European Commission

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

AUGMENT Biosimilars
Country fiche LATVIA

Excerpt from:

European Commission: European Health and Digital Executive Agency, Vogler, S., Habimana, K., Helter, T., Knoll, V. et al., Capacity building to support the uptake of biosimilars in a multistakeholder approach – Final study report. Annex 7, AUGMENT, Country fiches, Publications Office of the European Union, 2025

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augment biosimilars

EUROPEAN COMMISSION

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Manuscript completed in November 2025

First edition

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Luxembourg: Publications Office of the European Union, 2025

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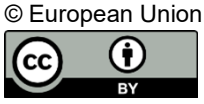

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PDF ISBN 978-92-95239-98-2 doi: 10.2925/9409811 HW-01-25-049-EN-N

Annex 7.17

AUGMENT Biosimilars country fiche: Latvia 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: Kuriata E: AUGMENT Biosimilars country fiche: Latvia 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 Latvia 2025

Key stakeholders

In Latvia, the key stakeholder in designing and implementing biosimilar policies is State Agency of Medicines.

Major biosimilar policies and practices

Latvian biosimilar pricing practices are based on biosimilar price link, furthermore, external price referencing is in use. Tendering is applied in all off-patent biosimilar medicines and is used in the inpatient sector. Reimbursement policies include the inclusion of biosimilars into the reference price system and reimbursement lists issued by the Agency State of Medicines.

Demand side measures include INN prescribing including biologicals and prescribing recommendations for physicians relating to biologicals and biosimilars. Automatic substitution for biosimilars at community pharmacy level is available (indicative).

Impact analysis

No information could be identified.

Barriers, facilitators and good practice examples

With regard to good practice examples – INN-prescribing, automatic substitution and switching are allowed. Biosimilars are included in the reference price system. Prescribing quotas for selected biological substances are in place.

Recent developments

From 1 April 2024 the changes to the regulation provide for easier placement for biosimilars medicines on the reimbursement list. In the event that medicines on the list prove ineffective for a patient or are contraindicated, the patient is able to receive other medicines for the appropriate diagnosis and at equivalent costs, no more than EUR 14,228.72 per year.

Highlights and learnings

Latvia has implemented several policies to manage the regulation and overall accessibility of biosimilars. The country employs a biosimilar price link and tendering for off-patent biosimilars (particularly in the inpatient sector). Reimbursement is guided by (internal) reference price system and reimbursement lists issued by the Agency State of Medicines. On the demand-side – measures such as INN prescribing and automatic substitution are in place.

2 Key data regarding biosimilars in Latvia

First biosimilar medicine launched (i.e. brought on the market):
Follitropin Alfa in 2015
Source: Medicines for Europe 2023 , Gascón et al. 2023

Number of the **biosimilars marketed**:
12 molecules with biosimilars available, as of November 2025
24 biosimilars (per trade name), as of November 2025
Source: NVD 2025

Key national publicly accessible sources reporting data on biosimilars

- National Health Service site: List of reimbursed medicines: https://www.vmnvd.gov.lv/lv/kompensejamo-zalu-saraksti?utm_source=https%3A%2F%2Fwww.google.com%2F

- No separate biosimilar register. https://www.vvc.gov.lv/en/laws-and-regulations-republic-latvia-english/cab-reg-no-899-procedures-reimbursement-expenditures-acquisition-medicinal-products-and-medical-devices-intended-outpatient-medical-treatment-amendments-07082018

