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

AUGMENT Biosimilars
Country fiche NORWAY

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augment biosimilars

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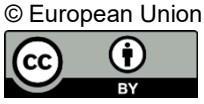

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Annex 7.23

AUGMENT Biosimilars country fiche: Norway 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:

Eirik Sverrisson, Sykehusinnkjøp / The Norwegian Hospital Procurement Trust

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1 Summary of biosimilar policies and practice in Norway

Key stakeholders

At operational level, the Norwegian Hospital Procurement Trust (Sykehusinnkjøp HF, plays an important role. Sykehusinnkjøp HF is the national procurement agency for all public hospitals, and it is owned by the Regional Health Authorities that fund inpatient care, including medicines. In addition, they also fund defined medicines for outpatient care ("H prescriptions"). The business area LIS within the Trust, responsible for the procurement of hospital medicines and "H prescription" medicines, has been very active in stakeholder engagement, towards their clients (public hospitals) and suppliers. For instance, Sykehusinnkjøp HF organises regular seminars and informs hospital staff about the medicines which were tendered and are recommended for use.

Major biosimilar policies and practices

The pricing, procurement and reimbursement policy framework in Norway is considered very competitive. For biologicals, which are mainly used in the inpatient sector and are thus procured by Sykehusinnkjøp HF, considerable price reductions were observed (e.g. for infliximab and etanercept).

To brigde potential gaps between the outpatient and inpatient sector, some biologics were included in the "H prescription" scheme, which allows their procurement through Sykehusinnkjøp HF, while being dispensing by community pharmacies to outpatients.

For outpatient medicines with competition, the "trinnpris model" (stepped price system) is in place, and it also includes biosimilars. For medicines included in the "trinnpris model" (both originator biologicals and biosimilars), the "stepped price" is reimbursed by the social health insurance, and it will be cut at the start of the biosimilar competition and in two further steps (six and 18 months after biosimilar competition), with the reduction rates depending on previous sales volumes.

In Norway, biosimilar substitution in community pharmacies is in place. As a prerequisite, biosimilar substances must be included in a "substitution list", which implies that the provision of the "trinnpris model" of "stepped" price reductions are applied.

Impact analysis

Literature about the impact of the biosimilar policies in Norway is mostly focused on signficant price reductions, which biological medicines (biosimilars as well as off-patent reference products) were able to generate in centralised tenders for the public hospitals. It has been argued that the savings have helped to provide access to more patients.

Barriers, facilitators and good practice examples

From Norway, mainly information on faciltators is available (not barriers). Key success factors and good practice examples include:

- Strategic procurement and stakeholder engagement: Centralised tendering is considered as an important policy to ensure patient access to biological therapies. Intensive dialogue with hospital staff about the tendered products help to improve their knowledge and acceptance of the recommendations for use of tendered medicines
- NOR-SWITCH study: The Norwegian authorities commissioned a "switch study" to analyse the safety of switching of infliximab. The findings of the safety of the switch are now used in the information activities.
- H-prescriptions: This "interface policy" measure across sectors ensures that biologicals for outpatient use may also be tendered by the national hospital procurement agency.

Recent developments

In July 2021, Norway introduced biosimilar substitution for selected molecules in a long, carefully planned process, including board stakeholder consultation.

Since 2022, biosimilars have been included in the stepped priced system.

Highlights and learnings

Norway has an advanced policy framework (both supply-side and demand-side measures) to encourage biosimilar competition, and the country has seen successful biosimilar uptake and low biosimilar prices. Evidence generation and information activities appear to play a major role to the effective implementation of biosimilar policies.

2 Key data regarding biosimilars in Norway

No information available.

