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

AUGMENT Biosimilars
Country fiche FRANCE

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augment biosimilars

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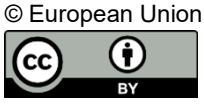

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Annex 7.10

AUGMENT Biosimilars country fiche: France 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.

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1 Summary of biosimilar policies and practice in France 2025

Key stakeholders

Major ministerial direction in charge of policy design for biosimilar are the general direction for Health and the social security directorate (regarding economic x. They are in charge of the drafting of the laws (including the social security budget law) before their adoption by the parlement and their implementation through regulatory texts publication (decrees and orders) The DSS and DGS have respectively a ministerial supervision of the CNAM and the ANSM. Major stakeholders in the public sector are the Medicines Agency (Agence nationale de sécurité du médicament et des produits de santé ANSM), which draws the list of the biological substances (reference products and their biosimilars) and issues statement on the conditions of substitution for selected biological substances, and the Social Insurance, represented by the national social insurance fund (Caisse Nationale d'Assurance Maladie / CNAM). The latter has been implementing measures to encourage the uptake of biosimilar medicines, such as prescribing quota (also for biosimilars) and gain-sharing models. Both ANSM and CNAM have been engaged in information activities targeted at health professionals and patients. In the public sector, the Pricing Committee CEPS also plays a role regarding biosimilars, as negotiator of the Framework Agreement with the pharmaceutical industry, with details on the biosimilar price link.

The biosimilar industry is represented by the same association as for the one for generics. In addition, doctors, pharmacists and patients are targeted by biosimilar policies and have also issued opinions on biosimilar policies.

Major biosimilar policies and practices

France has been implementing a range of measures to encourage the uptake of biosimilar medicines. For instance, the biosimilar price link, stipulated in the Framework Agreement between the Pricing Committee (Comité Economique des Produits de Santé / CEPS) and pharmaceutical industry association, is designed in a sophicated manner (with different reduction rates for the prices of biosimilars and the reference products, depending on market shares of biosimilar medicines). The Frence reference price system (Tarif forfaitaire de responsabilité, TFR), however, does not include biological medicines.

A special focus has been put on demand-side measures. In addition to information activities targeted at health professionals and patients, doctors are encouraged to prescribe biosimilar medicines, and to switch to biosimilars. This prescription pattern is incentivized by prescribing quota, which have been common for generics for a long time, and now also include a few biosimilars. Gain-sharing models for doctors have also been piloted. Pharmacists are allowed to substitute, under defined conditions, among biological substances; the list of biological substances (three as of end of 2024) is aimed to be constantly increased.

Impact assessment

Studies showcased the price reductions and reductions in the public expenditure due to the market entry of biosimilar medicines. However, several studies lack an analysis of underlying policies responsible for these changes.

The introduction of two different types of gain-sharing models for hospitals some years ago, quasi a natural experiment, showed that a design which redirects savings to the responsible wards (and not solely to the hospitals) was more effective in encouraging biosimilar uptake.

Barriers, facilitators and good practice examples

France has been working on extending its toolbox of biosimilar policies, particularly in the demand-side sector, to encourage biosimilar uptake. However, in the legal area, implementation was put on hold, which created some unsecurity. While official statements of associations of health providers and patients suggest a positive attitude towards biosimilars, implementation of specific measures has been met with opposition. In the hospital sector, procurers and hospital pharmacists were reported to play an important role in explaining the relevance of prescribing biosimilars to doctors.

Recent developments

Nearly a decade after adaption of the first legal framework for biosimilar substitution (however, lack of implementing acts impeded actual introduction), France permitted biosimilar substitution at pharmacy level in 2022 (initially for two biological substances in the group of growth factors). In October 2024, biosimilar substitution was extended for another substance (ranibizumab). In November 2024 the Medicines Agency (ANSM) published a statement on conditions for substitution in the biological groups of teriparatide, etanercept and adalimumab and in December 2024 a statement on conditions for substitution in the biological groups of enoxaparin, epoietin and follitropin but insulins remain out of the scope of substitution.However these substitutions ave yet to be implemented by a ministerial order (expected before the end of february 2025).

For 2025 and the future, there are plans for further extending biosimilar substitution in community pharmacy and potentially linking a refusal of a biosimilar by the patient to a co-payment.

Highlights and learnings

France appears to have a strong focus on demand-side measures to encourage the uptake of biosimilar medicines, targeted at health professionals and patients. It builds on the learnings from fostering generic uptake and uses, in some but not all cases, similar instruments, in particular financial incentives (doctors) and avoiding financial disadvantages (pharmacists).

