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

AUGMENT Biosimilars
Country fiche ITALY

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Vogler S, Walter M, Knoll V, Habimana K, Helter T

augment biosimilars

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Directorate-General for Health & Food Safety
Unit: SANTE-D2 (Medical products: quality, safety, innovation)

Contact: François Janssens

E-mail: sant-atf@ec.europa.eu

European Commission
B-1049 Brussels

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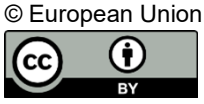

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Annex 7.16

AUGMENT Biosimilars country fiche: Italy 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:

Simona Montilla, Agenzia Italiana del Farmaco (AIFA) / Italian Medicines Agency

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1 Summary of biosimilar policies and practice in Italy 2025

Key stakeholders

A key public institution for medicines, including biosimilars, is the **Italian Medicines Agency AIFA** (Agenzia Italiana del Farmaco). AIFA is responsible for marketing authorisation, pricing, reimbursement and vigilance of medicines, including biosimilars, whereas the Italian regions, represented by the **Regional Healthcare Authorities**, are the public procurers and payers and responsible for keeping the budgets. It is up to the latter to impose additional demand-side policies targeted at prescribers, aligned with national legislation. In 2018, AIFA issued a position document about the interchangeability among biologics, thus supporting "switches" to and among biosimilars initiated by a prescriber. AIFA regularly publishes data about biosimilar use and spending and offers information materials for stakeholders; in the private sector it is mainly the **Italian Biosimilar Group** within the Italian Generic Medicines Association Egualia, which is active in information activities. The **Italian Competition Authority AGCM** (Autorità Garante della Concorrenza e del Mercato) has been publishing opinions on how to encourage competition in the biological market (e.g., in tendering procedures) and has been enforcing in anti-trust legislation (e.g., investigations against companies that deter market entry of a biosimilar).

Major biosimilar policies and practices

Key supply-side policies are a **biosimilar price link** that requests biosimilar prices to be at least 20% below the price of the biological originator, **facilitated pricing and reimbursement procedures for biosimilars** (and generics) and specific provisions for **tendering**. Since 2017 tenders must be organised as **framework agreements and awarded to the three top-ranking bidders** if three or more biosimilars of an active biological substance are marketed. Biosimilar medicines are not included in the reference price system.

On the demand-side, **prescribing biosimilars** for treatment-naïve patients and **switching to and among biosimilars** is recommended. This general provision at national level is implemented by the Regional Healthcare Authorities through different **regional policies**, e.g., additional regional guidelines, prescribing quotas, gain-sharing models (rather rarely) and information and engagement activities, particularly with prescribers. Biosimilars must be **prescribed by the trade name** (prescribing by the International Non-Proprietary Name is not allowed), and biosimilar **substitution** at community pharmacy level is **not permitted**.

Impact analysis

Some studies **analysed biosimilar uptake** (increased market shares) **and savings** for the public payers in Italy, however not linking the effect to a specific policy. Biosimilar **market shares increased** over the years, however, with **variation**

across the substances and particularly across **the regions** (and also intra-regional). While no impact analyses for a specific policy exist, a few studies analysing regional differences in Italy point to a **facilitating impact of the implementation of policy package by the regional authorities on biosimilar use**.

Barriers, facilitators and good practice examples

As public payers and procurers of medicines, the Italian regions are incentivised to implement policies to encourage biosimilar uptake. Some regions appear to be more effective in doing so than others; thus, the **fragmented organisation on the Italian healthcare system** may be considered as a barrier.

However, there are **national laws, policies and statements** which **likely support the regional initiatives**. The **AIFA position document on interchangeability** published in 2018 is supportive for the regions in implementing their switching guidance and provisions. The 2017 Budget Law introduced new **rules for biosimilar tendering** (multi-winner awards), which has also supported the regions in shaping their policies and practices. However, unclarity in the interpretation of that law (e.g., on the ranking of three winners) may have undermined some of the positive effects.

Recent developments

No recent developments or ongoing discussions were identified. Major earlier milestones include the provisions on **biosimilar tendering** in the 2017 Budget Law, the switching position in **AIFA's position paper** from 2018 and **facilitated pricing and reimbursement rules** in 2021.

