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

AUGMENT Biosimilars
Country fiche ESTONIA

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augment biosimilars

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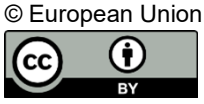

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Annex 7.8

AUGMENT Biosimilars country fiche: Estonia 2025

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

The AUGMENT Consortium produced this country fiche as part of the project "Capacity building to support the uptake of biosimilars in a multistakeholder approach (HADEA/2023/OP/0040)" commissioned by the European Health and Digital Executive Agency (HaDEA). The AUGMENT Consortium consists of the Austrian National Public Health Institute (Gesundheit Österreich Forschungs- und Planungs GmbH / GÖ FP), as consortium lead; the Polish Agency for Health Technology Assessment and Tariff System (Agencja Oceny Technologii Medycznych i Taryfikacji / AOTMiT), the Medical University Sofia (MUS), and the NOVA National School of Public Health in Lisbon.

In this project (abbreviated AUGMENT Biosimilars project), the AUGMENT Consortium performed a **comprehensive study** which aimed to offer a **mapping and** an **analysis of existing policies and practices** to encourage biosimilar uptake and competition in 32 European countries (all European Union (EU) and European Free Trade Association (EFTA) Member States, and the United Kingdom). In the analysis, the impact of biosimilar policies on improving patient access to medicines as well as barriers and facilitators in the policy implementation will be studied. For further information see biosimilars.goeg.at.

Key terms related to biosimilar policies can be found in the project's Glossary.

Contributors

This country fiche was produced by GÖ FP based on information the PPRI network was used, and findings from systematic and narrative literature reviews.

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1 Summary of biosimilar policies and practice in Estonia 2025

Key stakeholders

A major stakeholder is the **Ministry of Social Affairs** that prepares the legislation for biosimilars and confirms the decision on the price and reimbursement, which is prepared by the **Estonian Health Insurance Fund (EHIF).** The EHIF acts also a centralised procurer, however not regarding biosimilars because the latter are mainly used in hospitals and are procured by the individual hospitals. There is no biosimilar specific industry association in Estonia.

Major biosimilar policies and practices and developments

Estonia has implemented **some biosimilar specific policies**.

A biosimilar price link is in place in the **outpatient** sector (15% price reduction for biosimilars compared to the reference product). Biosimilars are included in the reference price system and patients are requested to co-pay if they oppose to be dispensed the lowest-priced medicine. Medicines must be prescribed by the International Non-Proprietary Name (INN), and this also applies for biologics. Community pharmacies must offer the lowest-priced medicines to patients, and biosimilar substation has been in place for long. However, it is not automatic since the prescriber must be informed by the community pharmacist. In the **inpatient** sector, medicines are covered at 100% reimbursement rates. Tendering is in place in hospitals and mainly done on facility level, with some exemptions where centralised procurement is performed by the Estonian Health Insurance Fund (EHIF).

Impact analysis

No studies that measure the impact of biosimilar policies on policy objectives such as accessibility or accessibility could be identified.

There are currently no publicly available studies specifically measuring the impact of biosimilar policies on access or affordability in Estonia.

Barriers, facilitators and good practice examples

Given the lack of impact analyses and literature on biosimilar policies, it is difficult to identify barriers and facilitators. However, Estonia was among the first countries to implement biosimilar substitution and prescribing of biologicals by the INN, both on a mandatory basis. These demand-side measures are likely to encourage biosimilar uptake.

Recent developments

No recent developments identified since most policies were implemented several years ago. A transposition of a European legislation on competition into Estonia law

in 2024 provided some legal tool to the Estonian Competition Authority to enforce anti-trust behaviour. Furthermore, Estonia has been working on introducing centralised procurement in the hospital sector.

Highlights and learnings

Estonia introduced some mandatory demand-side measures to encourage biosimilar uptake and competition several years ago, frequently earlier than other countries (e.g., biosimilar substitution). This is supplemented by targeting biosimilars also through measures at the supply side (e.g., inclusion of biosimilars into the reference price system, for instance).

