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

AUGMENT Biosimilars
Country fiche ICELAND

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augment biosimilars

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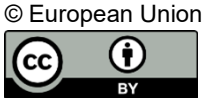

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Annex 7.14

AUGMENT Biosimilars country fiche: Iceland 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.

This country fiche has not been validated by national experts.

How to quote: Petrova G: AUGMENT Biosimilars country fiche: Iceland 2025. Annex to the study on "Capacity building to support the uptake of biosimilars in a multistakeholder approach", AUGMENT, 2025. Commissioned by the European Health and Digital Executive Agency (HaDEA)

1 Summary of biosimilar policies and practice in Iceland 2025

Key stakeholders

Key stakeholders with regard to biosimilar policies are the Ministry of Health, Icelandic Medicines Agency (IMA), and Lyfjanefnd Landspítala, which is the Medicine Committee of the National Hospital of Iceland (MCL). The role of the Ministry of health is to endorse legislation regarding biosimilars. The Medicines Agency is authorising for sale biosimilars, control prices, observe safety.

Major biosimilar policies and practices

In Iceland, no biosimilar price link is in place, but external price referencing (to the four other Nordic countries) is applied, also for biosimilars, with a linkage element for the originator biological. Centralised tender at national level is organised for hospital medicines, including biosimilars. For medicines in outpatient care there is a positive list. There are recommendations for physicians to prescribe biosimilars for naïve patients, and to switch patients for economic reasons. In Iceland, prescribing by INN for biologicals is allowed, and so is automatic biosimilar substitution at community pharmacy level. Icelandic medicines agency stated that they will organise education on biosimilars to improve knowledge and acceptance.

Impact analysis

Iceland is a small country with well-developed biosimilars policy. The expectations that biosimilars will decrease the cost burden to payer and will provide more opportunities to treat patients in need.

Barriers, facilitators and good practice examples

Despite the small market size as barrier, Icelandic authorities are trying to stimulate the biosimilar uptake and to ensure patients access to affordable medicines through a variety of measures, such as price control, tendering, publishing price list.

Recent developments

In August 2023, the Iceland Medicines Agency extended the classification in the Medicines Price List from previously three categories (original medicines, generic medicines, parallel imported medicines) into a more extended list which explicitly mentions biologicals and biosimilars.

2 Key data regarding biosimilars in Iceland

Key national publicly accessible sources reporting data on biosimilars

- List of medicines marketed in Iceland: https://www.serlyfjaskra.is/ (IMA 2024a)

- Information in the Icelandic Medicinal Product Information Database and the Icelandic Medicine Price Catalogue (general, not focused on biosimilars): https://www.ima.is/wp-content/uploads/sites/3/2023/11/20231124-Publication-of-information-in-the-Icelandic-Medicinal-Product-Information-Database-and-the-Icelandic-Medicine-Price-Catalogue-BIRT.pdf (IMA 2024b)