Highlights and learnings

The Italian experience highlights the importance of the **alignment between the national and regional policies** and the **importance of regional initiatives** given the decentralisation in the funding responsibility in the Italian National Health Service. Additionally, it confirms the **importance of data collection and monitoring** (e.g., of biosimilar use and spending), which is performed on a regular basis in Italy.

2 Key data regarding biosimilars in Italy

First biosimilar medicine launched (i.e. brought on the market):
epoetin alfa (Binocrit ®) from 31 October 2012
Source: AIFA 2019

Number of the **biosimilars marketed**:
19 molecules with biosimilars available, as of October 2024
Source: AIFA 2025

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

50.8 % **in volume** in 2023
Volume is defined as standard units, as defined by IQVIA

Source: Egualia 2024

Key national publicly accessible sources reporting data on biosimilars

Reports about spending and consumption of biosimilars at the website of the Medicines Agency AIFA: https://www.aifa.gov.it/monitoraggio-consumi-e-spesa-biosimilari (at bi-monthly basis and yearly till 2022, spending trends, variation across regions, …)

3 Stakeholders involved in and targeted by biosimilar policies in Italy

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Ministero Della Salute / Italian Ministry of Health	Prepares legislation	
National regulatory authority	Agenzia Italiana del Farmaco (AIFA) / Italian Medicines Agency	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance, published position paper on interchangeability (recommending "switch")	Website about biosimilars (www.aifa.gov.it/farmaci-biosimilari): with FAQ about biosimilars, a Position Paper about biosimilars (AIFA 2018), spending and consumption data – latest version with data of October 2024 (AIFA 2025)
Pharmaceutical pricing authority	Agenzia Italiana del Farmaco (AIFA) / Italian Medicines Agency	Implements pricing legislation regarding biosimilars, decides on the biosimilar prices in line with provisions in the legislation	
Pharmaceutical reimbursement authority	Agenzia Italiana del Farmaco (AIFA) / Italian Medicines Agency	Decides on inclusion into reimbursement for biosimilar. monitors biosimilar spending and consumption	
	Itailan Regions (represented by the Regional Healthcare Authorities)	May (or may not) impose prescribing and switching guidelines for biosimilars, prescription quotas, gain-sharing models (differences in implementation across regions). Monitors biosimilar spending and consumption	
Procurement agency	Consip Regional CPBs	Central purchasing body (CPB) at national level. Not involved in open procedures and negotiations for medicines, but providing the platform for framework agreement	
	Regional CPBs	Regional procurers, launch their tenders or participate in framework agreements tender launched by Consip.	
HTA agency / body	Agenzia Italiana del Farmaco (AIFA) / Italian Medicines Agency Agenzia Nazionale per i Servizi Sanitari Regionali (AGENAS) / National Agency for Regional Health Services		
National competition authority	Autorità Garante Della Concorrenza e del Mercato (AGCM) / Italian Competition Autorities	Enforcement of competition and anti-trust law, anti-trust cases Expresses views on competition action related to biologics	Summary of positions: Raffaelli and Fausto 2019 Recent investigation in companies coordinating to potentially delay market entry of a BS: AGCM 2024
National patent office	Ufficio Italiano Brevetti e Marchi / Italian Patent and Trademark Office	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri (FNOMCeO) *Medical societies in*	Prescribe biosimilars. Inform patients	Position statement of the use of biosimilar and generic insulins of the Italian Diabetes Society: SID 2016

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
	disease areas with biologics use: Società Italiana di Diabetologia (SID) / Italian Diabetes Society Italian National Rheumatism Association Società Italiana di Gastroenterologia (SIGE) / Italian Society of Gastroenterology Società Italiana di Ematologia (SIE) / Italian Society of Hematology		
Nurses	*Represented by:* Federazione Nazionale Ordini Professioni Infermieristiche (FNOPI) / Italian National Federation of Nursing Orders		
Community pharmacists	*Represented by:* Federazione Ordini Farmacisti Italiani (FOFI) / Federation of the Order of Italian Pharmacists Federfarma / Italian Pharmacy Owners Federation	Dispense medicines, inform patients	
Hospital pharmacists	*Represented by:* Società Italiana di Farmacia Ospedaliera e dei Servizi Farmaceutici delle Aziende Sanitarie (SIFO) / Italian Society of Hospital Pharmacy	Support procuring medicines, inform patients / health professionals / procurers	Regular link to news about biosimilars on the AIFA website
Patient organisations	*Represented by:* no general association *Patient organisations in diseases with particular biologics use:* Federazione Diabete Italia (FDI) / Diabetes Federation Italy Associazione Amici onlus / Italian Crohn's and Colitis Association Associazione Italiana contro le Leucemie-Linfomi e Mieloma (AIL) Associazione Italiana per la Ricerca sul Cancro (AIRC) / Italian Association for Cancer Research Associazione Nazionale Malati Reumatici (ANMAR) / Italian National Rheumatism Association		
Consumer organisations	Altroconsumo Adiconsum	Inform consumers / the public	Background information on biosimilars on the Altroconsumo website: Che cosa sono i farmaci

