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

AUGMENT Biosimilars
Country fiche SPAIN

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augment biosimilars

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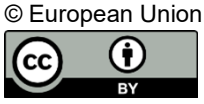

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Annex 7.29

AUGMENT Biosimilars country fiche: Spain 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:

Lourdes Álvarez Callejo, Ministerio de Sanidad / Ministry of Health, Spain

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1 Summary of biosimilar policies and practice in Spain in 2025

Key stakeholders

The Ministry of Health (Ministerio de Sanidad) is responsible for the pharmaceutical policy, and coordinate pricing, and reimbursement decisions procedure related to biosimilars. It oversees the Inter-Ministerial Commission for Pharmaceutical Prices (CIMP), which sets biosimilar prices. It works with the Autonomous Communities (ACs) regional agencies, which provide recommendations for biosimilar use at the regional level.

The Spanish Agency for Medicines and Health Products (AEMPS - Agencia Española de Medicamentos y Productos Sanitarios) oversees the approval, safety, quality assurance, and pharmacovigilance of biosimilars. Also, it conducts clinical assessments as part of health technology evaluations.

Spain's decentralised healthcare system gives 17 ACs and INGESA authority over procurement and implementation of biosimilar policies. Regional agencies perform HTA evaluations, tendering, and formulary inclusion decisions at the hospital level.

Major biosimilar policies and practices

In Spain, a biosimilar price link is in place, though the price reduction for the first biosimilar compared to the reference product is non-binding. Tendering processes are applied for medicines used in the inpatient sector. There is also procurement of biosimilars for outpatient use.

In Spain, biosimilars have been reimbursed under a positive list for outpatient medicines. Standard reimbursement rates are 40%-60% for the working population, 90% for people with chronic diseases, and 100% for low-income and unemployed individuals. Biosimilars are subject to these population-group-based percentage co-payments, as other reimbursable medicines. In the inpatient sector, biosimilars are included in hospital formularies alongside originators, and switching is recommended. The reimbursement process follows the same rules as other inpatient medicines. No co-payments apply to biosimilars in hospitals.

Impact analysis

Several studies have reported in the dynamics and increases in the biosimilar market shares following the market entry, and important savings for the public sector were reported. However, no study was identified which evaluated the impact of specific (biosimilar) policies.

Barriers, facilitators and good practice examples

Spain faces multiple barriers to biosimilar uptake, including lack of some demand-side policies, since there is the requirement to prescribe biosimilars by brand name

and the prohibition of automatic substitution in pharmacies. There is also a lack of biosimilar-specific pricing policies which could enhance competition. Organisational barriers arise from inconsistencies in policies across regions and hospitals, leading to variable adoption rates. Communication gaps and stakeholder resistance also hinder adoption, with physicians and pharmacists lacking confidence in biosimilars and professional associations opposing prescription incentives. In Spain, clinical practice guidelines are not consistently updated after the introduction of new biosimilars.

Facilitators include regional procurement innovations, such as multi-winner tenders in some Autonomous Communities and Extremadura's Profit Sharing Program, which reinvests biosimilar savings into healthcare. Educational initiatives by professional societies and strong real-world evidence have also improved physician confidence, supporting broader biosimilar adoption.

Recent developments

The *Autoridad Independiente de Responsabilidad Fiscal* has proposed measures to promote biosimilar use, including prescribing incentives, legal clarity on switching, patient information, education for healthcare providers, outcome measurement, and open procurement procedures.

A recent development was the introduction of a Profit Sharing Program targeted at doctors for prescribing biosimilar medicines in February 2023 in Extremadura, making it the first Autonomous Community to adopt such an approach. The program promotes biosimilar use by reinvesting savings into healthcare, enhancing access to innovation.

Highlights and learnings

Several initiatives, in particular in the areas of education and information activities, were identified. However, the level of policy implementation differs across regions, and this may impact biosimilar uptake and competition.

2 Key data regarding biosimilars in Spain

First biosimilar medicine launched (i.e. brought on the market): Somatropina-Omnitrope® in February 2007

Source: Spanish Ministry of Health, Directorate General for NHS Common Services Portfolio and Pharmacy:

- Consumption of official medical prescriptions receipts issued by the National Health System and dispensed in community pharmacies (Data exclude non-reimbursed drugs, OTC drugs and private medical prescriptions)

- Hospital consumption, for hospitals belonging to the public network of the National Health System. (Data coverage is total, for in-patients and out-patients)

20 molecules with biosimilars available, as of December 2024

80 biosimilars (per trade name, 75 financed), as of December 2024

Source: Official database on the price and reimbursement of medicines in the Spanish National Health System (Nomenclátor oficial de la Prestación Farmacéutica), as of December 2024

Biosimilar market shares in 2023 (or latest available data): Latest Data available 2024

43,9% **in volume** in year 2024. Volume is defined as percentage of units of biosimilar medicines/units of originator and its biosimilars.

