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

AUGMENT Biosimilars
Country fiche DENMARK

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Vogler S, Walter M, Knoll V, Habimana K, Helter T

augment biosimilars

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Directorate-General for Health & Food Safety
Unit: SANTE-D2 (Medical products: quality, safety, innovation)

Contact: François Janssens

E-mail: sant-atf@ec.europa.eu

European Commission
B-1049 Brussels

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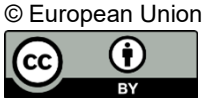

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Annex 7.7

AUGMENT Biosimilars country fiche: Denmark 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:

Diana Ina Lauritzen, Lægemiddelstyrelsen / Danish Medicines Agency (DKMA)

Dorthe Bartels, AMGROS

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1 Summary of biosimilar policies and practice in Denmark 2025

Major biosimilar policies and practices and developments

Biosimilar policies in Denmark are characterised by its **tendering (-likey) systems** supporting quick uptake of biosimilars and substantial influence on the price of biosimilars on the market.

Reimbursement wise, Denmark does not include biosimilars into its reference price system (RPS). Biosimilars are reimbursed when included in the outpatient reimbursement list and funded when adminstrated in hospitals (100% reimbursement for reimbursable medicines in the outpatient and inpatient sectors).

There is **neither INN prescribing nor biosimilar substitution** allowed in Denmark, but the Danish Medicines Agency is in the process of developing new guidelines for substitution, which will establish a framework for biosimilar substitution in the outpatient sector.

Key stakeholders

In Denmark, the **Danish Medicine Agengy (DKMA)** and the **Danish Medicines Council** (established by the Danish regions) are the main regulatory authorities with regard to biosimilars. The Danish Medicines Council has **national biosimilar prescription guidelines** in place, which many health care professionals follow. The DKMA implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance and also decides (advised by the **Reimbursement Committee**) about the inclusion into reimbursement for biosimilars. The price is defined based on free pricing but largely influenced by a tendering(-like) system in the outpatient sector and a centralized procurement performed by **AMGROS** for public hospitals. The biosimilars industry is represented together with generics manufacturers by the **Danish Generic and Biosimilars Medicines Industry Association (IGL)** including in total 12 member companies specialized in the field of generics and biosimilars.

Impact analysis

Savings for the public payer from the use of biosimilars were shown in several publications for Denmark. Besides an **effective tendering system,** the supportive organisational setting with a **national procurement agengy that is well prepared** of biosimilars implementation and the joint view on biosimilars as equally safe and effective contribute to high and fast biosimilar uptake in Denmark.

Barriers, facilitators and good practice examples

The **centralised tendering system in Denmark** in general can be considered a facilitating factor for fast availability and **advantageous pricing** for the public expenditure. **Clear treatment recommendations** and biosimilar guidelines support the uptake of biosimilars in addition. Amgros the national procurement body also implements a range of **educational activities to support understanding, uptake and use of biosimilars** in the Danish health system.

Recent developments

Since 26 January 2023, the **Danish Medicines Council no longer assess biosimilar medicines**. A biosimilar medicine that has the same indication and route of administration as a medicine that has already been recommended by the Danish Medicines Council can be put into use without an assessment by the Danish Medicines Council. If the Medicines Council has a treatment guideline in the area, the biosimilar medicine will *automatically be included in the next Amgros tender* and the subsequent medicine recommendation.

Highlights and learnings

Denmark has been **successful in quick and fast uptake of biosimilar medicines in the in-patient sector**. This appears to be attritutable to the collaboration of several stakeholders in the field, in particular AMGROS, the hospital procurement agency which procures for all public hospitals, and the Danish Medicines Council, for providingguidance and advice. Importantly, AMGROS invested in good preparation in advance of biosimilar market entry, with intensive information and education to prescribers and patients, which eventually allows smooth switching to a biosimilar and thus large uptake.

2 Key data regarding biosimilars in Denmark

First biosimilar medicine launched (i.e. brought on the market):
Epoetin (Binocrit®) in **2010**

***Source*:** Medicines for Europe 2023

Number of the **biosimilars marketed**:
6 molecules with biosimilars available, as of 2020
11 molecules with biosimilars available, as of 2022

Sources: IQVIA 2020, Medicines for Europe 2023

Biosimilar market shares in 2023 (or latest available data):

63% in volume in **2019**, no information available, how "volume" is defined.

