnish Medicines Agency (FIMEA) and by the Social Insurance Institution of Finland (KELA). Nonetheless, studies suggest that information appears not to reach all stakeholders sufficiently.

Finland's pharmaceutical system is **organised differently for the outpatient and inpatient sector**s, and some biosimilar measures are targeted only at the outpatient sector, where biosimilars may play a less important role.

Recent developments

Following up on earlier policy implementation relating to biosimilars (e.g., biosimilar price link, impact of the inclusion of a biosimilar into reimbursement on the price of the reference product, and obligation for doctors to prescribe the lowest-priced medicine in 2017), the years 2023 and 2024 saw the introduction of further policies: In 2023, the Social insurance Institution started to **monitor the prescribing obligation** through prescribing feedback, and the legal basis was prepared to allow for **biosimilar substitution**. From 2024, biosimilar substitution was introduced through a stepwise approach, and biosimilar medicines were included into the reference price system.

Highlights and learnings

The case of Finland confirms **the importance of constant monitoring and impact analyses of policy measures and subsequent policy adaption**, if needed. The Social Insurance Institution of Finland (KELA) has been conducting analyses which support policy decisions.

FIMEA and KELA offer a wealth of information on biosimilars and on biosimilar policies targeted several stakeholders. This stresses the relevance of **information and capacity-building activities**.

2 Key data regarding biosimilars in Finland

First biosimilar medicine launched (i.e. brought on the market):
Omnitrope® (Somatropin) in November 2007.
Source: Luukanen et al. 2022

Number of the **biosimilars marketed**:
22 molecules with biosimilars available, as of November 2024.
Source: Fimea 2024

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

50.8% **in volume** in 2023

Volume is defined as all outpatient prescriptions.

Great variations per active variations (with high uptake rates for infliximab, filgrastim, somatropin and insulin lispro and low uptake rates for insulin aspart and follitropin alfa)
Source: Sarnola et al. 2025a

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):

- FIMEA website: Database with medicines with marketing autorisation for Finland, with a filter on the status of whether or not it is a biosimilar: https://fimea.fi/laakehaut_ja_luettelot/laakehaku (FIMEA 2025a)
- Statistical report on prescribing – public reports https://tietotarjotin.fi/en/statistical-data/2051231/statistical-database-kelasto

3 Stakeholders involved in and targeted by biosimilar policies in Finland

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Sosiaali-ja terveysministeriö / Ministry of Social Affairs and Health	Prepares legislation.	
National regulatory authority	Fimea - Lääkealan turvallisuus- ja kehittämiskeskus / Finnish Medicines Agency	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance. Published a statement on interchangeability on biologicalmedicines in 2015. Publishes the list of interchangeable medicines. Publishes information materials and documents.	Statement on interchangeability (FIMEA 2015) Information for patients: FIMEA 2025b (Information on biosimilar substitution) FIMEA 2025c (What is a biosimilar?) Information for health professionals: FIMEA 2025d (Information on biosimilar substitution including a link to product-specific guidance for pharmacists on substitution) Publishes information series on biosimilars, including summaries of studies (Sarnola et al. 2019, Tolonen et al. 2019)
Pharmaceutical pricing authority Pharmaceutical reimbursement authority	Lääkkeiden hintalautakunta (Hila) / Pharmaceuticals Pricing Board (subordinated to the Ministry of Social Affairs and Health)	Decides on reimbursement status and price and inclusion into reimbursement for biological products used in outpatient care. To reevaluate the price of the reference products as soon as a biosimilar is included into outpatient reimbursement and entered the market.	
Public payer	Kansaneläkelaitos (KELA) / The Social Insurance Institution of Finland	Reimburses medicines. Do prescribing feedback to prescribers (e.g., on biosimilar prescribing). Publishes medicine use statistics. KELA research department to investigate medicine use and expenses and policy impacts.	Activities of KELA encouraging and explaining biosimilar prescribing, e.g., KELA 2021 (press release), KELA 2024a (description of the prescribing guidelines, also on biologic and interplay with biosimilar substitution) and information in Medical Journal (no direct link, information at KELA 2025) and also targeted at pharmacists (KELA 2023, KELA 2024c on biosimilar substitution) Studies on biosimilar prescribing by KELA researchers (e.g., Sarnola et al. 2024a,