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
			biologici e biosimilari
Biosimilar industry	*Represented by:* IBG - Italian Biosimilars Group within Egualia - Industrie farmaci accessibili / Italian Generic Medicines Association	Produces and supplies biosimilars Involved in information and educational activities The IBG is a working group within the Italian Generics Medicines Associations focused on biosimilars	Information on the IBG website: https://www.egualia.it/it/biosimilari/cosa-sono.html Offering background information about biosimilars, national and European norms and national and international studies, in the annual publication on the Italian biosimilar market (latest version: Egualia 2024)
Generic industry	*Represented by:* Egualia - Industrie farmaci accessibili / Italian Generic Medicines Association	Produces and supplies generics. Umbrella association for "affordable medicines" (off-patient medicines) also host the Italian Biosimilars Group.	
Pharmaceutical industry in general	*Represented by:* Farmindustria - Associazione delle imprese del farmaco / National Association of Pharmaceutical Industry	Produces and supplies medicines.	Position paper of the pharmaceutical companies on biosimilars: Farmindustria 2018
Pharmaceutical industry for new biological medicines	*Represented by:* Associazione nazionale di Federchimica (ASSOBIOTEC) / Italian Association for the Development of Biotechnology		

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

4 Biosimilar policies and practices in Italy 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 reimbursement
Price reduction of the first biosimilar compared to the reference product	Minimum 20% lower than the price of the originator biological
Price reduction of the second, third and further biosimilars	
Price reduction for the reference product	No

Any further specificities	If the biosimilar price is set at 20% lower than the price of originator biological, then the biosimilar will be priced in the same reimbursement category (e.g. A or C) than the originator biological.
Generic price link	Yes, the generic must be priced at least 20% lower than the originator and reference medicine.

Source: PPRI 2025, Vogler 2021, Barcina-Lacosta et al. 2023

External price referencing

External price referencing is applied for biosimilars.	No
If yes, it is applied for the following situations:	Not applicable
Any specificities	Not applicable
External price referencing is in place for other medicines than biosimilars.	Yes, but no specific external price referencing policy but rather a supplementary pricing policy for reimbursable medicines in outpatient and inpatient sectors (prices in other European countries are, among others, considered to inform price negotiations)

Source: PPRI 2025, Vogler 2021

Tendering

Some (or all) biosimilars are procured through tendering (or tendering-like) processes.	Yes
If yes, the scope with regard to the care sector:	Inpatient and outpatient sectors
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All off-patent biological medicines
Institutional framework	Conducted by regional centralised procurement bodies (Centrali di Committenza Regionali) and hospitals For biosimilars framework agreement are applied (according to the provision of the 2017 Budget Law. The Dynamic Purchasing System (DPS), a variant of framework agreements (allowing suppliers to join on a rotating basis), managed at the platform of the national CPB Consip has also been used.
Information available on procurement procedures and practices	Price is a significant criterion, and in some cases, quality and safety of the product are also considered. Since 2017 Budget Law: Legal obligation to procure via framework agreements and multiple-winner tenders, when three or more biosimilars of an active substance are on the market.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	Some off-patent biological medicines
Institutional framework	Conducted by regional centralised procurement bodies (Centrali di Committenza Regionali) and hospitals For use of DPS managed by Consip is above.
Information available on procurement procedures and practices	Price is a significant criterion, and in some cases, quality and safety of the product are also considered. Since 2017 Budget Law: Legal obligation to procure via framework agreements and multiple-winner tenders, when three or more biosimilars of an active substance are on the market.
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes, generics are procured through competitive tendering procedures by regional procurement bodies and hospitals. Outpatient: Yes, generics are procured through competitive tendering procedures by regional procurement bodies and hospitals.

