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

AUGMENT Biosimilars
Country fiche GREECE

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augment biosimilars

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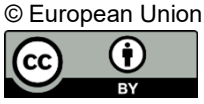

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Annex 7.12

AUGMENT Biosimilars country fiche: Greece 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:

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1 Summary of biosimilar policies and practice in Greece 2025

Key stakeholders

In Greece, the Greek Ministry of Health (Υπουργείο Υγείας), the Greek Medicines Agency (National Organization for Medicines / EOF) and the National Organization for Healthcare Services Provision (Ε.Ο.Π.Υ.Υ) are the main public institutions regulating and implementing policies regarding biosimilars.

Major biosimilar policies and practices

Biosimilar prices are set based on external reference pricing, which takes into account the average of the lowest two prices within a basket of 19 Eurozone countries. While there is generic price link, no such policy (i.e., setting the prices of the off-patent medicines based on the originator products) is applied for biosimilars. HTA is conducted for biosimilars but is based on shorter procedures compared to HTA for other medicines. In Greece there are prescribing quotas for biosimilars, and physicians operate under prescription budgets, which, while is not exclusive to biosimilars, influence prescribing behaviour. Medicines, including biologicals, must be prescribed under International Non-Proprietary Name (INN), and exemptions, i.e. prescribing by trade name, are only allowed on an exceptional basis, must be duly justified and may not exceed 15% of all annual prescriptions for a doctor. Biosimilars are included in the (internal) reference price system, but biosimilar substitution is not permitted. The prescribing quota of 15% in the e-prescription system is for all medicines, including biosimilars and e-prescription does not differentiate between the public and the private sector.

Impact assessment

There were a few studies which analysed biosimilar uptake and implications for public spending: For instance, biosimilar market entry was found to reduce the acquisition cost of adalimumab of 39% on average. Annual relative cost reduction resulting from use of newly marketed biosimilar adalimumab vs. originator was 53.5%.

Following extensive changes in the legislation after 2009 (INN prescribing; **bioequivalence reports of generic drugs conducted by the Hellenic Medicines Organization (EOF); price linkage for generics (**65% of originator**)**; financial incentives to producers to remove claw-back in case of R&D investment.), a sustained and steady increase in the use of generic medicines, including biosimilars has been observed from 2010 to 2022, and the total consumption reached 32.6%, with an increase rate of 8.5% during 2022. These evidence for savings for the public payer relate to both for generic and biosimilar penetration but the individual effect for generic, or biosimilar use, respectively, could not be disentangled.

No study could be identified which investigated the impact of specific biosimilar policies, or a mix of policies, on biosimilar uptake and savings.

Barriers, facilitators and good practice examples

A key barrier to biosimilar uptake is the reluctance of physicians, including those working on diseases with biologic therapy, such as rheumatologists, towards measures to encourage biosimilar uptake, such as INN prescribing (in place, including for biologics) and substitution (not allowed for biologics). Some doctors even oppose starting a biologic therapy for therapy-naive patients with biosimilars. The Greek Rheumatology Society had some concerns about the safety of biosimilars (which motivate their reluctance towards switching and even starting a therapy on biosimilars), and thus they urge for a register.

A facilitator is the INN prescribing, which is allowed even for biologicals highlighting concerns about automatic substitution. Switching is generally allowed under physician's supervision. Physicians and patients can opt out

Prescription budgets for physicians is a good practice example for stimulating biosimilars prescribing due to their low cost.

Recent developments

No recent developments with regard to biosimilar policies were identified. Financial investments in new pharmaceuticals production facilities, including for biosimilars, have been observed in some Greek regions as a reaction to the governmental policy to exempt companies from the claw back in case of investment in R&D. These might positively influence biosimilar market.

Highlights and learnings

Greece has been implementing several demand-side measures, particularly targeting prescribers, to encourage prescribing of biosimilars. Data on the impact of these measures appear to be missing for biosimilars. However, anecdotal evidence points to hesitancy and reluctance of prescribers, and also patients, towards biosimilars. On the supply side, fast-track and simplified HTA processes support an uptake on biosimilars. Prices of generics are linked to prices of the originators, but this policy is not applicable for biosimilars.