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
			Sarnola et al. 2024b, Sarnola and Koskinen 2024)
Procurement agency	National Advisory Committee on Pharmaceuticals, Health Care regions (official translation Wellbeing services county)	Not an agency, but established by hospital districts in early 2021 for the procurement of new medicines for hospital use. Health care regions acquire the medicines through tendering and price negotiations. Very expensive medicines are acquired nationally.	
HTA agency / body	Fimea - Lääkealan turvallisuus- ja kehittämiskeskus / Finnish Medicines Agency Kansallinen HTA-koordinaatioyksikkö / Finnish Coordinating Center for Health Technology Assessment (FINCCHTA)	Fimea performs HTA with a focus on the assessment of new hospital-only medicines. FinCCHTA performs cordinates national HTA network and produces Digi-HTA reviews	
National competition authority	Kilpailu- ja kuluttajavirasto / Finnish Competition and Consumer Authority	Enforces competition regulation and informs consumers.	
National patent office	Patentti- ja rekisterihallitus / Finnish Patent and Registration Office	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Suomen Lääkäriilitto / Finlands Läkarförbund *Medical societies:* • Suomen Endokrinologiyhdistys / Finnish Endocrinological Society • Suomen Gastroenterologiayhdistys (SGY) / Finnish Gastroenterology Association • Suomen Hematologiyhdistys (SHY) / Finnish Society of Hematology • Suomen Onkologiyhdistys (SOY) / Finnish Oncology Society • Suomen Reumatologiyhdistys (SRY) / Finnish Rheumatology Society	Prescribe biosimilars and decide regarding switches. Inform patients about biosimilars. Several medical societies in disease areas with biologics use identified (see left).	
Nurses	*Represented by:* Suomen Sairaanhoitajaliitto / Finnish Nurses Association	May prescribe medicines, but not biologicals. Advice patients in the use of biologicals, e.g. injection technique etc.	
Community pharmacists	*Represented by:* Suomen Apteekkariliitto / Finlands	Dispense medicines and conduct biosimilar substitution, inform patients	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
	Apotekareförbund / Association of Finnish Pharmacies	in the technical use of the drug injection device and possible differences in the interchanged products. .	
Hospital pharmacists	*Represented by:* Farmasilaliitto / The Finnish Pharmacists' Association[3]	Procure medicines, inform mainly physicians and nurses.	
Patient organisations	*Represented disease related associations:* • Suomen Diabetesliitto / Finnish Diabetes Association • Crohn ja Colitis ry / Finnish Crohn's and Colitis Association • Suomen Hemofiliayhdistys (SHY) / The Finnish Hemophilia Society • Suomen Syöpäyhdistys / Finnish Cancer Society • Suomen Reumaliitto / Finnish Rheumatism Association • Invalidiliitto / Finnish Association of People with Physical Disabilities	Patient organisations in diseases with biologics use (see left). No general patient organisation identified.	
Consumer organisations	No representation identified		
Biosimilar industry	*Represented by:* Suomen Bioteollisuus (FIB) / Finnish Bioindustries	Represents Finnish bioindustries.	
Generic industry	Rinnakkaislääketeollisuus Ry / Finnish Generic Pharmaceutical Association (FGA)	Represents Finnish generic industry, offer information on biosimilar on its website	
Pharmaceutical industry in general	*Represented by:* Lääketeollisuus ry / Pharma Industry Finland (PIF)	Represents Finnish pharmaceutical industry in general.	PIF 2021 (PIF position paper: opposition to INN prescribing for biologics and biosimilar substitution)
Pharmaceutical industry for new biological medicines	*Represented by:* Suomen Bioteollisuus (FIB) /Finnish Bioindustries	See above.	
Parallel imported products	Suomen rinnakkaislääketuojat ry / Suppliers of Parallel Imported Medicines in Finland	Represent parallel importers.	