68,1% **in market share (value)** in year 2024

Market share (value) is defined as percentage of total sales* of biosimilar medicines/ total sales* of originator and its biosimilars.

*(Total sales at ex-factory prices taking in to account the applicable regulatory deductions)

Source: Spanish Ministry of Health, Directorate General for NHS Common Services Portfolio and Pharmacy:

- Consumption of official medical prescriptions receipts issued by the National Health System and dispensed in community pharmacies (Data exclude non-reimbursed drugs, OTC drugs and private medical prescriptions)

- Hospital consumption, for hospitals belonging to the public network of the National Health System. (Data coverage is total, for in-patients and out-patients)

Additional information:

- Market share for biosimilars account for 77,1% in hospital settings and 36,9% in pharmacies, in December 2024.

- Dimension of the market of more than 3 million units (number of packages) in December 2024.

Source: Spanish Ministry of Health, Directorate General for NHS Common Services Portfolio and Pharmacy:

- Consumption of official medical prescriptions receipts issued by the National Health System and dispensed in community pharmacies (Data exclude non-reimbursed drugs, OTC drugs and private medical prescriptions)

- Hospital consumption, for hospitals belonging to the public network of the National Health System. (Data coverage is total, for in-patients and out-patients)

Key national publicly accessible sources reporting data on biosimilars
Biosim - Spanish Association of Biosimilar Medicines:

https://www.biosim.es/informes-biosimilares/

3 Stakeholders involved in and targeted by biosimilar policies in Spain

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
National regulatory authority	Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) / Spanish Agency for Medicines and Health Products	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance	European Commission Biosimilar Guidance for Patients (AEMPS 2016) AEMPS 2020a (Campaign on biosimilar medicines) AEMPS 2020b Information for patients (AEMPS 2023a) AEMPS 2023b
Pharmaceutical pricing authority	Ministerio de Sanidad / Ministry of Health, Inter-Ministerial Commission for Pharmaceutical Prices (CIMP)	Implements pricing legislation regarding biosimilars	Action Plan for biosimilar medicines (MSCBS 2019)
Pharmaceutical reimbursement authority	Ministerio de Sanidad, Consumo y Bienestar Social / Ministry of Health, Consumption and Social Welfare Autonomous Communities (AC)	MSCBS: Decides on inclusion into reimbursement for biosimilars and their price. Produces prescribing guidelines for biosimilars, responsible for prescription quotas AC (regional agencies) Recommendations of use	
Procurement agency	Regional: 17 Autonomous Communities, though CBP. Centralised procurement for allowed, through the National Institute for Health Management (INGESA)	Involved in tenders and procurement procedures INGESA is developing a centralized procurement framework for off-patent biologics and biosimilars, which regions can choose to adopt	
HTA agency / body	Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) / Spanish Agency for Medicines and Health Products AETSA / Andalusian HTA Agency Agència de Qualitat i Avaluació Sanitàries de Catalunya (AQuAS) / Agency for Health Quality and Assessment of Catalonia AVALIA/ Galician Agency for HTA Hospitals	The HTA only includes clinical dimensions and is performed by AEMPS; Health regional authorities and hospitals may perform HTA at local level, and decide about medicine inclusion in formularies	AEMPS 2020b