2 Key data regarding biosimilars in Estonia

First biosimilar medicine launched (i.e. brought on the market):
Filgrastim in **2008**
***Source*:** Medicines for Europe 2023

Number of the **biosimilars marketed**:
14 molecules with biosimilars available, as of 2022
***Sources**:* Medicines for Europe 2023

Key national publicly accessible sources reporting data on biosimilars

There are no national publicly accessible sources in Estonia that provide biosimilar-specific data.
While general pharmaceutical data is available from the State Agency of Medicines (https://www.ravimiamet.ee/en/statistics/statistical-yearbooks), biosimilars are not reported separately.

3 Stakeholders involved in and targeted by biosimilar policies in Estonia

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant ublications by stakeholder
Legislator	Sotsiaalministeerium / Ministry of Social Affairs	Prepares legislation.	
National regulatory authority	Ravimiamet / State Agency of Medicines	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance. Also checks information can be presented to prescribers and patients. It participates in the Biologics Working Party (BWP) of the EMA.	
Pharmaceutical pricing authority	Tervisekassa / Estonian Health Insurance Fund (EHIF)	Sets the price of biosimilars based on legislation prepared by the Ministry of Social Affairs. EHIF applies tendering for biosimilars for use in the in-patient sector	
Pharmaceutical reimbursement authority	Sotsiaalministeerium / Ministry of Social Affairs Tervisekassa / Estonian Health Insurance Fund (EHIF)	Ministry of Social Affairs makes final decision on medicines eligible for reimbursement (positive list), but EHIF is responsible for reimbursement (debursement).	
Procurement agency	Tervisekassa / Estonian Health Insurance Fund (EHIF)	Covers the costs of health services provided to insured persons. Also finances the purchase of medicines and partly certain medical technical aids. Performs centralised procurement for HIV/AIDS and tuberculosis medicines as well as vaccines for the entire popu-ation of Estonia (outpatient) and list of priority immunoglobulins/ antitoxins/ antidotes (inpatient). Plans for expanding role for procurement of inpatient medicines.	
HTA agency / body	Tervisetehnoloogiate hindamise keskus (Tartu Ülikooli peremeditsiini ja rahvatervishoiu instituut) / Centre for Health Technology Assessment (part of the Department of Public Health at the University of Tartu)	Performs HTA, which results are used by the EHIF to make decisions on the reimbursement of medicines	
National competition authority	Konkurentsiamet / Republic of Estonia Competition Authority	Monitors the market situation, may launch anti-trust enforcement measures	
National patent office	Eesti Patendiamet / Estonian Patent Office	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Eesti Arstide Liit / Estonian Medical Association	Prescribe biosimilars or biologics by INN, inform patients.	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant ublications by stakeholder
Nurses	*Represented by:* Eesti Õdede Liit / Estonian Nurses Union	No formal role; nurses may administer biosimilars in hospital settings but are not officially tasked with informing patients. Nurses may prescribe medications used for the treatment of diabetes, except for the initial prescription.	
Community pharmacists	*Represented by:* Eesti Proviisorapteekide Liit / Estonian Pharmacies Association	Dispense medicines, inform patients.	
Hospital pharmacists	*Represented by:* Eesti Haiglaapteekrite Selts / Estonian Society of Hospital Pharmacists (EHAS)	Involved in hospital-level procurement including biosimilars.	
Patient organisations	*Represented by:* MTÜ Patsientide Esindusühing (EPÜ) / Estonian Patients Advocacy Association	Advocate for patients. No patient organisations with specific advocacy or education work on biosimilars identified.	
Conssumer organisations	*Represented by:* Tarbijakaitse ja Tehnilise Järelevalve Amet (TTJA) / The Consumer Protection and Technical Regulatory Authority (CPTRA)	Performs different activities in safety regulation, market regulation and compliance with legal obligations.	
Biosimilar industry	*Represented by:* Ravimitootjate Liit (RTL) / The Association of Pharmaceutical Manufacturers in Estonia (APME)	Represents research-based manufacturers of original medicines and generic and biosimilar medicine companies operating in Estonia. No specific biosimilar industry assocation	
Generic industry			
Pharmaceutical industry in general			
Pharmaceutical industry for new biological medicines			
Other	Terviseamet / Health Board	Responsible for central stock management.	