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium), KELA 2025

4 Biosimilar policies and practices in Finland 2025

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

4.1 Pricing and procurement policies

Biosimilar price link

A **biosimilar price link** is in place.	Yes, in place.
It applies for the following situations:	All biosimilars entering the market (outpatient sector only)
Price reduction of the first biosimilar compared to the reference product	Minus 30% compared to reference product.
Price reduction of the second, third and further biosimilars	Same for first biosimilar (minus 30% compared to reference product
Price reduction for the reference product	Yes. Not automatically, but when a biosimilar of the same active substance enters the reimbursement system and the market, the Pharmaceuticals Pricing Board is required to re-evaluate the reasonable wholesale price for the reference product.
Any further specificities	
Generic price link	Yes, in place.

Source: PPRI 2025, Luukanen et al. 2022

External price referencing

External price referencing is applied for biosimilars.	Yes
If yes, it is applied for the following situations:	-
Any specificities	
External price pricing is in place for other medicines than biosimilars.	Yes

Source: PPRI 2025, Medicines for Europe 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.
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All biologic medicines
Institutional framework	Regional procurement in procurement pools by university hospitals.
Information available on procurement procedures and practices	Tender contracts are awarded by active substance. Tender contracts must be reopened once biosimilar medicines enter the market. In practice, tenders are usually reopened shortly after expiry of loss of exclusivity. Prices of the winning tender are made transparent to competitors. Contracts are typically awarded to one winner only. Main award criteria are price – for "less sophisticated' medicines"– and MEAT criteria as preferred approach. MEAT criteria include price, usability, patient and work safety and (seldom) expenses for switching from formerly used products.

Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	Not applicable as not in place.
Institutional framework	
Information available on procurement procedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes Outpatient: No

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Medicines for Europe 2023

4.2 Reimbursement policies 2025

Reference price system

Biosimilars are **included into the reference price system (RPS)** applied in the outpatient sector.	Yes
If yes, how many and under which specifications	Prerequisite is that they have been put on the list of interchangeable medicines by FIMEA and that they have reimbursement status.
If publicly accessible, indicate URL of RPS list	List of substitutable products: Keskenään vaihtokelpoisten valmisteiden luettelo - Fimea.fi - Fimea Decisions on RP groups and reference prices: Viitehintaryhmät ja viitehinnat - päätökset - Lääkkeiden hintalautakunta
When were first biosimilars included in the reference price system?	Since 2024 (reference price system – for generics – was introduced in 2009)
Any further specificities	See link to biosimilar substitution introduced in 2024 (see below): if the patient refuses biosimilar substitution, s/he has to pay the difference between the reimbursed reference price and the actual higher price
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	Yes, in place. ATC-5 cluster.

Source: PPRI 2025, Medicines for Europe 2023, Martikainen and Sarnola 2025, FIMEA 2025c

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, the reimbursement procedure is the same as for other medicines.
If yes, how many and date of inclusion into reimbursement, if known)	Decisions on RP groups and reference prices: Lääkkeiden hintalautakunta
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	See below for different reimbursement schemes applicable in Finland.
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	No
Indicate URL of outpatient positive list	Medicinal Products Database

Co-payments for biosimilars for outpatient use	Yes, there are three categories of reimbursement (for all medicines, not only biosimilars): • Basic rate of reimbursement 40% • Lower special rate of reimbursement 65% • Higher special rate of reimbursement 100%. A co-payment of € 4.50 per medicine and per purchase is charged." There is an annual deductible of € 50 that must be paid before reimbursement applies. Upon reaching the threshold for the deductible, the co-payment drops to € 2.50 per medicine.
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	National positive list(s). 100% reimbursement for some medicines and lower rates for other medicines included in reimbursement lists. Co-payments are charged for funded medicines in the outpatient sector.
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes, included in hospital pharmaceutical formularies.
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 published.
Co-payments for biosimilars for inpatient use	Medicines are included in the client fee that patients pay.
For medicines for inpatient use in general (other medicines than biosimilars): Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	No national list(s), but regional /hospital level pharmaceutical formularies. Medicines are included in the client fee that patients pay

Source: PPRI 2025, Medicines for Europe 2023, KELA 2025b

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))	There is no principle barrier to confirm conditional substitution status for biosimilars. However, not applied.
Enforcement of anti-trust policies	Nothing special for bioisimilars.
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Predominantly financial MEAs and some performance-based MEAs.

