European Commission

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

AUGMENT Biosimilars
Country fiche PORTUGAL

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augment biosimilars

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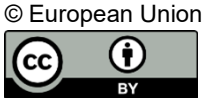

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Annex 7.25

AUGMENT Biosimilars country fiche: Portugal 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:

Ana Correia, Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED) / National Authority of Medicines and Health Products

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1 Summary of biosimilar policies and practice in Portugal

Key stakeholders

INFARMED, I.P. plays a central role in the regulation of biosimilars in Portugal. As the National Authority of Medicines and Health Products, it is responsible for implementing regulations related to quality assurance and pharmacovigilance for biosimilars, as well as setting pricing legislation and deciding on the prices of these medicines. Additionally, INFARMED oversees the inclusion of biosimilars in reimbursement lists and produces prescribing guidelines through the National Pharmacy and Therapeutics Committee. The authority also manages prescription quotas for biosimilars, helping to shape the uptake and use of these medicines in the healthcare system.

INFARMED, I.P. maintains a dashboard that is regularly updated with key indicators on the use of biosimilars in Portugal. The dashboard includes data on quotas for biosimilars by hospital group and active substance, which is updated monthly.

The procurement process is managed centrally by the Shared Services of the Ministry of Health (SPMS).

Major biosimilar policies and practices

In Portugal, a biosimilar price link is in place for biosimilars in both the outpatient and inpatient sectors when they enter the market. The price for the first biosimilar compared to the reference product is set at 80% of the originator product's price. For subsequent biosimilars, the price is 70% for each new entrant if the biosimilars already has at least 5% of market share. However, there is no compulsory price reduction for the reference product.

In Portugal, biosimilars are procured through tendering processes in the inpatient sector, including medicines delivered by hospitals as part of outpatient care. There is a list of biological medicines, categorised by disease area, that are subject to centralized purchasing and tendering. Within hospitals, the Pharmacy and Therapeutic Committee decides whether the medicine is purchased and used in the hospital.

There are recommendations to prescribe biosimilars for naïve patients, in case the price is lower than the originator. Switching must be approved by the physician and cannot be implemented before 6 months of treatment.

Impact analysis

Biosimilars potentially resulted in cost containment and improved patient access. However, there are no studies explicitly linking to specific policies. Despite these savings for the public payer, there were few direct financial benefits for patients, as co-payments are not required for most biologic medicines with biosimilar alternatives. In the inpatient sector, there are no co-payments for the patient nor

there is any co-payment with insulin glargine in the outpatient sector. However, in the outpatient sector, there are co-payments with Enoxaparin, Follitropin and Teriparatide, which have 69%, 90% and 69% of reimbursement coverage, respectively.

Barriers, facilitators and good practice examples

In Portugal, INFARMED has issued recommendations on biosimilar use. However, despite regulatory efforts and procurement strategies, biosimilar uptake remains highly inconsistent across hospitals. Several structural, financial, and policy-related barriers limit biosimilar adoption, including weak enforcement of guidelines, a lack of financial incentives, and the strong influence of originator pharmaceutical companies. At the same time, some facilitators, such as centralized procurement and transparency initiatives, have contributed to competition and price reductions.

Recent developments

The reference countries selected for external price referencing for the year 2025 were updated: Spain, France, Italy, and Belgium (Ordinance No. 293/2024/1, of November 15).

In 2025, biosimilars were exempted from international price referencing. Instead, a price alignment was implemented for those biosimilars whose price would otherwise exceed that of the reference medicine, following the price referencing of the latter.

Highlights and learnings

Although gainsharing mechanisms are already in place, the system remains complex and has yet to be fully evaluated. Additionally, it accounts for only a small share of hospital budgets, potentially limiting its impact.

There is extensive data collection through monitoring tools and dashboards, offering valuable opportunities to track performance and develop evidence-based recommendations.

