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

AUGMENT Biosimilars
Country fiche NETHERLANDS

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augment biosimilars

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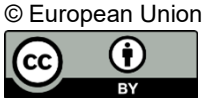

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Annex 7.22

AUGMENT Biosimilars country fiche: The Netherlands 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 the Netherlands 2025

Key stakeholders

The Medicines Evaluation Board (MEB), the national regulatory authority for medicines, has been publishing statements on interchangeablity and information materials. The Ministry of Health, Welfare and Sport is responsible for preparing legislation relating to medicines, including the tendering-like Preferential Pricing policy, and also takes final pricing and reimbursement decisions; the latter was prepared by the National Health Care Institute (Zorginstituut Nederland, ZIN). Medicines, including biosimilar medicines, are funded by health insurers, which are organised as competitive entities. The health insurers implement policies on biosimilars, such as prefential pricing, and also some demand-side measures, mainly targeted at doctors. The Competition Authority (Autoriteit Consument & Markt, ACM) plays an important role in reacting to anti-trust cases and publishing analyses regarding the biosimilar market.

Major biosimilar policies and practices and developments

Biosimilars are procured through decentralised tendering procedures conducted by the health insurers in the outpatient sector (the so-called preferential pricing policy, a tendering-like policy awarding reimbursed to the winner) and (groups of) hospitals in the inpatient sector. The competition in the market is thus comparably high (both on the payer and the provider side). The winning medicines are considered the "preferred option" and are required to be used in the hospitals (major use of biosimilars) and dispensed in the outpatient sector. It is to be noted that biosimilars are mainly used in hospitals. Switching to biosimilars has been recommended since 2015. Biosimilars are included in the reference price system. INN prescribing is voluntary but allowed for biologicals and so is biosimilar substitution.

Impact analysis

Despite a comparably high level of policies for biosimilars, no impact analyses on specific policies could be identified. Some studies showed the decrease in public expenditure due to biosimilar use. A study based on a narrative review and interviews did not identify availability issues (e.g, manufacturers leaving the market) due to the tendering-like preferential pricing policy.

Barriers, facilitators and good practice examples

In the Netherlands, health insurers are obliged by law to compete. Thus, each health insurer individually implements the preferential pricing policy and demand-side measures to encourage biosimilar uptake. This fragmentation may undermine the positive effects.

At the same time, the Netherlands have some good practice examples, such as a strong role in anti-trust enforcement against originator biological companies by the

Competition Authoritiy and a large government-supportive capacity-building initiative (originally known under the name “Biosimilars Nederlands”). A statement of the Medicines Agency in 2015 in support for switching to and amount bioismilars proved to be positive.

Recent developments

No recent developments with regard to biosimilars.

Highlights and learnings

The Netherlands were among the first countries which extended generic policies to biosimilars (e.g. substitution, inclusion of biosimilars in the reference price system). Their system on foster biosimilars update is advanced, however suffers from fragmentation since some policy measures are to be implemented by the health insurers expected to compete.

2 Key data regarding biosimilars in the Netherlands

First biosimilar medicine launched (i.e. brought on the market):
Somatropin (Omnitrope) marketed in **2006**
***Source*:** Gabi 2012

Number of the **biosimilars marketed**:
14 molecules with biosimilars available, as of 2022 in the hospital sector
***Source**:* Medicines for Europe 2023