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
National competition authority	Comisión Nacional de los Mercados y la Competencia (CNMC) / National Commission of Markets and Competition	Enforcement of the competition law, anti-trust cases	Action Plan for use of biosimilars and generics (CNMC 2019a) Statement with positive assessment on the Action Plan (CNMC 2019b)
National patent office	Oficina Española de Patentes y Marcas / Spanish Patent and Trademark Office	Granting and managing patents on biologic medicines	
Independent public fiscal authority	Independent Authority for Fiscal Responsibility (AIReF) and Commission for Social and Economic Reconstruction	AIReF and the Commission have issued recommendations to increase the biosimilar uptake	Evaluation of hosptial expenditure, with recommendations on biosimilar uptake (AIReF 2020)
Doctors	*Represented by:* Organización Médical Colegial (OMC) / Spanish Medical Colleges Organization *Medical societies in disease areas with biologics use:* Sociedad Española de Diabetes (SED) / Spanish Diabetes Society Sociedad Española de Patología Digestiva (SEPD) / Spanish Society of Digestive Pathology Sociedad Española de Hematología y Hemoterapia (SEHH) / Spanish Society of Hematology and Hemotherapy	Prescribe biosimilars. Inform patients Constant review of position papers on biosimilars by scientific societies in most relevant specialties, such as Oncology, Rheumatology, Hematology, or Digestive Pathology	OMC 2014 OMC 2017 OMC 2022a OMC 2022b
Nurses	*Represented by:* Consejo General de Enfermería / Spanish General Nursing Council	Published a bosimilar guide for nurses and a statement on the importance of nurses in the area	Biosimilar guide for nurses (Consejo General de Enfermería e Biosim 2023) Statement on the importance of nurses in building trust into biosimilars (Consejo General de Enfermería e Biosim 2025)
Community pharmacists	*Represented by:* Consejo General de Colegios Farmacéuticos de España / General Pharmaceutical Council of Spain	Dispense medicines, inform patients	Diffrent position papers, e.g. Consejo General de Colegios Farmaceuticos de España 2023a Consejo General de Colegios Farmaceuticos de España 2023b Consejo General de Colegios Farmaceuticos de España 2024 Portero 2023

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Hospital pharmacists	*Represented by:* Sociedad Española de Farmacia Hospitalaria (SEFH) / Spanish Society of Hospital Pharmacists	Support procuring medicines, inform patients / health professionals / procurers	Spanish Society of Hospital Pharmacy position paper on biosimilar medicines (Castro et al. 2018) Article about biosimilars in the hospital pharmacy journal (Martos-Rosa et al. 2015)
Patient organisations	*Represented by:* Foro Español de Pacientes (FEP) / Spanish Patients' Forum Plataforma de Organizaciones de Patientes (POP) *Patient organisations in diseases with particular biologics use:* Federación Española de Diabetes (FEDE) / Spanish Diabetes Federation Acción de Crohn y Colitis Ulcerosa (ACCU España) / Spanish Crohn's and Colitis Association Federación Española de Hemofilia (FEDHEMO) / Spanish Federation of Hemophilia Asociación Española Contra el Cáncer (AECC) / Spanish Association Against Cancer Liga Reumatológica Española (LIRE) / Spanish Rheumatism League	Declarations on patient views on biosimilars, news items on biosimilars published by patient associations	Declaration on treatment with biologicals and biosimilars (POP 2017) Statement on interchangeability (POP 2018a) News item regarding biologics and biosimilars from patent perspective (POP 2018b) Joint declaration of doctors and patients on biologics and biosimilars (FEP 2017) News on collaboration of patients with biosimilar industry association on biosimilar guide for patients (FEP 2019) News about patient forum to inform about biosimilars (FEP 2021) Patient declaration on biologics and biosimilar use (UIMP 2017)
Consumer organisations	*Represented by:* Confederación de Consumidores y Usuarios (CECU) / Organización de Consumidores y Usuarios (OCU)	Biosimilars are mentioned in their work, see right column	Campaign on cancer medicines, including calls for biosimilar market entry (CECU 2018)
Biosimilar industry	*Represented by:* Asociación Española de Medicamentos Biosimilares (BioSim) / Spanish Biosimilar Association	Produces and supplies biosimilars Association promotes biosimilar use, including offering education and information material	Position paoer on biosimilar medicines (Biosim 2024a) Proposal for the establishment of a national observatory for biosimilar medicines (Biosim 2024c) Publications on biosimilars in the pipeline (Biosim 2024b, Biosim 2025)

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Generic industry	*Represented by:* *Asociacion Espanola de Medicamentos Genéricos (ASEG) / Spanish Association of Manufacturers of Generics* *Asociación Española de Fabricantes de Productos de Química Fina (AFAQUIM)*	Produces and supplies generics	
Pharmaceutical industry in general	*Represented by:* Farmaindustria / Association of Pharmaceutical Industry	Produces and supplies medicines. Association published press release on biosimilars	Press release defending the non-interchangeabiltiy of biological and biosimilar medicines (Farmaindustria 2015) Press release on the Plan for the promotion of generics and biosimilars (Farmaindustria 2019)
Pharmaceutical industry for new biological medicines	*Represented by:*		
Further relevant stakeholder group (e.g., regions, health trusts, municipalities)	Salud Por Derecho		

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

4 Biosimilar policies and practices in Spain 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:	
Price reduction of the first biosimilar compared to the reference product	30% (non-binding reduction rate)
Price reduction of the second, third and further biosimilars	Not fixed
Price reduction for the reference product	Yes. In case of building a reference group in the reference price system (internal price referencing) the price of the reference product must be lowered down to the price of the biosimilars.
Any further specificities	
Generic price link	Yes, 40% for first and all other generics, in case of building a reference group in the reference price system, the price of the originator must be lowered down to the price of the generics.