3 Stakeholders involved in and targeted by biosimilar policies in Latvia

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-specific publications by this stakeholder group
Legislator	Veselības ministrija / Ministry of Health	Prepares legislation	https://www.vvc.gov.lv/en/laws-and-regulations-republic-latvia-english/cab-reg-no-899-procedures-reimbursement-expenditures-acquisition-medicinal-products-and-medical-devices-intended-outpatient-medical-treatment-amendments-07082018
National regulatory authority	Zāļu valsts aģentūra (ZVA) / State Agency of Medicines	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance	Brief information about biosimilars (ZVA 2019) General information about new biosimilars approved by EMA (ZVA 2025)
Pharmaceutical pricing authority	Zāļu valsts aģentūra (ZVA) / State Agency of Medicines	Implements pricing legislation regarding biosimilars, decides on the prices	Medicines for which the National Health Fund has concluded a financial co-participation agreement with a MAH or a wholesaler
Pharmaceutical reimburse-ment authority	Zāļu valsts aģentūra (ZVA) / State Agency of Medicines	Decides on inclusion into reimbursement for biosimilars and their price.	Medicines for which the National Health Fund has concluded a financial co-participation agreement with a MAH a wholesaler
Procurement agency	Zāļu valsts aģentūra (ZVA) / State Agency of Medicines Iepirkumu nodaļa / Procurement Division of the National Health Service	Involved in tenders and procurement procedures: Procurement is organised by the Procurement Division of the National Health Service (Iepirkumu nodaļa) which acts as a centralised purchasing body (CPB) (Behmane et al. 2019). For inpatient medicines on the list of centrally tendered products, individual hospitals enter contracts with suppliers on the basis of a framework agreement created by the CPB. For other medicines, hospitals conduct their own procurement (Anda et al. 2009). In addition to a core list of hospital medicines available at all hospitals Pharmaceuticals and Therapeutics Committee (PTCs) at individual hospitals define lists of medicines according to the hospital's specialisation and budget (Anda et al. 2009).	
HTA agency / body	Zāļu valsts aģentūra (ZVA) / State Agency	Health technology assessment, inclusion of	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-specific publications by this stakeholder group
	of Medicines	medicines in the list of reimbursable medicines	
National competition authority	Konkurences padome / Competition Councin	Enforcement of the competition law, anti-trust cases	
National patent office	Latvijas Republikas Patentu valde / Patent Office of the Republic of Latvia	Granting and managing patents on biologic medicines	
Doctors	Latvijas Ārstu bioedriba / Latvian Physicians Association *Medical societies in disease areas with biologics use*: Latvijas Gastroenterologu Asociācija (LGA) / Latvian Gastroenterology Association Latvijas Hematologu asociācija / Latvian Hematology Association Latvijas Onkoloģijas asociācija / Latvian Oncology Association Latvijas Reimatologu asociācija (LRA) / Latvian Rheumatology Association	Prescribe biosimilars and by INN. Inform patients	
Nurses	*Represented by:* Latvijas Māsu asociācija / Latvian Nurses Association		
Community pharmacists	*Represented by:* Latvijas farmaceitiskās aprūpes asociācija (LFAA) / Pharmaceutical Care Association of Latvia	Dispense medicines, inform patients	
Hospital pharmacists	*Represented by:* Latvijas Farmaceitu Biedriba (LFB) / Pharmacists' Society of Latvia	Support procuring medicines, inform patients / health professionals / procurers	
Patient organisations	*Represented by:* Patient organisations in diseases with particular biologics use: Latvijas Diabēta Federācija / Latvian Diabetes Federation	Informing patients	Hemophilia Association: Information on Biosimilars

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-specific publications by this stakeholder group
	Latvijas Krona slimības un čūlaina kolīta biedrība / Latvian Crohn's and Colitis Association Latvijas Hemofilijas Biedrība / Latvia's Hemophilia Association Latvijas Onkoloģisko pacientu asociācija (LOPA) / Latvian Cancer Patients Association Latvijas Reimatologu Asociācija / Latvian Rheumatology Association		
Consumer organisations	*Represented by:* Latvijas Patērētāju interešu aizstāvības asociācija (LPIAA) / Latvian Consumer Protection Association		
Biosimilar industry	*Represented by:* Latvijas Patentbrivo Medikamentu Asociacija (PMA) / Latvian Generic Medicines Association	Produces and supplies biosimilars	
Generic industry	*Represented by:* Latvijas Patentbrivo Medikamentu Asociacija (PMA) / Latvian Generic Medicines Association		
Pharmaceutical industry in general	*Represented by:* Starptautisko inovatīvo farmaceitisko firmu asociācija / Association of International Research-based Pharmaceutical Manufacturers (AFA)		
Pharmaceutical industry for new biological medicines	Represented by: -		

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium), WHO 2022

4 Biosimilar policies and practices in Latvia 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
It applies for the following situations:	
Price reduction of the first biosimilar compared to the reference product	30%
Price reduction of the second, third and further biosimilars	Second biosimilar must be priced at least 10% lower than the first biosimilar, and any further biosimilars priced at least 5% lower than the previous one.
Price reduction for the reference product	
Any further specificities	
Generic price link	Yes. The price of the first generic must be at least 30% lower than the price of the reference product. Additionally, the second and third generics must be priced at least 10% lower than the previous generic, and any further generics must be priced at least 5% lower than the previous one.