3 Stakeholders involved in and targeted by biosimilar policies in Iceland

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Sjúkrahúsið Akureyri / Ministry of Health	Prepares legislation	Medicinal Products Act, No. 100/2020, as amended by Act No. 132/2020, 14/2022 and 29/2024)
National regulatory authority	Lyfjastofnun / Icelandic Medicines Agency (IMA)	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance. Maintains and publishes on its webpage the substitution list, see next column	Maintain and publish on its webpage the substitution list in which interchangeable preparations, biosimilars and medicinal products with comparable efficacy in treatment are grouped together listed. (art. 52, Medicinal Products Act, No. 100/2020, as amended by Act No. 132/2020, 14/2022 and 29/2024)
Pharmaceu-tical pricing authority	Lyfjastofnun / Icelandic Medicines Agency (IMA)	Implements pricing legislation regarding biosimilars, decides on the prices	Icelandic Medicinal Product Information Database and the Icelandic Medicine Price Catalogue (general, not focused on biosimilars)
Pharmaceu-tical reimburseme nt authority	1. Lyfjastofnun / Icelandic Medicines Agency (IMA) 2. Lyfjanefnd Landspítalans / Medicine Committee of the National Hospital of Iceland (MCL)	Lyfjastofnun decides on inclusion into reimbursement for biosimilars and their price in the outpatient sector The MCL decides on procuring of medicines, including biosimilars, in hospitals	
Procurement agency	Landspítali - University Hospital	Landspítali is by far the largest purchaser of medicine and medical supplies in Iceland and all tenders are processed through the State Trading Center (Ríkiskaup).	Landspítali information
HTA agency / body	Lyfjastofnun / Icelandic Medicines Agency (IMA)		Iceland joined in April 2024 the Nordic HTA-collaboration – FINOSE
National competition authority	Samkeppniseftirlitið / Icelandic Competition Authority (ICA)	Enforcement of the competition law, anti-trust cases	
National patent office	Einkaleyfastofan / Icelandic Intellectual Property Office	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Læknafélag Íslands (LÍ) / Icelandic Medical Association	Prescribe biosimilars, Inform patients and Medical societies in disease areas with biologics use	
Nurses	*Represented by:* Félag íslenskra hjúkrunarfræðinga (FÍH) / Icelandic Nurses' Association		
Community pharmacists	*Represented by:* Lyfjafræðingafélag Íslands (LFÍ) / Icelandic Pharmacists' Association	Dispense medicines, inform patients	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Hospital pharmacists	*Represented by:* Lyfjafræðingafélag Íslands (LFÍ) / Hospital Pharmacy Group within the Pharmaceutical Society of Iceland	Support procuring medicines, inform patients / health professionals / procurers	
Patient organisations		Patient organisations in diseases with particular biologics use a/o organisations with specific advocacy or education work on biosimilars	
Consumer organisations	Neytendasamtökin (NS) / Consumers' Association of Iceland		
Biosimilar industry	*Represented by:* Frumtök, the Icelandic Association of the Pharmaceutical Industry	Produces and supplies biosimilars	Frumtök's membership comprises various pharmaceutical companies operating in Iceland, including those involved in biosimilar development and manufacturing
Generic industry	*Represented by:* Frumtök, the Icelandic Association of the Pharmaceutical Industry		
Pharmaceutical industry in general	*Represented by:* Frumtök, the Icelandic Association of the Pharmaceutical Industry		
Pharmaceutical industry for new biological medicines	*Represented by:* Frumtök, the Icelandic Association of the Pharmaceutical Industry		

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

4 Biosimilar policies and practices in Iceland 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
It applies for the following situations:	
Price reduction of the first biosimilar compared to the reference product	Not applicable
Price reduction of the second, third and further biosimilars	Not applicable
Price reduction for the reference product	Not applicable
Any further specificities	There are some linkage elements in external price referencing which has implications (see below).
Generic price link	No

Source: PPRI 2025, Vogler et al. 2024 ; https://www.centerforbiosimilars.com/view/policy-differences-among-european-nations-affect-biosimilar-uptake?utm_source=chatgpt.com

External price referencing

External price referencing is applied for biosimilars.	
If yes, it is applied for the following situations:	For biosimilar medicines in the outpatient and inpatient sectors entering the market
Any specificities	For new medicines, the benchmark price set through external price referencing is the lowest wholesale price of the four reference countries (Denmark, Norway, Sweden and Finland), however, in case of the availability of the biosimilar medicine on the market, the price of the biological originator is decreased to 80%.
External price referencing is in place for other medicines than biosimilars.	Yes, both in inpatient and outpatient sectors. According to the Medicines law: The Icelandic Medicines Agency shall take account of medicines prices and cost participation elsewhere in the Nordic countries and also in member states of the European Economic Area when taking its decisions.

