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

AUGMENT Biosimilars
Country fiche LITHUANIA

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augment biosimilars

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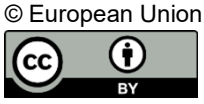

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Annex 7.19

AUGMENT Biosimilars country fiche: Lithuania 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 Lithuania in 2025

Key stakeholders

In Lithuania, the key stakeholder in designing and implementing biosimilar policies are MoH and National Health Insurance Fund under the Ministry of Health as well as the State Medicines Control Agency under the Ministry of Health.

Major biosimilar policies and practices

Lithuania uses the biosimilar price link policy for biosimilar pricing. Biosimilars are included in the reference pricing system. Biosimilars are not required to undergo health technology assessment, regarding the fact that active substance is already on the positive reimbursement list (List A - https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.94805/asr). Nevertheless, biosimilars do not require an HTA process, they should be included in the Price list while making its amendment. After biosimilar medicine comes into a price list, their price should be 15 % lower than the reference medicine, note that reference medicine also should lower its price by 15% to be included into a Price list to make their impact for a budget equal. In the inpatient sector biosimilars are also procured., Demand side-measures regarding biosimilar medicines include prescribing recommendations for physicians to switch to biosimilars. While prescribing by the International Non-Proprietary Name is mandatory, there is an exemption for biological pharmaceuticals, they could be prescribed by brand name, substitution to biosimilars is allowed, but it is not mandatory in a level of doctor. For biosimilars as any other pharmaceuticals internal and external reference pricing applies. Treatment in some conditions (if biologics isn’t grouped / clustered) with biologics (original or biosimilars) needs to be initiated with the cheapest one.

Impact analysis

No information found

Barriers, facilitators and good practice examples

In Lithuania, substitution from the reference drug to a biosimilar drug is possible within the physician's competence. Pharmacists are not allowed to change a biological medicine. Biosimilars are not required to undergo health technology assessment what may speed up the biosimilar uptake. Nevertheless, biosimilars do not require an HTA process, they should be included in the Price list while making its amendment.

Recent developments

To reduce the workload of doctors working in university hospitals, prescriptions for continued treatment could be issued at lower-level healthcare providers (e. g. prescription could be written by a specialist working in out-patient healthcare facilities).

Highlights and learnings

In Lithuania, biosimilar pricing and reimbursement involves grouping / clustering medicines into the therapeutic groups (reference price system). Price of a biosimilar entering the reimbursement system should be 15 % lower comparing to a reference medicine. It is notable that the reference medicine also has to educe its price by the same percentage to stay in a reimbursement system.

In Price List we have 83 biological medicines molecules, 16 out of them has biosimilar molecules and 39 trade names of biosimilars. Considering the fact that most of those reference biological medicines are still protected by a patent we could assess the availability of biosimilar medicines as good.

2 Key data regarding biosimilars in Lithuania

Number of the **biosimilars marketed**:
16 molecules with biosimilars available, as of November 2024
39 biosimilars (per trade name), as of November 2024

Source: Price List https://www.e-tar.lt/portal/lt/legalAct/8c...

In 2024, Oyavas (Bevacizumab) was centrally purchased and used.
Source: LRV 2024a

Biosimilar market shares in 2024 (or latest available data):

0.4 % **in volume** in 2024

Volume is defined as share of reimbursable medicines

2.1% **in value** in 2024
Value is defined as share of reimbursable medicines

Market to which the biosimilar market shares data relate to: total public market (outpatient and hospital, public sector only)

Source: data of NHIF systems which is publicly available here:
https://ligoniukasa.lrv.lt/lt/veiklos-sritys/gydym...

Key national publicly accessible sources reporting data on biosimilars

List of reimbursed medicines on the National Health Insurance Fund under the Ministry of Health site: available at: https://www.e-tar.lt/portal/lt/legalAct/8f... or https://kainynas.vlk.lt/webapp/index.html
Data on reimbursed amounts and expenditure available at:
https://ligoniukasa.lrv.lt/lt/veiklos-sritys/gydym...