Source: PPRI 2025, Vogler et al. 2025, Moorkens et al. 2017

External price referencing

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

Source: PPRI 2025, Machado et al. 2025

Tendering

Some (or all) biosimilars are procured through tendering (or tendering-like) processes.	Yes
If yes, the scope with regard to the care sector:	Inpatient and outpatient sectors
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All off-patent biological medicines
Institutional framework	Conducted by hospitals
Information available on procurement procedures and practices	Award criteria include price, quality and efficacy, supply reliability. Both single and multiple-winner tenders. Average contract duration of the tender is 12 months.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	No
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

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

4.2 Reimbursement policies

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	Note: generic reference pricing system (RPS)
If publicly accessible, indicate URL of RPS list	
When were first biosimilars included in the reference price system?	2014
Any further specificities	
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	Yes Broader clusters than ATC 5

Source: PPRI 2025, Roediger et al. 2015

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)	12 molecules, 24 brand names
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	75% (but 100% for certain patient groups)
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	
Indicate URL of outpatient positive list	
Co-payments for biosimilars for outpatient use	Percentage co-payments (25% standard co-payment)
<u>For medicines for outpatient use in general (other medicines than biosimilars)</u> Positive list for medicines in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	For medicines in general for outpatient use: - Positive list - Percentage reimbursement rates are in place - Percentage co-payments

Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level)	Yes, additionally to the original biologicals (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
For medicines for inpatient use in general (other medicines than biosimilars): 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

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	Mix of financial and 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	
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)	For biosimilar medicines aiming to be included into the reimbursement list
Differences in criteria and processes of HTA for biosimilars compared to other medicines	
Any specificities	Economic analysis and BIA

Source: PPRI 2025, Kawalec 2017, Chamova 2017

4.5 Demand-side measures

Doctors (and further prescribers)

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

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes
If yes, what is recommended for naïve patients?	Mandatory 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	
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)	No information
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, mandatory
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	No exemptions for biologicals from INN prescribing: biologics and biosimilars may be prescribed by INN
Further measures targeted at doctors	
Information materials for doctors	
Information events for doctors (e.g., seminars, trainings)	
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	

Source: PPRI 2025, Barcina Lacosta et al. 2023

Pharmacists (and further dispensers)

Country context: no information

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	No information
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	No information
Information events for pharmacists (e.g., seminars, trainings)	

Source: PPRI 2025

Patients

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

Source: Barbier et al. 2022, PPRI 2025

5 Impact of biosimilar policies and practices in Latvia

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 Latvia

Outcome indicator	Caused by	Findings	Publication
Improved uptake	No specific policy analysed	Regarding three anti-TNF-α biosimilars (adalimumab, etanercept, and infliximab), the market share increased from 15% to 51% (2018 to 2023).	Grieco and Bodin 2024: https://www.ispor.org/docs/default-source/euro2024/isporeurope24griecohpr25poster142729-pdf.pdf?sfvrsn=8228559c_0

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 Latvia

Policy-related barriers

Limited reimbursement for biosimilars (information from a decade ago: not all indications of certain biosimilars are reimbursed (infliximab on plaque psoriasis or etanercept on axial spondyloarthritis and plaque psoriasis) (Kawalec et al. 2017).

Stakeholder-related barriers

Patients' limited knowledge and acceptance of biosimilars can be attributed to the insufficient availability of information and educational resources about biosimilars at the national level.

7 Facilitators and good practice examples in Latvia

Latvia implemented some supply-side policies related to biosimilars (e.g., inclusion of biosimilars in the RPS, biosimilar price link) and some demand-side measures (e.g., biosimilar substitution, allowing INN prescribing for biologics). This mix of policies suggests potential facilitating effect on biosimilar uptake.

8 Developments in Latvia

Recent changes

From July 2024 on, reimbursement rules changed for reimbursed medicines, including biosimilars For several medicines the reimbursement was increased from 50% to 75%, thus reducing the co-payment rates. Additionally, the changes provided for easier inclusion of generic and biosimilars in the reimbursement list from April 2024 and revised conditions for individual medicine reimbursement, expanding the possibility for patients to receive individual medicine reimbursement. The changes also provided that in cases where medicines included in the reimbursement list were not effective for a particular patient or are contraindicated, the patient would be able to receive other medicines for the relevant diagnosis, at equivalent costs. However, there was a cap of co-payment of 14,228.72 Euro per year (VMNVD 2014).

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