2 Key data regarding biosimilars in Greece

First biosimilar medicine launched (i.e. brought on the market):
Binocrit (epoetin alfa) has a price from 23rd of December, 2011

Inflectra (infliximab): 30rd of December, 2014

Zarzio (filgrastim): 23rd of December, 2011

Source: Medicines for Europe 2023

Number of the biosimilars marketed:

14 molecules with biosimilars available, as of 2023 published data

Source: Medicines for Europe 2023

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

75% **in volume** in 2025 (data of February 2025)
Volume is defined as unit of biosimilars compared to the total market of reference and biosimilars products dispensed from EOPYY's pharmacies (for the active substances epoetin, follitropin alfa, teriparatide, rituximab, trastuzumab, bevacizumab, filgrastim, pegfilgrastim, etanercept, infliximab, adalimumab, ranibizumab)

73 % **in value** in 2025 (data of February 2025)
Value is defined as share of public pharmaceutical expenditure or

Please indicate the market to which the biosimilar market shares data relate to: value of biosimilars compared to the total market of reference and biosimilars products dispensed from EOPYY's pharmacies (for the active substances epoetin, follitropin alfa, teriparatide, rituximab, trastuzumab, bevacizumab, filgrastim, pegfilgrastim, etanercept, infliximab, adalimumab, ranibizumab)

Source: EOPYY's

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

Ministry of Health -Website for medicinal products- Latest positive list 27/05/2025
https://www.moh.gov.gr/articles/times-farmakwn/epitroph-aksiologhshs-kai-apozhmiwshs-farmakwn/13369-anathewrhsh-katalogoy-apozhmioymenwn-farmakwn-toy-arthroy-251-toy-n-4512-2018-opws-tropopoihthhke-me-to-arthro-24-toy-n-4633-2019

3 Stakeholders involved in and targeted by biosimilar policies in Greece

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-related publications by this stakeholder group
Legislator	Υπουργείο Υγείας / Ministry of health	Develops and enacts healthcare policies and legislation, including those pertaining to the approval, pricing, and reimbursement of biosimilars.	https://www.moh.gov.gr/articles/times-farmakwn
National regulatory authority	Εθνικός Οργανισμός Φαρμάκων (ΕΟΦ) / National Organization for Medicines	In 2013 EOF recommends prescribing both biological reference products and biosimilars with their brand-name. This, according to EOF, was in order to enable the traceability and safety of patients receiving these products. (Gabi online) In 2018 the position was changed, and Hellenic National Organization for Medicines (EOF) permits biosimilar use and switching with reference products under physician supervision and promotes proper pharmacovigilance. (EOF circular regarding biosimilar medicines)	GABI online, Editorial, Greece says no to automatic substitution of biologicals EOF: Circular regarding biosimilar medicines
Pharmaceutical pricing authority	Υπουργείο Υγείας / Ministry of health	Implements pricing legislation regarding biosimilars, decides on the prices	Greek Ministry of Health; Positive Drug List; 18/06/2015.
Pharmaceutical reimbursement authority	Εθνικός Οργανισμός Παροχής ΥπηρεσιώνΥγείας (Ε.Ο.Π.Υ.Υ.)/ National Organization for the Provision of Health Services	Decides on inclusion into reimbursement for biosimilars and their price. Produces prescribing guidelines for biosimilars for reimbursement, responsible for budget limits for prescribers. It details procedures related to approvals, reimbursements, and regulatory pathways, aiming to support patients and healthcare professionals within the national health system.	EOPYY Access Guide: outlines how patients—especially those with rare diseases—can obtain treatments like orphan drugs, biologics, and biosimilars in Greece.