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium), Vogler et al. 2022 and further publications as indicated in the last column

4 Biosimilar policies and practices in Estonia 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:	For biosimilar medicines aiming to be included into the outpatient reimbursement list

Price reduction of the first biosimilar compared to the reference product	Minus 15% (applies to both outpatient and hospital use, e.g. for IV-administered medicines like eculizumab used in day-care settings).
Price reduction of the second, third and further biosimilars	Second and third biosimilar have to be minus 10% than first biosimilar.
Price reduction for the reference product	No reduction However, it depends — if the product falls under the same reimbursed healthcare service code, the price needs to be lowered in order for hospitals to be able to use it. Otherwise, hospitals would have to pay the price difference themselves. Similarly, in the outpatient sector, if a reference price is set, the originator remains more expensive and the patient must pay the difference out of pocket.
Any further specificities	No.
A generic price link is in place.	Yes.

Source: PPRI 2025, Gigov 2021, Habicht 2018

External price referencing

External price referencing is applied for biosimilars.	No.
It applies for the following situations:	Not applicable, as not in place.
Any specificities	
External price pricing is in place for other medicines than biosimilars.	No.

Source: PPRI 2025

Tendering

Some (or all) biosimilars are procured through tendering (or tendering-like) processes.	Yes, Estonia applies tendering for biosimilars.
If yes, the scope with regard to the care sector:	Tendering for biosimilars is only done in the inpatient sector.
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All off-patent and on-patent biological medicines. Procurement of hospital medicines is mainly done by the hospitals, For a list of biosimilars and few on-patent biologicals centralised procurement by the EHIF is initiated. There were several pilot projects already performed (e.g. for one biosimilar, the price decrease was 8-fold compared to the previous price level in the service list).
Institutional framework	Tenders are performed both on national level and on hospital level. The health insurance fund and hospitals are responsible for the performance of the tenders.
Information available on procurement procedures and practices	Tenders awarded based on active substance. Winning prices are made transparent to competitors. Contracts are only awarded to one winner based on the lowest price offer. Open procedures and dynamic purchasing systems (different type of contracts) are used. All public tenders and winner prices are public information. .

Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	No tendering in the outpatient sector in place.
Institutional framework	Not applicable, as no tendering in the outpatient sector in place.
Information available on procurement procedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes (centralized for list of priority immunoglobulins, antitoxins and antidotes and COVID medicines) Outpatient: Yes (centralized for HIV/AIDS and tuberculosis medicines as well as vaccines for entire population, c-hepatitis medicines for prisoners)

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

4.2 Reimbursement policies 2025

Reference price system

Biosimilars are included into the **reference price system (RPS)** applied in the outpatient sector.	Yes.
If yes, how many and under which specifications	Applied for Adalimumab, Etanercept, Follitropin Alfa, and Somatropin. The internal reference price is established based on the lowest priced biosimilar.
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?	Yes, broader clusters than ATC 5

Source: PPRI 2025, Medicines for Europe 2023

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, biosimilars are included into the positive list.
If yes, how many and date of inclusion into reimbursement, if known	Adalimumab 1. AMGEVITA 01.01.2019-2025 2. HYRIMOZ –01.01.2020 3. HUKYNDRA –01.04.2021 4. IMRALDI –01.07.2018 5. IDACIO –01.10.2020 6. YUFLYMA –01.01.2022 Etanertsept – 7. BENEPALI –01.07.2017 8. ETANERCEPT SANDOZ –01.04.2018 Insuliin glargiin - ABASAGLAR –01.01.2016 Ustekinumab PYZCHIVA –01.01.2025 IMULDOSA –01.01.2025 7. UZPRUVO Follitropin afla

