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

AUGMENT Biosimilars
Country fiche IRELAND

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augment biosimilars

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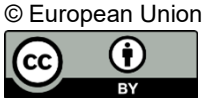

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Annex 7.15

AUGMENT Biosimilars country fiche: Ireland 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 Ireland 2025

Key stakeholders

In Ireland, the Department of Health (DoH), the Health Products Regulatory Authority (HPRA) and the Health Service Executive (HSE) are the main regulatory bodies in connection with biosimilars. The HSE acts reimbursement and procurement authority at the same time, while the DoH is responsible for pricing policies. Reimbursement decisions are based on health technology assessments (economic evaluations) by the National Centre for Pharmacoeconomics (NCPE). Health care professionals including doctors, nurses and pharmacists are represented in professional associations, and patients mainly represented by the Irish Patients Association. Some further disease related patient organisations also work specifically on biosimilars (Arthritis Ireland, Crohn's and Colitis Ireland for example). The pharmaceutical industry is mainly represented by Medicines for Ireland (MFI) and the Irish Pharmaceutical Healthcare Association (IPHA).

Major biosimilar policies and practices and developments

In Ireland, several biosimilar policies are in place to support use and uptake of biosimilars. A biosimilar price link is in place, leading to mandatory discounts for innovator biological medicines as well. No external price referencing is applied to biosimilars. Tendering of biosimilars is done in the inpatient sector on facility, i.e. hospital level. Tenders are awarded by active substance based on price only criteria and to one winner only. Biosimilars are included in national positive lists (different schemes) in the outpatient sector. In the inpatient sector the High-Tech Drug Arrangement (HT) mainly includes biologicals and biosimilars.

Switches to biosimilars are recommended and supported by the relevant guidelines. There are also incentives (gain sharing) in place for hospitals attributing 500 Euro per switch, and another gain-sharing arrangement for prescribers ended mid-2023. Biologics are not considered interchangeable, so biologics are excluded from INN prescribing and substitution at community pharmacy level.

Impact analysis

Evidence from the literature regarding the impact of biosimilar policies and practices in Ireland on different outcomes shows that gainsharing agreements are often researched. Three research papers indicate that gainsharing agreements with health care providers have improved biosimilar uptake and public budget savings. Biosimilar awareness can be improved for some health provider groups, as was found in two studies.

Barriers, facilitators and good practice examples

In general, very few barriers could be identified regarding biosimilar policies in Ireland. Some financial barriers may occur from the manufacturers having to prove comparability of biosimilars with the reference medicine. In connection with the policy-related barrier, that biologics are not considered interchangeable, this could hamper increased uptake of biosimilars. While there are no gainsharing agreements in place for patients and pharmacists, for health care providers in hospitals such agreement is in place (another gainsharing agreement for doctors ended in 2023). Health care providers differ in their awareness about biosimilars with doctors having lower awareness than pharmacists.

There are several good practice examples regarding biosimilar policies in Ireland, including the availability of several guidance documents, some of which were developed in a multi-stakeholder approach, a gainsharing agreement in hospitals as well as the HSE Medicines Management Programme (MMP) for best-value biological (BVB) medicines (see highlights and learning for more details).

Recent developments

Mentioned good practice examples including the BVB Initiative (see highlights and learning for more details), gain-sharing initiatives as well as the developed guidance documents in place are recent changes in the Irish biosimilar policy landscape.

Highlights and learnings

The HSE Medicines Management Programme (MMP) for best-value biological (BVB) medicines is a good practice example of demand-side measures. It aims to encourage clinicians to switch existing patients to BVB medicines (which may be the biological reference product and/or biosimilar) or to prescribe a BVB medicine to naïve patients commencing their therapy. Biosimilar (or BVB) substitution at community pharmacy-level is not permitted.