Source: PPRI 2025; Vogler et al. 2022b, Vogler et al. 2024

4.2 Reimbursement policies 2025

Reference price system

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	No
If yes, how many and under which specifications	Not applicable
If publicly accessible, indicate URL of RPS list	Not applicable
When were first biosimilars included in the reference price system?	Not applicable
Any further specificities	Not applicable
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered?	Yes, for originator and generic medicines. So-called "Lista di trasparenza" (at national and regional level). Only medicines included in these lists are allowed to be subject to generic substitution. ATC 5 cluster

Source: PPRI 2025

Inclusion into reimbursement and co-payments

Reimbursement in the outpatient sector	
Apart from their potential inclusion into the reference price system (see above), biosimilars are included in outpatient reimbursement (positive list).	Yes (in some cases)
If yes, how many and date of inclusion into reimbursement, if known)	
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	100% for reimbursable biosimilars (as for any other reimbursed medicines)
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	In February 2021, simplified procedures and requirements for generics and biosimilars of non-reimbursed medicines were introduced: automatic inclusion in the reimbursement category C, without negotiations with AIFA's HTA Department and with AIFA's Technical Scientific advisory Committee (CTS) and the Price and Reimbursement Committee (CPR)
Indicate URL of outpatient positive list	
Co-payments for biosimilars for outpatient use	Prescription fee
<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	Positive and negative lists Percentage reimbursement rates are in place
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	URL of national hospital pharmaceutical formulary: Not publicly available
Co-payments for biosimilars for inpatient use	No
For medicines for inpatient use in general (other medicines than biosimilars): Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	Levels: Hospital pharmaceutical formularies exist at national, regional, and facility (hospital) levels. Inclusion process: Medicines are included in these formularies based on evaluations by the Pharmaceutical and Therapeutics Committees (PTCs) at the respective levels. The process involves assessing the therapeutic value, safety, and cost-effectiveness of the medicines. No co-payments for medicines for inpatient use

Source: PPRI 2025, Vogler 2021, GaBi Online 2021

4.3 Specific pricing, procurement and funding policies 2025

Application of special pricing, procurement and reimbursement models for biosimilars (e.g., delinkage / subscription-model, management-entry agreements (MEA))	No
Enforcement of anti-trust policies	Yes, see below the Byooviz case For views of the AGCM see below
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Mix of financial and performance-based MEAs

Source: PPRI 2025, AGCM 2024, Raffaelli and Fausto 2019
Further information on anti-trust enforcement:

The Byooviz case:

In June 2024, the Italian Competition Authority (Autorità Garante della Concorrenza e del Mercato, AGCM) opened an investigation against eight pharmaceutical companies (Samsung Bioepis co. Ltd., Samsung Bioepis NL B.V., Biogen Inc., Biogen Italia S.r.l., Genentech Inc., Novartis AG, Novartis Europharm Ltd. and Novartis Farma S.p.A) for their alleged agreement to restrict the market for the active ingredient ranibizumab. The investigations were conducted in Italy and in the Netherlands.

The allegation was about a coordination of commercial strategies between these companies to delay the entry into the Italian market of Byooviz (active ingredient ranibizumab), a biosimilar developed and marketed by the Samsung Bioepis and Biogen groups. Byooviz is the biosimilar of Lucentis, itself developed by Genentech and marketed in Italy by the Novartis group

Source: AGCM 2024

Additionally, the AGCM has been active on expressing views to encourage biosimilar competition on several occasions, e.g.,

- Already in 2011, the AGCM criticised a draft law under consideration in the Parliament that sought to prohibit the grouping of biological originators and their corresponding biosimilars in the same lot.

- On the 2017 draft Budget Law (which introduced new rules for biosimilar tendering), the AGCM expressed an opinion: it appreciated that biologicals and their biosimilars should be purchased on the basis of framework agreements, but the AGCM strongly contested the choice of considering the maximum price as a basis for the purchase of biosimilar medicines, as setting the starting invitation to tender at the highest price level 'discourages any possible stimulus to the presentation of competitive offers' (it proposed instead to fix the starting invitation to tender at price levels attributable to the availability of several competing products).

Source: Raffaelli and Fausto 2019

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
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	There is an elaborated horizon scanning process for new medicines by AIFA, but not on the LoE.