It depends on which markedsshare we are talking about.

Adalimumab – biosimilær 98%

Etnercept – biosimilar 98%

Infliximab – biosimilar 99%

No information available for biosimilar market share in value.

Source: Safe Biologics 2021

Additional information:

- A study found that Denmark had the fastest and most thorough uptake of biosimilars with a 90% market share three months after first registered sales. Source: Böhm et al. 2023.
- Data found that for anti-TNF biosimilars (adalimumab, etanercept and infliximab) Denmark had 96% biosimilar uptake. Source: Safe Biologics 2021.

Key national publicly accessible sources reporting data on biosimilars (e.g., on numbers of biosimilars marketed, reimbursed, dispensed, on (public) spending on biosimilars):

- DKMA 2016: Biological and biosimilar medicinal products

3 Stakeholders involved in and targeted by biosimilar policies in Denmark

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by stakeholder
Legislator	Ministry of the Interior and Health (Indenrigs- og Sundhedsministeriet, ISM)	Prepares legislation.	SUU, Alm.del - 2023-24 - Bilag 330: Orientering om substitution mellem biosimilære lægemidler i primærsektoren, fra indenrigs- og sundhedsministeren
National regulatory authority	Lægemiddelstyrelsen (Danish Medicines Agency, DKMA) advised by Medicintilskudsnævnet (Reimbursement Committee). *Note: there is no pricing authority, but the DKMA has influence on the prices via tendering-like procedures.*	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance.	Authorisation Biosimilars
Pharmaceutical pricing authority	Lægemiddelstyrelsen (Danish Medicines Agency, DKMA) advised by Medicintilskudsnævnet (Reimbursement Committee). *Note: there is no pricing authority, but the DKMA has influence on the prices via tendering-like procedures.*	Decides on inclusion into reimbursement for biosimilars and their price (based on free pricing, and tendering, see below). Companies submit prices every two weeks, resulting in a tendering-like system for off-patent medicines, as the DKMA selects the preferred medicine based on the lowest price.	Pricing Reimb. Not specific to biosimilars.
Pharmaceutical reimbursement authority	Lægemiddelstyrelsen (Danish Medicines Agency, DKMA) advised by Medicintilskudsnævnet (Reimbursement Committee). *Note: there is no pricing authority, but the DKMA has influence on the prices via tendering-like procedures.*		
Procurement agency	AMGROS	Is the central procurement body for the five Danish regions and responsible for strategic procurement and supply of medicines (and hearing aids) for hospitals (mandatory for all public Danish hospitals). Involved in tenders and procurement procedures.	Price analysis Biosimilars news Horizon Scanning
	Statens Serum Institut (SSI)	Responsible for procurement of vaccines and their supply to the Danish national immunisation programmes, including supplies for pandemic preparedness.	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by stakeholder
HTA agency / body	Danish Health Technology Council (Behandlingsrådet, DHTC)	Carries out evaluations and comprehensive analyses for Danish regional governments. Provides recommendations concerning the use of specific health technologies. For medicines, the Danish Medicines Council is responsible (see below).	
Medicines Council	Medicinrådet (Danish Medicines Council)	The Danish Medicines Council (established by the Danish regions in 2017) assesses new medicines for use in hospitals. Products deemed to be of potential use then undergo price negotiations with Amgros. Based on the negotiated price, the Medicines Council makes recommendations about the routine use of new medicines. Note that these are rec-ommended treatment guidelines, but individual hospitals and doctors may prescribe other medicines. Since 26 January 2023, the Danish Medicines Council has no longer assessed biosimilar medicines.	About the Council Assessment stop Assessment stop announcement
National competition authority	Danish Competition and Consumer Authority (Konkurrence- og Forbrugerstyrelsen, KFST)	Enforces the the Danish competition act, monitors the market situation, provides guidance and information etc.	
National patent office	Patent- og Varemærkestyrelsen / Danish Patent and Trademark Office	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Danish Medical Association (Lægeforeningen, DMA) *Medical societies*: Organisation of Danish Medical Societies (Organisationen af Lægevidenskabelige Selskaber, LVS)	Prescribe biosimilars (by trade name), inform patients.	
Nurses	*Represented by:* Danish Nurses' Organization (Dansk Sygeplejeråd, DNO)	*Yes, they might have a role at hospitals or in the outpatient sector to inform patients of devices and how to use them.*	
Community pharmacists	*Represented by:* Danmarks Apotekerforening (The Association of Danish Pharmacies)	Dispense medicines (but are not allowed to substitute biologicals with biosimilars when prescribed), inform patients.	Preparedness
Hospital pharmacists	*Represented by:* The Association of Professionals in Phar-maceutical Sciences (Pharmadanmark), which, however, also involves any other pharmacy graduates in the other business areas	Order needed medicines with the centralised procurement agency Amgros, ensure internal pharmaceutical suppy in the hospitals, responsible for administration of medicines and inform and educate doctors and patients	
Patient organisations	*Represented by:* Danish Patients (Danske Patienter)	Advocate for patients. Several patient organisations in diseases with particular biologics/biosimilars or with specific advocacy or education work on biosimilars identified.	Perspective Advocacy