	13. BEMFOLA 14. OVALEAP Teriparatide 15. SONDELBAY- 01.04.2025
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	Same as in in-patient sector. If we have a biosimilar then it is the reference price of the active ingredient
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	The reimbursement conditions are similar to corresponding original biological. Biosimilars are reimbursed by simplified procedure likewise generics.
Indicate URL of outpatient positive list	Ravimitest | Tervisekassa
Co-payments for biosimilars for outpatient use	Co-payment depends on the reimbursement category (100 percent, 90 percent/75 percent, 50 percent) and is set based on the severity of the disease, the efficacy of the medication, and the social status of the patient by the regulations of the SM. Co-payment includes prescription fee (3,5eur) as well → out-patient sector.
For medicines for outpatient use in general (other medicines than biosimilars) Positive list for medicines in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	National positive list with 100% reimbursement for some medicines and lower rates for other medicines included in reimbursement lists. Co-payments are charged for funded medicines in the outpatient sector.
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes.
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	Only available at hospital level. Not published.
Co-payments for biosimilars for inpatient use	No, all medicines used in hospitals are reimbursed at 100% rate. Even though, hospitals charge a fixed amount co-payment per day in hospital.
For medicines for inpatient use in general (other medicines than biosimilars): Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	No national and/or regional /list list(s), but hospital pharmaceutical formularies at hospital level. Full (100%) coverage for all medicines used in hospitals. No co-payments for medicines for inpatient use.

Source: PPRI 2025, Sotiaalministeerium Estonia 2016, Habicht 2018

4.3 Specific pricing, procurement and funding policies 2025

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 (MEAs))	No
Enforcement of anti-trust policies	No formal anti-trust enforcement measures related to biosimilars are known in Estonia. However, public information campaigns have promoted the use of more affordable alternatives, such as generics and biosimilars, by emphasizing therapeutic equivalence with originators.
Specific pricing and **funding** (e.g., subscription models, MEAs, …) for other medicines	Yes, MEA (pe-dominantly financial MEAs) for other medicines than biosimilars are in place.

Source: PPRI 2025, Vogler et al. 2022

Further information on anti-trust enforcement:

In February 2024 (with three years' delay), the "Directive (EU) 2019/1 of the European Parliament and of the Council of 11 December 2018 to empower the competition authorities of the Member States to be more effective enforcers and to ensure the proper functioning of the internal market" was transposed into Estonian law. This law allows taking measures such as penalties payment in case of violation of the law.

Source: Antitrust Alliance 2024

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	Yes
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	Horizon scanning scoping meeting with stakeholders We aim to meet annually with all major pharmaceutical companies operating in Estonia and the broader Baltic region. These meetings serve as a platform to discuss a wide range of topics—not limited to patent-related issues but including mutual concerns and relevant updates. We always meet with one company at a time and inquire about their pipeline for the next three years.

Source: PPRI 2025, Vogler 2022

Health technology assessment

HTA is applied for biosimilar medicines	Yes, HTA (full dossier) is done for all medicines.
If yes, in which situations and settings (outpatient and inpatient)	For all new medicines including biosimilars.
Differences in criteria and processes of HTA for biosimilars compared to other medicines	No differences.
Any specificities	No.

Source: PPRI 2025, Craddy 2022

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	Yes, switches are highly encouraged. Physicians have to justify when they want to "opt out", i.e. when they want to prescribe the biological.
If yes, what is recommended for naïve patients?	Strong 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, physicians have to justify if they "opt out", i.e., do not switch.
Prescription guidelines (including switching guidelines) were issued by	No guidelines for doctors, they have to prescribe by the active ingredient.
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 quotas	
Prescribing quotas were issued by	
URL of prescribing quotas	
Prescribing quotas 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	No exemption for biologicals: biologics and biosimilars may be prescribed by INN
Further measures targeted at doctors	
Information materials for doctors	yes, https://www.ravimiamet.ee/sites/default/files/documents/2022-09/biosimilarid_tervishoiutootajale.pdf
Information events for doctors (e.g., seminars, trainings)	yes
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	

Source: PPRI 2025, Medicines for Europe 2023, Noce and Ernst 2018

Pharmacists (and further dispensers)

Substitution policies	
(Automatic) **substitution for biosimilars**	Yes, mandatory (but not automatic, see below). If the biological product has been prescribed by INN, the pharmacy has to offer the most advantageous product in the group (the possibility to prescribe by trade name exists as well).
If yes, for which biologic substances and under which prerequisites?	All
If yes, since when, and when was it extended? (process of implementation)	
Any specificities	Pharmacists are obliged to inform the prescriber when substituting a biological with a biosimilar. Pharmacists also inform the patient about the lowest-priced alternative, which may be refused by the patient resulting in payment of the difference between the originator and the biosimilar out-of-pocket. The physician can upfront specify why substitution is not appropriate by providing a medical justification (see above).
URL of underlying law	
Generic substitution in place	Yes, mandatory with pharmacists having to ffer the lowest-priced alternative to patients.
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	Pharmaceutical companies' information leaflets and seminars. However, these are more commonly available for generic medicines.
Information events for pharmacists (e.g., seminars, trainings)	Pharmaceutical companies' information leaflets and seminars. However, these are more commonly available for generic medicines.