2 Key data regarding biosimilars in Portugal

First biosimilar medicine launched (i.e., brought on the market):
Epoetin, 2008

Source: INFARMED 2021b

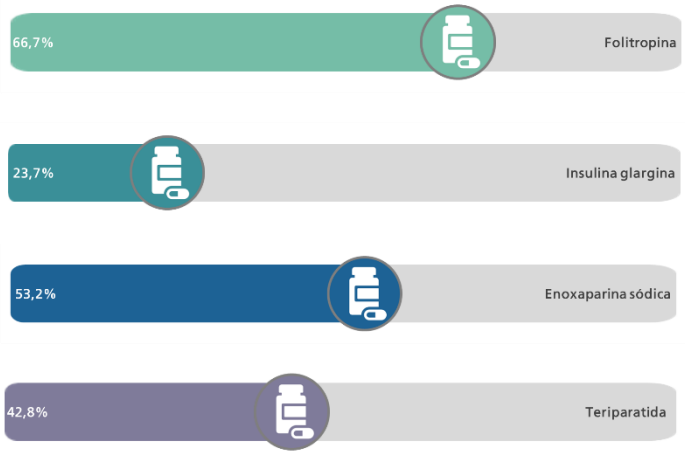
Number of the **biosimilars marketed**:
18 molecules with biosimilars available, as of December 2024

Source: INFARMED 2025

Biosimilar market shares in 2024, for the inpatient sector:

78.7% **in volume**, defined by the number of units sold of biosimilars to public hospitals, divided by the number of units sold of the INNs with biosimilar available.

Biosimilar market shares in 2024, for the outpatient sector:



In **volume,** defined by the number of units dispensed in community pharmacies, divided by the number of units dispensed of the INNs with biosimilar available.

Source: INFARMED 2024*,* INFARMED 2025

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

INFARMED 2024 — *INFARMED. Monitoring of health expenditures. Lisboa: INFARMED; 2024. Available from: https://www.infarmed.pt/documents/15786/10121749/setembro/d07346e6-5478-6f4d-4c76-f47b168b9db2?version=1.0 (accessed 10 January 2025)*

NHS Transparency Website (Monitor the evolution of the use of biosimilars in substances where there is already a biosimilar medicine on the market):

Ministério da Saúde 2025 — *Ministério da Saúde. National Health Service Transparency Website. Lisboa: Ministério da Saúde. Available from: https://transparencia.sns.gov.pt/explore/embed/dataset/medicamentos-biossimilares/table/?disjunctive.ars_hospital&disjunctive.nome_hospital&disjunctive.grupo_hospital&sort=periodo (accessed 10 January 2025)*

Dashboard INFARMED:

INFARMED 2025 — *INFARMED. Biosimilar dashboard. Lisboa: INFARMED. Available from: https://www.infarmed.pt/web/infarmed/entidades/farmacia-hospitalar/medicamentos-biossimilares (accessed 10 January 2025)*