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by stakeholder
Consumer organisations	*Represented by:* Danish Consumer Council		
Biosimilar industry Generic industry	*Represented by:* Danish Generic and Biosimilars Medicines Industry Association (Industriforeningen for Generiske og Biosimilære Lægemidler, IGL)	Produce and supply biosimilars. Joint association for generic and biosimilars medicines industry. Includes 12 member companies working in production, marketing and sale of generic and biosimilar medicines in Denmark. IGL represents the Danish generics and biosimilar companies in Medicines for Europe.	
Pharmaceutical industry in general	*Represented by:* The Danish Association of the Pharmaceutical Industry (Laege-middelindustriens, Lif)		
Pharmaceutical industry for new biological medicines	*Represented by:* Not applicable (covered by Lif)	Not applicable.	

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

4 Biosimilar policies and practices in Denmark

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

A **biosimilar price link** is in place.	No (free pricing).
It applies for the following situations:	Not applicable, as not in place.
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	
A **generic price link** is in place.	No (free pricing).

Source: PPRI 2025

External price referencing

External price referencing is applied for biosimilars.	No (free pricing) for biosimilars in the outpatient secor
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.	Not in the outpatient sector, but in the inpatient sector

Source: PPRI 2025

Tendering

Some (or all) **biosimilars are procured through tendering** (or tendering-like) processes.	Yes, Denmark applies tendering for biosimilars both in the inpatient and outpatient sectors.
If yes, the scope with regard to the care sector:	Inpatient and outpatient sector: • Inpatient responsible body: Amgros • Outpatient responsible body: Pharmaceuticals DKMA • Outpatient responsible body; vaccine. SSI Scope of medicines: • Inpatient medicines with analogue competition (interchangeability assessed by DMC), • generic and biosimilar medicines, • vaccines.
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All (on-patent and off)-patent biological medicines
Institutional framework	Amgros, the procurement body for public hospitals, uses tenders for biosimilar medicines. Amgros is the central procurement body for public hospitals in Denmark and was established by the five Danish regions. AMGROS performs hoizon scanning, does proce negotiations for new medicines and performs tenders for medicines with analogue, biosimilar, or generic competition and make the implementation in the hospitals
Information available on procurement procedures and practices	Tenders awarded based on active substance plus indications. Some tenders allow for multiple winner award. Other factors than price can be considered for award.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	Some or all off-patent biosimilars
Institutional framework	Bi-weekly auctions where market authorisation holders notify their prices for a 14 days period. Parallel imports can offer competitive pricing against the patent holder of the biological medicine, but in 2024 the biosimilars are not included in the tendering.
Information available on procurement procedures and practices	Information to be added. Prices of medicines
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes Outpatient: Yes (tendering-like)

Source: PPRI 2025; Vogler et al. 2022

4.2 Reimbursement policies 2025

Reference price system

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	No, no RPS in place for biosimilars.
If yes, how many and under which specifications	Not applicable as not in place.
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, reference price system includes generics (but no biosimilars). ATC-5 cluster.