Source: PPRI 2025

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	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

Health technology assessment

HTA is applied for biosimilar medicines	Yes (in some cases)
If yes, in which situations and settings (outpatient and inpatient)	Outpatient partly, inpatient no
Differences in criteria and processes of HTA for biosimilars compared to other medicines	FIMEA performs HTA with a focus on new hospital medicines. In outpatient process health economic evaluation is obligatory to new active ingredients, only.
Any specificities	

Source: PPRI 2025

4.5 Demand-side measures

Physicians (and further prescribers)

Country context: Physicians prescribe medicines.

Source: InfoFinland 2025

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes, since 2017 doctors have been mandated to prescribe the biologic medicine with the lowest expenditure (price) as soon as a biosimilar is available. If not, a written justification must be provided by the prescriber. Since beginning of the 2023, this obligation has been strengthened through regulation in law
If yes, what is recommended for naïve patients?	See above mandatory prescribing of lowest price biological product.
If yes, what is recommended for patients already on biologic treatment	See above, mandatory switching to the lowest price biological when renewing the prescription (Prescription is valid one year)
Prescription guidelines (including switching guidelines) were issued by	Decree of the Ministry of Social Affairs and Health from 2017 Since 2023 also regulated in Act on Electronic Prescriptions from 2023, which allowed monitoring of prescribing behaviour of individual physicians to be supervised by KELA (see also below)
URL of prescription & switching guidelines	Laki sähköisestä lääkemääräyksestä | 61/2007 | Lainsäädäntö | Finlex
Prescribing quotas	
Prescribing quotas for doctors regarding prescription of biosimilars exist	No, not in place.
If yes, which quotas are defined for biosimilars	Not applicable as not in place.
Any exemptions	
Any sanctions in case of non-achievement	
Any (financial) incentives for achieving the quotas	
Prescribing quotas were issued by	
URL of prescribing quotas	
Prescribing quotas for other non-biosimilar medicines exists	No, not in place.

Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	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	
INN prescribing	
In general, prescribing by **INN is in place** (information not focused on biologics)	Yes, INN prescribing is allowed (voluntary); if prescriptions are issued by trade name, it is mandatory to prescribe the biologic that accounts for the lowest expenses (see above)
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	In regulation there is no exemption for biologicals. In practice INN prescribing of biologicals is not recommended.
Further measures targeted at doctors	
Information materials for doctors	Yes, information on website, leaflets, etc. Key producers are Medicines Agency FIMEA and Social Insurance Institution KELA **FIMEA**: Statement on interchangeability (FIMEA 2015) Published information series on biosimilars, including summaries of studies (Sarnola et al. 2019, Tolonen et al. 2019) **KELA**: e.g. KELA 2021, KELA 2024a Since 2023 monitoring of prescribing behaviour of individual physicians by KELA, which offers: - online service where doctors can view their personal prescription information - targeted prescription feedback in the form of letters (KELA 2025) In 2023, 520 physicians (48% of all physicians who had prescribed at least a biologic where a comparator at a different price was available) received a guidance letter to support responsible prescribing (Sarnola and Koskinen 2024).
Information events for doctors (e.g., seminars, trainings)	Yes, seminars, conferences or workshops, mainly provided by authorities. Finnish Medicines Agency for example has sent a letter to chief physicians.
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	Yes, Nikkonen and Kolho 2020 found that *"the first-year therapy outcomes of infliximab and its biosimilar were comparable. There were no alarming signs of differences in safety."*

Source: PPRI 2025, KELA 2025, Nikkonen and Kolho 2020, Sarnola et al. 2025b, Sarnola and Koskinen 2025

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense.

Substitution policies	
(Automatic) substitution for biosimilars	Yes, mandatory
If yes, for which biologic substances and under which prerequisites?	Implementation in a stepwise approach during 2024-2026: • Low-molecular-weight heparins from 1 January 2024 • Other biologicals except insulins from 1 October 2024 • Insulin glargine from 1 January 2025 • Long-acting insulins from 1 October 2025 Short acting insulins and biological products used by patients under 18 years are excluded from substitution.