Source: PPRI 2025, Vogler et al. 2025

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:	
Any specificities	
External price referencing is in place for other medicines than biosimilars.	Yes, but only as a supplementary criterion

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 sector only
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All biological medicines
Institutional framework	Conducted by hospitals or regional health services
Information available on procurement procedures and practices	Award criteria include price, quality, supply security, environmental considerations, packaging and labeling. Most regions also use multiple-winner tenders.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	
Institutional framework	Law 9/2017 of 8 November on public sector contracts
Information available on procurement procedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes Outpatient: No, normally not, but the region of Andalusia has a tendering-like practice

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Vogler et al. 2025, Rio-Alvarez and Cruz-Matos 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	
If publicly accessible, indicate URL of RPS list	https://www.boe.es/boe/dias/2024/10/08/pdfs/BOE-A-2024-20293.pdf Reference Price Order 20293, Official Spanish Gazette number 243 of 2024
When were first biosimilars included in the reference price system?	2006
Any further specificities	
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	Yes ATC 5 cluster

Source: PPRI 2025, García-Goñi et al. 2021

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)	Since 2009
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	Standard rates: 40%, 50%, or 60% for the working population, depending on income. Chronic diseases: 10% for medicines for chronic diseases. Special cases: 100% reimbursement for unemployed people without benefits, people with the lowest social pension, and those suffering from occupational diseases.
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	
Indicate URL of outpatient positive list	
Co-payments for biosimilars for outpatient use	Percentage co-payments (extent dependent on the population-group)
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	For medicines in general for outpatient use: - Positive list - Percentage reimbursement rates are in place (rate depending on patient group and not the medicines, see above) - Percentage co-payments (in line with the reimbursement rates)
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level)	Yes, additionally to the originator biological (and doctors are recommended to switch)
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	

Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	
Co-payments for biosimilars for inpatient use	No
<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-payments for medicines for inpatient use

Source: PPRI 2025, Vogler et al. 2025

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))	The National Institute of Healthcare Management (INGESA) is developing a centralized procurement framework for off-patent biologics and biosimilars, which regions may opt into. The framework would prioritize price in awarding contracts, with the possibility of adjusting rankings over the two-year period. However, this continuous price-based competition has raised concerns from the pharmaceutical industry about unsustainable price reductions that could threaten long-term supply (Barcina Lacosta et al. 2023).
Enforcement of anti-trust policies	
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Mix of financial and performance-based MEAs

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	No, but BioSim (Spanish Association of Biosimilars) produces regular reports on the biosimilar pipeline.
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, Biosim 2025b, Biosim 2025

Health technology assessment

HTA is applied for biosimilar medicines	Yes
If yes, in which situations and settings (outpatient and inpatient)	Inpatient
Differences in criteria and processes of HTA for biosimilars compared to other medicines	
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?	Recommendation to prescribe biosimilars for naïve patients
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	Yes, in some Autonomous Communities (decentralised competence). The absence of clear national targets for biosimilar uptake has prompted most regional health authorities to issue guidelines encouraging the use of best-value biologics in biologic-naïve patients. Nevertheless, only a few regions have introduced specific prescribing targets for these patients, and even fewer promote switching based on cost-effectiveness. For instance, regions like Cataluña have not set targets for patients already treated with biologics, leaving decisions on switching to individual hospitals' Pharmacy and Therapeutics Committees. In contrast, regions such as Asturias, La Rioja, and Andalusia have taken a more proactive stance, actively supporting switching practices guided by cost-effectiveness considerations (Barcina Lacosta et al. 2023).
URL of prescription & switching guidelines	
Prescribing quotas	
Prescribing quotas for doctors with regard to prescription of biosimilars exist	Yes
If yes, which quotas are defined for biosimilars	
Any exemptions	
Any sanctions in case of non-achievement	
Any (financial) incentives for achieving the quota	
Prescribing quotas were issued by	
URL of prescribing quotas	
Prescribing quotas for other non-biosimilar medicines exists	
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	Yes
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	A notable example of innovation is Extremadura's introduction of a Profit Sharing Program targeted at doctors for prescribing biosimilar medicines in February 2023, making it the first Autonomous Community to adopt such an approach (Río-Álvarez 2024).
Publicly accessible information	
INN prescribing	
In general, prescribing by INN is place (information not focused on biologics)	Yes, mandatory