3 Stakeholders involved in and targeted by biosimilar policies in the Netherlands

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant publications by stakeholder
Legislator	Ministerie van Volksgezondheid, Welzijn en Sport (VWS) / Ministry of Health, Welfare and Sport	Prepares legislation, including relevant legislation for pricing (e.g., the "Preferential Pricing Policy"), funding and procurement	
National regulatory authority	College ter Beoordeling van Geneesmiddelen (CBG) / Medicines Evaluation Board (MEB)	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance	CBG no year (info on bisoimilars) GaBI 2015 (GBG position on biosimilars) CBG 2018 (Information for patients)
Pharmaceutical pricing authority	Ministerie van Volksge-zondheid, Welzijn en Sport (VWS) / Ministry of Health, Welfare and Sport	Final decision on the reimbursement of medicines, concludes price / reimbursement negotiations and clustering in the RPS.	
Pharmaceutical reimbursement authority	Zorginstituut Nederland (ZIN) / National Health Care Institute	Prepares the decision on reimbursement of medicines	CVZ 2011 (position paper by ZIN predecessor on interchangeability and und use of biosimilars in preferential pricing policy)
Public payers	Different sickness funds, e.g., VGZ Zorgverzekeraar / VGZ Health Insurance, Menzis Zorgverzekeraar / Menzis insurance	Cover pharmaceutical expenses, do tendering-like procedure (preferential pricing policy) in different variants, implement different demand-side measures to encourage biosimilar uptake	
Procurement agency	No dedicated agency for procurement of medicines	Procurement of biosimilars is done by the health insurers in the outpatient sector and (groups of) hosptials in the inpatient sector based on tendering (e.g., Inkoopcombinatie Ziekenhuis Apotheken Academische Ziekenhuizen for group procurement organisation for teaching hospitals)	
HTA agency / body	Zorginstituut Nederland (ZIN) / National Health Care Institute	Prepares the decision on reimbursement of medicines. Biosimilars generally do not undergo HTA.	See above for CVZ 2011
National competition authority	Autoriteit Consument & Markt, ACM / Consumer and Market Authority	Reacts in ant-trust cases, some of which relating to biosimilars	ACM 2019 ACM 2022
National patent office	Octrooicentrum Nederland / Netherlands Patent Office	Granting and managing patents on biologic medicines	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant publications by stakeholder
Doctors	*Represented by:* Koninklijke Nederlandsche Maatschappij (KNMG) / Royal Dutch Medical Association (RDMA) *Medical societies in disease areas with biologics use:* Nederlandse Vereniging voor Diabetes Onderzoek (NVDO) / Dutch Diabetes Research Association Nederlandse Vereniging voor Gastro-enterologie (NVGE) / Dutch Society of Gastroenterology Nederlandse Vereniging voor Hematologie (NVvH) / Dutch Society for Hematology Nederlandse Vereni-ging voor Medische Oncologie (NVMO) / Dutch Society for Medical Oncology Nederlandse Vereniging voor Reumatologie (NVR) / Dutch Society of Rheumatology	Prescribe biosimilars, inform patients.	
Nurses	*Represented by:* Verpleegkundigen & Verzorgenden Nederland (V&VN) / Dutch Nurses Association		
Community pharmacists	*Represented by:* Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP) / Royal Dutch Pharmaceutical Association	Dispense medicines, inform patients	KNMP 2022 (positon on biosimilars)
Hospital pharmacists	*Represented by:* Nederlandse Vereniging van Ziekenhuisapothekers (NVZA) / Dutch Association of Hospital Pharmacists	Responsible for administration of medicines in hospitals. Inform and educate doctors and patients about biosimilars. Involved in the procurement of biosimilars via tendering.	NVZA 2017 (toolbox for successful use of biosimilars)

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-relevant publications by stakeholder
Patient organisations	*Represented by:* Patiëntenfederatie Nederland / National Coalition of Dutch Patients *Patient organisations in disease areas with biologics use*: Diabetesvereniging Nederland (DVN) / Dutch Diabetes Association Crohn en Colitis Ulcerosa Vereniging Nederland (CCUVN) / Dutch Crohn's and Colitis Association Nederlandse Vereniging van Hemofilie-Patiënten (NVHP) / Dutch Association of Hemophilia patients KWF Kankerbestrijding / Dutch Cancer Society ReumaNederland / Dutch Rheumatism Association Stichting Zeldzame Bloedziekten / The Rare Blood Diseases Foundation facilitates patient groups	Provides information about biosimilars to patients	CBG 2025 (biosimilars Q&A) DVN 2025 (biosimilars for diabetes patients) CCNL 2025 (statement on switching to biosmilars for patients with chronic intestinal diseases)
Consumer organisations	*Represented by:* Consumentenbond (CB) / Consumers Association		
Biosimilar industry Generic industry	*Represented by:* Bogin	Represents generic and biosimilar medicines producers in the Netherlands.	Medicines for Europe 2023 (market review)
Pharmaceutical industry in general Pharmaceutical industry for new biological medicines	*Represented by:* Vereniging Innovatieve Geneesmiddelen (VIG) / Association for Innovative Medicines	Represents pharmaceutical industry with a focus on innovative medicines.	
Initiative to promote biosimilar use	Instituut Verantwoord Medicijngebruik / Institute for Responsible Use of Medicines	Government funded information and capacity-building initiative to encourage the uptake of biosimilars (based on a time-limited project of "Biosimilars Nederlands"	IVM 2025 (comprehensive information for health care professionals and patients mainly on biologicals but also on biosimilars, including videos, podcasts, reports and brochures)