3 Stakeholders involved in and targeted by biosimilar policies in Portugal

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Ministério da Saúde/ Ministry of Health	Prepares legislation	
National regulatory authority	Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED) / National Authority of Medicines and Health Products	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance	INFARMED 2025a INFARMED 2025b INFARMED 2021b INFARMED 2026b INFARMED 2016c INFARMED 2018b INFARMED 2018a INFARMED 2017 INFARMED/ACSS 2016
Pharmaceutical pricing authority	Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED) / National Authority of Medicines and Health Products	Implements pricing legislation regarding biosimilars, decides on the prices	
Pharmaceutical reimbursement authority	Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED) / National Authority of Medicines and Health Products	Decides on inclusion into reimbursement lists of biosimilars. Produces prescribing guidelines for biosimilars, responsible for prescription quotas	
Procurement agency	Serviços Partilhados do Ministério da Saúde (SPMS, EPE) / Shared Services of the Ministry of Health	Coordinates centralized procurement procedures for some medicines, including biosimilars, by running national framework agreements and tenders. For other medicines, hospitals and healthcare units may either conduct their own procurement procedures or request SPMS to act on their behalf.	SPMS 2019
HTA agency / body	Comissão para a Avaliação de Tecnologias da Saúde (CATS) / Health Technology Evaluation Committee	No role regarding biosimilar medicines	
National competition authority	Autoridade da Concorrência / Competition Authority	Enforcement of the competition law, anti-trust cases	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
National patent office	Instituto Nacional da Propriedade Industrial / Portuguese Institute of Industrial Property	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Ordem dos Médicos (OM) / Physicians' Association *Unions:* Sindicato Independente dos Médicos / Independent Physicians' Union Federação Nacional dos Médicos / National Physicians' Federation Several societies within OM, and several associations, related to specific diseases (e.g., Portuguese Society of Rheumatology)	Inform patients Medical Societies in disease areas with biologics use and prescribing biosimilars	Ordem dos Médicos 2014
Nurses	*Represented by:* Ordem dos Enfermeiros (OE) / Nurses' Association		
Community pharmacists	*Represented by:* Ordem dos Farmacêuticos / Pharmacists' Association Associação Nacional de Farmácias (ANF) / National Pharmacy Association	Inform pharmacists and patients about medicines	ANF 2020 ANF 2022 ANF 2023 ANF 2024
Hospital pharmacists	*Represented by:* Ordem dos Farmacêuticos / Pharmacists' Association Associação Nacional de Farmacêuticos Hospitalares (APFH) / Portuguese Association of Hospital Pharmacists	Support procuring medicines, inform patients / health professionals / procurers	Ordem dos Farmacêuticos 2018 Ordem dos Farmacêuticos 2022 Gonçalves 2022

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Patient organisations	*Represented by:* Plataforma Saúde em Diálogo / Health in Dialogue Platform (groups 72 patients' associations) Mais Participação, mais saúde / "More participation, more Health" (is a project grouping various patients' associations to promote the patients' participation and empowerment European Patients') *EUPATI Portugal /* Academy on Therapeutic Innovation Several patients' associations related to diseases treated with biological medicines: Liga Portuguesa contra o Cancro (LPCC) / Portuguese League Against Cancer Associação Portuguesa da Psoríase (PSOPortugal) / Portuguese association of psoriasis Associação Protectora dos Diabéticos de Portugal (APDP) / Portuguese Diabetes Association Associação Portuguesa da Doença Inflamatória do Intestino (APDI) / Portuguese Crohn's and Colitis Association	Patient organizations in diseases with particular biologics use a/o organisations with specific advocacy or education work on biosimilars	Plataforma Saúde em Diálogo 2024

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
	Associação Portuguesa de Hemofilia e de outras Coagulopatias Congenitas (APH) / Portuguese hemophilia association and other congenital coagulopathies Associacao Portuguesa contra a Leucemia-(APLC) / Portuguese Leukemia and Lymphoma Association Liqa Portuguesa Contra as Doenças Reumáticas (LPCDR) / Portuguese Leaque Against Rheumatic Diseases		
Consumer organisations	DECO		
Biosimilar industry	*Represented by:* Associação Portuguesa de Medicamentos pela Equidade em Saúde (EQUALMED) / Portuguese Association of Medicines for Health Equity	Produces and supplies biosimilars, promotes the uptake of biosimilar medicines	EQUALMED (no year)
Generic industry	*Represented by:* Associação Portuguesa de Medicamentos pela Equidade em Saúde (EQUALMED) / Portuguese Association of Medicines for Health Equity		
Pharmaceutical industry in general	*Represented by:* Associação Portuguesa da Indústria Farmacêutica (APIFARMA) / Portuguese Association of the Pharmaceutical Industry	Mostly focuses innovative/originator medicines – discussing health policies and promoting interests of its associates	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Pharmaceutical industry for new biological medicines	*Represented by:* Associação Portuguesa de Bioindústria (P-BIO) / Portuguese Association of Bioindustry	Groups companies in various areas related to biotechnology, including the health sector. Associates include major pharmaceutical companies producing biologic medicines. Discussing scientific and health policies and promoting interests of its associates	
Further relevant stakeholder group	Administração Central do Sistema de Saúde (ACSS) / Central Administration of the Health System, IP	The institution sets budgets with hospitals, which include a performance indicator on biosimilar use aimed at promoting the financial sustainability.	INFARMED/ACSS 2016

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium)

4 Biosimilar policies and practices in Portugal 2025

Note that the information relates to the year 2025, to the national level and to outpatient and inpatient sectors, unless specified differently.