If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	Exemptions for biologicals from INN prescribing: biologics and biosimilars must not be prescribed by INN
Further measures targeted at doctors	
Information materials for doctors	
Information events for doctors (e.g., seminars, trainings)	
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	

Source: PPRI 2025, Lobo and Rio-Alvarez 2021, Barcina Lacosta et al. 2022, Riesgo 2021

Pharmacists (and further dispensers)

Country context: no information available

Substitution policies	
(Automatic) substitution for biosimilars	No
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	
Generic substitution in place	Yes, mandatory
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	
Information events for pharmacists (e.g., seminars, trainings)	

Source: PPRI 2025

Patients

Information and educational measures	
Information materials for patients	A Joint Declaration of Medical Societies and Patient Organizations on treatments with originator biologics and biosimilars in 2017 A campaign targeted at patients in 2022
If yes, provide URL of most common materials	UIMP 2017
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	Yes, through reference pricing system
If yes, pls. describe	
Publicly accessible information	

Source: PPRI 2025, Lobo and Rio-Alvarez 2021, UIMP 2017

5 Impact of biosimilar policies and practices in Spain

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 Spain

Outcome indicator	Caused by	Findings	Publication
Savings for the public payer	Policy not specified	3.92% of total pharmaceutical spending in 2019 (2.306 million euros cumulative savings over the 2009-2019 period). The highest contributors are epoetin, somatropin, adalimumab, and rituximab biosimilars.	García-Goñi et al. 2021
Time to biologic treatment	Policy not specified	The mean time to availability of the biologic medicines in the hospitals was 15.9 ± 6.7 months, (20.0 ± 12.4 for originators and 11.8 ± 5.2 for biosimilars). Mean time to biologic treatment was 7.7 ± 9.0 years (8.6 ± 8.9 for originators and 7.0 ± 9.0 for biosimilars). Showing statistically significant differences among conditions.	Vázquez-Sánchez et al. 2024
Biosimilar market share	Policy not specified (but assumption of change in prescribing practice)	Upon introduction of biosimilar infliximab for the treatment in rheumatology (rheumatoid arthritis and ankylosing spondylitis) and inflammatory bowel disease (Crohn's disease and ulcerative colitis), the growth in market share of biosimilar infliximab was primarily influenced by its use among treatment-naïve patients. The proportion of total patients from rheumatology and gastroenterology receiving biosimilar infliximab 5 years after its introduction would be 1.8% and 13.1%, respectively. Focusing on naïve patients, the proportion of total patients from rheumatology and gastroenterology receiving biosimilar infliximab 5 years after its introduction would be 16.3% and 67.5%, respectively.	Kanters et al. 2017
Savings for the public payer	Policy not specified (but assumption of change in prescribing practice)	Upon introduction of biosimilar infliximab for the treatment in rheumatology (rheumatoid arthritis and ankylosing spondylitis) and inflammatory bowel disease (Crohn's disease and ulcerative colitis), and considering a price discount of 18% on biosimilar infliximab compared to reference infliximab, savings in year 5 after the introduction of the biosimilar would amount to € 689,832 in rheumatology and € 2,695,510 in gastroenterology.	Kanters et al. 2017
Biological medicines utilisation	Policy not specified	Over the course of one year (Q4 2018 – Q4 2019), and in the presence of adalimumab biosimilars, adalimumab consumption increased 0.7 standard units (SU) per 1,000 population, from 4.3 SU to 5.1 SU, 17%.	Woo et al. 2024
Savings for the public payer	Policy not specified	Over the course of one year (Q4 2018 – Q4 2019), and in the presence of adalimumab biosimilars, adalimumab expenditure decreased 30%.	Woo et al. 2024
Biosimilar uptake	Demand-side policies (e.g., prescription targets and switching protocols) and supply-side policies (e.g., tender design)	In Spain, biosimilar uptake of infliximab, etanercept and adalimumab varied widely across regions. As a matter of fact, as of 2021, biosimilar uptake (%) of infliximab ranged from 50.5% in Ceuta to 95.1% in Navarra; biosimilar uptake (%) of etanercept ranged from 0% in Melilla to 92.2% in Asturias; biosimilar uptake (%) of adalimumab ranged from 33.4% in Melilla to 98.0% in Asturias. In Spain, biosimilar uptake is influenced by regionally fragmented procurement and prescribing policies. On the supply side, some regions use competitive tenders that group biosimilars and originators, with single-winner tenders (e.g., in Andalucía) generally supporting higher uptake, though concerns about price pressure and supply persist. A proposed national procurement	Barcina Lacosta et al. 2023

Outcome indicator	Caused by	Findings	Publication
		framework by INGESA could standardize practices but remains contested. On the demand side, while most regions recommend initiating biologic-naïve patients on biosimilars, few set concrete targets or endorse switching for experienced patients. Exceptions like Asturias, which implemented centralized, cost-effectiveness-based switching protocols, show significantly higher uptake. Overall, the absence of national coordination and benchmarking limits consistent biosimilar adoption across the country.	