Source: PPRI 2025

Inclusion into reimbursement and co-payments

Reimbursement in the outpatient sector	
Apart from their potential inclusion into the reference price system (see above), biosimilars are included in outpatient reimbursement (positive list)	Yes, biosimilars are included in the national outpatient positive lists and have both unconditional and conditional reimbursement status. In some exceptions, individual reiburesement is also granted by doctos depending on the needs of the patient.
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	
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	
Indicate URL of outpatient positive list	Medicines eligible for reimbursement
Co-payments for biosimilars for outpatient use	Prescription fee and depending on individual exepences for reimbursable medicines the patient can recieve up to 100% reimbursement.
For medicines for outpatient use in general (other medicines than biosimilars) Positive list for medicnes in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	Positive lists (conditional and unconditional reimbursement) + in some cases individual reimbursement granted by doctors. Prescription fee and depending on individual exepences for reimbursable medicines the patient can recieve up to 100% reimbursement.
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes, additionally to the orginator biological (and doctors are recommended to switch). Full (100%) coverage for all medicines used in hospitals. Regional list(s), but hospital pharmaceutical formularies at hospital level.
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	Since 26 January 2023, the Danish Medicines Council have no longer assesses biosimilar medicines. A biosimilar medicine that has the same indication and route of administration as a medicine that has already been recommended by the Danish Medicines Council can be put into use without an assessment by the Danish Medicines Council.
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	
Co-payments for biosimilars for inpatient use	No, all medicines used in hospitals are reimbursed at 100% rate.
For medicines for inpatient use in general (other medicines than biosimilars): Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	Hospital pharmaceutical formularies at regional level. No co-payments for medicines for inpatient use.

Source: PPRI 2025, DKMA 2019b, Danish Medicines Council 2025

4.3 Specific pricing, procurement and funding policies 2025

Application of **special pricing, procurement and reimbursement models for biosimilars** (e.g., delinkage / subscription-model, management-entry agreements (MEAs)	No, not applied.
Enforcement of anti-trust policies	Yes, *"enforcement of competition law violations in Denmark is carried out both by the European Commission, the Danish Competition and Consumer Authority (through the Competition Council and the Competition Appeals Council), and domestic courts". Between 2010 and 2022, there are no cases identified having been treated by the Danish Competition and Consumer Authority regarding pharmaceutical companies violating competition rules. However, the Authority "has ordered pharmaceutical companies to cease non-competitive actions that violate EU competition law rules and successfully defended such orders in Danish courts."*
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Yes, MEAs (predominantly financial MEAs and some performance-based MEAs) in place.

Source: PPRI 2025, Law Library 2022

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, always. horizon scanning / forecasting activities are in place, also on the loss of exclusivity for the inpatient sector.
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	*"Through Horizon Scanning, Amgros provides an overview of medicines and extensions of indication that are expected to be marketed in Denmark within the next two to three years. This enables the Danish Medicines Council to plan its work, and Amgros can better prepare upcoming price negotiations with suppliers and organise tendering procedures. They also prepare financial estimates for the Regions, so they have a good foundation for their pharmaceuticals' budgets."* *Amgros are looking for everything relatet to patent expiring – to plan the tendering and implementation.*

Source: PPRI 2025, Amgros 2024b, Vogler 2022

Health technology assessment

HTA is applied for biosimilar medicines	No (biosimilars are explicitly exempt from the Danish Medicines Council's prior assessment since 2023). If a biosimilar for the outpatient is marketed it will automatically receive the same reimbursement status as the reference product if the prices are at the same level.
If yes, in which situations and settings (outpatient and inpatient)	Not applicable, as not in place.
Differences in criteria and processes of HTA for biosimilars compared to other medicines	
Any specificities	