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-related publications by this stakeholder group
Procurement agency	Εθνική Κεντρική Αρχή Προμηθειών Υγείας (ΕΚΑΠΥ) / National Central Authority of Health Procurements	Implementation of centralised procurement, as well as the control of consumption, pricing of the entire supply chain. The National Central Authority of Health Procurements (EKAPY) in Greece aims to improve the efficiency and transparency of public health procurement by centralizing procedures for medicines and medical supplies. Its vision includes ensuring equitable access to high-quality healthcare resources and optimizing public health expenditure.	National Central Authority of Health Procurements
HTA agency / body	Committee on the Assessment and Reimbursement of Medicinal Products for Human Use (so called "HTA Committee") within Εθνικός Οργανισμός Φαρμάκων (EOF) / National Organization for Medicines	Conduct simplified Health Technology Assessments (HTA) for biosimilars to facilitate market entry.	Stamouli M, Kaló Z, Linari S, Tesar T, Vella Bonanno P, Gulácsi L, et al. Pharmaceutical access in eight European countries: A comparison of time to pricing and reimbursement. Value Health Reg Issues. 2023;38:9–15. Available from: https://www.valuehealthregionalissues.com/article/S2212-1099(23)00023-7/pdf
National competition authority	Hellenic Competition Commission	Enforcement of the competition law, anti-trust cases The Hellenic Competition Commission (Επιτροπή Ανταγωνισμού) has acknowledged the importance of biosimilars in promoting competition in the pharmaceutical market. In its 2023 annual report, it highlights that biosimilars contribute to price reduction and increased access to treatments, but also notes market entry barriers such as complexity and pricing rules.	Hellenic Competition Commission: Annual Report 2023
National patent office	Οργανισμός Βιομηχανικής Ιδιοκτησίας / Hellenic Industrial Property Organisation	Granting and managing patents on biologic medicines	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-related publications by this stakeholder group
Doctors	ΠΑΝΕΛΛΗΝΙΟΣΙΑΤΡΙΚΟΣ ΣΥΛΛΟΓΟΣ (PIS) Panhellenic medical association	Prescribe medicines including biosimilars. All biologics (reference and biosimilars) must be prescribed with their brand names, and not with the International Non-proprietary Name. The Greek Rheumatology Society and Professional Association of Greek Rheumatologists published a position paper in 2018 outlining recommendations for biosimilar use, including prescribing by brand name and considerations for switching, but according to **EOPYY's** data penetration of biosimilars for products dispensed by EOPYY's pharmacies is currently high	Hellenic Society for the Study and Education of Biosimilars: Statement on the use of biosimilars in clinical practice Greek Rheumatology Society and Professional Association of Greek Rheumatologists: Position statement on the use of biosimilars
Nurses	*Represented by:* ΕθνικόΣυμβούλιοΝοσηλευτώνΕλλάδας (ΕΣΝΕ) / Hellenic Regulatory Body of Nurses		
Community pharmacists	*Represented by:* Πανελλήνιος Φαρμακευτικός Σύλλογος (PFS) Panhellenic Association of Pharmacists	Dispense medicines, inform patients The promotion, defense, and improvement of the professional, financial, scientific and social interests of its members in Greece and abroad.	Organized: 5th BBBB Conference, 26-28 Σεπτεμβρίου 2013, Αθήνα (with comments on biosimilar)
Hospital pharmacists	*Represented by:* Πανελλήνια Ένωση Φαρμακοποιών Νοσηλευτικών Ιδρυμάτων. Panhellenic Association of Hospital Pharmacists	Support procuring medicines, inform patients / health professionals / procurers	Co-Organized: 5th BBBB Conference, 26-28 Σεπτεμβρίου 2013, Αθήνα (with comments on biosimilar) Although biosimilars were listed among the conference topics, the abstracts available do not include discussions or presentations on this subject.
Patient organisations	*Represented by:* Etnikos Opranismos Dнmosias yreias (EODY) / Greek Patients Association	Advocate for patient access to safe and effective biosimilar treatments.	
Panhellenic Federation of Associations of Patients, Parents, Guardians and Friends of children with rheumatic diseases	RHEUMAZIN	Advocacy, patient education, patients' summits	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Biosimilar-related publications by this stakeholder group
Biosimilar industry	*Represented by:* Πανελλήνια Ένωση Φαρμακοβιομηχανίας / Panhellenic Union of Pharmaceutical Industries (PEF)	Produces and supplies biosimilars The Panhellenic Union of Pharmaceutical Industries (PEF) promotes pharmaceutical research to position Greece as a hub for innovation and ensures medicine availability by operating 42 production facilities at full capacity.	Greece's leap in advancing pharmaceutical research Greek pharma sector faces challenges amid drug shortages
Pharmaceutical industry in general	*Represented by:* Σύνδεσμος Φαρμακευτικών Επιχειρήσεων Ελλάδος (ΣΦΕΕ) / Hellenic Association of Pharmaceutical Companies	Represents pharmaceutical companies operating in Greece, including those involved with biosimilars. Engages in policy discussions and advocacy related to the pharmaceutical industry.	
Pharmaceutical industry for new biological medicines	Hellenic Bio Cluster (Hbio)	Supports the development and innovation of new biological medicines, which may include biosimilars.	