If yes, since when, and when was it extended? (process of implementation)	2023 (legal basis and preparation), 2024-2026 (stepwise implementation)
Any specificities	If the patient refuses substitution, s/he has to pay the difference between the reimbursed reference price and the actual higher price. A doctor may oppose substitution on therapeutic grounds, and s/he must document this on the prescription. In such cases, the patient is reimbursed for the prescribed (higher-priced) medicine. The patient is always entitled to the have same product for 6 months.
URL of underlying law	https://finlex.fi/fi/lainsaadanto/1987/395
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	Yes, information, mainly provided by FIMEA and KELA **KELA**: the Social Insurance Institution of Finland to inform about implications of the prescription control for doctors (guideline to prescribe the lowest-priced biologic) on pharmacies (KELA 2023) and information for pharmacists on biosimilar substitution including related changes in the database, guidance in case of non-availability of the substitutable medicine and a leaflet that pharmacists may offer to patients (KELA 2024c) **FIMEA**: Information for health professionals: FIMEA 2025d (information on biosimilar substitution including a link to product-specific guidance for pharmacists on substitution)
Information events for pharmacists (e.g., seminars, trainings)	

Source: PPRI 2025, Martikainen and Sarnola 2023, KELA 2023, KELA 2025c

Patients

Information and educational measures	
Information materials for patients	Yes, information campaigns, leaflets, and websites, mainly provided by authorities.
If yes, provide URL of most common materials	Information for patients: FIMEA 2025b (Information on biosimilar substitution) FIMEA 2025c (What is a biosimilar?)
If yes, key producers of education measures	Medicines Agency FIMEA and Social Insurance Institution of Finland KELA
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. However, there is a financial incentive to patient to accept lowest price biological product in the outpatient sector due to the grouping of biosimilars and reference products into the reference price system. In case of insisting of a higher priced medicine (e.g. originator biologicals), patients have to co-payment.
If yes, pls. describe	Not applicable as not in place.
Publicly accessible information	

Source: PPRI 2025, Martikainen and Sarnola 2025, FIMEA 2025c

5 Impact of biosimilar policies and practices in Finland

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 Finland

Outcome indicator	Caused by	Findings	Publication
Price reductions and market shares of biosimilars and biologicals	Mix of policies in the outpatient setting during the (long) study period (e.g., biosimilar price link, including reduction of the price of the reference product, prescribers' obligation to prescribe the lowest-priced biologic)	The study examined prices and market shares of biologics in the outpatient setting in Finland during 2009–2020, in particular the prices of the reference products upon market entry of biosimilars, and the development of the prices and market shares of outpatient biosimilars in the study period. The study showed that the prices of the reference products mainly decreased after the biosimilar entered the market; otherwise they would have lost reimbursement status. The changes in in the prices of reference products were steeper than the changes in the prices of biosimilars which decreases and even remained stable. There was large variation in the uptake of biosimilars between the active substances. The study concluded that changes in pricing and reimbursement policies during the observation period (in 2013 and 2017) had an impact on the prices of reference products.	Luukkanen et al. 2022
Patient knowledge about biologic medicines and their attitude on biosimilar substitution	Not applicable	The study conducted a survey with patients in Finnish outpatient care about their knowledge about biological medicines and the opinions of biosimilar substitution in 2022 (at this time, biosimilar substitution was being prepared in Finland). The study showed limited knowledge of prescribed biologics. Approximately 60% of the respondents (n: 199) stated that they would oppose to the prescribed medicine substituted in pharmacy, since they wanted to keep the medicine the doctor had prescribed for them. In general, biosimilar users were more accepting towards possible interchange than originator users.	Pölkki and Prami 2024
Biosimilar prescribing	Physician attitude towards biosimilars	The study aimed to investigate the attitudes of physicians who prescribe biological medicines and their views on the uptake of biosimilars, the factors that promote and prevent the uptake of biosimilars, and the sources of information about biological medicines that are used by physicians. This was done through semi-structured interviews and focus groups, with a focus on physicians on dermatological, gastroenterological and rheumatological diseases in specialised medical care and on the treatment of diabetes in specialised medical care and primary health care. The prescribers' views were rather positive but biosimilars were not as commonly prescribed (either for naïve patients as well as switching) as could have been expected based on the physicians' largely positive view. Prescribers were rather sceptical toward biosimilar substitution by pharmacists.	Sarnola et al. 2019
Biosimilar prescribing	No policy specified	The study investigated the biosimilar prescribing in Finland from 2018 to 2023 (outpatient sector only). The share of biosimilars increased from 13.1% to 50.8% in all outpatient prescriptions (and from 11.9% to 50.6% for new prescription). However, there was largely variation across the therapeutic groups. Low biosimilar prescribing was particularly observed for insulins glargine and aspart, and the authors attributed this to evergreening phenomena.	Sarnola et al. 2024a