Source: PPRI 2025; Medicinal Products Act, No. 100/2020, as amended by Act No. 132/2020, 14/2022 and 29/2024 https://www.centerforbiosimilars.com/view/policy-differences-among-european-nations-affect-biosimilar-uptake?utm_source=chatgpt.com**;** https://www.ima.is/wp-content/uploads/sites/3/2023/11/20231124-Publication-of-information-in-the-Icelandic-Medicinal-Product-Information-Database-and-the-Icelandic-Medicine-Price-Catalogue-BIRT.pdf

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 and outpatient sectors
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All biological medicines and sone further
Institutional framework	Centralized tendering process managed by Landspítali, the University Hospital of Iceland
Information available on procurement procedures and practices	Award criteria is based on the Most Economically Advantageous Tender (MEAT) criteria, including factors such as price, quality, and security of supply. Environmental criteria have been included in tenders since 2013, alongside other criteria like having a valid marketing authorisation in Iceland and guaranteeing two months' supply in warehouses. Primarily uses a single-winner approach, but a multi-award procedure is used when there are competing treatments.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	No, no tendering-like practices
Institutional framework	Not applicable
Information available on procurement procedures and practices	Not applicable
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes Outpatient: No, no tendering or tendering-like practices

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Vogler et al. 2024, Landspítali 2019

4.2 Reimbursement policies 2025

Reference price system

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	
If yes, how many and under which specifications	
If publicly accessible, indicate URL of RPS list	Icelandic Medicine Price Catalogue, available on IMA website - https://www.lyfjastofnun.is/verd-og-greidsluthatttaka/lyfjaverdskra/
When were first biosimilars included in the reference price system?	
Any further specificities	
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	Yes ATC 5 cluster

Source: PPRI 2025

Inclusion into reimbursement and co-payments

Reimbursement in the outpatient sector	
Apart from their potential inclusion into the reference price system (see above), biosimilars are included in outpatient reimbursement (positive list).	Yes
If yes, how many and date of inclusion into reimbursement, if known)	
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	Percentage reimbursement rates are in place, depending on the patient's medicine expenses with-in a 12 months period
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	
Indicate URL of outpatient positive list	Icelandic Medicine Price Catalogue, available on IMA website - https://www.lyfjastofnun.is/verd-og-greidsluthatttaka/lyfjaverdskra/
Co-payments for biosimilars for outpatient use	Deductible
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	For medicines in general for outpatient use: - Positive list - Percentage reimbursement rates are in place, depending on the patient's medicine expenses within a 12 months' period - Deductible only
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level)	Yes, additionally to the originator biological (and doctors are recommended to switch)
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	

Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	
Co-payments for biosimilars for inpatient use	No
<u>For medicines for inpatient use in general (other medicines than biosimilars):</u> Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	No co-payments for medicines for inpatient use

Source: PPRI 2025, Vogler et al. 2025

4.3 Specific pricing, procurement and funding policies

For defined medicines, public payers and payers have been piloting and implementing specific funding models (such conditional reimbursement, managed-entry agreements, and subscription models such as the Netflix models). Typically, these funding models apply for high-priced medicines with high uncertainties (e.g., originator biologicals) or for medicines with small populations whose uptake is aimed to be encouraged. The section provides information whether biosimilar medicines are also subject to specific funding models. Furthermore, it also looks into possible anti-trust cases.

Application of special pricing, procurement and reimbursement models for biosimilars (e.g., delinkage / subscription-model, management-entry agreements (MEA))	
Enforcement of anti-trust policies	
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Few managed entry agreements (volume based) – not clear whether they concern biosimilars.

