European Commission

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

## AUGMENT Biosimilars
## Country fiche LUXEMBOURG

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augment biosimilars

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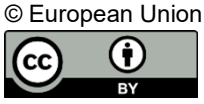

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Annex 7.20

# AUGMENT Biosimilars country fiche: Luxembourg 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.

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# 1 Summary of biosimilar policies and practice in Luxembourg 2025

**Key stakeholders**

The Ministry of Health and Social Security is responsible for the legislative framework. Prices are set by the Ministry of Economy, and National Health Fund (CNS) is the reimbursement authority. Medicines for the inpatient sector are procured by hospitals.

Not much is known about the role of the public institutions regarding their activities on policies to encourage biosimilar uptake. No documents from healthcare professionals and their associations and industry association regarding biosimilars could be identified.

**Major biosimilar policies and practices**

Luxembourg has a biosimilar price link in place, requesting biosimilar prices to be lower than the prices of the biological originator. In the hospital sector, biosimilar medicines are tendered. Few demand-side policies to encourage the biosimilar uptake are in place: Prescribing of biologics by the International Non-Proprietary Name and biosimilar substitution in the community pharmacy are not allowed.

**Impact analysis**

No studies that evaluated the impact of (biosimilar) policies on biosimilar use and competition could be identified.

**Barriers, facilitators and good practice examples**

Barriers: There is limited demand- and supply-side measures to encourage biosimilar uptake. Originator companies use anti-competitive strategies (e.g., discounts), limiting the market penetration of biosimilars. There is a systematic lack of national prescribing and switching guidelines regarding biosimilar medicines. Although scientific evidence on interchangeability. Demand-side policies, such as biosimilar substitution at community pharmacies, are absent.

Facilitators: Actions by Luxembourg’s national authorities might had a positive, impact, though limited — mainly by stimulating price reductions of the originator biologics following biosimilar entry or allowing biosimilar substitutions for naïve patients in the hospital setting. However, overall uptake remains low.

# 2 Key data regarding biosimilars in Luxembourg

No information available.

# 3 Stakeholders involved in and targeted by biosimilar policies in Luxembourg

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| Legislator | Ministère de la Santé et de la Sécurité sociale / Ministry of Health and Social Security (MSS) | Prepares legislation | |
| National regulatory authority | Ministère de la Santé et de la Sécurité sociale / Ministry of Health and Social Security (MSS) | Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance | |
| Pharmaceutical pricing authority | Ministère de l'Economie / Ministry of Economy | Implements pricing legislation regarding biosimilars, decides on the prices | |
| Pharmaceutical reimbursement authority | Caisse nationale de santé (CNS) / National Health Fund<br><br>Ministère de la Santé et de la Sécurité sociale / Ministry of Health and Social Security (MSS) | CNS decides on inclusion into reimbursement for biosimilars and their price. | |
| Procurement agency | Not applicable<br>Fédération des Hôpitaux Luxembourgeois (FHL) / Federation of Luxembourg Hospitals | Luxembourg has no national procurement agency for medicines. Hospitals in FHL are involved in tenders and procurement procedures | |
| HTA agency / body | Not applicable | Luxembourg has no HTA body | |
| National competition authority | Autorité de la Concurrence, Grand-Duché de Luxembourg | Enforcement of the competition law, anti-trust cases | |
| National patent office | Office de la propriété intellectuelle / Luxembourg Intellectual Property Office | Granting and managing patents on biologic medicines | |
| Doctors | *Represented by:*<br>Association des Médecins et Médecins-Dentistes du Grand-Duché de Luxembourg (AMMD)<br>*Medical societies*: | Prescribe biosimilars a/o by INN.<br>Inform patients<br>Medical societies in disease areas with biologics use | |
| Nurses | *Represented by:*<br>Association Nationale des Infirmiers et Infirmières Luxembourgeois (ANIL) / Luxembourg Nurses Association | | |
| Community pharmacists | *Represented by:*<br>Syndicat des Pharmaciens Luxembourgeois (a.s.b.l.) / Union of Luxembourg Pharmacists | Dispense medicines, inform patients | |
| Hospital pharmacists | *Represented by:*<br>Association des Pharmaciens Hospitaliers du Luxembourg (APHL) | Support procuring medicines, inform patients / health professionals / procurers | |