2 Key data regarding biosimilars in France

First biosimilar medicine launched (i.e. brought on the market):
Epoetin alpha (Binocrit®) 30 July 2008 (source: Medicines for Europe 2023, Gascon et al. 2023)

Number of the **biosimilars marketed**:
20 molecules with biosimilars available, as of 10 November 2024:
Adalimumab, Etanercept, Infliximab, Follitropine alpha, Insuline glargine, Insuline asparte, Somatropine, Bevacizumab, Rituximab, Trastuzumab, Eculizumab, Teriparatide, Enoxaparine sodique, Epoétine, Tocilizumab, Ustékinumab, Natalizumab, filgrastim, pegfilgrastim et ranibizumab
70 biosimilars (per trade name), as of 10 November 2024
Source: Ameli 2024a

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

32 % **in volume** in 2023
Volume is defined as packages dispensed in the community (retail pharmacies)

42 % **in value** in 2023
Value is defined as share of reimbursable_medicines dispensed in the community (retail pharmacies) as biosimilars/(biosimilars+reference)

Please indicate the market to which the biosimilar market shares data relate to: outpatient market (dispensed in the community by community prescribers or by hospital prescribers) as (biosimilars+reference products)

Key national publicly accessible sources reporting data on biosimilars

- Number of biosimilars (substances and medicines marketed): on the Social Insurance website: latest version available at: https://www.ameli.fr/sites/default/files/Documents/memo-liste-novembre%202024.pdf and included in: https://www.ameli.fr/medecin/exercice-liberal/regles-de-prescription-et-formalites/medicaments-et-dispositifs/medicaments-biosimilaires/regles-de-prescription-et-de-delivrance (Ameli 2024a)
- List of biosimilar substances allowed to be substituted in the pharmacy: latest version available at: https://www.ameli.fr/sites/default/files/Documents/memo-liste-novembre%202024.pdf and included in: https://www.ameli.fr/medecin/exercice-liberal/regles-de-prescription-et-formalites/medicaments-et-dispositifs/medicaments-biosimilaires/regles-de-prescription-et-de-delivrance (Ameli 2024)
- List of biosimilar groups (reference medicine and biosimilars, basis for potential permission of biosimilar substances to be substituted): https://ansm.sante.fr/documents/reference/medicaments-biosimilaires (ANSM 2024a)
- Biosimilar market shares in volume since 2012, published by the ministry of health : https://evaluation.securite-sociale.fr/home/maladie/2105-taux-de-penetration-des-bio.html

3 Stakeholders involved in and targeted by biosimilar policies in France

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Ministère des Solidarités et de la Santé / Ministry of Solidarity and Health	Prepares legislation	Budget Law for Social Security, e.g., LFSS 2024 (République Française 2023a), 2024a) Orders to allow substitution for defined biological substances: République Française 2022, 2024b
National regulatory authority	Agence nationale de sécurité du médicament et des produits de santé (ANSM) / National Agency for Safety of Medicines and Health Products	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance, publishes the list of biosimilar groups, guidance for patients, issues a statement on the conditions for substitution of some biological substances	List of biosimilar medicines (ANSM 2024a) 2022 report on biosimilars (ANSM 2022) Document on good use of biosimilars (bon-usage-medicaments-biosimilaires_has.pdf) Statement on conditions for substitution, e.g., ANSM 2024b
Pharmaceutical pricing authority	Comité Economique des Produits de Santé (CEPS) / Economic Committee of Health Products	Implements pricing legislation regarding biosimilars, negotiates medicine prices with pharmaceutical industry and the Framework Agreement	Annual report on activities of CEPS, with some details for biosimilars (latest report for 2022: CEPS 2024)
Pharmaceutical reimbursement authority	Caisse Nationale d'Assurance Maladie (CNAM) / National Social Insurance Fund	Produces prescribing guidelines for biosimilars, sets and monitors prescription quota, inciuding for biosimilars. Information for patients about biosimilars	Offers information on biosimilars, including links to HAS and ANSM documents on its website: for doctors and pharmacists (Ameli 2024a , Ameli 2024b and Ameli 2024c) and for insured (Ameli 2024d)
Procurement agency	Réseau des Acheteurs Hospitaliers (Resah) and UniHA (Union des Hôpitaux pour les Achats) assigned as national centralised purchasing bodies (CPB) for hospital procurement, additionally several regional group purchasing organisations	Involved in tenders and procurement procedures	
HTA agency / body	Haute Autorité de Santé (HAS) / French National Authority for Health	Conducts assessments for medicines, including biosimilar medicines	
National competition authority	Autorité de la concurrence France	Enforcement of the competition law, anti-trust cases	Opinion of pharmaceutical market as of 2019 (Autorité de la concurrence 2019)