Source: PPRI 2025

4.5 Demand-side measures 2025

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes, (non-medical) switch recommended, which is often followed by physicians. Recommendation of biosimilar prescribing for bio-naïve patients (in the inpatient sector) and for switch patient. For the outpatient sector, recommendations from the five regions, which may also include the prescription of biosimilars. Recommendations from the Danish Health Council: Since 2023, biosimilars can be used in the same indication and composition as a medicinal product already recommended by the Health Council without evaluation (see also recent developments).
If yes, what is recommended for naïve patients?	Recommendation to prescribe biosimilars for naïve patients by the Danish Health Council. National guideline in place.
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	Danish Health Council for the inpatient sector
URL of prescription & switching guidelines	
Prescribing quotas	
Prescribing quotas for doctors with regard to prescription of biosimilars exist	No, not in place.
If yes, which quotas are defined for biosimilars	Not applicable, as not in place.
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 quota for other non-biosimilar medicines exists	No, not in place.
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	No, not in place.
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	Not applicable, as not in place.
Publicly accessible information	
INN prescribing	
In general, prescribing by INN is place (information not focused on biologics)	No, not allowed.
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	Not applicable as not allowed.
Further measures targed at doctors	
Information materials for doctors	Yes, general information provided by DKMA online and by the DMC/Amgros. Patients and doctors are in addition targeted with information on biosimilars. Prescription of biosimilars included in treatment recommendations and guidelines.
Information events for doctors (e.g., seminars, trainings)	AMGROS to organise information events for doctors.
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	Not identified.

Source: PPRI 2025, Medicines for Europe 2023, Machado et al. 2024, Schneider 2022, Lunddahl 2016

Pharmacists (and further dispensers)

Country context: Pharmacists and in a few cases also other health professionals may dispense. Staff working in pharmacies are pharmacists and pharmaconomists.

Substitution policies	
(Automatic) substitution for biosimilars	No, not allowed.
If yes, for which biologic substances and under which prerequisites?	Not applicable, as not allowed. **Note: Biosimilar substitution will be gradually introduced from November 2025, starting with teriparatide.**
If yes, since when, and when was it extended? (process of implementation)	
Any specificities	
URL of underlying law	
Generic substitution in place	Yes, mandatory.
Gain-sharing models	
Gain-sharing models for pharmacists	No, not in place.
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	Not applicable, as not in place.
Publicly accessible information	
Further measures targeted at pharmacists	
Information materials for pharmacists	Yes, general information provided by DKMA on its website to inform about biosimilars. No activities targeted specifically towards pharmacists identified from public sources.
Information events for pharmacists (e.g., seminars, trainings)	Not identified.

Source: PPRI 2025, Lunddahl 2016

Patients

Information and educational measures	
Information materials for patients	Yes.
If yes, provide URL of most common materials	Frequently asked questions about biological and biosimilar medicinal products Reporting of adverse events and side effects of biosimilars (and all other pharmaceuticals) to the DKMA via a web-service in cooperation with the Danish regions.
If yes, key producers of education measures	DKMA (see previous link), in addition educational work by Amgros, informing patients especially regarding specific switches to adalimumab, infliximab and eternacept.
Information events for patients (e.g., seminars, trainings)	No.
If yes, key providers of educational events	Not applicable as not in place.
Gain-sharing models	
Gain-sharing models for patients	Not directly, but patient organisations sometimes receive funds from industry, such as by Abbvie (with Humira in their portfolio, for which after introduction of biosimilars sales declined). Funding of patient organisations by industry can result in these organisations not advocating for switching patients to biosimilars.
If yes, pls. describe	Not applicable as not in place.
Publicly accessible information	Not applicable as not in place.