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| Patient organisations | *Represented by:* Patiente Vertriedung A.s.b.l. | Patient organisations in diseases with particular biologics use a/o organisations with specific advocacy or education work on biosimilars | |
| Consumer organisations | *Represented by:* Union luxembourgeoise des consommateurs (ULC) / Luxembourg Consumer Association | | |
| Biosimilar industry | *Represented by:* *No specific association, represented by* Innovative Medicines for Luxembourg (IML)? | | |
| Generic industry | *Represented by:* *No specific association* | | |
| Pharmaceutical industry in general | *Represented by:* Innovative Medicines for Luxembourg (IML) | | |
| Pharmaceutical industry for new biological medicines | *Represented by:* Innovative Medicines for Luxembourg (IML) | | |

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

# 4 Biosimilar policies and practices in Luxembourg 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. | No |
| It applies for the following situations: | |
| Price reduction of the first biosimilar compared to the reference product | |
| Price reduction of the second, third and further biosimilars | |
| Price reduction for the reference product | |
| Any further specificities | |
| Generic price link | Yes |

Source: PPRI 2025, Vogler et al. 2025

### External price referencing

| | |
|---|---|
| External price referencing is applied for biosimilars. | Yes<br>Available information confirms the existence of a reference price system for both generics and biosimilars used in oncology (Hofmarcher et al. 2024). |

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

Source: PPRI 2025, OCDE 2025, Hofmarcher 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 sector only |
| **Tendering biosimilars in the inpatient sector** | |
| Scope of biological medicines tendered | Some off-patent biological medicines |
| Institutional framework | Conducted by hospital procurement groups, the Federation of Luxembourg Hospitals (FHL)<br><br>Information on at least one procurement procedure for infliximab acquired through the Fédération des Hôpitaux Luxembourgeois (procurement procedure for the Centre Hospitalier Émile Mayrisch (CHEM), the Centre Hospitalier de Luxembourg (CHL), the Centre Hospitalier du Nord (CHdN), and the Hôpitaux Robert Schuman (HRS)). Further details can be found in the procurement notice available at the Luxembourg Public Procurement Portal (FHL, 2018). |
| Information available on procurement procedures and practices | |
| **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<br>Outpatient: No |

Source: PPRI 2025; Vogler et al, 2022, Vogler et al. 2025, FHL 2018.

## 4.2 Reimbursement policies

### Reference price system

| | |
|---|---|
| Biosimilars are included into the reference price system (RPS) applied in the outpatient sector. | Not applicable |
| If yes, how many and under which specifications | |
| If publicly accessible, indicate URL of RPS list | |
| 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? | No |

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 | It depends on the molecule. Yet, according to the positive list mentioned below, 100% coverage applies to most biologic medicines. |
| Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use | |
| Indicate URL of outpatient positive list | https://cns.public.lu/fr/assure/publications/legislations/textes-coordonnes/liste-positive.html |
| Co-payments for biosimilars for outpatient use | Percentage copayments, according to the CNS website:<br>- 60% for medicines of moderate benefit and intended to treat the symptoms of benign pathologies,<br>- 0% for medicines with a specific therapeutic indication<br>- 20% for all other medicines. |
| For medicines for outpatient use in general (other medicines than biosimilars)<br>Positive list for medicines in general<br>Percentage reimbursement rates are in place<br>Co-payments for reimbursable outpatient medicines | Health insurance covers all or part of the cost of medicines included on the positive list.<br>Copayments of 60%, 20% and 0%. |
| **Reimbursement in the inpatient sector** | |
| Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level) | Yes |
| 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):<br>Hospital pharmaceutical formularies<br>Co-payments for medicines for inpatient use | No co-payments in the inpatient sector |

Source: PPRI 2025, Vogler et al. 2054, Vogler et al. 2022, CNS, 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)) | No |
| Enforcement of anti-trust policies | |
| Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines | |

Source: PPRI 2025

Further information on specific pricing and funding policies and models

Further information on anti-trust enforcement:

## 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 |
| 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) | Not applicable |
| Differences in criteria and processes of HTA for biosimilars compared to other medicines | |
| Any specificities | HTA agency is currently being established (legal preparatory process ongoing) |