4.1 Pricing and procurement policies

Biosimilar price link

A **biosimilar price link** is in place.	Yes
It applies for the following situations:	For biosimilar medicines in the outpatient and inpatient sectors entering the market
Price reduction of the first biosimilar compared to the reference product	80% of the price of the originator product
Price reduction of the second, third and further biosimilars	70% for each new entrant
Price reduction for the reference product	No compulsory price reduction
Any further specificities	
Generic price link	Yes The price reduction is 50% for the new generic medicine compared to the originator, and further 5% for each new product

Source: Decree-Law 97/2015

External price referencing

External price referencing is applied for biosimilars.	Yes
If yes, it is applied for the following situations:	All situations. Portugal applies external price referencing to biosimilars to set a maximum price before procurement. Internal price referencing exists but does not apply to biosimilars, as they are mainly hospital-dispensed and fully covered by the National Health Service, with no cost to the patient (thus, no reimbursement reference price needed).
Any specificities	The reference countries are fixed on a yearly basis, by the Ministry of Health (Spain, France, Italy and Slovenia in 2024)
External price pricing is in place for other medicines than biosimilars.	Yes, for all medicines

Source: Decree-Law 97/2015, Ordinance 39-C/2024

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 sector only (includes medicines delivered by hospitals as part of outpatient care)
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	There is a list of medicines, by disease area, subject to centralised purchase (and tendering). The current list has been approved in March 2017. The list is quite extensive and potentially includes biologic medicines. This lists medicines both for outpatient and inpatient sectors.
Institutional framework	Conducted centrally, by the Shared Services of the Ministry of Health (SPMS). Hospitals may procure medicines directly under national framework agreements or individually when needed—such as at the beginning of the year, before the central procurement procedure is completed, or when specific medicines are not covered by existing agreements.
Information available on procurement procedures and practices	Public procurement in Portugal is governed by the Public Procurement Code, which transposes the EU Procurement Directive into national legislation. Although the Code allows the use of the Most Economically Advantageous Tender (MEAT) criteria, in practice, it is rarely applied. Procurement procedures aim to apply multi-award contracts wherever possible, particularly for off-patent medicines. Since 2020, efforts have been made to avoid the "winner-takes-it-all" model. For on-patent medicines, typically a single bidder is awarded a contract valid for the calendar year, but in cases where feasible, contracts may be awarded to two suppliers to increase competition and ensure supply continuity.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	There is a list of medicines, by disease area, subject to centralized purchase (and tendering). The current list has been approved in March 2017. The list is quite extensive and potentially includes biologic medicines. This lists medicines both for outpatient and inpatient sectors.

Institutional framework	Conducted centrally, by the Shared Services of the Ministry of Health (SPMS). Hospitals may procure medicines directly under national framework agreements or individually when needed—such as at the beginning of the year, before the central procurement procedure is completed, or when specific medicines are not covered by existing agreements.
Information available on procurement procedures and practices	Public procurement in Portugal is governed by the Public Procurement Code, which transposes the EU Procurement Directive into national legislation. Although the Code allows the use of the Most Economically Advantageous Tender (MEAT) criteria, in practice, it is rarely applied. Procurement procedures aim to apply multi-award contracts wherever possible, particularly for off-patent medicines. Since 2020, efforts have been made to avoid the "winner-takes-it-all" model. For on-patent medicines, typically a single bidder is awarded a contract valid for the calendar year, but in cases where feasible, contracts may be awarded to two suppliers to increase competition and ensure supply continuity.
Generics are tendered (or procured through competitive tendering-like policies).	Yes, if included in the closed list of medicines subject to centralized purchase.