Source: PPRI 2025

4.4 Supportive tools and practices for policy-makers 2025

Horizon scanning

Public authorities or public payers use a horizon scanning system to identify loss of exclusivity (patent expiry) of biologics	No
If yes, describe the process and the tools (e.g. regular consultation of a database, horizon scanning scoping meeting with stakeholders), including who use horizon scanning	

Source: PPRI 2025

Health technology assessment

HTA is applied for biosimilar medicines	No
If yes, in which situations and settings (outpatient and inpatient)	
Differences in criteria and processes of HTA for biosimilars compared to other medicines	
Any specificities	

Source: PPRI 2025

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Country context: Only doctors may prescribe / doctors and in a few cases also other health professionals may prescribe, pls. specify

Definitions:

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes
If yes, what is recommended for naïve patients?	Recommendation to prescribe biosimilars for naïve patients
If yes, what is recommended for patients already on biologic treatment	Recommendation to switch patients for economic reasons
Prescription guidelines (including switching guidelines) were issued by	The Drugs and Therapeutics Committee (DTC) at Landspitali is responsible for assessing new medicines and determining their benefit to patients. Through guidelines, the DTC advises for or against the use of these medicines for all health care institutions in Iceland.
URL of prescription & switching guidelines	
Prescribing quotas	
Prescribing quotas for doctors with regard to prescription of biosimilars exist	Yes
If yes, which quotas are defined for biosimilars	
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	
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	
Publicly accessible information	

INN prescribing	
In general, prescribing by INN is place (information not focused on biologics)	Yes, indicative
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	No exemption for biologicals from INN prescribing: biologics and biosimilars may be prescribed by INN
Further measures targeted at doctors	
Information materials for doctors	No There are educational materials for generic medicines, but not for biosimilars. https://www.lyfjastofnun.is/lyf/lyf-a-skiptiskra/upplysingar-um-lyf-a-skiptiskra-fyrir-starfsfolk-apoteka/
Information events for doctors (e.g., seminars, trainings)	
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	

Source: PPRI 2025

Pharmacists (and further dispensers)

Substitution policies	
(Automatic) substitution for biosimilars	Yes, indicative
If yes, for which biologic substances and under which prerequisites?	
If yes, since when, and when was it extended? (process of implementation)	
Any specificities	
URL of underlying law	
Generic substitution in place	Yes, indicative
Gain-sharing models	
Gain-sharing models for pharmacists	
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	
Publicly accessible information	
Further measures targeted at pharmacists	
Information materials for pharmacists	IMA is publishing information materials for generic medicines, reference clusters of generic medicines, prices of the reference clusters but not on the biosimilars.
Information events for pharmacists (e.g., seminars, trainings)	

Source: PPRI 2025

Patients

Information and educational measures	
Information materials for patients	No information
If yes, provide URL of most common materials	
If yes, key producers of education measures	
Information events for patients (e.g., seminars, trainings)	No information
Gain-sharing models	
Gain-sharing models for patients	No information
If yes, pls. describe	
Publicly accessible information	

Source: PPRI 2025

5 Impact of biosimilar policies and practices in Iceland

No literature was found on the impact of biosimilar policies and practices.

6 Barriers for biosimilar uptake and policy implementation in Iceland

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

The Icelandic healthcare system is highly centralized, with the Ministry of Health responsible for both outpatient and inpatient services. This centralized structure enables coordinated healthcare delivery and funding across different sectors. *Source: Iceland: health system review (https://iris.who.int/handle/10665/152934)*

Financial barriers

As a small country Iceland suffers from limited financial and human resources, as well as lack of control activities. There is no evidence of how the prescribing quotas are applied and controlled. (Medicinal Products (Act, No. 100/2020, as amended by Act No. 132/2020, 14/2022 and 29/2024)

7 Facilitators and good practice examples in Iceland

Icelandic Medicines Agency managed to increase the number of authorised medicines and thus improving the access to biosimilars.

8 Developments in Iceland

Recent changes

In August 2023, the Iceland Medicines Agency changed the classification in the Medicines Price List from previously three categories (orignator medicines, generic medicines, parallel imported medicines) into a more extended list which also explicitly mentions biologicals and biosimilars. This is intended to support prescribing and dispensing.

Source*: IMA 2023*

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