Key national publicly accessible sources reporting data on biosimilars

https://www.dmp.no/

3 Stakeholders involved in and targeted by biosimilar policies in Norway

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Helse- og omsorgsdepartementet / Ministry of Health and Care Services	Prepares legislation	https://www.regjeringen.no/no/dep/hod/id421/
National regulatory authority	Legemiddelverket / Norwegian Medicines Agency	In charge of marketing authorisation, classification, pharmaco-vigilance and montiring of information / promoting activities. Published switching recommendation	Position paper on switching
Pharmaceutical pricing authority	Legemiddelverket / Norwegian MedicinesAgency	Implements pricing legislation regarding biosimilars, decides on the prices	https://www.dmp.no/
Pharmaceutical reimbursement authority	Legemiddelverket / Norwegian Medicines Agency Regionale helseforetakene (RHF) / Regional Health Auhoritiies	Decides on inclusion into reimbursement for biosimilars in the primary care. Produces prescribing guidelines for biosimilars, responsible for prescription quotas	https://www.dmp.no/
Public payer	*Outpatient (primary care):* Norwegian Health Economics Administration (HELFO) (Subordinate of Helsedirektoratet) *Inpatient (specialist care):* Regionale helseforetakene (RHF) / Regional Health Auhoritiies	Operational level reimbursement Responsible for financing, planning and provision of specialist services (including hospital care) and funding responsibility for "H prescriptions" (i.e., defined medicines for outpatient use). Owner of the inpatient procurement agency Sykehusinnkjøp HF	https://www.helfo.no/lege/blaar eseptordningen/legemidler-pa-bla-resept-forhandsgodkjent-og-individuell-stonad https://www.nyemetoder.no/

Procurement agency	Sykehusinnkjøp HF 7 Norwegian Hospital Procurement Trust	Is the national procurement agency in the inpatient sector and procures for all public hospitals. One business area deals with medicines (LIS previously a separate procurement unit). It procures biologics nation-wide for the inpatient sector and organizss seminars and trainings for hospital staff, including on biosimilars. Also involved in joint Nordic Tenders together with Denmark and Iceland, as part of the part of Nordic Pharmaceutical Forum.	Pharmaceutical procurement strategy of the Sykehusinnkjøp HF 2018
HTA agency / body	Helsedirektoratet / Norwegian Directorate of Health, The Norwegian Institute of Public Health (NIPHNO)		
National competition authority	Konkurranse Tilsynet / Norwegian Competititon Authority	Enforcement of the competition law, anti-trust cases	
National patent office	Patentstyret / Norwegian Industrial Property Office	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Den norske legeforening / Norwegian Medical Association Medical societies: Norsk Gastroenterologisk Forening / Norwegian Gastroenterological Association Norsk Selskap for Hematologi / Norwegian Society of Hematology Norsk Revmatologisk Forening / Norwegian Rheumatology Association Norsk forening for sjeldne diagnoser / Norwegian Association for Rare Diseases	Prescribe biosimilars a/o by INN. Inform patients	
Nurses	*Represented by:* Norsk Sykepleierforbund (NSF) / Norwegian Nurses Organisation		https://www.ahus.no/nyheter/forskning/trygt-bytte-til-billigere-medisiner-gir-behandling-til-flere
Community pharmacists	*Represented by:* Apotekforeningen / Norwegian Pharmacy Association	Dispense medicines, including biosimilars, substitute biologicals for biosimilars where allowed, inform patients	

Hospital pharmacists	*Represented by:* Norske Sykehusfarmasøyters Forening (NSF) / Norwegian Association of Hospital Pharmacists	Support procuring medicines (involved in technical preparation of tenders), inform patients, health professionals and procurers	
Patient organisations	*Patient organisations on specific diseases:* Diabetesforbundet / Norwegian Diabetes Association Landsforeningen mot fordøyelsessykdommer (LMF) / Norwegian Digestive Diseases Association Foreningen for blødere i Norge (FBIN) / Association of Hemophilia patients in Norway Kreftforeningen / Norwegian Cancer Society Norsk Revmatikerforbund / Norwegian Rheumatism Association	Patient organisations on diseases with biological therapies. Included in all tenders with Sykehusinnkjop, in dialogue and patient advocate	
Consumer organisation	Forbrukerrådet		
Biosimilar industry	*Represented by:* Farma Norge – Forening for generiske og biotilsvarende Medisiner	Produces and supplies biosimilars	
Generic industry	*Represented by:* Farma Norge – Forening for generiske og biotilsvarende Medisiner		
Pharmaceutical industry in general	*Represented by:* Legemiddelindustrien (LMI)		
Pharmaceutical industry for new biological medicines	*Represented by:* Life Science Cluster		
Further relevant stakeholder group	Regional Health Authorities	They own the hospitals and they are decision makers in procurement through their doctors and specialist groups	https://www.helse-sorost.no/ https://www.helse-midt.no/ https://www.helse-vest.no/ https://www.helse-nord.no/