Source: PPRI 2025

## 4.5 Demand-side measures 2025

### Doctors (and further prescribers)

Country context: Only doctors may prescribe

| | |
|---|---|
| **Prescribing and switching recommendations** | |
| Prescribing recommendations for doctors with regard to prescription of biosimilars exist | No |
| If yes, what is recommended for naïve patients? | |
| If yes, what is recommended for patients already on biologic treatment | |
| 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 | 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 | |
| Prescribing quota were issued by | |
| URL of prescribing quota | |
| Prescribing quota for other non-biosimilar medicines exists | |
| **Further gain-sharing models** | |
| Further gain-sharing models exist (beyond those mentioned above) | No, except that hospital medicines are paid through annual hospital budgets, without specific payment. That is, there is an incentive for hospitals to encourage doctors to prescribe lower-priced medicines to avoid excess expenditures. |
| 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 | Exemptions for biologicals from INN prescribing: biologics and biosimilars must not 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 2025, Barbier et al. 2022

### Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense.

| | |
|---|---|
| **Substitution policies** | |
| (Automatic) substitution for biosimilars | Yes, indicative.<br>Substitution for biosimilars is only allowed in the hospital setting. |
| If yes, for which biologic substances and under which prerequisites? | For treatment of naïve patients |
| If yes, since when, and when was it extended? (process of implementation) | |
| Any specificities | |
| URL of underlying law | |
| Generic substitution in place | Yes, but only for some medicines (e.g. reimbursement list of substitution medicines) |
| **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 | |
| **Further measures targeted at pharmacists** | |
| Information materials for pharmacists | No |
| Information events for pharmacists (e.g., seminars, trainings) | No |

Source: PPRI 2025, Barbier et al. 2022, CNS 2025, Hofmarcher et al. 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:

# 5 Impact of biosimilar policies and practices in Luxembourg

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 Luxembourg**

| Outcome indicator | Caused by | Findings | |
|---|---|---|---|
| Biosimilar uptake | No specific policy mentioned | Since biosimilar entry, utilisation of etanercept decreased by 27% in Luxembourg, while utilisation of adalimumab increased by 14.9%. Utilization trends were measured by the change in volume in 2019 versus year before biosimilar entry. | Car et al. 2023 |

*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 Luxembourg

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

Lack of national plans with limited demand and supply side measures to encourage the uptake of biosimilar medicines (Barbier et al., 2022).

### Evidence and communication-related barriers

In Luxembourg, there is lack of publicly available information and guidance on biosimilars from the national medicines' agency. This includes no educational materials and no visible use of EMA or European Commission communication tools (Barbier et al., 2022). This situation reflects evidence and communication-related barriers, such as the lack of evaluation or dissemination of switching studies, limited outreach to key stakeholders, and an absence of guidance from national authorities on prescribing or using biosimilars (Barbier et al., 2022). While scientific evidence on the interchangeability of biosimilar medicines exists, its dissemination remains limited in Luxembourg.

### Policy-related barriers

One key barrier is the absence of demand-side measures such as pharmacy-level substitution of biosimilars, which is explicitly prohibited by law (Reiland et al., 2017). Additionally, Luxembourg does not implement biosimilar prescribing quotas, which in other countries serve as instruments to promote uptake (Reiland et al., 2017). While biologicals are included in internal reference pricing under a Generic Reference Pricing (GRP) scheme, this policy does not appear to influence treatment choices for non-clinical reasons, thus limiting its impact on biosimilar penetration (Reiland et al., 2017). INN prescribing is left to the discretion of physicians, and although this preserves clinical autonomy, it provides no systemic mechanism to steer prescribers toward biosimilars (Reiland et al., 2017).

In addition to these policy design limitations, the use of anti-competitive pricing strategies—such as deep discounts by originator manufacturers—further constrains the market uptake of biosimilars (Car et al., 2023).

# 7 Facilitators and good practice examples in Luxembourg

Policy measures taken by the Luxembourg national authorities have resulted in some positive impact. The allowance of biosimilar substitutions for naïve patients in the hospital setting may have encourage their uptake following their market entry (Hofmarcher et al., 2024, Car et al., 2023). Pricing competition following the entry of biosimilars may have resulted in price reductions of the originator biologic, which

may have unintended effects, such as a decrease in the market share of biosimilars (Car et al., 2023).

Contrary to what is observed in many other European countries, Luxembourg does not impose strict eligibility criteria for the reimbursement of biologic treatments (Baumgart et al., 2019). In particular, no minimum disease activity score (Disease Activity Score based on 28 joint count [DAS28]) is required for biologic medicines to be reimbursed. The absence of a DAS28 threshold removes a key administrative barrier and may allow for earlier or more individualized use of biologic therapies, including biosimilars.

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