Source: PPRI 2025

Health technology assessment

HTA is applied for biosimilar medicines	No
If yes, in which situations and settings (outpatient and inpatient)	
Differences in criteria and processes of HTA for biosimilars compared to other medicines	*No HTA for biosimilars but HTA for new medicines*
Any specificities	

Source: PPRI 2025

4.5 Demand-side measures 2025

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	While doctors may decide on a case-by-case basis, switching is recommended (by AIFA) and even strongly recommended in some regions.
Prescription guidelines (including switching guidelines) were issued by	AIFA's Position Paper on biosimilars (AIFA 2018): biosimilars are considered interchangeable and a switching is recommended – as overall guidance document. In addition, regional prescribing and switching guidance (e.g., linked to (regional) tendering procedures or prescribing quotas) which aim to encourage biosimilar prescribing and switching.
URL of prescription & switching guidelines	e.g. for the Veneto Region: Regione di Veneto. Decreto n. 112 del 13 settembre 2018. Medicinali biosimilari.
Prescribing quotas	
Prescribing quotas for doctors with regard to prescription of biosimilars exist	Yes (regional quotas, e.g., in Veneto)
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	Regional health authorities and the Italian Medicines Agency (AIFA)
URL of prescribing quotas	
Prescribing quotas for other non-biosimilar medicines exists	Yes
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	Yes, at regional level, e.g., in Lombardy (but rather rarely)
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	There is one example from the Campania region in the form of a tri-party agreement between the regional government, hospital administration and prescribers. The division of savings has been fixed by regional law.
Publicly accessible information	Information collected in Barcina Lacosta et al. 2022
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	AIFA website "Farmaci biosimilari", including FAQ and EU information (HMA/EMA statement 2022 on interchangeability, EU Guide on biosimilars for health care providers)
Information events for doctors (e.g., seminars, trainings)	At regional level, e.g., as part of a comprehensive strategy in Tuscany, with regular meetings with managers and specialists of the local health authorities and teaching hospitals to discuss biosimilar uptake and savings (in 2018)
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	

Source: PPRI 2025, Barcina Lacosta et al. 2022, Barcina Lacosta et al. 2023, Caputi et al. 2016, Guidotti et al. 2021, Moorkens et al. 2021, Vogler 2021

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense.

Substitution policies	
(Automatic) substitution for biosimilars	Not, not allowed
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	
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	Yes
If yes, provide URL of most common materials	AIFA subsite "Farmaci biosimilari", including FAQ and the EU Guide on biosimilars for patients in Italian language https://www.egualia.it/it/biosimilari/cosa-sono.html
If yes, key producers of education measures	Medicines Agency AIFA Biosimilar industry, represented by Egualia
Information events for patients (e.g., seminars, trainings)	
If yes, key providers of educational events	
Gain-sharing models	
Gain-sharing models for patients	
If yes, pls. describe	
Publicly accessible information	