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium), Aure and Festoy 2022

4 Biosimilar policies and practices in Norway 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:	Other The Norwegian "trinnpris model" (stepped price system) can be considered as a variant of a generic and biosimilar price link price policy. It requires price cuts for the originator biologicals and the biosimilars, depending on sales, at first step of biosimilar competition and 6 and 12 months afterwards. In principle, biosimilars may be priced at the price of the reference product but experience the same price cut as the reference product. The price cut relates to the "stepped price" which is the price reimbursed by the social health insurance.
Price reduction of the first biosimilar compared to the reference product	First price cut at the start of biosimilar competition: -2% (independent from sales volume)
Price reduction of the second, third and further biosimilars	**2nd price cut 6 months after start of 1st step:** 50% in case of sales of < 100 mio. NOK / 8.4 mio. € 70% in case of sales above Sales relate to a 12-month period during the last two years before biosimilar competition, expressed at pharmacy retail price (PRP) level **3rd price cut 12 months after start of 2nd step:** 60% (for sales > 15 mio. NOK / 1.3 mio. € 75% (sales: 30 mio. NOK – 100 mio. NOK / 2.5 mio. E – 8.4 mio. €) 80% (sales: > 100 mio. NOK / 8.4 mio. €= Sales relate to a 12-month period after start of 2nd step, expressed at RPP
Price reduction for the reference product	Yes. Indeed, the price cut concerns the "stepped price" (reimbursement price); the maximum pharmacy retail price of the reference product (and the biosimilars) could be higher (patients have to pay the difference)
Any further specificities	The "trinnpris model" (stepped price system) has been existing for generics since 2005 and was later extended to biological medicines. The latter were included in the stepped price system from 1 January 2022. The "trinnpris model" requires three price cuts for biological medicines, which was also the case for chemical medicines till January 2022, when an initial price cut was removed.
Generic price link	In place: Yes, in the form of "trinnpris model". Two steps: **1st step (at start of generic competition):** 59% (sales < 100 mio. NOK) and 81% (sales > 100 mio. NOK) **2nd step (18 months after start of 1st step):** 69% (sales > 15 mio. NOK), 88% (> 30 mio. NOK & > 100 mio. NOK), 90% (> 100 mio. NOK), further conversion in € see above Sales expressed at RPR, within 12-month during last 2 years before generic competition and 18 months after 1st step, respectively Same mechanisms as biosimilars (price cut of "stepped price" = reimbursement price)

Source: PPRI 2025, NOMA 2025 (description on "trinnpris model")

External price referencing

External price referencing is applied for biosimilars.	Yes, but only as supplementary policy
If yes, it is applied for the following situations:	For biosimilar medicines in the outpatient sector entering the market, but only if they are prescription-only medicines

Any specificities	
External price pricing is in place for other medicines than biosimilars.	Yes, for all prescription-only medicines with (generic / biosimilar) competition

Source: PPRI 2025

Tendering

Some (or all) biosimilars are procured through tendering (or tendering-like) processes.	Yes
If yes, the scope with regard to the care sector:	Inpatient and outpatient sectors
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All (off-patent and on-patent) biological medicines
Institutional framework	Conducted by the national procurement agency Sykehusinnkjøp HF (centralised procurement for all public hospitals nation-wide) In principle, hopitals are allowed to procre medicines on their own (will obtain different prices than by Sykehusinnkjøp HF)
Information available on procurement procedures and practices	Open procedures are common. Tenders are at therapeutic level. Sykehusinnkjøp HF aims to apply the MEAT (Most Economically Advantageous Tender) criteria, e.g. security of supply, environmental criteria, but also for biosimilar tendering. Usually single-winner tenders, but two winners may also be announced in biosimilar procurement to avoid shortages (e.g, splitting out the country into two parts (65% of the market: South Eastern and Northern Regions and 35% of the market: Central and Western regions), for which a different supplier will be responsible). Preparation of tenders in an interdisciplinary manner; close involvement of clinicians, pharmacists, patient organisations, and other relevant stakeholders in preparing tenders and communicating their results. A health economic adviser is also part of the group. For each category of medicines, an expert group is formed to provide input for the design of the tenders (e.g. an expert group for TNF-inhibitors was convened to prepare a tender for these products). The panel then endorses the results of the tender by issuing recommendations indicating the preferred treatment choice. Follow-up information and communication activities by Sykehusinnkjøp HF to clinicians, see below demand-side measures to doctor Sykehusinnkjøp HF is also involved in joint Nordic tenders (with Denmark and Iceland)
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	Some: medicines for outpatient use and dispensed by community pharmacies, are also tendered by Sykehusinnkjøp if labelled as so-called "H prescription" – some bioloigic substances are "H prescription" Norway reported to start using tendering for other outpatient medicines,
Institutional framework	Conducted at national level by Sykehusinnkjøp for "H prescription"
Information available on procurement procedures and practices	For inpatent sector and H prescriptions: see above For other tenders in the outpatient sector:
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes (all generics) Outpatient: Yes (some generics)