Source: PPRI 2025, Lunddahl 2016, Mulinari et al. 2022

5 Impact of biosimilar policies and practices in Denmark

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 Denmark

Outcome indicator	Caused by	Findings	Publication
Savings for the public payer	Tender system effective on prices	*'In Denmark, there is a tender system that creates competition between manufacturers of reference drugs and biosimilars. This system is very effective at controlling pricing – in 2019, AbbVie offered a price reduction of about 80% for Humira in the tender, which was still not good enough for it to gain exclusivity. This price reduction had ripple effects across Europe, especially in countries that have policies precluding them from paying more than other members of the EU.'*	Mehr 2018 in Kvien et al. 2022
Savings for the public payer	Supportive organisational setting	*'A rapidly increasing use of biological drugs has led to substantial costs. Shift to biosimilars enables considerable reduction of these costs without jeopardizing the treatment of patients, but most countries have extensive possibilities of untapped cost-savings. The aim of this study was to describe the Danish quick and near-complete implementation of the two first TNF inhibitor biosimilars (infliximab and etanercept).'*	Jensen et al. 2020a
High and fast biosimilar uptake	Organisational preparation and procurement by national procurement agency	*"The price cuts of adalimumab to less than one-fifth was crucial to maximize health care services given the health budget. Previously, Denmark had succeeded with fast and near complete shifts of infliximab and etanercept to biosimilars, resulting in substantial price cuts. Like generic drugs, there is no reason to switch if the originator matched the price of biosimilars, but access to generic and biosimilar drugs is generally needed to ensure market competition and lower drug prices. […] Thorough preparation and multidisciplinary collaboration between all stakeholders were key points in the Danish implementation […]."*	Jensen et al. 2020b
High and fast biosimilar uptake	Accompanying taskforce during implementation	*"Biosimilars were adopted into the Danish market after a very quick introduction. The market share of the biosimilars was 95% within 3-4 months. The price reduction after introducing biosimilar medicines was approx. 60%, and the quick implementation of the drugs in the clinical setting has significantly reduced medical costs. Total annual savings in Denmark: 22 mio € (infliximab) and 15 mio € (etanercept. Estimate based on the first 6 months)." This was accompanied by a Taskforce for the implementation of biosimilars.*	Bentzen 2017

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 Denmark

Legal barriers

In Denmark there are no regulations that are either missing or require changes to uptake and use biosimilar products.

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

The use of biosimilars in the outpatient sector in 2025 depended on the prescribing doctors and their knowledge of the medicines available on the market. In 2025 biosimilar substitution was not implemented in Denmark. However, the Danish Medicines Agency is in the process of establishing a framework for biosimilar substitution. Once this framework is in place, the use of biosimilars in the outpatient sector will no longer rely on the prescribing doctors' knowledge. Instead, primary sector pharmacies will be able to substitute the prescribed product with a cheaper biosimilar if one is available.

Financial barriers

The price of biosimilars significantly influences their adoption in the secondary sector, as most biological medicines are primarily used in hospitals. Lower-priced biosimilars have a substantial positive impact on the public expenditures and they have a better chance of winning the tender. **Evidence and communication-related barriers**

Some patient organizations still believe that switching between biosimilars can cause autoimmune reactions in patients. This concern may stem from the limited dissemination of switching studies and the fact that biosimilar substitution has not yet been implemented in the primary sector.

Policy-related barriers

In 2025, the absence of biosimilar substitution in Denmark may have led to fewer biosimilar products being used in the outpatient sector.

Stakeholder-related barriers

As mentioned above, some patient organizations still believe that switching between biosimilars can cause autoimmune reactions in patients. This concern may affect patients and their willingness to switch from an original product to a biosimilar one.

7 Facilators and good practice examples in Denmark

The centralised tendering system in Denmark in general can be considered a facilitating factor for fast availability and advantageous pricing for the public expenditure. Clear treatment recommendations and biosimilar guidelines support the uptake of bisiomilars in addition. Amgros the national procurement body also implements a range of educational activities to support understanding, uptake and use of biosimilars in the Danish health system.

8 Developments in Denmark

Recent changes

As of 26 January 2023, the Danish Medicines Council will no longer assess biosimilar medicines. A biosimilar medicine that has the same indication and route of administration as a medicinal product that has already been recommended by the Danish Medicines Council can be put into use without an assessment by the Danish Medicines Council. If the Medicines Council has a treatment guideline in the area, the biosimilar medicine will automatically be included in the next Amgros tender and the subsequent drug recommendation. *Source: Biosimilære lægemidler*

Plans or under discussion

The Danish Medicines Agency is currently updating the guidelines for substitution, which will lay the foundation for biosimilar substitution and its practical implementation