Certification on the range of biological and synthetic disease-modifying medicines according to the minimum patient treatment price indicated in the price list of reimbursed medicines in 2024 on the National Health Insurance Fund under the Ministry of Health: available at: https://ligoniukasa.lrv.lt/public/canonical/1...pdf (Ligoniukasa 2024b)

https://ligoniukasa.lrv.lt/public/canonical/1735...pdf – 2025

3 Stakeholders involved in and targeted by biosimilar policies in Lithuania

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant publications by this stakeholder group
Legislator	Lietuvos Respublikos sveikatos apsaugos ministerija / Ministry of Health	Prepares legislation	Pharmaceutical Law Pharmaceutical Policy Action Plan
National regulatory authority	Valstybinė vaistų kontrolės tarnyba (VVKT) / State Medicines Control Agency	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance	General information for biologicals and biosimilars
Pharmaceutical pricing authority	Lietuvos Respublikos sveikatos apsaugos ministerija / Ministry of Health	Implements pricing legislation regarding biosimilars.	P&R rules for biologicals and biosimilars
Pharmaceutical reimbursement authority	Valstybinė ligonių kasa prie Sveikatos apsaugos ministerijos / National Health Insurance Fund under the Ministry of Health (NHIF)	NHIF implements a policy on biosimilars NHIF prepares a price list which includes biological medicines and biosimilars and calculates prices of medicines including biosimilars according to approved rules NHIF prepares recommendations to prescribe economically beneficial biological medicines for certain diseases (link to the list is added in next column)	Monitoring rate for TNF ALPHA inhibitors of reimbursed biosimilars National Health Insurance Fund under the Ministry of Health certification on the range of biological and synthetic disease-modifying medicines according to the minimum patient treatment price indicated in the price list of reimbursed medicines in 2025
Procurement agency	Centrinė perkančioji organizacija/ Central purchasing organisation (CPO) Valstybinė ligonių kasa prie Sveikatos apsaugos ministerijos / National Health Insurance Fund under the Ministry of Health	The main procurement agency is CPO Involved in tenders and procurement procedures for some medicines included into the Centrally purchased medicines list	Public Procurement Permanent Comission

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant publications by this stakeholder group
HTA agency / body	Valstybinė vaistų kontrolės tarnyba (VVKT) / State Medicines Control Agency	HTA is not performed for biosimilars	Recommendation regarding a medicine to the Reimbursement Commission for Medicinal Products and Medical Devices of the Ministry of Health of the Republic of Lithuania - example
National competition authority	Lietuvos Respublikos konkurencijos taryba / The Competition Council of the Republic of Lithuania	Enforcement of the competition law, anti-trust cases	
National patent office	Lietuvos Respublikos valstybinis patentų biuras / State Patent Bureau of the Republic of Lithuania	Granting and managing patents on biologic medicines	
Doctors	Different associations of doctors involved in the preparation of guidelines depending on the disease	Prescribe biosimilars a/o by INN. Inform patients Medical societies in disease areas with biologics use	Visuomeninės organizacijos - Lietuvos Respublikos sveikatos apsaugos ministerija
Patient organisations	Different patients representatives by the diseases	Patient organisations in diseases with particular biologics use a/o organisations with specific advocacy or education work on biosimilars	General information about biologics and biosimilars
Biosimilar industry	Represented by: Vaistų gamintojų asociacija (VGA) / Association of Generic Manufacturers	Part of generic association. Produces and supplies biosimilars Further educational or promotional activities? Proposals for policies of biosimilars pricing and reimbursement	
Generic industry	Represented by: Vaistų gamintojų asociacija (VGA) / Association of Generic Manufacturers	Same association as for biosimilars	General information about biosimilars Conference materials
Pharmaceutical industry in general	Represented by: Inovatyvios farmacijos pramonės asociacija (IFPA) / Innovative Pharmaceutical Industry Association Local American Working Group (LAWG) in the American Chamber of Commerce in Lithuania	Represents originators Proposals for policies of biologics pricing and reimbursement	

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

4 Biosimilar policies and practices in Lithuania 2025

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

4.1 Pricing and procurement policies 2025

Biosimilar price link

A **biosimilar price link** is in place.	Yes
It applies for the following situations:	~~F~~or biosimilar medicines in the outpatient sector entering the market
Price reduction of the first biosimilar compared to the reference product	15%
Price reduction of the second, third and further biosimilars	No
Price reduction for the reference product	Yes, same 15 %
Any further specificities	
Generic price link	Yes. The price of the first generic must be at least 30% lower than the reference product, while the price of reference product should be lowered as well.