2 Key data regarding biosimilars in Ireland

First biosimilar medicine launched (i.e. brought on the market):
Rituximab in 2012
***Source*:** Medicines for Europe 2023

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

Biosimilar market shares in 2023 (or latest available data):
'Biosimilar medicines represent only 6% of the total share of the market in Ireland, compared to as much as 90% in other EU states.' No information available about definition of market share (volume/value) used.

***Source*:** TEVA 2018

*'Biosimilars currently account for 52–54% of the market share of oncology **biologicals** in Ireland.'* No information available about definition of market share (volume/value) used.

***Source*:** Kieran et al. 2024

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

- Medicines for Ireland 2025
- *HPRA 2025a*

3 Stakeholders involved in and targeted by biosimilar policies in Ireland

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by stakeholder
Legislator	Department of Health (DoH)	Prepares legislation.	No
National regulatory authority	Health Products Regulatory Authority (HPRA)	Responsible for market approval for new medicines, including biosimilars.	Biosimilars HPRA guide Q&A patients
Pharmaceutical pricing authority Pharmaceutical reimbursement authority Procurement agency	Health Service Executive (HSE)	The HSE Corporate Pharmaceutical Unit is the interface between the HSE and the pharmaceutical industry in relation to medicine pricing and reimbursement applications and the operation of the national pricing framework agreements. The HSE makes reimbursement decisions based on a health economic evaluation by the NCPE. The HSE procures selected medicines centrally.	Biosimilars Position Paper Managed Medicines Programm (MMP) Teeling 2016 Hospital Guidance (HSE 2024a)
HTA agency / body	National Centre for Pharmacoeconomics (NCPE)	Provides advice to the HSE Corporate Pharmaceutical Unit (CPU), the HSE-Medicines Management Programme (MMP), the HSE National Cancer Control Programme (NCCP), the HSE Drugs Group and HSE-Leadership to inform medicines reimbursement decision-making. NCPE assesses evidence for comparative clinical-effectiveness, cost-effectiveness, and potential budget impact of introducing the new medicine into the Irish healthcare system.	Glossary Etanercept summary Ravulizumab report
National competition authority	Competition and Consumer Protection Commission (CCPC)	Is the statutory body responsible for promoting compliance with, and enforcing, competition and consumer protection law.	No.
National patent office	Oifig na bPaitinní / Intellectual Property Office of Ireland	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Irish Medical Organisation (IMO)	Prescribe biosimilars, inform patients.	No.
Nurses	*Represented by:* Irish Nurses and Midwives Organisation (INMO)	May dispense medicines, inform patients	No.
Community pharmacists	*Represented by:* Irish Pharmacy Union (IPU)	Dispense medicines, inform patients.	No.
Hospital pharmacists	*Represented by:* Hospital Pharmacists Association of Ireland (HPAI)	Conduct hospital-level procurement including for biosimilars.	No.
Patient organisations	*Represented by:* Irish Patients Association (IPA)	Advocate for patients. Some patient organisation with specific work on biosimilars identified.	Artritis Ireland Biosimilars Crohns and Colitis Ireland Biosimilars

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by stakeholder
Consumer organisations	*Represented by:* Consumers' Association of Ireland (CAI)	Represents consumers as non-profit organisation.	No.
Biosimilar industry	*Represented by:* Medicines for Ireland	Represents Irish-based manufacturers and suppliers of generic OTC, biosimilars and hybrid medicines.	Biologics MfI Strategy
Generic industry			
Pharmaceutical industry in general	*Represented by:* Irish Pharmaceutical Healthcare Association (IPHA)	Represent different pharmaceutical manufacturers operating in Ireland.	
Pharmaceutical industry for new biological medicines	*Represented by:* Biopharmachem Ireland	Represents biopharma & chemical sector in Ireland.	
Parallel importers	Affordable Medicines Ireland	Represents active parallel importers in Ireland.	No.
Other	Irish Platform for Patient Organisations, Science & Industry (IPPOSI)	Provides online educational material about biological medicines (including biosimilars) for patients.	Onlinematerial
Other	Pharmaceutical Society of Ireland (PSI)	Regulates pharmacy in Ireland.	No.