Source: Decreto-Lei 111-B/2017, SPMS 2024, Vogler et al. 2021, Vogler et al. 2022

4.2 Reimbursement policies

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	No
If yes, how many and under which specifications	
If publicly accessible, indicate URL of RPS list	
When were first biosimilars included in the reference price system?	
Any further specificities	Most biologic medicines are delivered by hospitals for free (as in-patient or out-patient care), without RPS. For the four biologic medicines delivered in ambulatory care (community pharmacy), the coverage is 100% for insulin glargine, 90% for folitropin and 69% for both teriparatide and enoxaparin. None of them are subject to RPS.
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	Yes, the clustering is by homogenous groups defined by same INN, administration mode, and dosage.

Source: Decreto-Lei n.º 97/2015

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

If yes, how many and date of inclusion into reimbursement, if known)	Four INN with biosimilar available in the outpatient sector: Insulin glargine, folitropin, enoxaparin and teriparatide.
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	For the biologic medicines delivered in ambulatory care (community pharmacy), the coverage is 100% for insulin glargine, 90% for folitropin and 69% for both teriparatide and enoxaparin. None of them are subject to RPS.
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	Biosimilar medicines benefit from the same public coverage/financing of originator biologic medicines.
Indicate URL of outpatient positive list	
Co-payments for biosimilars for outpatient use	Applicable, except for insulin glargine
<u>For medicines for outpatient use in general (other medicines than biosimilars)</u> Positive list for medicines in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	There are percentage rates in place of 90%, 69% and 37%, with co-payments for patients. Depending on the medicine dispensed and/or the patient (low income or with a certain disease), medicine can be dispensed with lower or no co-payment.
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	The biosimilar reimbursement only depends on price being 20% lower than the approved originator biologic medicine.
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	Not applicable
Co-payments for biosimilars for inpatient use	Not applicable
<u>For medicines for inpatient use in general (other medicines than biosimilars):</u> Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	No co-payment. Approved biosimilars are included in the national formulary (i.e., the medicine can be purchased and used in any public hospital). Within hospitals, the Pharmacy and Therapeutic Committee decides whether the medicine is purchased and used in the hospital

Source: Decree-Law 97/2015

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 (MEA))	Biosimilars are purchased by local health units (ULS, which includes hospitals and primary care centers of the hospital catchment area) using their yearly budget, which covers all services (no specific financing for medicines). Biosimilars must have a price at least 20% lower than the originator to be included in public financing. All medicines used in the inpatient sector have managed entry agreement if market authorisation after 2007.
Enforcement of anti-trust policies	

Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	There are financial MEAs for all new approved originator medicines (price-volume cap), while performance-based MEAs are implemented only very rarely.

Source: Decreto-Lei n.º 97/2015

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	Yes
If yes, describe the process and the tools (e.g. regular consultation of a database, horizon scanning scoping meeting with stakeholders), including who use horizon scanning	The horizon scanning consists in a platform from the National Medicines and Health Products Authority (INFARMED, IP), where pharmaceutical companies indicate the medicines for which they will request public financing in the next three years. These submissions are however not compulsory. Portugal is part of the International Horizon Scanning Initiative.

Source: INFARMED. Horizon scanning

Health technology assessment

HTA is applied for biosimilar medicines	No
If yes, in which situations and settings (outpatient and inpatient)	N/A
Differences in criteria and processes of HTA for biosimilars compared to other medicines	A HTA process is in place for all new originator medicines requesting public financing, which includes a pharmaco-therapeutic evaluation which, if positive (added therapeutic value), is followed by an economic evaluation. Biosimilars and generics are approved conditional on a price reduction and on the originator medicine being approved. https://www.infarmed.pt/web/infarmed/entidades/medicamentos-uso-humano/avaliacao-tecnologias-saude/avaliacao-terapeutica-e-economica2018/-i-horizon-scanning-/i-
Any specificities	