9 Bibliography

AfPA 2023	AfPA. Nordic Patient Groups Tackle Biosimilar Policy Issues - Alliance for Patient Access. Online information. Alliance for Patient Access. 2024. Last accessed on 11/11/2024
Amgros 2018	Amgros. Price Analysis of hosptal pharmaceutical in seven European countries 2018. Price analysis of hospital pharmaceuticals in seven European countries. Available from: https://amgros.dk/media/2186/price-analysis-of-hospital-pharmaceuticals-in-seven-european-countries.pdf (accessed 10 December 2024)
Amgros 2024a	Amgros. News related to biosimilars. Search function use on 11/11/2024. 2024a. Available from: https://www.amgros.dk/about-amgros/news/ (accessed 10 December 2024)
Amgros 2024b	Amgros. Horizon Scanning - Amgros. Online information. 2024b. Available from: https://amgros.dk/pharmaceuticals/horizon-scanning/ (accessed 11 November 2024)
Arnet et al. 2021	Arnet I, Verbeek M, Almarsdóttir AB, et al. Community pharmacists' preparedness for substituting biologics and dispensing biosimilars – Lessons learned from a multinational survey. Explor Res Clin Soc Pharm. 2021;4:100084
Böhm et al. 2023	Böhm AK, Steiner IM, Stargardt T. Market diffusion of biosimilars in off-patent biologic drug markets across Europe. Health Policy. 2023;132:104818. doi.org/10.1016/j.healthpol.2023.104818
Bräuner 2024	Bräuner H. Horizon Scanning in Denmark. Providing the health care system with an overview and impact estimation of new medicines. Factsheet by H. Bräuner, Amgros I/S, Denmark for EAHP. 2024. Available from: https://eahp.eu/wp-content/uploads/2024/05/spd10215.pdf (accessed 10 December 2024)
DMC 2024a	Danish Medicines Council. About the council. Online information. 2024a. Available from: https://medicinraadet.dk/om-os/in-english (accessed 11 November 2024)
DMC 2024b	Danish Medicines Council. About biosimilars. Online information. 2024b. Available from: https://medicinraadet.dk/om-os/medicinradets-arbejde/biosimilaere-laegemidler accessed 11 November 2024)
DKMA 2012	DKMA. Medicines eligible for reimbursement. Online information. Danish Medicines Agency. 2012 (Updated 08 May 2012). Available from: https://laegemiddelstyrelsen.dk/en/reimbursement/general-reimbursement/medicines-eligible-for-reimbursement (accessed 11 November 2024)
DKMA 2016	DKMA. Biological and biosimilar medicinal products. Online information. Danish Medicines Agency. 2016 (Updated 08 July 2016). Available from: https://laegemiddelstyrelsen.dk/en/sideeffects/biological-and-biosimilar-medicinal-products/ (accessed 11 November 2024)
DKMA 2018	DKMA. General reimbursement of medicines (updated 01 July 2019). Available from: https://laegemiddelstyrelsen.dk/en/reimbursement/general-reimbursement/ (accessed 11 November 2024)
DKMA 2019a	DKMA. Prices of medicines. Online information. Danish Medicines Agency. 2019a (Updated 01 July 2019). Available from: https://laegemiddelstyrelsen.dk/en/reimbursement/prices/ (accessed 11 November 2024)