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium), Vogler et al. 2022, Walsh et al. 2025

4 Biosimilar policies and practices in Ireland 2025

Note that the information relates to the year 2025, to the national level and to out-patient 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:	All biosimilars allowed for use in the Irish market.
Price reduction of the first biosimilar compared to the reference product	Biosimilar entering the market must be priced at (or below) 55% of the price of the reference product as 1 October 2021
Price reduction of the second, third and further biosimilars	Same price reduction for all biosimilars
Price reduction for the reference product	Yes, a mandatory price reduction of the same extent (maximum 55% of 2021 price)
Any further specificities	No.
A **generic price link** is in place.	Yes, must be priced at (or below) 40% of the originator product price as of 2021

Source: PPRI 2024, IPHA 2021, MFI 2021

External price referencing

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

External price pricing is in place for other medicines than biosimilars.	Yes.

Source: PPRI 2024

Tendering

Some (or all) biosimilars are procured through tendering (or tendering-like) processes.	Yes, Ireland applies tendering for biosimilars.
If yes, the scope with regard to the care sector:	Tendering for biosimilars is only done in the inpatient sector on facility level.
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	Medicines authorised on the market.
Institutional framework	Tendering in the inpatient sector is performed at hospital level only (individual facilities).
Information available on procurement procedures and practices	Tenders are awarded by active substance. Winning prices are not transparent to other competitors. Tenders are awarded to one winner only. Tenders are awarded based on price only.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	Not applicable, as no tendering in the outpatient sector in place.
Institutional framework	
Information available on procurement procedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes (on hospital level for off-patent medicines) Outpatient: Yes (for Hepatitis C medication, direct acting anti-retroviral drugs, orphan medicines, and vaccines)

Source: PPRI 2024, Vogler et al. 2022, Medicines for Europe 2023

4.2 Reimbursement policies 2025

Reference price system

Biosimilars are included into the **reference price system (RPS)** applied in the outpatient sector.	No.
If yes, how many and under which specifications	Prices established by average price of medicines.
If publicly accessible, indicate URL of RPS list	
When were first biosimilars included in the reference price system?	
Any further specificities	Used for all biosimilars on the market.
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	Yes, by ATC 5 cluster.

Source: PPRI 2024, Medicines for Europe 2023, HPRA 2025b

Inclusion into reimbursement and co-payments

Reimbursement in the outpatient sector	
Apart from their potential inclusion into the reference price system (see above), biosimilars are included in outpatient reimbursement (positive list)	Yes, biosimilars are included into the national positive list.
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	*'In Ireland, the Health Service Executive (HSE) Primary Care Reimbursement Service (PCRS) provides reimbursement services to primary-care contractors for the provision of health services which are funded by the HSE. The PCRS database contains pharmacy claims data for medicines reimbursed through Community Drugs Schemes (including General Medical Services (GMS), Long Term Illness (LTI) and the High Tech Drug Arrangement (HT)) and hospital-based schemes (including the Oncology Drug Management System (ODMS)'.*. There are two framework agreements running from 2021 till 2025. One, concluded by PPHA concerns pricing of new medicines, and another one by Medicines for Ireland addresses pricing procedures for generic, biosimilar and hybrid medicines which include setting maximum prices.
Indicate URL of outpatient positive list	*Several lists (see above): List of Reimbursable Items - HSE.ie* *In addition, a prescription formulary is in place covering all marketed medicines in Ireland: Formulary | irish Medicines Formulary*
Co-payments for biosimilars for outpatient use	Full (100%) coverage for all medicines in the reimbursement list. No co-payments charged for biosimilars.
For medicines for outpatient use in general (other medicines than biosimilars) Positive list for medicines in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	National positive lists (several schemes, see above) with different co-payment regulation per scheme
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes.
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	No information available.
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	*Several lists (see above): List of Reimbursable Items - HSE.ie* *In addition, a prescription formulary is in place covering all marketed medicines in Ireland: Formulary | Irish Medicines Formulary*
Co-payments for biosimilars for inpatient use	No, all medicines used in hospitals are reimbursed at 100% rate. Co-payments are charged for funded medicines in the inpatient sector.
For medicines for inpatient use in general (other medicines than biosimilars): Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	No national and/or regional /list list(s), but hospital pharmaceutical formularies at hospital level.