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

4 Biosimilar policies and practices in Greece

Below, information on different biosimilar policies and practices is provided (and in some cases, also on further medicines, e.g., on generics or other biosimilars – presented in the grey shaded lines in the tables). 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.	No
It applies for the following situations:	
Price reduction of the first biosimilar compared to the reference product	No
Price reduction of the second, third and further biosimilars	
Price reduction for the reference product	No
Any further specificities	To receive reimbursement status without negotiations, a biosimilar medicine needs to be priced below the original price
Generic price link	Yes, generic medicine price must be 35% lower than the originator price

Source: PPRI 2025, Vogler et al. 2024, Medicines for Europe – Biosimilar Medicines Group, 2023

External price referencing

External price referencing is applied for biosimilars.	Yes
If yes, it is applied for the following situations:	For biosimilar medicines in the outpatient and inpatient sectors entering the market
Any specificities	The average of the lowest two prices within a basket of 19 Eurozone countries.
External price referencing is in place for other medicines than biosimilars.	Yes, namely for new monopoly medicines (but external price referencing is NOT in place for generics)

Source: PPRI 2025, Medicines for Europe – Biosimilar Medicines Group, 2023

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	Several off-patent biological medicines. Tendering is based on active substances
Institutional framework	Conducted by the National Central Authority of Health Procurements (EKAPY) but also on hospital level
Information available on procurement procedures and practices	Multiple-winner tenders with different ratio of participation. In Greece, it is mandatory to use the e-procurement system for any open procedure, negotiated procedure or restricted procedure with a value exceeding 60,000 euros. The tendering is by active substances. Public contracts may be awarded on the basis of the MEAT criterion, which can be identified either on the price or cost, or on the basis of the best price-quality ratio. The average contract duration of the tender is 30 months. The winning price is transparent for competitors. As a result of the tender the minimum volume is agreed, with the transparent price for the competitors. The three lowest bidders are awarded with percentages of 50%, 30% and 20% respectively of tender volume. Quality criteria for suppliers and the lowest price are applied as a main award criteria.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	No
Institutional framework	
Information available on procurementprocedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes Outpatient: No

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Vogler et al. 2023, Medicines for Europe 2023

4.2 Reimbursement policies 2025

Reference price system

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	Yes
If yes, how many and under which specifications	Biosimilar medicines are included in internal reference price system for reimbursement purposes. The internal reference price is based on the lowest priced biosimilar medicine
If publicly accessible, indicate URL of RPS list	
When were first biosimilars included in the reference price system?	
Any further specificities	
In general, a reference price system is in place (for medicines other than biosimilars), and how are those medicines clustered?	Yes Broader clusters than ATC 5

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)	Internal reference price system is applied for almost all biosimilar (excluding insulins), somatropin, and enoxaparin.
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	100% reimbursement, except for enoxaparin, in the outpatient setting co-payment is applied (25%) Majority of biosimilars refer to high cost medicinal products and are provided to patients without co=payment
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	A shorter and more simplified HTA process is in place
Indicate URL of outpatient positive list	
Co-payments for biosimilars for outpatient use	Prescription fee and percentage co-payment.
<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	For medicines in general for outpatient use: - Positive list - Percentage reimbursement rates are in place - Percentage co-payment
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 (doctors are recommended to switch)
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	According to current legislation the HTA procedure for biosimilars should have finished in one month after submission. Clinical-epidemiological and budget impact are requested for submission.