Outcome indicator	Caused by	Findings	Publication
Improved prescribing (increased share of prescribing of lowest-priced biologic)	"Steering of prescribing" (i.e. monitoring of compliance in biosimilar prescribing to guideline) and follow-up action	The study examined the impact of the measure of "steering of prescribing" by examining outpatient biologic prescriptions between March 2023 to January 2024. In March 2023, the lowest-priced product was prescribed in 8% of the cases, while after the steering took place, the share of the least expensive rose to 55% by January 2024 (one active ingredient, which is not specified in that piece of literature). Throughout the observation period, the lowest-priced biologic medicine was prescribed in average of 51% of the cases.	Sarnola et al. 2024b
Improved prescribing (increased share of prescribing of lowest-priced biologic)	"Steering of prescribing" (i.e. monitoring of compliance in biosimilar prescribing to guideline) and follow-up action	The study investigated the effect of the measure of "steering of prescribing", starting in 2023 (i.e. the Social Health Insurance KELA to monitor the prescribing behaviour of doctors, whether or not they follow the prescribing guidelines to prescribe the biologic with the lowest price) and, if not, to follow up with action (e.g., feedback on prescribing, guidance letter). During the observation period, in 52% of all prescriptions, physicians selected the least inexpensive biologic medicine. The share of the least inexpensive product out of all prescribed products rose in 2023 (from 8% in March-May to 54% in July for one active ingredient, which is not specified in that piece of literature).	Sarnola and Koskinen 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 Finland

Legal barriers

In principle, no legal barriers were identified. However, the fact that the obligation for prescribers to prescribe the lowest-priced biologic was strengthened by the inclusion into a law in 2023 (introduced on the basis of a decree in 2017) suggests that there appeared to have been room to stronger legal regulation and regulation.

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

Finland has a fragmented pharmaceutical system, with different pricing, reimbursement and procurement policies for outpatient and inpatient sectors (Luukkanen et al. 2022). A mix of policies has been implemented to encourage biosimilar uptake in the outpatient sector; not all policies may be applicable for the inpatient sector.

Evidence and communication-related barriers

In a study that surveyed the position of different health care providers, pharmaceutical industry and distribution actors, and patients in 2019, strong opposition was expressed regarding biosimilar substitution. Arguments expressing concerns about medication safety were raised. The authors commented that several statements made by the interviewees suggested that objective information about the comparability of biological reference products and their biosimilars had not sufficiently reached all stakeholders (Tolonen et al. 2019). It was also echoed at the Biosimilar Multistakeholder Workshop organised by the European Commission in 2024, in which it was confirmed that numerous information materials had been produced but had apparently not been successful in conveying the message, and novel channels and forms of communication were suggested.

Policy-related barriers

Research suggested that existing policies were not able to generate competition, motivate doctors to prescribe biosimilars and encourage the uptake of biosimilars as the potential for biosimilar would allow (Tolonen 2023). This led to further development and introduction of new policies recently (2023 and 2024).

Stakeholder-related barriers

Despite extensive information activities, knowledge about biosimilars of (some) health professionals and patients was still found to be limited.