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 Spain

Legal barriers

In Spain, biosimilar medicines must be prescribed by their brand name, and current regulations prohibit pharmacists to substitute biologic medicines (Río-Álvarez and Cruz-Martos 2024). However, it remains unclear whether this restriction applies exclusively to community pharmacies, as decisions in hospitals are often made by their Pharmacy and Therapeutics Committees (Río-Álvarez and Cruz-Martos 2024). Consequently, switching practices vary widely across regions and hospitals (Barcina Lacosta et al. 2023).

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

The adoption of biosimilars is hindered by a lack of coordination and misalignment within hospitals where these medicines are administered (Marín-Jiménez et al. 2021). Additionally, poor collaboration and insufficient teamwork between physicians and hospital pharmacists further impede their broader use (Río-Álvarez and Cruz-Martos 2024).

The literature indicates that this lack of coordination is not limited to individual hospitals but extends to broader policy and governance structures, further complicating biosimilar adoption. The lack of clear national targets for biosimilar adoption has led most regional health administrations to issue guidelines recommending the initiation of biologic-naïve patients on best-value biologics (Barcina Lacosta et al. 2023). However, only a few regions have set specific prescription targets for biologic-naïve patients, and even fewer support switching practices based on cost-effectiveness criteria (Barcina Lacosta et al. 2023). For example, regions like Cataluña have not established targets for biologic-experienced patients, leaving switching guidance to the discretion of individual hospitals' Pharmacy and Therapeutics Committees. In contrast, regions such as Asturias, La Rioja, and Andalucía have adopted more proactive approaches, actively promoting switching based on cost-effectiveness considerations (Barcina Lacosta et al. 2023). The absence of consistent regional guidelines on switching is considered as a barrier for broader uptake of biosimilars across the country.

Financial barriers

In the outpatient sector, reimbursed prices of biosimilars are regulated by an internal reference price system that sets a maximum reimbursement price for groups of biosimilars, aligning all prices to the lowest cost per defined daily dose (Río-Álvarez and Cruz-Martos 2024). This effectively means that both biosimilars and originator biologics are reimbursed at the same price. In contrast, in the hospital setting, price competition is driven by tendering processes. The absence of price differentiation in the outpatient sector partially explains the lower uptake of biosimilars in community pharmacies compared to hospitals (Río-Álvarez and Cruz-Martos 2024).

To address procurement challenges, the National Institute of Healthcare Management (Instituto Nacional de Gestión Sanitaria, INGESA) is developing a centralised procurement framework for off-patent biologics and biosimilars, which regions can choose to adopt. Under the proposed framework, the award decision would primarily be based on price, with competitors' offers potentially fluctuating throughout the 2-year agreement period. This mechanism, allowing continuous revisions to the award order, has raised concerns within the pharmaceutical industry about triggering a downward price spiral, potentially jeopardising long-term supply sustainability (Barcina Lacosta et al. 2023).

The introduction of financial incentives for prescribing biosimilars has also been a topic of debate (AIReF 2020). However, several significant barriers impede their implementation. These include systemic rigidity and fragmentation, with the current payment system favoring fixed salaries over performance-based remuneration, limiting the flexibility required for financial incentives. Furthermore, bureaucratic budget management and inflexible administrative procedures were reported to delay the rollout of innovative approaches, such as gain-sharing agreements, that could incentivise biosimilar uptake (Lobo and Río-Alvarez 2020).

Evidence and communication-related barriers

Barriers to biosimilar uptake are significantly influenced by gaps in knowledge and communication among key stakeholders. Hospital physicians and pharmacists often lack adequate education, confidence, and awareness regarding biosimilars, which limits their ability to effectively prescribe these treatments (Marín-Jiménez et al. 2021). Furthermore, many healthcare professionals express low confidence in switching patients from reference biologics to biosimilars, further hindering adoption (Marín-Jiménez et al. 2021). This is compounded by the absence of robust clinical trial data in certain contexts, which undermines trust in these therapies (Marín-Jiménez et al. 2021). Moreover, clinical practice guidelines in Spain are not consistently updated following the introduction of a new biosimilar. As a result, the decision to prescribe a biological medicine at an early stage rests entirely with individual physicians (Río-Álvarez and Cruz-Martos 2024).