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
National patent office	Institut National de la Propriété Industrielle / National Institute of Industrial Property	Granting and managing patents on biologic medicines	
Doctors	*Represented by:* Conseil National de l'Ordre des Médecins (CNOM) *Medical societies*: Société Francophone du Diabète (SFD) / Francophone Diabetes Society Société Française de Gastro-Entérologie (SNFGE) / French Society of Gastroenterology Société Française d'Hématologie (SFH) / French Society of Hematology	Prescribe biosimilars and by INN. Inform patients Medical societies in disease areas whti biologics use	CNOM to oppose financial incentives for prescribing / switching to biosimilars 2022: CNOM 2022
Nurses	*Represented by:* Ordre National des Infirmiers / French National Order of Nurses		
Community pharmacists	*Represented by:* Féderation des Syndicats Pharmaceutiques de France / Federation of Pharmaceutical Unions of France Ordre National des Pharmaciens / The National Chamber of Pharmacists USPO - Union des Syndicats de pharmaciens d'officine / Trade Union of Community Pharmacists	Dispense medicines, substitute defined biological substances, inform patients	News item calling for advancing (legal framework) in biosimilar substitution: FSFP 2024
Hospital pharmacists	*Represented by:* Syndicat National des Pharmaciens Praticiens Hospitaliers et Praticiens Hospitaliers-Universitaires (SNPHPU) Syndicat national des pharmaciens des établissements publics de santé (SYNPREFH) Fédération Nationale des Syndicats d'internes en Pharmacie et en Biologie Médicale (FNSIP-BM) Ordre National des Pharmaciens / The National Chamber of Pharmacists	Support procuring medicines, inform patients / health professionals / procurers	
Patient organisations	France Assos Santé - La Voix des Usagers List patient organisations on specific diseases with focus on biologicals Fédération Française des Diabétiques (FFD) / French Diabetes Federation Association François Aupetit (AFA) / French Crohn's and Colitis Association Association Française des Hémophiles (AFH) / French Hemophilia association Ligue nationale contre le cancer / French League Against Cancer Association Française des	Any role with regard to biosimilars? Eg. Informing patients	France Assos Santè 2024

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
	Polyarthritiques et des Rhumatismes Inflammatoires Chroniques (AFPric) / French Association of Rheumatoid Arthritis and Chronic Inflammatory Rheumatism		
Conssumer organisations	Consommation, logement et cadre de vie – CLCV UFC-Que choisir	Any engagement of consumer organisations with regard to biosimilars?	
Biosimilar industry	*Represented by:* Association Générique Méme Médicament (GEMME) / Association of Generics	Produces and supplies biosimilars Further educational or promotional activities?	GEMME website
Generic industry	*Represented by:* Association Générique Méme Médicament (GEMME) / Association of Generics	Same association as for biosimilars	
Pharmaceutical industry in general	*Represented by:* Les entreprises du médicament (LEEM)	Party to Framework Agreement with CEPS, with stipulations on generic and biosimilar price link Any role with regard to biosimilars? Anti-trust cases?	Framework Agreement (CEPS and LEEM 2021)
Pharmaceutical industry for new biological medicines	*Represented by:* France Biotech Pôle de compétitivité Industries & Agro-Ressources (IAR) / French Bioeconomy Cluster		

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium), Vogler et al. 2020, Vogler, Salcher-Konrad and Habimana 2022, for documents see links in the Table

4 Biosimilar policies and practices in France 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 2025

Biosimilar price link

A **biosimilar price link** is in place.	Yes
It applies for the following situations:	For biosimilar medicines in the outpatient and inpatient sectors entering the market, with specifications for reimbursed medicines
Price reduction of the first biosimilar compared to the reference product	*Outpatient sector*: -40% compared to the reference product *Inpatient*: -30% compared to the reference product
Further Price reductions of biosimilars	*Outpatient*: further price reductions (resp -15%, -10% and -5%)) dependent on originator market shares (resp. < 40%, 40 - 60%, > 60%) after 24 and 42 months. After 60 months, prices of the reference product and biosimilars may converge. *Inpatient*: price reductions of -10% after 24 and 48 months. , it can be increased to -30% depending on the percentage difference between the observed purchase price and the price set by the CEPS. At 48 months, further reductions are possible if the highest observed purchase price is lower than or equal to 50% of the reimbursement amount.

Price reduction for the reference product	*Outpatient*: yes, -20% at the market entry of the first biosimilar. Further price reductions (resp -5%, -10% and -15%) dependent on originator market shares (resp. < 40%, 40 - 60%, > 60%) after 24 and 42 months. After 60 months, prices of the reference product and biosimilar may converge. *Inpatient*: yes, -30% % at the market entry of the first biosimilar. Further price reductions of 10% after 24 and 48 months, it can be increased to 30% depending on the percentage difference between the observed purchase price and the price set by the CEPS. At 48 months, further reductions are possible if the highest observed purchase price is lower than or equal to 50% of the reimbursement amount.
Any further specificities	Based on the Framework Agreement between the Pricing Committee CEPS and the pharmaceutical industry (CEPS and LEEM 2021), valid till 5 March 2025
Generic price link	In place: yes For generics: *Outpatient*: - 60% than originator. If the generic market share is lower than target rates set by the Framework Agreement (60% after 12 months, 65% after 18 months, 70% after 24 months), CEPS can propose a common *reimbursement rate* within the equivalent medicines groups (which include an originator and its generics) called "tarif forfaitaire de responsabilité (TFR)" (a kind of a reference price system) after 12, 18 or 24 months. Patients are reimbursed based on this reimbursement amount, and if they choose the (more expensive) originator medicine, they pay the difference out of pocket. If no TFR has been implemented within 18 months, then a price reduction of 7% is implemented. *Inpatient*: -40% lower than originator For the originator: *Outpatient*: -20%. If no TFR has been implemented within 18 months, then a price reduction of 12.5% is executed *Inpatient*: -40% upon market entry of the generics