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium), Vogler, Salcher-Konrad and Habimana 2022

4 Biosimilar policies and practices in the Netherlands 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.	No, but the price of the biosimilar must be lower than the originator biological.
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, but the price of the generic must be lower than the originator.

Source: PPRI 2025

External price referencing

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

Source: PPRI 2025, Medicines for Europe 2023

Tendering

Some (or all) biosimilars are procured through tendering (or tendering-like) processes.	Yes, the Netherlands apply tendering for biosimilars in the inpatient sector and the outpatient sector (preferential pricing policy). In practice, biosimilars are mainly available in hospitals.
If yes, the scope with regard to the care sector:	Inpatient and outpatient sectors
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All off-patent biological medicines
Institutional framework	Hospitals or groups of hospitals perform the tenders in the inpatient sector.
Information available on procurement procedures and practices	Tenders are performed by active substance. Winning prices are not transparent to competitors. Price is used as the sole award criterion.

Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	Some off-patent biological medicines (applies rather in theory as mostly biosimilars are available from hospitals). It depends on the health insurer which biosimilars are included in their preferential procurement lists. Since 2016 on, some health insurers added biosimilars into the preferential pricing policy (the preferential pricing policy started in 2005 with joint tender of all health insurer and since 2008 as individual tenders, following a court ruling requesting the performance of the policy by each health insurer individually
Institutional framework	Perfomed by health insurner (organised as private companies, in competition with each other).
Information available on procurement procedures and practices	Award of bids normally on the lowest price. Winning bid is 'preferred' option per active ingredient to be dispensed in community pharmacies. The pharmacist should dispense the "preferred' medicine". Since health insurers have to compete each other, they run the tendering-like processes under the preferential pricing policy separately. As a result, there may be different preferred biosimilars in the community pharmacy. The details of tendering proceses may vary across the health insurers, e.g., with regard to the duration of the contract or the award criteria even. In the beginning, the contracts were rather short (6 months) but over the years some insurers grant longer contracts (1 or up to 2 years depending on the insurer). Some health insurers moved away from the security of supply criterion. For security of supply, the health insurers apply different approaches including delivery guarantees or obliging the winner to inform about the availability status of the medicines regularly or to publish information about delivery problems on their website. Aiming to reduce dependency from one supplier, some health insurers have been experimenting with similar procurement and reimbursement models to generate savings from off-patent products. The health insurer ACHMEA runs the IDEA model, which offers a fixed price for all off-patent medicines plus an increased pharmacy remuneration to the pharmacies. The fixed remuneration price is set by the health insurer, and pharmacies are incentivised to procure at a lower price and retain the difference. Participation in this model is voluntary; however, in case of non-participation, the preferential pricing policy is applied.
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes Outpatient: Yes (tendering-like), preferential pricing policy

Sources: PPRI 2025; Kanavos et al. 2009, Kanavos 2012, Vogler et al. 2017; Vogler, Salcher-Konrad and Habimana 2022, Vogler et al. 2025

4.2 Reimbursement policies

Reference price system

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	Biosimilars are included in the outpatient RPS system. This is however applicable in practice to a limited extent as biosimilars are mainly available in the inpatient sector.
If yes, how many and under which specifications	The Dutch reference price system groups interchangeable medicines into thematic clusters and defines a maximum reimbursement amount per cluster. Some health insurers include biosimilars in these clusters.