The hesitancy is further exacerbated by the cautious stance of some healthcare organisations. While the Spanish Medicines Agency acknowledges the quality of EMA-approved biosimilars, it delegates decisions on interchangeability to these hospital committees (Barcina Lacosta et al. 2023). At the same time as healthcare organisations recognise biosimilars as safe, effective, and high-quality alternatives that can enhance pharmaceutical efficiency, these organisations have raised concerns about the extrapolation of indications and interchangeability. Despite scientific evidence supporting these practices, they oppose automatic substitution by pharmacists and emphasise the need to uphold the doctor-patient relationship (Río-Álvarez 2024).

Communication challenges also play a role in limiting biosimilar uptake. Public awareness campaigns are often not specifically designed to address the unique aspects of biosimilars. For example, the 2022 campaign, "Generic and Biosimilar

Medicines: Effective for you, effective for health," was criticised for lacking sufficient emphasis on the distinct characteristics and benefits of biosimilars, diluting its potential impact (Río-Álvarez and Cruz-Martos 2024). These potential gaps highlight the need for targeted educational and communication strategies to build trust and confidence in biosimilars among healthcare professionals and patients alike.

Policy-related barriers

Since the introduction of the first biosimilar in 2006, Spain was said to have lacked a well-structured and comprehensive policy to support the rapid and effective integration of biosimilars into routine clinical practice (Río-Álvarez 2024). Although the Ministry of Health introduced an Action Plan in 2019 (MSCBS 2019) to promote the use of generic and biosimilar medicines, it failed to become a formal policy instrument due to its lack of approval by the Interterritorial Council of the Spanish NHS (Río-Álvarez and Cruz-Martos 2024).

While biosimilar substitution is prohibited in community pharmacies, it is permissible in the hospital setting (Barcina Lacosta et al. 2023). At the hospital level, switching protocols are established, and prescribers are informed about patients eligible for a switch. However, the process cannot proceed without the explicit consent of the prescriber, leading to inconsistencies between the actions of individual clinical departments or prescribers and the intentions of the hospital's Pharmacy and Therapeutics Committee (Barcina Lacosta et al. 2023).

Tendering practices also vary significantly across regions. While originator and biosimilar medicines can be grouped within the same tender lot, this has not been consistently applied for biologic-experienced patients in certain regions or hospitals (Barcina Lacosta et al. 2023). Although single-winner tenders have proven effective in promoting the early adoption of biosimilars, they have raised concerns over the excessive pressure they place on prices and supply sustainability (Barcina Lacosta et al. 2023).

Additionally, the system has sometimes failed to adapt to the introduction of biosimilars. For example, long-term purchase contracts (1–2 years) for originator reference products, such as Remicade, were finalised just before the market entry of biosimilars, temporarily restricting their accessibility and delaying uptake (Barcina Lacosta et al. 2023). These policy-related barriers highlight the need for greater alignment, flexibility, and strategic planning to maximise the benefits of biosimilar integration.

Stakeholder-related barriers

Physicians and pharmacists in hospitals often lack the confidence, experience, and knowledge needed to fully embrace biosimilars (Lobo and Río-Alvarez 2021; Marín-Jiménez et al. 2021; Río-Álvarez and Cruz-Martos 2024). This issue is particularly pronounced among primary care physicians, where limited familiarity with biosimilars exacerbates concerns about their use (Río-Álvarez and Cruz-Martos 2024).

Patient organisations have played a limited role in promoting biosimilar awareness, with the first significant publication appearing in 2017 (UIMP 2017). This joint document, issued by medical societies and patient organisations, supported the inclusion of biosimilars in the Spanish NHS but opposed replacing prescribed medicines, despite evidence supporting the safety of switching from reference products to biosimilars (Río-Álvarez and Cruz-Martos 2024). Furthermore, as of early 2024, information shared by the Spanish Platform of Patient Organisations contradicted the EMA and HMA's official stance on the interchangeability of biosimilars within the EU, adding to confusion and mistrust (Río-Álvarez and Cruz-Martos 2024).

Limited evidence on Spanish patients' perspectives (distinct from patient organisations) indicates that patients generally view biosimilars positively, perceiving them as safe and effective. However, there remains a critical need for improved education and accessible information about biologic therapies to address knowledge gaps (Río-Álvarez 2024).