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Sverrisson 2025

4.2 Reimbursement policies

Reference price system

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	Yes
If yes, how many and under which specifications	Only those which are for outpatient use and not H prescription
If publicly accessible, indicate URL of RPS list	xls list of substances and clusters accessible from the website: www.dmp.no/offentlig-finansiering/pris-pa-legemidler/trinnpris
When were first biosimilars included in the reference price system?	1 January 2022
Any further specificities	The pharmacies are obliged to secure the capacity to deliver at least one medicine at a retail price equal to the stepped price. If a medicine is delivered in both small and large packages, the pharmacy is obliged to deliver both small and large packages at the stepped price. The wholesalers are obliged to offer the pharmacies medicines at prices that enable them to fulfil these obligations.
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	Yes At ATC 5 level

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 (in some cases)
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	100% and 50%
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	
Indicate URL of outpatient positive list	Searchable database: https://www.legemiddelsok.no/
Co-payments for biosimilars for outpatient use	Percentage co-payments and deductible
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	Positive list Percentage reimbursement rates are in place: 100%, 50% Percentage co-payments and deductible

Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes, in those cases when they won the national tenders
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	Specialist group of leading specialist in the field
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	
Co-payments for biosimilars for inpatient use	No
For medicines for inpatient use in general (other medicines than biosimilars): Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	No co-payments for medicines for inpatient use

Source: PPRI 2025

4.3 Specific pricing, procurement and funding policies

For defined medicines, public payers and payers have been piloting and implementing specific funding models (such conditional reimbursement, managed-entry agreements, and subscription models such as the Netflix models). Typically, these funding models apply for high-priced medicines with high uncertainties (e.g., originator biologicals) or for medicines with small populations whose uptake is aimed to be encouraged. The section provides information whether biosimilar medicines are also subject to specific funding models. Furthermore, it also looks into possible anti-trust cases.

Specific pricing, procurement and funding policies and practices	
Application of special pricing, procurement and reimbursement models for biosimilars (e.g., delinkage / subscription-model, management-entry agreements (MEA))	No
Enforcement of anti-trust policies	
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Financial-based and performance-based MEAs are in place for new medicines with high price tags

Source: PPRI 2025

4.4 Supportive tools and practices for policy-makers

Horizon scanning

Public authorities or public payers use a horizon scanning system to identify loss of exclusivity (patent expiry) of biologics	
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	Sykehusinnkjøp HF monitors upcoming patent expiries to provide tenders

Source: PPRI 2025

Health technology assessment

HTA is applied for biosimilar medicines	
If yes, in which situations and settings (outpatient and inpatient)	
Differences in criteria and processes of HTA for biosimilars compared to other medicines	Norway has a process of "managed entry for medicines" which is a systematic process for new health technologies, including new medicines, to conduct HTA (different types of HTA for different medicines, identified based on a horizon scanning process)
Any specificities	

Source: PPRI 2025

4.5 Demand-side measures

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
If yes, what is recommended for naïve patients?	No specific recommended but INN prescribing is in place, and if prescribed by trade name, doctors should prescribe the lowest-priced medicine (outpatient) or tendered medicine (inpatient)
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	
URL of prescription & switching guidelines	Not necessarily a prescription guideline but a position of the Norwegian Medicines Agency that switching (between biosimilars, between originator biological and biosimilar and vice versa) is safe, further clinical sutduies confirming safety of switching are considered unnecessary. The decision on switching is made by the doctor or hospitals. See position (as October 2017, updated in October 2023): www.dmp.no/en/news/switching-between-a-reference-product-and-a-biosimilar
Prescribing quota	
Prescribing quota for doctors with regard to prescription of biosimilars exist	No
If yes, which quota are defined for biosimilars	
Any exemptions	
Any sanctions in case of non-achievement	Not applicable
Any (financial) incentives for achieving the quota	
Prescribing quota were issued by	
URL of prescribing quota	
Prescribing quota for other non-biosimilar medicines exists	
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	No