Source: PPRI 2024, GaBi 2022, Walsh et al. 2022

4.3 Specific pricing, procurement and funding policies

Application of special pricing, procurement and reimbursement models for biosimilars (e.g., delinkage / subscription-model, management-entry agreements (MEAs))	Predominantly financial MEAs and some performance-based MEAs
Enforcement of anti-trust policies	
Specific pricing and **funding** (e.g., subscription models, MEAs, …) for other medicines	Yes, MEA for new medicines in place.

Source: PPRI 2025, Vogler et al. 2022

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	

Source: PPRI 2025, Vogler 2022

Health technology assessment

HTA is applied for biosimilar medicines	Yes, HTA is done for all new medicines aiming for reimbursement status. All biosimilars are thus reviewed by the NCPE to evaluate the potential cost-effectiveness for the Irish health system.
If yes, in which situations and settings (outpatient and inpatient)	For all new medicines including biosimilars. The Health Service Executive (HSE) considers cost-effectiveness and budget impact of new medicines before deciding on reimbursement. Thus, all medicines aiming for reimbursement status, undergo HTA in Ireland.
Differences in criteria and processes of HTA for biosimilars compared to other medicines	No differences.
Any specificities	No.

Source: PPRI 2025 Vogler et al. 2022, Walsh et al. 2025, Teeling 2016

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Country context: Different healthcare professionals can prescribe medicine in Ireland, including GPs, consultants, dentists or nurses. Nurses can only prescribe medicines relevant to the area they work in and when employed by a health service provider. There are restrictions on certain controlled medicines. GPs and specialists can email pre*scriptions to pharmacists.*

Source: Prescribed drugs and medicines

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes, switches are recommended for all patients under certain circumstances (e.g., stable and well cared for patients, with clinical monitoring, information to the patients that biosimilars are not considered fully interchangeable with the reference products). A national biosimilar policy is in development.
If yes, what is recommended for naïve patients?	Recommendation to prescribe/switch.
If yes, what is recommended for patients already on biologic treatment	Recommendation to prescribe/switch.
Prescription guidelines (including switching guidelines) were issued by	HSE Guidance for Biological and Biosimilar Medicines use in Acute Hospitals

URL of prescription & switching guidelines	The HSE Medicines Management Programme have produced several documents to support the prescribing and implementation of the Best-Value Biological Medicines: https://www.hse.ie/eng/about/who/cspd/medicines-management/best-value-medicines/ HPRA information guide for healthcare professionals: Guide to Biosimilars for Healthcare Professionals
Prescribing quota	
Prescribing quota for doctors with regard to prescription of biosimilars exist	No, not in place.
If yes, which quota 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 quota	
Prescribing quota were issued by	
URL of prescribing quota	
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)	Yes, there were different incentives in place (hospitals and doctors). The gain sharing for doctors ended in 2023.
If yes, pls. describe (care setting: outpatient / in-patient, contract parties, content and incentives of gain-sharing, when was it introduced)	Hospitals: 500 Euro are given to hospitals for each new start and switch to biosimilar medicines. Doctors: '*A gain-sharing arrangement was introduced in June 2019 to fund service delivery or enhancement, when consultant-led teams initiated a patient on, or switched them to a BVB medicine on the High Tech Hub. The gainshare arrangement ended on 30 June 2023*.' (Lynch 2024)
Publicly accessible information	Medicines for Europe 2023 and Lynch 2024
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.
Further measures targeted at doctors	
Information materials for doctors	Yes, information campaigns targeting patients or healthcare professionals (handbooks, media campaigns and videos).
Information events for doctors (e.g., seminars, trainings)	
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	Not identified.