Source: PPRI 2025, CEPS and LEEM 2021, LEEM 2024

External price referencing

External price referencing is applied for biosimilars.	YES: price in similar European countries (UK, DE, IT and ES) can be used to lower the price of drugs, among other criteria. This applies for all the drugs.
If yes, it is applied for the following situations:	Yes
Any specificities	Yes, as a supplementary policy to inform price negotiations, which are concluded for reimbursable medicines with major, important and moderate added therapeutic benefit (ASMR I, II, III) and for some minor added therapeutic benefit (ASMR IV) in the outpatient and inpatient sectors. In this case, the price must be within the "European price corridor"
External price pricing is in place for other medicines than biosimilars.	

Source: PPRI 2025, Vogler et al. 2020

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 off-patent and on-patent biological medicines
Institutional framework	Conducted by CBPs, regional group purchasing organisatoins and hospitals
Information available on procurement procedures and practices	Mainly price as a award criterion, but Most Economically Advantegeous Tenders (MEAT) have increasingly been encouraged Mainly single winner tenders but sometimes also vs. multiple-winner tenders (less for biosimilars) For biosimilars open procedures are common
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	No (apart from the medicines on the "retrocession list", this is a specific hospital reimbursement list which includes medicines which are supplied to outpatients)
Institutional framework	Not applicable
Information available on procurement procedures and practices	Not applicable
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes, mainly open procedures: Outpatient: N (apart from the medicines on the "retrocession list"

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

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	
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

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)	
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	Same reimbursement rates (15%, 30%, 65%, 100%)

Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	The process is simplified as pricing rules are well defined (internal price link)
Indicate URL of outpatient positive list	
Co-payments for biosimilars for outpatient use	Prescription fee and percentage co-payments
<u>For medicines for outpatient use in general (other medicines than biosimilars):</u> Positive list for mediicnes in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	Positive list Percentage reimbursement rates are in place Prescription fee and percentage co-payments (15%, 30%, 65%, 100%) Reimbursement rates according to the medical benefit value (resp. poor = 15%, moderate = 30%, major=65%). For Irreplaceable and expensive medicines =100%
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes, additionally to the original 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	To be authorized to be marketed in the inpatient sector, product have to be registered in the positive list for inpatient sector (shorter HAS evaluation and price negociation if applicable. The product can be included in the add on list as well (process shorten, no price negotiation) The inclusion on the hospital pharmaceutical formularies as such is similar to the other drugs (tendering)
Indicate URLs of hospital pharmaceutical formularies, if publicly accessilble	Not publicly available: might be available, not centralized
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	Hospital pharmaceutical formularies at national and facility (hospital) level No co-payments for medicines for inpatient use

Source: PPRI 2025

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 on the Avastin-Lucentis case
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	

Source: PPRI 2025, EC DG Competition 2024

Further information on anti-trust enforcement:

The French National Competition Authority (NCA) has been active in investigations of disparagement (i.e. dominant companies (denigrate) their competitors, usually new entrants, with the aim to hinder the uptake of competing products. The French NCA

pioneered the enforcement in disparagement practices with decisions against companies. In the biologics area, there is the well-known Avastin-Lucentis case related to an agreement between Hoffmann-La Roche and Novartis aiming at discouraging and limiting off-label use of Hoffmann-La Roche's oncology medicine Avastin for treatment of Age-related Macular Degeneration (AMD):

"Avastin (authorised for the treatment of tumorous diseases) and Lucentis (authorised for the treatment of eye diseases) are medicines developed by Genentech, a company which belongs to the Hoffmann-La Roche group. Genentech transferred the commercial exploitation of Lucentis to the Novartis group by way of a licensing agreement, whereas Hoffmann-La Roche markets Avastin for cancer treatments. Nonetheless, the active ingredient in both medicines being similar (though developed in different ways), Avastin was frequently used off-label (i.e. without authorisation by a medicines agency) to treat eye diseases instead of Lucentis because of its significantly lower price. […]

… the *French NCA* fined Novartis, Roche and Genentech for a total of EUR 444 million in 2020.However, the French NC Adid not find an anticompetitive agreement in this case but an abuse of collective dominant position of these three undertakings aiming at preserving the position and the price of Lucentis by curbing the off-label use of Avastin. The NCA established that Novartis disparaged Avastin, since it unjustifiably exaggerated the risks associated with its off-label use in comparison with Lucentis for the same purpose. This communication campaign targeted ophthalmologists, patient associations and the general public in order to discredit the off-label use. Moreover, the NCA found that Novartis, Roche and Genentech unduly interfered with the French healthcare authority's initiatives to encourage this off-label use by engaging in obstructive behaviour and disseminating alarmist or misleading information in this regard. In 2023, the Paris Court of Appeal annulled the NCA's decision, ruling that no anti-competitive practice had been established against the three undertakings. An appeal against this judgment is pending before the Court of Cassation." (EC DG Competition 2024).