If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	
Publicly accessible information	
INN prescribing	
In general, prescribing by INN is place (information not focused on biologics)	Yes, indicative
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	No exemption for biologicals: biologics and biosimilars may be prescribed by INN
Further measures targeted at doctors	
Information materials for doctors	NOR-SWITCH study NOMA website
Information events for doctors (e.g., seminars, trainings)	Sykehusinnkjop trainingevents
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	

Source: PPRI 2025; on switching: NOMA 2023, on gainsharing: Barcina Lacosta, Vulto, Turcu-Stiolica et al. 2022

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense.

Biosimilar substitution: Practice of dispensing a biosimilar medicine instead of the prescribed equivalent and interchangeable biosimilar or biological originator medicine at the pharmacy level without consulting the prescriber.

Substitution policies	
(Automatic) substitution for biosimilars	Yes, indicative
If yes, for which biologic substances and under which prerequisites?	For those biological substances that have been put on the "substitution list" When put on the substitution list, then these medicines also fall under the "Trinnpris model" with stepped price reduction
If yes, since when, and when was it extended? (process of implementation)	Since July 2021 An earlier attempt in 2012, but industry brought the earlier regulation to court The Ministry and NOMA prepared a legislation for introduction of biosimilar substitution, had an intensive stakeholder consultation in 2017
Any specificities	For community pharmacies (outpatient sector)
URL of underlying law	
Generic substitution in place	Yes, indicative
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)	Not applicable
Publicly accessible information	
Further measures targeted at pharmacists	
Information materials for pharmacists	
Information events for pharmacists (e.g., seminars, trainings)	

Source: PPRI 2025; on gainsharing: Barcina Lacosta, Vulto, Turcu-Stiolica et al. 2022

Patients

Information and educational measures	
Information materials for patients	No information available
If yes, provide URL of most common materials	
If yes, key producers of education measures	
Information events for patients (e.g., seminars, trainings)	No information available
If yes, key providers of educational events	
Gain-sharing models	
Gain-sharing models for patients	No information available
If yes, pls. describe	
Publicly accessible information	

Source: PPRI 2025

5 Impact of biosimilar policies and practices in Norway

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 Norway

Outcome indicator	Caused by	Findings	Publication
Lower prices	Centralised tenders in the hospital sector	Reports on high discount / price reductions offered for biosimilar infliximab (discount of 72%, compared 69% offered for the originator biological) in 2015 (for one-year contract from 3/2015-2/2016) Offered discount was higher before (in 2014: biosimilar discouts of 39%)	GaBI Online 2015
Lower prices (for originator biological)	Centralised tenders in the hospital sector	Changes in the prices of originator adalimumab: - Before loss of exclusivity: Since May 2015 to end of September 2018: €539.93 per unit (€1,079.86 per package of 2), further confidential discounts, national procurement agency may reduce prices in the hospital sector by 30%. - After loss of exclusitivy: priced at €531.26 per unit (€1,062.51 per package of 2); further confidential discounts, up to 80%. According to tender recommendations for - 2019, originator is the least expensive product	Mookens, Godman, Huys et al. 2021
Market shares and price reductions	Centralised tenders in the hospital sector	Study of price and volume data for all originator biologicals and biosimilars for TNF inibitors procured by the centralised procurement agency for hospitals, data from January 2006 to December 2016 Infliximab biosimilars gained 10% of entire TNF market in Norway after one year and 40% after two years. It took the biosimilar 2 years to replace the original brand in the Norwegian hospitals 2014 tender for infiliximab: 40% lower price for biosimilar (Remsima) than originator (Remicade); in 2016. Second biosimilar (Infectra). 60% lower price than originator Etanercept: Biosimilar market entry in 2016, price cut of 40% Authors conclude that an increase in the market share of biosimilars from 10 % to 60 %, will be accompanied with a 50 % reduction in the expected price and biosimilar market entry fostered competition	Dalen, Strøm and Locatelli 2021

Source: see last column and further details on the full citation in the bibliography at the end of this country fiche

6 Barriers for biosimilar uptake and policy implementation in Norway

No barriers reported.