Source: PPRI 2024, Medicines for Europe 2023, HSE 2024, Lynch 2024

Pharmacists (and further dispensers)

Country context: In Ireland, medicines are only dispensed to the public through community pharmacies by pharmacists. Pharmacies offer further services such as vaccinations. Hospital pharmacies are only for inpatients and are not allowed to dispense medicines to out-patients (with some exceptions).

Source: Elliot and Byrne 2007

Substitution policies	
(Automatic) **substitution for biosimilars**	No, not allowed.
If yes, for which biological substances and under which prerequisites?	Not applicable, as not allowed.
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 incentives in place.
If yes, pls. describe (care setting: outpatient / in-patient, 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, HPRA guide for healthcare professionals, however mainly targeted at prescribers (HPRA 2020).
Information events for pharmacists (e.g., seminars, trainings)	Not identified.

Source: PPRI 20245 Vogler et al. 2022, Medicines for Europe 2023, HPRA 2020

Patients

Information and educational measures	
Information materials for patients	Yes, online Q&A section of the HPRA.
If yes, provide URL of most common materials	Biological and biosimilar medicines - What patients should know
If yes, key producers of education measures	HPRA
Information events for patients (e.g., seminars, trainings)	Yes, information campaigns targeting patients or healthcare professionals (handbooks, media campaigns and videos). The Irish Platform for Patient Organisations, Science & Industry (IPPOSI) provides online educational material about biological medicines (including biosimilars) for patients.
If yes, key providers of educational events	Mainly Biosimilars industry.
Gain-sharing models	
Gain-sharing models for patients	No.
If yes, pls. describe	*Not applicable.*
Publicly accessible information	

Source: PPRI 2025, Medicines for Europe 2023

5 Impact of biosimilar policies and practices in Ireland

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 Ireland

Outcome indicator	Caused by	Findings	Publication
Public budget savings	Introduction of infliximab biosimilar, no specific policy mentioned	*'The objective of this study sought to estimate the budget impact of introducing an infliximab biosimilar (CT-P13) as a treatment option for rheumatoid arthritis (RA) patients in Ireland.' 'Introducing an infliximab biosimilar as a treatment option for RA patients in Ireland represents a cost saving of up to €5,313,184 over five years; equivalent to treating an extra 337 new patients with a biosimilar for one year.'*	McCarthy et al. 2013
Public budget savings	Gainsharing	*'In June 2019, just over 90 patients had been initiated on, or switched to a best-value biological for adalimumab or etanercept. Over the next 12 months this increased to over 8500 patients. With the best-value biologicals accounting for approximately 50% of market share in June 2020, the combined estimated savings and avoided costs are €22.7 million to date. The gain-share prescribing incentive has raised over €3.6 million for the specialties to invest back into patient care. Conclusion Against the background of a finite healthcare budget, this study shows that increasing use of biosimilars can create the financial savings and space to invest in new innovative therapies for the benefit of many patients.'*	Duggan et al. 2021
Public budget savings	Gainsharing	*The 'Best Value Biologic' initiative, used in rheumatology for drugs such as adalimumab, provided a €500 gain share to the hospital for each patient switched to a preferred biosimilar saving €22.7 million in a year.*	Kieran et al. 2024
Biosimilar awareness	Information about biosimilars	Biosimilar awareness was significantly lower among 'Doctors and Medical Students' compared to 'Pharmacists and Pharmacy Students'. Room for improvement in the use.	Coakley et al. 2024
Biosimilar awareness	Attitude towards biosimilars	*In comparison to GPs, medical specialists and pharmacists claimed to be more familiar with the. term [biosimilars]. The majority of medical specialists (>95%) were not supportive of pharmacist-led substitution indicating that they believe decisions to change a patient's medicine should be either prescriber led or agreed with the prescriber in advance.*	O'Callaghan et al. 2017
Biosimilar uptake improvement	Gainsharing	*'After a slow and geographically varied start, there has been a significant increase in the prescribing of biosimilar medicines nationally under the HDTS since June 2019. In April 2023, 81.1 per cent of Irish patients in receipt of adalimumab 40mg PFP/PFS under the HDTS were prescribed a BVB medicine; with the remainder (18.9 per cent) prescribed Humira. As of 12 June 2023, over 24,800 patients had been prescribed one of the identified MMP BVB medicines for adalimumab or etanercept.'*	Lynch 2024

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 Ireland

In general, very few barriers could be identified regarding biosimilar policies in Ireland. Some are presented below.