DKMA 2019b	DKMA. Reimbursement and prices. Online information. Danish Medicines Agency. 2019b. Last accessed on 11/11/2024 (Updated 23 September 2019). Available from: https://laegemiddelstyrelsen.dk/en/reimbursement/prices/ (accessed 11 Nov. 2024)
DKMA 2020	DKMA. Authorisation procedures. Online information. Danish Medicines Agency. Available from: https://laegemiddelstyrelsen.dk/en/licensing/authorisation-procedures/ (accessed 11 November 2024)
IQVIA 2020	IQVIA. Denmark Biosimilar Scorecard prepared June 2020. Available from: iqvia-biosimilar-scorecard-denmark.pdf (accessed 11 November 2024)
Jensen et al. 2020a	Jensen TB, Bartels D, Sædder EA, et al. The Danish model for the quick and safe implementation of infliximab and etanercept biosimilars. Eur J Clin Pharmacol. 2020a;76:35–40. doi.org/10.1007/s00228-019-02765-3
Jensen et al. 2020b	Jensen TB, Kim SC, Jimenez-Solem E, Bartels D, Christensen HR, Andersen JT. Shift From Adalimumab Originator to Biosimilars in Denmark. JAMA Intern Med. 2020b;180(6):902-3
Kvien et al. 2022	Kvien TK, Patel K, Strand V. The cost savings of biosimilars can help increase patient access and lift the financial burden of health care systems. Semin Arthritis Rheum. 2022;52:151939. doi.org/10.1016/j.semarthrit.2021.11.009
Law Library 2022	Law Library. Pharmaceutical Antitrust Cases. November 2022. LL File No. 2023-021798. LRA-D-PUB-002595. Available here: Pharmaceutical Antitrust Cases
Lunddahl 2016	Lunddahl B. Pharmacovigilance on biologicals and biosimilars: a Danish perspective. Generics Biosimilars Initiat J. 2016;5(3):123-4. doi.org/10.5639/gabij.2016.0503.030
Machado et al. 2024	Machado S, Cruz A, Ferreira PL, Morais C, Pimenta RE. Policy measures and instruments used in European countries to increase biosimilar uptake: a systematic review. Front Public Health. 2024;12:1263472. doi.org/10.3389/fpubh.2024.1263472
Medicines for Europe 2023	Medicines for Europe. Market review – European Biosimilar Medicine Markets Policy Overview. Presentation. 2023. Available from: Biosimilars-Market Review-2023-final-06-09-2023.cdr (accessed 11 November 2024)
Medicinraadet 2024a	Medicinraadet. Medicinrådets vurdering af biosimilære lægemidler. Online information. Available from: https://medicinraadet.dk/om-os/medicinradets-arbejde/biosimilaere-laegemidler (accessed 11 November 2024)
Medicinraadet 2024b	Medicinraadet. Medicinrådets vurdering af biosimilære lægemidler (gældende fra 26. januar 2023). Available from: https://medicinraadet-dk.b-cdn.net/media/4ftbhk20/medicinr%C3%A5dets-vurdering-af-biosimil%C3%A6re-l%C3%A6gemidler.pdf (accessed 11 November 2024)
Mehr 2018	Mehr S. Abbvie's Humira Price Cuts Don't Win the Business in Denmark. 2018. Online Information. Available from: https://biosimilarsrr.com/2018/11/21/abbvies-humira-price-cuts-dont-win-the-business-in-denmark/ (accessed 11 November 2024)s
Mulinari et al. 2022	Mulinari S, Pashley D, Ozieranski P. Advancing international comparison of pharmaceutical industry funding of patient advocacy: Focus on Denmark. Health Policy. 2022;126(12):1256-62. doi.org/10.1016/j.healthpol.2022.11.003
Safe Biologics 2021	Safe Biologics. Future of Biosimilar Market/Long-Term Sustainability. Presentation. 2021. Available from: https://safebiologics.org/wp-content/uploads/2021/09/Malta5.pdf (accessed 11 November 2024)

Schneider 2022	Schneider P. Biosimilar Policies in European Countries. Stakeholder Event on Biosimilar Medicinal Products Brussels, 13 December 2022. Austrian National Public Health Institute. Available from: https://ec.europa.eu/assets/sante/health/human-use/20221213/mp20221213co04_en.pdf
Varma et al. 2022	Varma M, Almarsdóttir AB, Druedahl LC. Biosimilar, so it looks alike, but what does it mean? A qualitative study of Danish patients' perceptions of biosimilars. Basic Clin Pharmacol Toxicol. 2022;130(5):581-91. Available from: https://doi.org/10.1111/bcpt.13719
Vogler et al 2022	Vogler S, Salcher-Konrad M, Habimana K. Study on best practices in the public procurement of medicines: final report. European Commission, European Health and Digital Executive Agency: Publications Office of the European Union, 2022. Available from: https://data.europa.eu/doi/10.2925/044781 (accessed 11 November 2024)
Vogler 2022	Vogler S. Ready for the future? - Status of national and cross-country horizon scanning systems for medicines in European countries. Ger Med Sci. 2022;20:Doc05. Available from: https://doi.org/10.3205/000307 (accessed 11 November 2024)



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