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

Source: PPRI 2025, Vogler et al. 2024, Medicines for Europe 2023

4.3 Specific pricing, procurement and funding policies 2025

For defined medicines, public payers and payers have been piloting and implementing specific funding models (such conditional reimbursement, managed-entry agreements, and subscription models such as the Netflix models). Typically, these funding models apply for high-priced medicines with high uncertainties (e.g., originator biologicals) or for medicines with small populations whose uptake is aimed to be encouraged. The section provides information whether biosimilar medicines are also subject to specific funding models. Furthermore, it also looks into possible anti-trust cases.

Application of special pricing, procurement and reimbursement models for biosimilars (e.g., delinkage / subscription-model, management-entry agreements (MEA))	There are no special pricing, procurement and reimbursement models for biosimilars
Enforcement of anti-trust policies	Yes, but no cases regarding biologics were identified till mid 2025.
Specific pricing and funding (e.g., subscription models, MEAs,…) for other medicines	Predominantly financial but also some performance-based MEAs

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

Further information on specific pricing and funding policies and models:

The "claw-back" system is a mechanism that was established in Greek legislation, according to Annex 5 of the Memorandum for certain economic policy conditions of 2012. Based on the limits of the monthly/yearly expenditure, an automatic recovery system is linked to the establishment of a "closed budget" for pharmaceutical products. The amounts that each Marketing Authorization Holder (MAH) is required to pay in the case of claw-back are determined based on:

- the percentage contribution of each medicine to pharmaceutical expenditure;
- the market share of each medicine within its therapeutic category on the reimbursement list; and
- the comparative consumption of each medicine relative to the market share it held during the corresponding period of the previous year.

Claw back system applies to all medicinal products. However, specific budgets can also be applicable.

Source: Manousakis and Panopoulou 2025

Further information on anti-trust enforcement:

The Greek national competition authority imposes anticompetitive preventive measures during COVID 19 pandemic by setting the maximal prices for COVID tests in 2020. During the same time fined pharmaceutical chain of pharmacies for operating during extended working hours. No public information for antitrust enforcement measures relating to biologics and biological companies was identified.

Source: European Commission 2024

4.4 Supportive tools and practices for policy-makers 2025

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	

Source: PPRI 2025

Health technology assessment

HTA is applied for biosimilar medicines	Yes, systematically, but for a shorter and more simplified procedure
If yes, in which situations and settings (outpatient and inpatient)	For biosimilar medicines aiming to be included into the reimbursement list
Differences in criteria and processes of HTA for biosimilars compared to other medicines	
Any specificities	

Source: PPRI 2025

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Country context: Only doctors can prescribe (there is a recent legislation for midwifes however- this is not applicable in any case for biologics and biosimilars.

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 are not applicable.

If yes, what is recommended for patients already on biologic treatment	Switching is generally allowed under physician's supervision. Physicians and patients can opt out. According to a circular of EOF physicians choose the biosimilar.
Prescription guidelines (including switching guidelines) were issued by	
URL of prescription & switching guidelines	
Prescribing quotas	
Prescribing quotas for doctors with regard to prescription of biosimilars exist	Yes, physicians operate under prescription budgets, which, while is not exclusive to biosimilars, influence prescribing behaviour
If yes, which quotas are defined for biosimilars	
Any exemptions	
Any sanctions in case of non-achievement	Yes, fines could be applied.
Any (financial) incentives for achieving the quota	No
Prescribing quota were issued by	
URL of prescribing quota	
Prescribing quotas for other non-biosimilar medicines exists	Yes
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	No
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	
Publicly accessible information	
INN prescribing	
In general, prescribing by INN is in place (information not focused on biologics)	Yes (Prescription by brand name is allowed only in specific cases as an exemption from compulsory INN prescribing. Prescribing patterns of physicians are closely monitored through the Web-based application of the Electronic Governance of Social Insurance (IDIKA)
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	No exemption for biologicals from INN prescribing: biologics and biosimilars have to be prescribed by INN As stated above, in up to 15% of annual prescriptions per doctors may be written by trade name, but must be duly justified..
Further measures targeted at doctors	
Information materials for doctors	No
Information events for doctors (e.g., seminars, trainings)	No
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	No

Source: PPRI 2025, Medicines for Europe 2023, Rémuzat et al 2017

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense

Substitution policies	
(Automatic) substitution for biosimilars	No
If yes, for which biologic substances and under which prerequisites?	