Source: PPRI 2025a, Vogler et al. 2024

External price referencing

External price referencing is applied for biosimilars.	Yes
If yes, it is applied for the following situations:	ERP is applied for all medicines including biosimilars and reference pharmaceuticals
Any specificities	
External price referencing is in place for other medicines than biosimilars.	Yes, in the outpatient sector EPR determines prices of for all outpatient medicines, if there is one drug of a kind, its price is determined via the average of 3 lowest prices of the relevant active substance and pharmaceutical form, for a pharmaceutical groups of drugs of two and more manufacturers, the price is determined using 5 lowest prices of the relevant active substance and pharmaceutical form. The reference is made to the prices of all countries published in the EURIPID database, except for countries that conduct procurement by tender

Source: PPRI 2025

Tendering

Some (or all) biosimilars are procured through tendering (or tendering-like) processes.	Yes. In Lithuania, expensive medicinal products used in hospitals are included in the List of Centrally Procured Medicine. The medicines included in this list are purchased by the National Health Insurance Fund and distributed to hospitals. The medicines are listed by their active substances. During procurement, the main criterion for evaluating proposals often is the price, which determines which medicine will be purchased (original or biosimilar). A significant part of the medicines used in inpatient care are purchased by the hospitals themselves"
If yes, the scope with regard to the care sector:	Inpatient sector only

Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	Tendered medicines are not classified as chemical or biological. Some biological medicines are included in List A (used for outpatient treatment), some are purchased for hospitals by the State Patient Fund, and some are purchased by the hospitals themselves
Institutional framework	Centralised procurement on national level (by the National Health Insurance Fund) and on hospitals level.
Information available on procurement procedures and practices	Hospitals purchased medicines through a system established of a central purchasing body. If medicines are not available in the catalog of CPO hospital using procurement procedures themselves. No specific processes for procurement of biosimilars. Award criteria include price, quality, supply security, environmental, considerations, packaging and labeling. A single hospital tender in not allowed for more than single winner. The average contract duration of the tender is 12 months. The same procedure is carried out if medicines are purchased centrally by the National Health Insurance Fund.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	No, not applied
Institutional framework	Not applicable
Information available on procurement procedures and practices	Not appliable
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes Outpatient: No

Source: PPRI 2025a; Vogler, Salcher-Konrad and Habimana 2022; Vogler et al. 2024; Machado et al. 2024, 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	All of the biosimilars that are in the Price list
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 In the Price list, medicines are clustered by their active substance and pharmaceutical form, also in some cases they are clustered according to their similar clinical effect by the decision of Reimbursement committee

Source: PPRI 2025b

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)	Since 2014
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	100%
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	When an active substance is in a positive list, a generic and biosimilar drugs enters the price list without an HTA process
Indicate URL of outpatient positive list	https://e-seimas.lrs.lt/portal/legal...
Co-payments for biosimilars for outpatient use	The same co-payments as for any other reimbursable medicines applies, it could be 20% of pharmaceutical reimbursement price, but can not exceed 5,87 Eur per package of a 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	For medicines in general for outpatient use: - Positive list - Percentage reimbursement rates are in place (100% Reimbursement rate applies for all the medicines: - the same co-payments as discussed in previous question - Co-payment basket .If a person spends more than the three average annual co-payments (in 2025 – 59.04 euros) during a calendar year when purchasing reimbursable medicines with the lowest co-payment, he would be covered for all other reimbursable medicines with the lowest co-payment later in the same year.
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). If a biosimilar medicine is purchased centrally, all patients are treated with the biosimilar medicine (only one medicine is purchased)
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 2025a, Vogler et al. 2024