Though interviewed **physicians** expressed a rather positive attitude towards biosimilars, their prescribing behaviour did not reflect this. According to a study,

major physician-related obstacles to biosimilar prescribing (mentioned by prescribers) included personal opinions and desire for prescription autonomy, limited price and cost awareness of biological medicines, limited knowledge of biosimilars, limited patient experience and familiarity of the reference product. Prescribers also mentioned patient-related obstacles such as the patient's desire to be treated with the reference product and the possibility of mix-up of medicines, and product-related barriers such as the non-availability of the biosimilar and the fact that the price difference between the reference product and the biosimilar was considered as too small. In that survey, nurses' preferences and competence were also mentioned as a barrier to biosimilar prescribing (Sarnola e al. 2019).

Patients were found to have limited knowledge about biosimilars and to be potentially hesitant towards biosimilar substitution (in 2022, thus before biosimilar substitution, 60% of surveyed patients, rather a small sample size of approximately 200 respondents). This reluctance was driven by the interest of patients to stick with the medicine prescribed by the doctors (Pölkki and Prami 2024).

The **pharmaceutical industry** association published a statement in 2021. Though acknowledging the value of biosimilars, strong opposition was expressed towards INN prescribing for biologics and biosimilar substitution, and it was requested that procuring hospitals have "sufficient selection of biological original medicines and biosimilars".

7 Facilitators and good practice examples in Finland

Among Europe, Finland is one of the leading and outstanding countries with regard to biosimilar policies and practices. Finland has introduced **several policies**, both in the supply-side as well as in the demand-side. Among others, Finland is one of the few countries which introduced biosimilar substitution, and Finnish authorities (in particular the Finnish Medicines Agency and the Social Insurance Institution of Finland) have been involved in numerous information activities. Their websites offer a **wealth of information**, which is even acknowledged by other stakeholders.

Finland has been **introducing biosimilar policies over the years**, in reaction of findings of **scientific evidence**. Researchers of the Social Insurance Institution KELA studied biosimilar uptake, prices and competition as well as stakeholder attitudes towards biosimilars and biosimilar policies. Based on identified gaps and room for improvement, further policies were implemented and introduced, and the introduction was frequently accompanied by the extensive information activities and by research to measure the impact of the policies. **KELA has a research department** which investigates policy implementation, and findings are broadly disseminated.

Biosimilar policy implementation has not only been performed gradually over the years to constantly align the system to existing challenges, but some measures were also introduced in a **stepwise approach** (e.g., biosimilar substitution, with extension of the scope of biologics covered over two years). Another interesting example was the strengthening of the obligation to prescribe the lowest-priced biologic (already

introduced in 2017) through stronger legal basis and an enforcement mechanism (prescribing behaviour monitoring and feedback by KELA) in 2023.

Public authorities collaborate on the topic of biosimilar uptake, complementing their activities. It appears that this is backed by strong political support, with biosimilar policy being high on the policy agenda.

8 Developments in Finland

Recent changes

1 January 2023:	Reduction of the **validity period of prescriptions of biological medicines** to 1 year only (previously it was 2 years)
1 January 2023:	**"Steering of prescribing" – enforcement**: Already since beginning of 2017, prescribers have been obliged to prescribe the lowest priced medicines of an active biological substance as soon as a biosimilar was available. Enforcement has been strengthened since the original legislation (a Decree of Ministry of Social Affairs and Health) valid from 2017 has been supplemented by a specification in the Act on Electronic Prescriptions from 2023. From 2023, monitoring of prescribing behaviour of individual physicians has been supervised by KELA
1 January 2024:	Introduction of **biosimilars into the existing reference price system** (outpatient sector)
1 January 2024:	Introduction of **biosimilar substitution in community pharmacy** through a step-wise approach: 1 January 2024: for low-molecular-weight heparins 1 October 2024: for all other biologicals except insulins 1 January 2025: for glargine insulin and 1 October 2025: for long-acting insulins.
1 January 2025:	Reevaluated price of the reference product can be no more than 75 percent of the highest wholesale price approved for the biosimilar preparation. Biosimilars will be priced at the same level.
1 January 2025:	Annual deductible increased to € 70.

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