Source: Decreto-Lei n.º 97/2015

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?	Recommendation to prescribe biosimilars for naïve patients, in case its price is lower than that of the originator.
If yes, what is recommended for patients already on biologic treatment	Recommendation to switch patients for economic reasons. The switching process must be approved by the physician during a medical consultation, and the hospital Pharmacy and Therapeutic Committee maintain a record of the medicines and treatment regimens prescribed to each patient. It cannot be implemented when the treatment has been initiated for less than 6 months, the patient must be adequately informed (and may refuse the switch), and a monitoring of adverse effects must be in place.
Prescription guidelines (including switching guidelines) were issued by	Infarmed, IP
URL of prescription & switching guidelines	INFARMED 2021a. Available from: https://www.infarmed.pt/documents/15786/1816213/Orienta%C3%A7%C3%B5es+n.%C2%BA+10+Estrat%C3%A9gia+para+mudan%C3%A7a+%28switch%29+entre+marcas+dos+medicamentos+infliximab%2C+etanercept%2C+adalimumab+e+rituximab*/1aa8fdec-5ed2-2a29-7e92-71eb7f8cf34b
Prescribing quotas	
Prescribing quotas for doctors with regard to prescription of biosimilars exist	From 2017 to 2023, biosimilar prescription has part of the pay-for-performance component of hospitals' financing, as defined by ACSS. Biosimilar pay-for-performance indicators were included in a broader set of indicators that could increase or decrease hospital budgets. Incentives or penalties were not directly linked to individual prescribers' payments. Since 2023, no specific financial incentives/penalties related to biosimilar prescribing have been applied. The system is described below: = From 2019 to 2022 = Institutional benchmarking incentives - Hospitals were grouped into peer clusters for benchmarking. - Incentives were awarded based on a Comparative Performance Index, which reflected each hospital's performance across all indicators relative to peers in the same group. - One of the indicators used was the percentage of biosimilar acquisition, measured both by market share and by active substance. - Subject to verification and a minimum biosimilar quota of 20%. - Hospitals performing better than peers received financial rewards, funded by underperforming hospitals in the same group. Institutional penalties - If the hospital expenditure growth on biological medicines exceeded the national average growth, a penalty was applied. - Penalties ranged from 10% in 2022 to 3% in 2019. - Penalties were capped at 3% of the hospital's total financing. Other incentives/penalties

	- Incentives were also used to promote rational medicine use, particularly in key outpatient areas. - Incentive indicator for biologics: share of biosimilar insulin glargine units in the total volume of long-acting insulin prescribed in hospitals and dispensed in community pharmacies. - Financial rewards/penalties were applied if hospitals meet at least two of a group of several indicators. = From 2017 to 2018 = Institutional incentives - Incentives were linked to several objectives, including the promotion of biosimilar use. - Indicator: variation in the use of biosimilars (measured in units dispensed from the previous year), with a weight of 6%. - Subject to verification and a minimum biosimilar quota of 20%. - Incentives represented 5% of the overall value of the financing. Institutional penalties - Penalties of 5% if the hospital expenditure on biological medicines increased more than the national average. - Penalties were capped at 2% of the hospital's total financing. Other incentives/penalties - As in later years, incentives promoted rational use of medicines in outpatient markets. - Hospitals could receive financial rewards or penalties based on performance in at least two indicators. - The same biosimilar insulin glargine indicator applied.
If yes, which quotas are defined for biosimilars	Performance indicators included in the contract-program for hospitals established a minimum prescribing quota of 20% for biosimilars.
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	
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	Local health units receive a fixed budget which may ensure financial benefits in case of lower expenditures. Yet, budgets have been usually set below expected expenditures, so that profits have been very unlikely in practice.
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
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	Absence of systematic information or support material, no update of guidelines to incorporate biosimilars or switching practices, which date from 2018 and are generic (no specific guidelines for specific therapeutic areas). Information on the market share of biosimilars is available monthly on the Infarmed website. Additionally, each hospital receives data on their share and unit cost per INN for benchmarking purposes
Information events for doctors (e.g., seminars, trainings)	A document has been issued with information on biosimilars, based on the EU Commission information. (INFARMED 2016a) Information, events and studies have been essentially promoted by the Generics and Biosimilars Association (EQUALMED).
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	No

Source: PPRI 2025, Moorkens et al. 2021, Barbier et al. 2022, ACSS 2017, ACSS 2018, ACSS 2019, ACSS 2020, ACSS 2021, ACSS 2022.