7 Facilitators and good practice examples in Norway

Specific role of centralised hospital tendering

In the literature (Dalen, Strøm and Locatelli 2021; Moorkens, Godman, Huys et. al 2021; Mack et al. 2021), the centralised tendering for all public hospitals through the national procurement agency LIS / Sykehusinnkjøp HF) has repeatedly been mentioned as a success story, also with regard to ensuring to achieve lower prices for biologicals (either the originator biological as well as the biosimilars) and foster uptake. LIS also applies strategic procurement elements, including multiple winner award (but rarely, e.g, splitting up the lot for two regions).

Evidence generation and dissemination

The Norwegian public authorities commissioned the NOR-SWITCH study to investigate the safety of switching of infliximab. While biosimilar uptake slowed down during the conduct of the study (results were awaited), the study showed that there is no risk in switching. This information was also then used for providing guidance to doctors.

Mix of policies and strong communication and stakeholder engagement activities

The Norwegian example highlights that for successful biosimilar policies, a mix of policy measures and actions is key (as illustrated by Mack 2015). The medicine which wins the tender (lowest-priced medicine) will be then recommended for use in the hospital, and to reinforce this message, LIS staff meet with hospital staff to inform. In tendering, Sykehusinnkjøp HF moves from penalties to dialogue and exploring new mechanisms (Sverrisson 2024).

Interface policy to use benefits across health care sectors

Norway introduced the "H prescriptions" measure to become the gap between outpatient and inpatient sector. Several defined medicines (including biological medicines) for outpatient use are paid from the hospital budget, and they can thus be tendered by LIS / Sykehusinnkjøp HF.

Biosimilar policies also for medicines for outpatient use

For outpatient medicines, biosimilar substitution has been introduced based on a broad consultation.

8 Developments in Norway

Recent changes

In July 2021, Norway introduced biosimilar substitution for selected molecules in a long, carefully planned process, including board stakeholder consultation.

Since 2022, biosimilars have been included in the stepped priced system.

9 Bibliography

Aanes et al. 2009	Aanes T, Ognøy AH, Festøy H. PHIS Hospital Pharma Report Norway. Vienna: PHIS Pharmaceutical Health Information System; 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Norway%20Hospital%20Pharma%20Report%202009_3.pdf (accessed 2024 Oct 21).
Aure et al. 2022	Aure OH, Festoy H. PPRI Pharma Profile: Norway 2022. Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI); 2022. Available from: https://ppri.goeg.at/system/files/inline-files/PPRINorway2022_final.pdf (accessed 2023 Jan 20).
Barcina et al. 2022	Barcina Lacosta T, Vulto AG, Turcu-Stiolica A, Huys I, Simoens S. Qualitative analysis of the design and implementation of benefit-sharing programs for biologics across Europe. BioDrugs. 2022;36(2):217-29.
Dalen et al. 2021	Dalen DM, Strøm S, Locatelli M. Biosimilar bidding in centralized tenders in Norway. Nordic Journal of Health Economics. 2021;9(1):11-23.
GaBI Online. 2015	GaBI Online. Huge discount on biosimilar infliximab in Norway. Generics and Biosimilars Initiative. 2015.
Mack et al. 2015	Mack A. Norway, biosimilars in different funding systems. What works? Generics and Biosimilars Initiative Journal (GaBI Journal). 2015;4(2):90-2.
Moorkens et al. 2021	Moorkens E, Godman B, Huys I, Hoxha I, Malaj A, Keuerleber S, et al. The expiry of Humira® market exclusivity and the entry of adalimumab biosimilars in Europe: An overview of pricing and national policy measures. Front Pharmacol. 2021;11.
Sverrisson 2024	Sverrisson E. Updates on national biosimilar policies. 8th Biosimilar Multistakeholder Event, Brussels, 5 December 2024
Vogler, Salcher-Konrad and Habimana 2022	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, https://data.europa.eu/doi/10.2925/044781



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