If yes, since when, and when was it extended? (process of implementation)	
Any specificities	
URL of underlying law	
Generic substitution in place	Yes, mandatory
Gain-sharing models	
Gain-sharing models for pharmacists	No
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	
Publicly accessible information	No
Further measures targeted at pharmacists	
Information materials for pharmacists	No
Information events for pharmacists (e.g., seminars, trainings)	No

Source: PPRI 2025

Patients

Information and educational measures	
Information materials for patients	Not known
If yes, provide URL of most common materials	
If yes, key producers of education measures	
Information events for patients (e.g., seminars, trainings)	No by authorities
If yes, key providers of educational events	
Gain-sharing models	
Gain-sharing models for patients	No by authorities
If yes, pls. describe	
Publicly accessible information	No by authorities

Source: PPRI 2025

5 Impact of biosimilar policies and practices in Greece

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 Greece

Outcome indicator	Caused by	Findings	Publication
Savings for the public payer	No specific policy mentioned but rather biosimilar adalimumab introduction in general	Comparison of new high concentration adalimumab biosimilar entered on the market with other adalimumab products in Greece. On average 39% lower acquisition cost is found for the new product compared to acquisition cost of originator and biosimilars. Annual relative cost reduction of new biosimilar adalimumab vs. originator was 53.5%. The Total cost reduction ranging from 20.2% to 43.3% depending on the comparing biosimilar and indication.	Rigopoulos et al,.2022
Increasing rate of generic consumption (incl. biosimilars)	A group of legislative changes to overcome the financial crisis in 2009 – INN prescribing; bioequivalence reports of generic drugs conducted by the Hellenic Medicines Organization (EOF); price linkage for generics (65% of originator); financial incentives to producers to remove claw-back in case of R&D investment.	Greece was one of the bottom countries in the European ranking of generic drug use in 2010, where only 15% of the medicinal products sold were generic or biosimilar products. Following extensive changes in the legislation, a sustained and steady increase in the use of generic medicines has been observed from 2010 to 2022, and the total consumption reached 32.6%, with an increase rate of 8.5% during 2022.	Manousakis I., Panopoulou D., 2025

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 Greece

Legal barriers

Lack of knowledge and incentives for pharmacists and doctors regarding biosimilars administration.

Source: Fragkiadakis et al.2023

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

There is evidence for decreasing stakeholder hesitancy towards biosimilars after the publication of the EOF position based on EMA recommendation.

Financial barriers

No financial incentives are in place for physicians.

Evidence and communication-related barriers

There are indications for lack of successful communication between physicians, health authorities and patients with regards to biosimilars safety and cost-savings, by preserving health.

Source: Chantzaras et al. 2024

Policy-related barriers

Pricing and reimbursement processes appear to be not well aligned, resulting potentially in long time to market access, as it takes 200 days for a biosimilar medicine to receive its P&R approval from the day of application and 90 days takes for a biosimilar medicine to be available in the hospital.

Source: Medicines for Europe 2023

Stakeholder-related barriers

There is a need for education about biosimilars for patients and healthcare providers. Literature suggests that health education progamme for patients appear not to offer updated information, and it was criticised that existing programmes were developed without sufficient involvement of patients.

Source: Chantzaras et al. 2024

7 Facilitators and good practice examples in Greece

In 2018 Hellenic National Organization for Medicines (EOF) permitted switching from the reference product to biosimilars under physician supervision and promotes proper pharmacovigilance.

Prescribing budgets for physicians could be considered as a good practice example even though it does not directly target biosimilars.

8 Developments in Greece

During the latest years significant investment by mostly Greek-owned generic medicines producers in building manufacturing facilities in Greece have been observed. Investments will include biosimilars production and might contribute to better access for patients.

Manousakis I., Panopoulou D., 2025

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