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense.

Substitution policies	
(Automatic) substitution for biosimilars	Not allowed in community pharmacies. Allowed in hospital pharmacies
If yes, for which biologic substances and under which prerequisites?	
If yes, since when, and when was it extended? (process of implementation)	
Any specificities	
URL of underlying law	INFARMED 2021a. Available from: https://www.infarmed.pt/documents/15786/1816213/Orienta%C3%A7%C3%B5es+n.%C2%BA+10+Estrat%C3%A9gia+para+mudan%C3%A7a+%28switch%29+entre+marcas+dos+medicamentos+infliximab%2C+etanercept%2C+adalimumab+e+rituximab*/1aa8fdec-5ed2-2a29-7e92-71eb7f8cf34b
Generic substitution in place	INN prescribing and generic substitution in place
Gain-sharing models	
Gain-sharing models for pharmacists	No
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	
Publicly accessible information	

Further measures targeted at pharmacists	
Information materials for pharmacists	Similar information as for physicians
Information events for pharmacists (e.g., seminars, trainings)	Similar information as for physicians

Source: PPRI 2025, INFARMED 2021a

Patients

Information and educational measures	
Information materials for patients	Some conferences were held on the challenges and opportunities of Biosimilars. Also, Informational brochures aimed at citizens (2016 and 2017
If yes, provide URL of most common materials	
If yes, key producers of education measures	
Information events for patients (e.g., seminars, trainings)	
If yes, key providers of educational events	
Gain-sharing models	
Gain-sharing models for patients	No, biosimilars are delivered for free at hospitals
If yes, pls. describe	
Publicly accessible information	

Source: PPRI 2025

5 Impact of biosimilar policies and practices in Portugal

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 Portugal

Outcome indicator	Caused by	Findings	Publication
Savings for the public payer	No specific policy was related to savings in the study	Expected savings achieved, by molecule, in 2020 (assuming expected consumption from past years and real price difference): Adalimumab 39M euros; epoietin € 12 million; etanercept € 8.2 millon; filgrastim € 18 million; infliximab € 27.9 million; pegfilgrastim 87% savings between 2010 and 2020; rituximab 6.6M; somatropin 50% savings between 2010 and 2020, and € 7.6 million savings in 2020;	INFARMED 2021b
More patients treated	No specific policy was studied. Analysed the competition generated by the increased availability of biosimilars	A study on TNF-alfa inhibitors showed an increase in the total number of patients receiving biologic treatments in 2020, compared to 2011: 3.1 times higher for rheumatic arthritis patients, 5.5 times higher for ankylosing spondylitis patients and 5.1 times higher for psoriatic arthritis. The volume consumption of adalimumab increased by 14%, despite the reduced expenditures. Expenditures also decreased for etanercept and rituximab but without change in consumption.	Barcina Lacosta et al. 2022a
Biosimilar uptake and potential savings	No specific policy. Analysed the biosimilars' adoption across the hospitals, determinants for different adoption, and the potential savings.	Academic hospitals had faster uptake of biosimilars like adalimumab and infliximab, but lower adoption of other biosimilars. Hospitals with higher overall biologic consumption had lower biosimilar uptake. Greater involvement in RCTs was linked to higher biosimilar uptake and quicker adoption, except for rituximab. If all NHS hospitals reached the highest observed biosimilar uptake rates, annual savings could be of €13.9 million.	Perelman et al. 2023
Biosimilar uptake	No specific policy. Assessed the impact of the different benefit-sharing strategies on the use of 'best-value' biologics.	Biosimilar uptake has been more than 50% for almost every molecule. This may be due to a combination of factors: a benefit-sharing strategy, communication between government and hospitals, early engagement of key opinion leaders, and reopening of hospital tenders following biosimilars market entry.	Barcina Lacosta et al. 2022b