Stakeholder-related barriers also hinder the implementation of prescription incentives for biosimilars. Professional associations, while supportive of clinical governance that enhances autonomy and responsibility, are often resistant to performance assessments and transparency measures. They fear that performance-related incentives could undermine professional independence. Similarly, professional associations oppose remuneration models tied to outcomes or productivity, favoring standardised salaries and rejecting differentiation based on individual or team performance. These positions present significant challenges to introducing financial or gain-sharing incentives, which depend on stakeholder alignment for success (Lobo 2020).

Any other barriers

In the national survey conducted by Marín-Jiménez et al. (2021), complicated, unsuitable, and non-user-friendly administration devices were identified as a significant technical barrier to the uptake of biosimilars in Spain. Specifically, 69% of physicians and 48% of hospital pharmacists acknowledged the administration device as a hindrance to biosimilar use. This concern reflects the perception that some biosimilar delivery mechanisms—such as injection pens or pre-filled syringes—may be harder to handle, less familiar, or less convenient compared to those of the original biologic or competing brands.

These usability issues can lead to reduced confidence among prescribers, increased hesitation when recommending biosimilars to patients, and a heightened sense of discomfort or anxiety among patients, particularly those who self-administer their treatments. In clinical practice, this may also result in a greater need for additional training or clinical support, such as involving nursing staff to assist with administration. The study underscores that even when biosimilars demonstrate clinical equivalence, technical aspects like the design and ease of use of the administration device can significantly influence both physician and patient acceptance, and ultimately, the integration of biosimilars into routine care.

7 Facilitators and good practice examples in Spain

With the 17 Autonomous Communities having the autonomy to establish their own public procurement procedures for off-patent biologicals and biosimilars, significant variation exists in the criteria applied. However, in some regions, tender conditions have aligned with recognised best practices, such as implementing multi-winner tenders and considering factors beyond price (Río-Álvarez and Cruz-Martos 2024).

A notable example of innovation is Extremadura's introduction of a Profit Sharing Program targeted at doctors for prescribing biosimilar medicines in February 2023, making it the first Autonomous Community to adopt such an approach (Río-Álvarez 2024). This program aims to encourage the efficient prescribing of biosimilars by reinvesting a portion of the savings generated into the healthcare system, improving areas such as access to innovative medicines. The success of this initiative relies on strong collaboration between healthcare management and prescribing professionals, as well as clear and effective communication with patients about the benefits of biosimilars (Junta de Extremadura 2023).

Educational efforts have also played a crucial role in promoting biosimilar use. Professional societies representing doctors, pharmacists, and nurses, in partnership with the national biosimilar trade association, have developed guides and training programs tailored to healthcare professionals, addressing knowledge gaps and fostering greater confidence in prescribing biosimilars (Río-Álvarez and Cruz-Martos 2024).

Another key facilitator has been the dissemination of robust efficacy and safety data from clinical trials and real-world studies, including post-marketing surveillance. This evidence has helped to strengthen healthcare professionals' trust in biosimilars (Marín-Jiménez et al. 2021). Recommendations from professional associations, endorsements by key opinion leaders, and the availability of comprehensive evidence have been highlighted by hospital pharmacists and physicians as critical factors in driving biosimilar uptake across the country (Marín-Jiménez et al. 2021).

8 Developments in Spain

Plans or under discussion

Debate among scientific societies in Spain has been sparked, particularly regarding early access for patients with rheumatoid arthritis and inflammatory bowel disease who have a poor prognosis. These organisations advocate for the inclusion of biosimilars in clinical practice guidelines and recommend their timely review whenever new biosimilar molecules become available (Río-Álvarez and Cruz-Martos 2024).

The Independent Authority for Fiscal Responsibility (*Autoridad Independiente de Responsabilidad Fiscal*, AIReF), tasked with safeguarding the sustainability of public

finances, proposed several measures to promote the rational use of biosimilars as alternatives to reference biological medicines, both for initiating treatment in new patients and switching treatment in patients already using reference biologics (AIReF 2020). These measures, which are intended to be implemented in a complementary and coordinated manner, include:

1. Introducing incentives for prescribing and using biosimilars (e.g., gain-sharing programmes).

2. Providing greater legal certainty for healthcare professionals in decisions involving switching or substituting reference biologics with biosimilars.

3. Offering clear and accessible information to patients, such as sharing experiences from other patients and providing brochures or infographics.

4. Conducting educational sessions for healthcare providers, led by clinical leaders, to highlight the resource-saving opportunities offered by biosimilars.

5. Collaborating with clinical leaders and physicians to measure outcomes and provide evidence on the benefits of biosimilars.

6. Utilising open procurement procedures (e.g., framework agreements) for the supply of biological medicines once the patents for reference biologics expire and biosimilars become available.

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