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 and biosimilars. Broader than 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, some biosimilars are included in the outpatient positive list – in the RPS (however, most biosimilars are available in the hospitals)
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	
Co-payments for biosimilars for outpatient use	Not applicable (see above).
<u>For medicines for outpatient use in general (other medicines than biosimilars)</u> Positive list for medicnes in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	Positive list with 100% reimbursement if reimbursed. Co-payments in place for reimbursed medicines.
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes, and doctors are recommended to switch. Medicines in hospitals are funded by the respective health insurers through the diagnosis-related group (DRG) system. Full (100%) coverage for all medicines used in hospitals. Hospital pharmaceutical formularies at hospital level established (some overlapping).
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	Not publicly available. However, there was a comparative study investigating to which extent hospital formularies in Dutch hospitals overlapped.
Co-payments for biosimilars for inpatient use	No, all medicines used in hospitals are reimbursed at 100% rate. When a hospital pharmacy disepeses to an outpatient (around half of the hospital pharamcies do so) co-payments may apply.
<u>For medicines for inpatient use in general (other medicines than biosimilars):</u> Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	Hospital pharmaceutical formularies at hospital level. No co-payments for medicines for inpatient use. When a hospital pharmacy disepeses to an outpatient (around half of the hospital pharamcies do so) co-payments may apply.

Source: PPRI 2025, Vogler et al. 2022, Storms/Schreurs 2009

4.3 Specific pricing, procurement and funding policies 2024

Application of **special pricing, procurement and reimbursement models for biosimilars** (e.g., delinkage / subscription-model, management-entry agreements (MEAs)	No, apart from tendering-like models as described above ("preferential pricing policy" and similar models (e.g. IDEA model by ACHMEA) by health insurers to exploit competition of generics and biosimilar medicines.
Enforcement of anti-trust policies	Yes, enforcement on anti-rust cases of originator biological medicines with illegal procurement practices, see below.
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Yes, (solely financial) MEAs in place.

Source: ACM 2019, ACM 2022, Vogler, Salcher-Konrad and Habimana 2022

Further information on anti-trust enforcement:

Between 2015 and 2018, the patents on the biological medicines for three TNF alpha inhibitors expired, allowing biosimilars to enter the market. Still, in the Netherlands the list prices of those medicines remained relatively high for a long time, while the uptake of biosimilars remained low in comparison with biosimilars – e.g., in the oncology area. The Dutch Competition Authority (Autoriteit Consument & Markt ACM) undertook an own-initiative sector inquiry into competition in TN alpha inhibitors in these years. As a result, two anti-trust cases were initiated:

The first anti-trust case on a TNF alpha inhibitor originator (Enbrel®, by Pfizer) adressed clauses in procurement contracts of the originator company that linked discounts in the inpatient sector to future orders and thus acted as a barrier to procurement and use of competitor (biosimilar) medicines. Upon action by the ACM, the originator company stopped this action.

Another anti-trust case involved the originator biological Humira® (AbbVie), where the originator company used discount schemes that required hospitals to purchase exclusively from AbbVie to receive significant discounts. ACM intervened, leading AbbVie to cease these exclusive purchasing obligations.

Source: ACM 2019, ACM 2022, Vogler, Salcher-Konrad and Habimana 2022

4.4 Supportive tools and practices for policy-makers 2024Horizon scanning

Public authorities or public payers use a horizon scanning system to identify loss of exclusivity (patent expiry) of biologics	Yes, systematic use of horizon scanning for some new medicines.
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	A national horizon scanning and horizon scanning through the International Horizon Scanning Initiative (IHSI) are systematically used to identify high-price medicines.

Source: PPRI 2025, Vogler et al. 2022

Health technology assessment

HTA is applied for biosimilar medicines	No Biosimilars do not systemically undergo an HTA.
If yes, in which situations and settings (outpatient and inpatient)	
Differences in criteria and processes of HTA for biosimilars compared to other medicines	
Any specificities	

Source: PPRI 2025, Wilsdon et al. 2022

4.5 Demand-side measures 2024

Doctors (and further prescribers)

Country context: Only doctors may prescribe medicines to patients.