4.4 Supportive tools and practices for policy-makers 2025

Horizon scanning

Public authorities or public payers use a horizon scanning system to identiy loss of exclusivity (patent expiry) of biologics	Yes, systematically
If yes, describe the process and the tools (e.g. regular consultation of a database, horizon scanning scoping meeting with stakeholders), including who uses horizon scanning	Companies, as part of their contractual obligations, inform the committee of upcoming patent losses

Source: PPRI 2025

Health technology assessment

HTA is applied for biosimilar medicines	Only in case of difference of presentation or indication. if the originator is registered
If yes, in which situations and settings (outpatient and inpatient)	Both
Differences in criteria and processes of HTA for biosimilars compared to other medicines	
Any specificities	The decree of August 25, 2020, stipulates that the opinion of the Transparency Commission is no longer required for generic and biosimilar drugs when the reference drug is listed on either of the reimbursement lists

Source: PPRI 2025

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Country context: Prescritpion by doctors mostly.

Other prescribers:

- Dentist: medicines needed in their area, no specific list
- Midwifes: list of medicines
- Specialized nurses (infirmiers de pratique avancée): list of medicines, depending on the speciality
- Pharmacist: list of medicines (vaccines, antibiotics with tests)

Specialized nurses are the most likely to prescribe biologics

Definitions:

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regrd to prescription of biosimilars exist	Yes
If yes, what is recommended for naïve patients?	No specific recommendation to prescribe biosimilars for naïve patients but financial incentives for prescribing biosimilars and prescribing quota for some substances
If yes, what is recommended for patients already on biologic treatment	ANSM recommends switch (since 2016) and maintains a list of the group of blological substances. Switching for economic reasons is supported by financial incentives for prescribing biosimilars (gain-sharing) and prescribing quota for one substance
Prescription guidelines (including switching guidelines) were issued by	General prescribing guidelines (both for the reference product and biosimilars) Switches (between the reference product and a biosimilar of the same biological group or among biosimilars of that group) are always possible for the doctors, while respecting three conditions: informing the patients and gaining consent, ensuring clinical monitoring, and ensuring tracabiliy of the prescribed medicine.
URL of prescription & switching guidelines	Ameli 2024a
Prescribing quota	

Prescribing quota for doctors with regard to prescription of biosimilars exist	Yes
If yes, which quota are defined for biosimilars	For the outpatient sector: A prescribing quota has been set for one biosimilar (Abasaglar, a biosimilar of insuline glargine) at least 40% in the 2022-2024 period of the target-based funding scheme ROSP (rémunération sur objectifs de santé publique) (before: it was 20%) For the inpatient sector: Tri-partite contracts between health care institution (hospital), regional health administration and Social Insurance called "Contrats d'Amélioration de la Qualité et de l'Efficience des Soins" (CAQES), which define monitoring indicators, including responsible use of medicines. Some regional CAQES contracts include targets for biosimilar prescribing. There are no longer national targets since 2022 (only at regional level)
Any exemptions	Limited to specific biosimilars
Any sanctions in case of non-achievement	No
Any (financial) incentives for achieving the quota	Yes for community prescribers (ROSP) hospital-targeting experiments of financial incentives for biosimilar prescription (CAQES, 2018-2022) (for *epoetin, etanercept, adalimumab, insulin glargine, filgrastim, pegfilgrastim)*
Prescribing quota were issued by	Social Insurance
URL of prescribing quota	ROSP: Ameli 2024e CAQES: regional contract
Prescribing quota for other non-biosimilar medicines exists	Yes, in ROSP and regional CAQES (e.g., for generics and antibiotics)
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)	In place since 1 January 2022, for outpatient doctors in relationship with the Social Insurance. Targeted active substances can change over the year, for 2024 six molecules are included: étanercept, adalimumab, follitropine alpha, énoxaparine, insuline asparte et ranibizumab. For newly prescribed biosimilars of the included active substances (either for naïve patients or after biosimilar substitution, see below), doctors will receive a share of the savings achieved: 30% in 2022, 20% in 2023, 10% in 2024 (except 30% for ranibizumab as it was included later, in july 2023). In 2025, gain sharing is set for only one year at 50% so far for: ranibizumab, tocilizumab, ustekinumab To note. In earlier times, there were also gain-sharing models experimentation in the inpatient sector (2018-2022, known as "art 51 experimentation), for an evaluation see Section 5.
Publicly accessible information	Yes: Ameli 2024a and Ameli 2024b
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 only (always prescription by INN and by trade name)
Further measures targeted at doctors	
Information materials for doctors	Yes, at the website of the Social Insurance: https://www.ameli.fr/medecin/exercice-liberal/facturation-remuneration/dispositif-interessement-prescription-biosimilaires E.g., a leaflet arguing why it is important to talk to patients about biosimilars, supporting fiches for doctors on the prescription of medicines with biosimilars (Etanerept, Adalimumab, Énoxaparine, Insulin aspart, Follitropine alpha) and a video on how to integrate biosimilar prescribing in daily practice)
Information events for doctors (e.g., seminars, trainings)	No
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	