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 Portugal

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

The medicines agency (INFAMED, IP) has launched recommendations for the use of biosimilars for naïve-patients, and for switching under specific conditions, in 2018 and updated in 2021. Publicly available information on biosimilar uptake by hospital is available through a dashboard (INFARMED 2025a), monthly reports, and the NHS Transparency website (Ministério da Saúde 2025). Yet, there is no central body to support the implementation of these recommendations, which would, e.g., ensure that information is well received and understood, help physicians and patients to understand, accept and implement the recommendations, and audit and possibly penalise the non-respect of recommendations. Also, clinical guidelines are also often lacking, are rarely updated and poorly monitored. This has led to an extremely diverse uptake of biosimilars among public hospitals, from zero to 100% (Perelman et al. 2022). A policy has also long been in place obliging public hospitals to deliver biologic medicines for rheumatic diseases to patients treated at private hospitals, which have thus no incentive for switching.

Financial barriers

Public hospitals face a "soft budget constraint". Initial budgets are generally low and expected to be insufficient to cover expected expenditures. In practice, hospitals deliver their services and, when the budget is exceeded, accumulate unpaid debts and arrears for medicines. By the end of the year, these debts are paid by the Central State. This mechanism results in weak incentives towards efficiency, including the use of biosimilars. No gain sharing mechanisms exist, since 2023. Previously, a 20% biosimilar quote was included in the pay-for-performance scheme; this is however a single indicator within a long list, while the pay-for-performance does not account for a substantial share of the hospital budgets.

Evidence and communication-related barriers

It appears that communication on biosimilars is very limited. First, guidelines are not systematically updated to incorporate biosimilars, or to orient switching practices. Second, information and support are lacking from public authorities, medical or scientific associations on biosimilars. Third, even if some recommendations have been provided in hospital settings, the application of recommendations is not subject to support or monitoring. Finally, there is no preparation of the biosimilar before the patent expiration, with would include discussions of potential biosimilar benefits among stakeholders, management plans for biosimilar adoption and uptake, and implementation plans to achieve this objective.

Policy-related barriers

Automatic substitution is not allowed, and this implementation is widely opposed by physicians (INFARMED 2021a). The norms for switching are weak, in the sense that they are conditional on various requirements. The price linkage may deter biosimilar companies to launch the product in Portugal, which is a small market and low ability to pay (e.g., the dramatic hospital arrears may represent a barrier for small pharmaceutical companies). The central procurement is functioning but is implemented without a close collaboration with physicians and hospitals, who do not feel engaged or committed with this practice, while tenders often fail to integrate information about clinical practices (e.g., to implement across product classes). Finally, originator companies are powerful in conditioning prescription practices (e.g., through conditional discounts or other benefits), pushing forward marginal innovations (e.g., in administration mode) or second-generation on-patent therapies. This power may be related to many causes, but the weaknesses of the NHS are in first place, marked by huge debts to pharmaceutical companies, conflicts of interest among decision makers, and insufficient regulation of companies' practices.

Stakeholder-related barriers

See above

7 Facilitators and good practice examples in Portugal

Recommendations have been issued by the medicine's authority (INFARMED, IP) to promote the use of biosimilars, and provide information on biosimilars to patients and physicians. The central procurement is also a good practice that overcomes the fragilities of local hospital tenders. Although the budget constraint is soft, several hospitals view biosimilars as an opportunity to achieve savings in the face of growing and unexpected expenditures related to new medicines, and limited budgets. This last aspect depends however on hospital managers' commitment to respect budget constraints, leadership and political support to implement changes in clinical practice, and links to originator pharmaceutical companies. This explains why the uptake of biosimilars is extremely heterogenous across hospitals.

8 Developments in Portugal

Recent changes

The reference countries selected for external price referencing for the year 2025 are Spain, France, Italy, and Belgium (Ordinance No. 293/2024/1, of November 15).

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