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes, switching has been recommended since 2015, the Medicines Evaluation Board updated its opinion on biosimilars. Switching to biosimilar medicines is now thus recommended, and prescribing of biosimilars is encouraged by a position paper of the regulatory agency and the publication of the Medical Professional Association.
If yes, what is recommended for naïve patients?	Start the therapy with a bioismilar
If yes, what is recommended for patients already on biologic treatment	Biosimilar switching (from reference product to the biosimilar and among biosimilars) is possible and recommendation under the defined conditions: - supervision of the doctor (clear clinical monitoring) - n consultation with the patient - interaction between doctors and (hospital) pharmacists - for any biological: to record the detailed product and batch information in the patient file
Prescription guidelines (including switching guidelines) were issued by	Position Paper by CBP
URL of prescription & switching guidelines	
Prescribing quotas	
Prescribing quotas for doctors with regard to prescription of biosimilars exist	Yes, imposed by some health insurers
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 quota were issued by	
URL of prescribing quotas	
Prescribing quota for other non-biosimilar medicines exists	Yes, for generics by some health insurers
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	Literature reported on gain-sharing models for hospitals

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, voluntary.
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	No exemptions for biologicals, but all on voluntary basis.
Further measures targeted at doctors	
Information materials for doctors	
Information events for doctors (e.g., seminars, trainings)	
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	

Source: PPRI 2025, GaBI 2015, Vogler et al. 2022, Medicines for Europe 2021, Medicines for Europe 2023, Barcina-Lacosta et al. 2022

Pharmacists (and further dispensers**)**

Country context: Pharmacists and dispensing doctors dispense medicines to the patients.

Source: Zuidberg 2010

Substitution policies	
(Automatic) substitution for biosimilars	Yes, voluntary.
If yes, for which biologic substances and under which prerequisites?	Though biosimilar substitution at community pharmacy level is voluntary, there are indications that for insulin biosimilars, health insurers are increasingly requiring pharmacies to substitute to the biosimilar.
If yes, since when, and when was it extended? (process of implementation)	
Any specificities	
URL of underlying law	
Generic substitution in place	Yes, voluntary.
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)	However, pharmacy remuneration is though a dispensing fee. This price-independent remuneration tends to encourage biosimilar uptake.
Publicly accessible information	
Further measures targeted at pharmacists	
Information materials for pharmacists	Yes, information materials from health authorities available.
Information events for pharmacists (e.g., seminars, trainings)	

Source: PPRI 2025, Wilsdon et al. 2022, Barbier et al. 2022

Patients

Information and educational measures	
Information materials for patients	Yes, through information information by health authorities, mainly the Medicines Agency CBG
If yes, provide URL of most common materials	Leaflet for patients, prepared together with patientorganisations: CBG 2018

	https://www.cbg-meb.nl/onderwerpen/medicijninformatie-originele-biologische-medicijnen-en-biosimilars Link to EMA information
If yes, key producers of education measures	Health authorities.
Information events for patients (e.g., seminars, trainings)	Yes.
If yes, key providers of educational events	Health authorities organise events (e.g., conferences) to educate about biosimilars.
Gain-sharing models	
Gain-sharing models for patients	No.
If yes, pls. describe	Not applicable as not in place.
Publicly accessible information	

Source: PPRI 2025, Wilsdon et al. 2022

5 Impact of biosimilar policies and practices in the Netherlands

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 the Netherlands

Outcome indicator	Caused by	Findings	Publication
Savings for the public payer	No specific policy identified.	Using infliximab biosimilars as the first treatment for pediatric Crohn's disease was shown to be cost-effective compared to traditional treatments. The study was not linked to a specific biosimilar policy.	Vujik et al. 2024
Savings for the public payer	No specific policy identified.	The study showed that public health expenses for trastuzumab decreased significantly after the introduction of biosimilars, focussing on different admisnitration forms. The intravenous biosimilar and the subcutaneous version, still under patent, saw price reductions, with the IV biosimilar's price falling more sharply. The study was not linked to a specific biosimilar policy.	Kirshner et al. 2024
Savings for the public payer	No specific policy identified.	This registry-study showed that three-year survival rates for DLBCL (Diffuse Large B-Cell Lymphoma) patients were similar whether they were treated with rituximab biosimilars or the original rituximab. By the end of 2018, 91% of rituximab purchased in the Netherlands were biosimilars, leading to a 43% reduction in annual expenses, this was not further linked to a specific biosimilar policy.	Brink et al. 2021
Availability and savings	Preferential pricing policy	The study based on a narrative review and stakeholder interviews identified major savings due to the preferential pricing policy (based on publications of health insurers). No supplier was found to have withdrawn from the Dutch market. The study was conducted at a time when biosimilars were rarely included in the preferential pricing policy and thus referred mainly to generics.	Vogler et al. 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 the Netherlands

Legal barriers

In the Netherlands, several court trials have been conducted with regard to policies relating to off-patent medicines (i.e., the preferential pricing policy) – though mainly at a time when biosimilars were not yet included. While the government won several court cases, this was still time- and resource-intensive (Vogler et al. 2017; Vogler, Salcher-Konrad and Habimana 2022).