Source: PPRI 2025, Vogler et al. 2022, Medicines for Europe 2023, Habicht 2018; Gigov 2021, Sotiaalministeerium Estonia 2016, Moorkens et al. 2017

Patients

Information and educational measures	
Information materials for patients	Yes

	Each package of the medication includes a patient information leaflet
If yes, provide URL of most common materials	https://www.ravimiamet.ee/sites/default/files/documents/2022-09/biosimilarid_patsiendile.pdf
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	

Source: PPRI 2025, Medicines for Europe 2023

5 Impact of biosimilar policies and practices in Estonia

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

6 Barriers for biosimilar uptake and policy implementation in Estonia

Legal barriers

The transposition of a European legislation on competition into Estonian law was done with three years' delay (Antitrust Alliance 2022), which thus delayed the mandate for action of the Competition Authority.

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

The Estonian health system organisation is split between inpatient and outpatient sectors, with sometimes different policies. While in the inpatient sector, biosimilars are procured by the hospitals and are fully reimbursed as part of the hospital services, in the outpatient sector their prices are set through the biosimilar price link, and some co-payments are in place for biosimilars.

Within the hospital sector, a decentralized system is in place (tendering by single hospitals, despite some pilots to procure in a centralised manner), which also limits the purchasing power of the procuring hospitals.

Financial barriers

Current information suggests that no financial incentives to encourage the use of biosimilars aer in place. This may be attritutable to little resources by the public payer. In the in-patient sector, the active substance price is regulated based on the price of the biosimilar that has entered the market, and the relevant institution, such as the Health Insurance Fund, pays hospitals for the service based on this (biosimilar) price.

It seems that a problem is emerging where the prices of original (reference) medicines are reaching the level of biosimilars, making it difficult for the biosimilar medicine to gain market share

Evidence and communication-related barriers

The fact that no impact analysis studies could be identified points to room for collecting more information.

On the other hand, information on the biosimilars is assessed in an HTA, since Estonia is one of the few European countries to request a full HTA for biosimilars (Craddy 2022). While this supports evidence generation, it may be a barrier to fast market entry of biosimilars.

Policy-related barriers

The key pricing policy is a biosimilar price link, which is considered to be rather static. Procurement of biosimilars is mainly done by the single hospitals in a decentralized manner (see above organizational barriers).

While Estonia was among the first countries to introduce biosimilar substitution, its design suggests that this is not automatic substitution because pharmacists need to contact the prescribers before substitution. This may reduce the substitution cases.

Stakeholder-related barriers

A policy analysis from one decade ago called for a continuation of information campaign on generics for patients, and for an inclusion of the topic of biosimilars in these campaigns (Ferrario et al. 2016). This suggests a need for awareness-raising and capacity building among patients.

7 Facilitators and good practice examples in Estonia

In principle, Estonia has a mix of policies related to biosimilars, including some demand-side measures: e.g., biosimilar substitution, INN prescribing for biologicals,

and inclusion of biosimilars into the reference price system. The latter thus provides financial incentives to patients to not oppose the dispensation of the biosimilar medicine.

In addition, pilots are ongoing to foster centralised procurement for the inpatient sector. Hereby, Estonia may draw from its cross-country procurement experience in the vaccines area, which it has built during the last ten years.

8 Developments in Estonia

Recent changes

Transposition of the "Directive (EU) 2019/1 of the European Parliament and of the Council of 11 December 2018 to empower the competition authorities of the Member States to be more effective enforcers and to ensure the proper functioning of the internal market" in Estonia law (February 2024) (Antitrust Alliance 2024)

Plans or under discussion

EHIF is considering to increase the price reduction of the first and second biosimilar compared to the reference product.

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