Source: PPRI 2025

5 Impact of biosimilar policies and practices in Italy

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 Italy

Outcome indicator	Caused by	Findings	Publication
Tender prices	Ensuring competition (sufficient suppliers in tenders)	An analysis of regional tenders (2008-2012) showed that prices of filgrastim and epoetin (higher number of competitors) dropped steeply, whereas for somatropin with limited number of competitors remained stable.	Curto et al. 2013, Curto et al. 2014
Biosimilar uptake for TNF-α inhibitors across regions	Mix of policies	An analysis of the biosimilar market shares of the TNF-α inhibitors infliximab, etanercept and adalimumab in 2019-2021 showed major regional differences. Biosimilar market shares in 2021: infliximab ranging from 76.9% (Umbria) to 100% (Valle d'Aosta), Italian average: 93.4%; etanercept ranging from 13.6% (Molise) to 94.3%, Italian average: 72.1%; adalimumab ranging from 56.0% to 95.7%, Italian average: 76.2%. The differences were explained by both supply- as well as demand-side policies. On the supply side, different interpretation and practice of the multi-winner tendering was mentioned. On the demand-side, regional differences in prescribing and switching policies were considered attributable for the differences in uptake.	Barcina Lacosta et al. 2023
Biosimilar uptake in an Italian region	Mix of policies (switching and awareness campaign explicitly mentioned)	For one local health authority, 2021 and 2022 data on biosimilar uptake was analysed. Increases in biosimilar uptake in that one year were observed, however with differences across the molecules. Continuous resistance of prescribers was listed as one barrier, whereas an awareness campaign for the use of biosimilars conducted in nephrology and dialysis units was reported to have led to significant savings.	Ferrara et al. 2024
Biosimilar uptake in 3 regions	Mix of policies, in particular a comprehensive policy package in Tuscany	Analysis of the biosimilar market shares for four biosimilar substances (the most expensive ones for the Tuscan regional health authority: rituximab, etanercept, epoetin, somatropin) in three regions that were considered as leaders in biosimilar policy (Friuli Venezia Giulia, Tuscany, Veneto). For the studied substances, Tuscany tended to have the highest market shares and stood particularly out in an increase in the shares from 2017 to 2018. However, there were also large intra-regional variations, particularly in Tuscany. The positive developments in Tuscany were attributed to a comprehensive strategy that consisted of three pillars: 1) A regional resolution (Resolution n °194/2018, dated 26 February 2018) on biosimilar prescribing and use: Tuscan healthcare organisations were only allowed to use biological products awarded through regional tendering; otherwise an evaluation by the regional authority was needed. If the awarded medicine was a biosimilar, doctors were asked to prescribe it; in case of an originator biological, evaluation and approval of the regional authority was needed. 2) An engagement with the managers and specialists of the Tuscan local health authorities and teaching hospitals to jointly define targets for biosimilar uptake, supplemented by bimonthly meetings of the chief medical officers of the Tuscan local health authorities to discuss achieved uptake rates and savings. 3) Development of a pay for performance system. The authors acknowledged that it was not possible to disentangle the effort of the different elements of the policy.	Guidotti et al. 2021

Outcome indicator	Caused by	Findings	Publication
Savings for public payers and more patients treated	No specific policy studied	According to a budget impact analysis for the introduction of rituximab and trastuzumab intravenous biosimilars. Net budget impact (savings) for 5 years: € 141 million Truxima, € 165 million for Herzuma Increased number of patients treated in 5 years: 8,177 for Truxima, 3,492 for Herzuma.. Further scenarios, no linking to policies.	Jang et al. 2021
Biosimilar uptake	No specific policy studied	Biosimilar uptake of filgrastim in five Italian centres from 2009-214 was observed after market entry, in particular in treatment-naïve patients. Switching was frequent during the first year. High variation in biosimilar use between the centres was observed. The study did not study the impact of specific policies, but called for harmonizing policies across Italy.	Marciano et al. 2016
Biosimilar uptake	No specific policy studied	Similar study as Marciano et al. 2016, but on somatropin. Biosimilar uptake was low, and discontinuation was frequent (40%). Geographical heterogeneity was found.	Marciano et al. 2018
Savings for the public payer	No specific policy studied	Estimated savings potential in 2020 (based on 2014 data) of € 163 million to € 295 million. Based on the assumption of increased biosimilar adoption, no policies studied.	Mennini et al. 2019

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 Italy

Legal barriers

While the introduction of multi-winner tendering for biosimilars since 2017 is, in principle, highly appreciated, there appears to be unclarity regarding the legal rules. The 2017 Budget Law requests to award three top winners of a biosimilar tender if three or more biosimilars have been marketed. However, the ranking for the three winners is open to interpretation, including the division of the supply quotas. It is also not clear whether the first-ranked medicine among the three winners should be preferred in prescribing (Barcina Lacosta et al. 2023).

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

Italy's health and pharmaceutical system is organised partially in a decentralised manner. Adding to the regulatory issues, HTA, pricing and reimbursement policies implemented at national level through the Medicines Agency AIFA, the regions are responsible for funding medicines and thus introducing policies to limit spending. While this could be perceived as an incentive for the regions to procure biosimilars for cost-containment reasons (see also below the facilitators), in practice differences in the biosimilar uptake across regions have been observed (AIFA 2025, Barcina Lacosta et al. 2023, Egualia 2024), pointing to regional health system and policy characteristics as potential exploratory factors. Differences exist across regions regarding implementation of demand-side measures (Caputi et al. 2016).

Financial barriers

See above, lack of financial incentives (e.g., gain-sharing) and lack of capacity of implementing policies in some regions (organizational barrier).