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

A fragmented health care system, with individual health insurers taking measures to encourage biosimilar uptake, such as some of them imposing prescribing quotas on doctors. In the case of the preferential pricing policy, the originally joint implementation of the health insurers (at that time done for generics done) was stopped by a court ruling which obliged the health insurers to implement the preferential pricing policy individually. The savings would have been higher in case of a joint endavour (Kanavos et al. 2009).

Financial barriers

The Dutch government funded a comprehensive information and capacity-building initiative to encourage the uptake of biosimilars ("Biosimilars Nederlands") was still considered as not sufficiently funded given the challenges around biosimilar uptake (finding from the exploratory interviews of this study).

Policy-related barriers

Illegal procurement practices by originator biological companies, see below (ACM 2019, ACM 2022).

Stakeholder-related barriers

Originator companies were found to use illegal practices to prevent and delay biosimilar competitors entering the markets (e.g, through tendering policies binding hospital procurers). The Competition Authority has been reacting and published some cases (ACM 2019, ACM 2022).

In the first years of the preferential pricing policy (however, only generics were included at that time), community pharmacists were fierce opponents of that policy and filed several court cases against the government, but most cases were won by the government. The reason for that opposition were financial disadvantages for community pharmacists resulting from the preferential pricing policy because before the introduction of that policy, community pharmacists had been able to generate bonuses from direct negotiations with the industry (no longer possible). Generic

companies were also against this policy due to their strong competitive character (single-winner model in the beginning) (Vogler et al. 2017). To note that that these findings may already be outdated and that some health insurers reacted by adapted their preferential pricing policy.

7 Facilators and good practice examples in the Netherlands

The Netherlands invested in a large capacity-building initiative (Biosimilars Nederlands) which was considered effective and have built trust in biosimilars (exploratory interview conducted as part of this project). This project ended but was continued as part of the IVM (Institute for Responsible Medicine Use) Iniative.

Dutch regulatory authorities take a position, wich may influence the uptake of biosimilars. The opinion paper on switching of the Medicines Evaluation Board in 2015 is considered helpful. Furthermore, the Competition Authority is actively involved in enforcing anti-trust legislation towards originator companies introducing illegal procurement practices. These moves by the Competition Authority appear to support biosimilar competition. In addition, the Compeittion Authority published a sector inquiry into TNF-Alpha inhibitors inquiring the competition before and after the entry of biosimilars (ACM 2019) and was active in communication policy on this mater.

One rather controversial policy is preferential pricing despite its ability to contribute to major savings. To mitigate the risk of potentially deferring suppliers due to a pricing and procurement policy, which is perceived as aggressive by some suppliers, some health insurers experimented with alternative designd of the preferential pricing policy, e.g., allowing for multiple-suppliers and considering further criteria (Vogler, Salcher-Konrad and Habimana 2022, Vogler et al. 2024).

Overall, the success of biosimilar policies in the Netherlands is likely attributable to the mix of policies and practices at both supply- and demand-side levels and the involvement of several stakeholders.

8 Developments in the Netherlands

The Netherlands have seen some changes over the years relating to biosimilars, with a change of the regulatory authority in 2015 towards the recommendation of switching (GaBI 2015) and investigations into anti-trust cases of originator companies launched by the competition authority ACM (ACM 2019, ACM 2022)

Furthermore, developments also took place at the level of individual health insurers who started to include biosimilars in their preferential pricing policies from 217 and some health insurers adapted these policies to less competitive variants (e.g., moving away from single-winner approaches and price-only award criteria) (Vogler et al. 2022, Vogler, Salcher-Konrad and Habimana 2022).

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