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))	No
Enforcement of anti-trust policies	No
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Mix of financial and performance-based MEAs

Source: PPRI 2025a

Source: Legislation on MEA's

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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, we are looking for a patent expiry dates of pharmaceuticals including biologicals, and checking our national registers for a new registered pharmaceuticals of a certain active substance including biological pharmaceuticals.
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	As stated in the previous question, yes, sometimes we check it

Source: PPRI 2025a

Health technology assessment

HTA is applied for biosimilar medicines	Not required
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 2025a, Kawalec et al. 2017

4.5 Demand-side measures

Doctors (and further prescribers)

Country context: Only doctors

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 its indicated in treatment guidelines, treatment is started by the cheapest one. For clustered/grouped biological medicine recommendation to prescribe biosimilars first for naïve patients is not required, because the price in the group of all biologics is the same
If yes, what is recommended for patients already on biologic treatment	Recommendation to switch patients for economic reasons is not applied because the reimbursed price of reference pharmaceuticals and biosimilars is the same
Prescription guidelines (including switching guidelines) were issued by Health Insurance	
URL of prescription & switching guidelines	
Prescribing quotas	
Prescribing quotas for doctors with regard to prescription of biosimilars exist	No
If yes, which quotas are defined for biosimilars	
Any exemptions	
Any sanctions in case of non-achievement	
Any (financial) incentives for achieving the quota	No
Prescribing quota were issued by	
URL of prescribing quotas	
Prescribing quota for other non-biosimilar medicines exists	No
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	No
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	Exemptions for biologicals from INN prescribing: biologics and biosimilars don’t need to be prescribed by INN
Further measures targeted at doctors	
Information materials for doctors	No
Information events for doctors (e.g., seminars, trainings)	No
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	

Source: PPRI 2025a, Barcina Lacosta et al. 2022

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense

Substitution policies	
(Automatic) substitution for biosimilars	No
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
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)	
Publicly accessible information	No
Further measures targeted at pharmacists	
Information materials for pharmacists	Yes
Information events for pharmacists (e.g., seminars, trainings)	Lectures Rational use of medicines

Source: Machado et al. 2024, Roediger et al. 2015, Barbier et al. 2022

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)	No
If yes, key providers of educational events	
Gain-sharing models	
Gain-sharing models for patients	No
If yes, pls. describe	
Publicly accessible information	No

Source: Machado et al. 2024, Barbier et al. 2022, PPRI 2025a

5 Impact of biosimilar policies and practices in Lithuania

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 Lithuania

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 31% to 68% (2018 to 2023).	Grieco 2024
Availability/improved uptake	No specific policy analysed but mix of policies considered	"to implement adalimumab on the market, new patients are prescribed the least expensive TNF- α inhibitor"	Moorkens et al. .2021

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 Lithuania

Legal barriers

The extended patent protection hinders biosimilar medicines from entering the market more quickly (there are cases where patent protection is applied only in Lithuania)

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 Lithuania

The Order No. 159 (Order on the approval of the description of the procedure for including medicinal products […] in the reimbursement lists) provides specific information on biosimilar medicines. Medicines registration data must include the status of biosimilar, registration as a biosimilar for the indication proposed for reimbursement. It should be also indicated whether are reference medicines for this biosimilar for specific indication. If the reference medicine for biosimilar has not been assessed for reimbursement in accordance with the indication the application is more complex.

No HTA for biosimilars
Recommendation to prescribe biosimilars for naïve patients, if its indicated in treatment guidelines, treatment is started by the cheapest one.
For clustered/grouped biological medicine recommendation to prescribe biosimilars first for naïve patients is not required, because the price in the group of all biologics is the same

8 Developments in Lithuania

Plans or under discussion

The implementation of the Medicines Policy Guidance is foreseen for 2027, increasing use of biosimilars is expected. Plan of action is available at: https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/72cff0618df811eea791d94269904d9b

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