Source: PPRI 2025, Ameli 2025a, Ameli 2025b, Ameli 2024e, CEPS 2025, Vogler et al. 2025, Jourdain et al. 2022

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense.

Substitution policies	
(Automatic) substitution for biosimilars	Yes, indicative
If yes, for wich biologic substances and under which prerequisites?	Only allowed for defined substances (currently 3 biological substances: filgrastim, pegfilgrastim and ranibizumab) and only within the group of the same active substance and if the doctor has not excluded the possibility for biosimilar substitution (this has to be mentioned on the prescription, requires a justification). The doctor must inform the patient about the possibility of substtution in the pharmacy; the pharmacists must indicate on the prescription the name of the dispensed medicine (to avoid confusion) and must inform the prescriber and the patient about the substitution.
If yes, since when, and when was it extended? (process of implementation)	Since 12 April 2022 (for two substances: filgrastim and Pegfilgrastim), extended to a third biological substance (ranibizumab) on 31 October 2024 The list of biologics a pharmacist can substitue is to be extended automatically as the Social security financial law for 2024 has introduced a provision aimed at encouraging the substitution of biosimilar drugs (LFSS 2024, art 54). This provision stipulates that two years after the first biosimilar of a reference group (including originators and their biosimilars) is listed for reimbursement, pharmacists will be allowed to substitute within that group, unless the national regulator (ANSM) issues a contrary opinion before the end of this two-year period.
Any specificities	France has a long history of introduction of biosimilar substitution. Already from 2014, the legal framework for the introduction of biosimilar substitution existed, however, the required implementing order detailing specific provisions was never passed, so that biosimilar substitution could not enter into force. The Social Security Law of 2020 abolished biosimilar substitution completely, before it was then allowed in 2022.

URL of underlying law	Arrêté du 12 avril 2022 : https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000045571129 Arrêté du 31 octobre 2024 : https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000050429728 Loi de Financement de la Sécurité sociale pour 2024 (art.54) : https://www.legifrance.gouv.fr/loda/article_lc/LEGIARTI000048670522
Generic substitution in place	Yes, indicative
Gain-sharing models	
Gain-sharing models for pharmacists	No gain-sharing model but equal remuneration for community pharmacists when they dispense biosimilars (instead of the originator biological) Arrêté du 5 juillet 2024 : https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000049892254 Further incentives measures in 2024 only: 100€ for at least one substitution (biosimilar or hybrid), First amendment Further incentives are to be defined in 2025 (ROSP, rémunération sur objectif de santé publique, remuneration based on public health objectives)
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	To prevent financial advantage to pharmacies for dispensing biosimilars (lower mark-up due to its reference on the price of the medicine), the pharmacist receives the same amount of money as mark-up when substituting for a biosimilar (where allowed) as if s/he had dispensed originator reference product (mark-up is calculated based on the price of the originator).
Publicly accessible information	Yes, for those biological substances for which buiosimilar substitution will be allowed also the mark-up will be adapted in law
Further measures targeted at pharmacists	
Information materials for pharmacists	Yes, information on the national health insurance website : https://www.ameli.fr/paris/pharmacien/exercice-professionnel/delivrance-produits-sante/regles-delivrance-prise-charge/medicaments-biosimilaires
Information events for pharmacists (e.g., seminars, trainings)	No

Source: PPRI 2025, Ameli 2025a, 5**,** Vogler et al. 2021 and Autorité de la concurrence 2019 (for the history of biosimilar substitution)

Patients

Information and educational measures	
Information materials for patients	Yes, mainly provided by the Social Assurance and Medicines Agency
If yes, provide URL of most common materials	See website of Social Insurance: https://www.ameli.fr/assure/sante/medicaments/comprendre-les-differents-medicaments/connaitre-medicaments-biosimilaires (Ameli 2024d) Offering: https://www.ameli.fr/sites/default/files/Documents/flyer-patient-medicaments-biosimilaires.pdf and https://www.ameli.fr/sites/default/files/Documents/725799/document/bon-usage-medicaments-biosimilaires_has.pdf
If yes, key producers of education measures	Social Assurance and Medicines Agency, also with reference to information materials produced at EU level
Information events for paitents (e.g., seminars, trainings)	Not at the national health insurance level
If yes, key providers of educational events	

Gain-sharing models	
Gain-sharing models for patients	No
If yes, pls. describe	
Publicly accessible information	