Evidence and communication-related barriers

In earlier times (around 2010), several Italian regions recommended starting the treatment with a biosimilar, but this savings potential was rather limited. In response, some regions requested switching. However, implementation was challenging, since AIFA's statement on interchangeability was only published in 2018. Before, the switching policies thus tended to include more bureaucratic practices, such as requesting the prescriber to report the reasons for the switch and justify it. With AIFA's position document, implementation for the regions regarding their prescribing and switching policies became easier. Now some (but not all) regions request prescribers to justify when they prescribe the biological originator (Barcina-Lacosta et al. 2023).

Policy-related barriers

Some policies which were considered as facilitator for biosimilar uptake, such as prescribing biologics by the INN and biosimilar substitution in the community pharmacy are not allowed. Some other policies which may encourage biosimilar uptake were only implemented in some regions (organisational barrier).

Stakeholder-related barriers

While AIFA's statement on the interchangeability of biological originators and biosimilars (AIFA 2018) is appreciated, the ultimate decision on treatment initiation and switching is with the prescriber. It was noted that there is still hesitancy from prescribers to switch, despite guidelines (Ferrara et al. 2024), and this may hinder biosimilar uptake. However, regions and hospitals have the possibility to take further policies (under the conditions that they contribute to cost-containment), which is done to different extents across the regions (Barcina Lacosta et al. 2023).

It is possible that the biological originator is not among the three awarded products in the tendering processes. In case that patients may not be eligible for and consent to the switch to biosimilars, this would require direct purchase of the biological originator (potentially to a higher price; most regions ensure that they procure at the tender prices). Originator companies issued appeals against the multi-tender award obligation in the 2017 Budget Law and requested to exclude the biological originator from the tendering but have direct purchase from the hospitals (Barcina Lacosta et al. 2023)

7 Facilitators and good practice examples in Italy

Italian's regions are responsible for procuring medicines and for staying within the budget. There is an annual ceiling for public expenditure: should the ceiling be exceeded (which occurred in some regions), the regions must pay 50% of the surplus and the pharmaceutical industry the remaining 50%. These spending caps were considered as an important supportive factor to drive payers to encourage biosimilar uptake (Barcina Lacosta et al. 2023). Some regions have been encouraging biosimilar uptake and competition through measures taken at regional levels, which included prescribing quotas, prescribing and switching guidelines and information and education activities targeted at prescribers and managers of local health authorities (Ferrara et al. 2024, Guidotti et al. 2021).

The 2017 Budget Law introduced the obligation that biologics must be procured through framework agreements and awarded to the top three winners if for three or more biosimilars of one biologic active substance have been marketed. This is generally seen as a facilitator to biosimilar competition, and also ended the practice that sometimes lots restricted to originator biologicals were included in the tender specifications (Barcona Lacosta et al. 2023). Additionally, it contributes to improved availability. Furthermore, the National Procurement Agency Consip managed DPS (a

kind of framework agreements where supplier could join at any time) for the regional procurers, and Consip considered it as useful tool (easy management of lots, possibility to generate single- and multi-award framework agreements, and it is appreciated by suppliers because they know in advance who is going to buy what and how much and it allows them to submit "custom-tailored" prices (Vogler et al. 2022a).

In Italy, some national studies were conducted which confirmed the safety of biosimilars (e.g., Cutroneo et al. 2014; summary in Trifiro et al. 2017).

Overall, Italy, and its regions, appear to invest into data collection and analysis (benchmarking across regions) as well as communication to prescribers and the public.

8 Developments in Italy

Recent changes

Not necessarily recent but important changes regarding biosimilars during the last years:

- 2017 Budget Law which introduced the obligation to run multi-winner tenders if three and more biosimilars are marketed from one active biological substance
- AIFA's second position paper on biosimilars (AIFA 2018)
- 2020 Budget Law allowed use of Dynamic purchasing system (DPS, Sistema dinamico di acquisto (Sdapa) for biosimilars (since 2011 used for generics) (Vogler et al. 2022b)
- In February 2021, simplified procedures and requirements for generics and biosimilar medicines of non-reimbursed medicines were introduced: automatic inclusion in reimbursement category C, without negotiations with AIFA's HTA Department and with AIFA's Technical Scientific advisory Committee (CTS) and the Price and Reimbursement Committee (CPR) (GaBI Online 2021)

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