Legal barriers

No such barriers identified in the literature.

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

No such barriers identified in the literature.

Financial barriers

'Manufacturers of biosimilars must perform an extensive head-to-head comparability with the reference medicine and demonstrate to regulators that they have similar quality, safety and efficacy to the reference medicine, such that there are no clinically meaningful differences between the two.' (Lynch 2024)

Evidence and communication-related barriers

No such barriers identified in the literature.

Policy-related barriers

Biologics are not considered interchangeable, so biologics are excluded from INN prescribing and substitution at community pharmacy level.

A gainsharing agreement for doctors introduced in 2019 ended in 2023. There are no gainsharing agreements for pharmacists or incentives for patients in place.

Stakeholder-related barriers

O'Callaghan et al. 2017 surveyed healthcare professionals regarding their awareness and attitudes to biosimilars. Different professions were differently aware of the term 'biosimilar' and *'physicians more likely to prescribe biosimilars at treatment initiation than switch'* and *'most medical specialists opposed substitution of biological medicines.'*

Coakley et al. 2024 supported the different levels of awareness of biosimilars among the professions stating that *'biosimilar awareness was significantly lower among 'Doctors and Medical Students' (45.3%; 95% [CI, 33.8–57.3%]) compared to 'Pharmacists and Pharmacy Students' (97.1%; 95% [CI, 94–98.8%; comparison $p < 0.001$]).*

7 Facilitators and good practice examples in Ireland

There are several good practice examples regarding biosimilar policies in Ireland.

First, several **guidance documents** are available for the use and uptake of biosimilars. Some of which were developed in a multi-stakeholder approach (see above).

Second, there is **gainsharing** agreements in hospitals and there was a gainsharing agreement for doctors, which was discontinued in 2023 (see above).

Third, the **HSE Medicines Management Programme (MMP)** for best-value biological (BVB) medicines aims to encourage clinicians to switch existing patients to BVB medicines (which may be the biological reference product and/or biosimilar) or to prescribe a BVB medicine to naïve patients commencing their therapy. Biosimilar (or BVB) substitution at community pharmacy-level is not permitted.

To identify BVB medicines the HSE MMP evaluates multiple criteria, such as acquisition costs, therapeutic indications, clinical guidelines, and patient factors, in a multi-stakeholder approach. An evaluation report listing the recommended BVB medicines is then published (HSE 2024b). In addition, to support stakeholder awareness and acceptance of the best-value prescribing, a range of supporting documents are provided. These include product sheets, Q&As for healthcare professionals, templates for switching letter, and patient information leaflets.

In January 2025, the HSE MMP published a list of 15 biological medicines for which they may conduct a BVB process (HSE 2025). An early BVB initiative was already launched in 2019-2021 for adalimumab and etanercept used in rheumatology. The application of the above criteria resulted in nine biologicals being selected as BVBs. Based on this recommendation, prescribing guidelines for treatment-naïve and established patients have been adapted. (updated in 2024: HSE 2024a) To increase prescribers' compliance to the guidelines a gain-sharing agreement was initiated: a €500 gain share to the hospital for each patient switched to a preferred BVB was provided, resulting in savings of €22.7 million (Barcina Lacosta 2022).

8 Developments in Ireland

Recent changes 2024/2025

The above-mentioned good practice examples including the BVB Initiative, gain-sharing initiatives as well as the developed guidance documents in place are recent changes in the Irish biosimilar policy landscape.

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