Source: PPRI 2025 Ameli 2025d

5 Impact of biosimilar policies and practices in France

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 France

Outcome indicator	Caused by	Findings	Publication
Savings for public payers	No specific policy identified but mix of policies (lower prices due to lower development costs and competition) mentioned	Potential savings for the social insurance are estimated to amount: 6.36 mio. € annually in case of 40% market share of d'Abasaglar (insulin glargine biosimilar) and 6.7 million € for one year in case of treating 50% of new naive patients with an etanercept biosimilar, and 35 million € for two years if 30% for all patients (naive and switched) were treated with an etanercept biosimilar.	Ameli 2024d
Savings for public payers	Competition due to availability of adalimumab (no specifici policy mentioned)	Decreases in adalimumab expenditure from Q4/2018 – Q4/2019, where adalimumab consumption rather stayed the same	Woo et al. 2024
Savings for public payers		Potential savings for the social insurance were estimated to amount 100 millions if the biosimilar market share reaches 80% (in volume)	Assurance Maladie. Améliorer la qualité du système de santé et maîtriser les dépenses : les propositions de l'Assurance Maladie pour 2023. Juillet 2022.
Higher biosimilar uptake (prescribing)		Biosimilar uptake in the hospital setting (adalimumab and etanercept treating rheumatoid arthritis)	Assurance Maladie. Améliorer la qualité du système de santé et maîtriser les dépenses : les propositions de l'Assurance Maladie pour 2023. Juillet 2022. (p.337)
Savings for public payers	Hospital tender by a large hospital group	Upon market entry of infliximab, an infliximab biosimilar won the tender of a large hospital group in Paris, leading to a price reduction of 45% compared to the originator biological (approximately 6 million € savings for the hospital gain). However, the originator biological are also used for those patients whose treatment had also been initiated (a switch was not allowed at that time), and the hospital group re-negotiated the originator infliximab price, resulting more than 1 million € savings	Bocquet and Paubel 2016
Higher biosimilar uptake (prescribing)	Gain-sharing models of different designs (for etanercept)	Gain-sharing models for hospitals on biosimilar prescribing resulted in higher biosimilar prescribing. An evaluation showed that one of the models, which redirected savings to the wards which were responsible for the biosimilar prescribing, instead of offering the savings of the hospitals in general had higher impacts	Tano et al. 2023
Higher biosimilar uptake (prescribing)	Gain-sharing model for insulin glargine and etancerpt	Another evaluation of a gain-sharing model for hospital prescribing of medicines (insulin glargine and etanercept) supplied in community pharmacies. Increase in biosimilar uptake for insulin glargine (+6.0 percentage points) and etanercept (+10.8 ppt) between October 2018 and September 2021. Savings for the public sector were considered rather	Attia et al. 2024 https://sante.gouv.fr/IMG/pdf/biosimilaires-rapport-final-partie-quantitative-2.pdf

Outcome indicator	Caused by	Findings	Publication
		minor (0.5% for insulin glargine, 0.1% for etanercept).	
Biosimilar uptake	No specific policy identified (reference of individual hospital negotiations, competition due to biosimilar market entry)	Analysis for three biological substances (etanercept, infliximab, adalimumab) in France showed increases in biosimilar uptake (and decreases in the market shares of the reference products) and price reduction of the reference products following the market entry of the biosimilars	Robinson and Jarron 2021s
Biosimilar uptake	No specific policy studied but considered in discussion	Biosimilar uptake among TNF-alpha inhibitors showed considerable differences (immediately upon market entry and over time), with higher and faster uptake rate for infliximab compared to etanercept and adalimumab. A potential explanation could be infliximab's hospital use, where hospital procurement may favour procuring of biosimilar. Adalimumab may still have benefited from experiences of previous biosimilars.	Jourdain et al. 2022

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

6 Barriers to biosimilar uptake and policy implementation in France

Legal barriers

France set the legal framework for biosimiar substitution rather early (in 2014). However, actual implementation was delayed for eight years, because implementing orders needed were not passed (Autorité de la concurrence 2019). This created uncertainty, and the current implementation is still rather complex. In a survey with pharmacists some years ago, pharmacists themselves expressed hesitancy about substitution, and this was partially explained by the legal uncertainty (Beck et al. 2017).

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

Different regulation framework between the outpatient and the inpatient sector.

Higher uptakes in the inpatient sector could be explained by the procurement through tendering and improved uptakes for naïve patients (mainly treated in the hospital setting), *see Cnam annual report Assurance Maladie, Améliorer la qualité du système de santé et maîtriser les dépenses : les propositions de l'Assurance Maladie pour 2023. Juillet 2022 (p.337).*

Evidence and communication-related barriers

There were indications that general practitioners had more limited knowledge on biosimilars than specialists (such as gastroenterologists in the case of infliximab) but served as major information source for patients and thus somewhat contributed to their reluctance towards biosimilars (Haghnejad et al. 2020).

Policy-related barriers

In France, prescribing of biologicals by the International Non-proprietary Name (INN) is not allowed. This also means that the prescriptions taken in the hospital setting (by trade name) may also impact the prescribing in the outpatient setting (Vogler, Sacher-Konrad and Habimana 2022).

In hospital procurement, through direct negotiations, the originator reference products may be purchased, and so the biosimilar may not be available (Vogler, Sacher-Konrad and Habimana 2022; Kim et al. 2020).

In the outpatient sector, originator is reimbursed at an higher level than the biosimilar even if the substitution is allowed.

Stakeholder related barriers

Hesitance of prescribers to switch to biosimilar medicines may exist. However, it was reported from the hospital sector that with good explanations of the Pharmaceutical and Therapeutics Commitees hospital clinicians could be motivated rather easily to switch. But doctors in the outpatient sector are considered to be less frequent to switch. This is an issue for those biological medications which may be started during a hospital stay but continued long-term in the outpatient sector (e.g., infliximab). It was reported that procurers and hospital pharmacists aim to encourage hospital clinicians to ensure that the patient receives at discharge the medicine (e.g., a biosimilar) which shall also be used in the long run (Vogler, Sacher-Konrad and Habimana 2022).

Doctors have expressed their reluctance towards gain-sharing models, since they want to take prescribing decisions without any monetary considerations (CNOM 2022).

Patients have limited knowledge about biosimilars and are reluctant towards biosimilar use (Frantzen et al. 2019). There might be less trust in substitution by pharmacists than in switches (or prescriptions) by doctors. A communication of a patient organisation on potential plans for progressing with biosimilar substitution and linking refusal of the patient to a co-pay for the reference product, argued by expressing preference tp the concept of interchangeability over substitution, which, they argued, should be introduced progressively, and announced opposition of patients in case of introduction of this measure (France Assos Santè 2024). A survey among rheumatologists (however some years ago) pointed to limited experience with biosimilars, and while these specialists were positive towards initiating treatment of naïve patients with a biosimilar, most expressed a negative opinion about substitution by a pharmacist (Beck et al. 2016).

7 Facilitators and good practice examples in France

The evaluation of a gain sharing model experimentation in some hospitals (2018-2021) known as "article 51 experimentation" concluded to an increased uptake of biosimilar, but with limited savings for the NHS (Attia et al. 2024) and therefore hasn't been extended.

Some switching studies were conducted in France (e.g., on TNF alpha inhibitors) and demonstrated no difference in safety (Meyer et al. 2019, Jourdain et al. 2023, Jourdain et al. 2024).

Switching has been recommended, and incentives for prescribing biosimilars (both in the outpatient sector as well as in the inpatient sector) are considered supportive for promoting biosimilar uptake (Jourdain et al. 2022; Kim et al. 2020).

There is a good practice example from a large hospital group in Paris from the time of the first biosimilars for monoclonal antibodies (at that time switching was not allowed, so biosimilars could only be used for naïve patients). The Pharmaceuticals and Therapeutics Committee actively informed physicians about biosimilars, also explaining the scientific work of the European Medicines Agency, and this led to support of the prescribers for biosimilars (Bocquet and Paubel 2016).

8 Developments in France

Recent changes

After more than a decade of discussion of potential implementation of biosimilar substitution (however, lack of the implementing act), France permitted biosimilar substitution at pharmacy level in 2022 (initially for two biological substances in the group of growth factors and in October 2024, biosimilar substitution was extended to another substance (ranibizumab)). In July, the remuneration for biosimilars, for which biosimilar substitution was allowed, was changed to provide the pharmacist the same amount of pharmacy remuneration as if for dispensing the biological orginator. The pharmacy remuneration was also adapted for these substances, to offer pharmacies the same amount of the mark-up as for the reference product.

The extension of biosimilar substitution is also linked to a new provision (Art. 54) in the 2024 Social Security Financial Law: It says that two years after the first biosimilar of a reference group (which includes the originator biological and its biosimilars) has been listed for reimbursement, pharmacists will be allowed to substitute within that group, unless the Medicines Agency ANSM has issued a contrary opinion before the end of this two-year period. For biosimilars that have been reimbursed (already before January 2024), the Medicines Agency (ANSM) published a statement on conditions for substitution in the biological groups of teriparatide, etanercept and adalimumab (Ameli 2024a, ANSM 2024b. FSFP 2024), and in December 2024 a statement on conditions for substitution in the biological groups of enoxaparin, epoietin and follitropin but insulins remain out of the scope of substitution.

Plans or under discussion

The Framework Agreement between the Pricing Committee and the pharmaceutical industry, which specifies the details of the biosimilar price link, was concluded for the period of 2021 till March 2024. It was prolonged till March 2025.

The draft Financial Social Security Law 2025 included plans to request co-payments for the reference products if patients refuse biosimilar substitution (France Assos Santè 2024). Due to political instability, the financial Social Security law for 2025 hasn’t been acted

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