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

AUGMENT Biosimilars
Country fiche ROMANIA

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

augment biosimilars

EUROPEAN COMMISSION

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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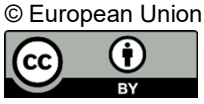

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Annex 7.26

AUGMENT Biosimilars country fiche: Romania 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:

Adrian Dumitru, Ministerul Sanatatii / Ministry of Health, Romania
Oana Ingrid Mocanu, Casei Naționale de Asigurări de Sanitate (CNAS) / National Health Insurance House
Mihaela Popescu, Agentiei Nationale a Medicamentului si a Dispozitivelor Medicale din Romania / National Agency of Medicines and Medical Devices of Romania

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1 Summary of biosimilar policies and practice in Romania 2025

Key stakeholders

Key stakeholders in Romania's biosimilar policy are the Ministry of Health, the National Medicines Agency with an HTA directorate, and the National Health Insurance Fund. Recently approved changes in the legislation regarding the biosimilar switch and transfer of patients are considered as a positive policy sign for enlarging the biosimilar market.

Major biosimilar policies and practices

Price linkage, tendering and inclusion in the national reimbursement list are among the major biosimilar policies and practices. In June 2023, in a new Framework Agreement between National Health Insurance House and healthcare providers it was stated that the initiation therapy must be done with a biosimilar. In addition, doctors have to switch 50% of their patients that receive the biological reference product to a biosimilar. For medical reasons specific to the patient, the doctor may make an exception to this rule and prescribe the reference biological product.

Impact analysis

In 2020, most of the newly launched biosimilars were included in reimbursement list. While there is evidence that patients have access to these biosimilars, there is still no evidence of cost savings from their use. The net price decreased upon the entry of a biosimilar, and changes in the volume of biologics was observed following their introduction. Notably, there was an increase in the use of certain biosimilars, such as those used in rheumatology. In the Romanian rheumatoid arthritis cohort, biosimilars appear to be more effective in maintaining remission.

Barriers, facilitators and good practice examples

INN prescribing and automatic substitution for biologicals and biosimilars is not allowed, and this creates a barrier to their wider adoption. Additionally, the request on pharmaceutical companies to provide clawbacks (also for biosimilars) is considered as financial burden for the industry and may reduce the attractiveness of the market. Physicians' cautious and potentially hesitant approach to prescribing biosimilars for patients with high disease activity in rheumatoid arthritis (RA) presents a significant barrier to their wider adoption and use in clinical settings.

The policies of price link of biosimilar to the originator price and centralised tenders may serve as facilitators but there is no evidence that these measures have resulted in higher biosimilar adoption. A significant information gap remains regarding biosimilars among the patient population.

Recent developments

In 2023, physicians were mandated to prescribe biosimilars to naïve patients and to switch 50% of their patients within one year or sooner if possible.

Highlights and learnings

The Romanian Government brought an innovator company to court for engaging in anti-trust practices aimed at slowing down competition.

2 Key data regarding biosimilars in Romania Error! Reference source not found.

First biosimilar medicine launched (i.e. brought on the market):
n.a.

Number of the **biosimilars marketed**:
16 molecules with biosimilars available, as of October 2021
71 biosimilars (per trade name), as of October 2021

Source: Sipos et al. 2021

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

0,14% **in volume** in 2024

Volume is defined as **therapeutic units dispensed**.

3,16% **in value** in 2024 as consumption value of the social health insurance system

Source: National Health Insurance House (CNAS) - Integrated Health Insurance Platform (PIAS)

Key national publicly accessible sources reporting data on biosimilars

- Ministry of Health. https://www.ms.ro/en/
- National agency for medicines and medical devices in Romania. https://www.anm.ro/en/medicamente-de-uz-uman/anunturi-importante-medicamente-de-uz-uman/
- National Health Insurance House. https://cnas.ro/medicamente/

3 Stakeholders involved in and targeted by biosimilar policies in Romania

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Ministerul Sanatatii / Ministry of Health	Prepares legislation, endorse regulations.	health technology assessment (HTA): criteria and methodology for inclusion in the list of reimbursed products in the social healthcare security system (MOH Order No. 861/2014); pricing methodology (MOH Order No. 368/2017);
National regulatory authority	Agentiei Nationale a Medicamentului si a Dispozitivelor Medicale din Romania / National Authority of Medicines and Medical Devices	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance	https://www.anm.ro/en/anunt-important-01-08-2014-2/ authorisation of medicinal products (MOH Order No. 895/2006);
Health insurance fund	Casei Naționale de Asigurări de Sanitate (CNAS) / Social Health Insurance House	National Health Insurance House (CNAS). CNAS is responsible for setting the reimbursement level and to draft the Government Decision for inclusion in the Reimbursement List (H.G. no. 720/2008). Reimburse all medicines, contract negotiations and discounts.	Government Emergency Ordinance No. 77/2011, MOH Order No. 735/976/2018; Government Decision No. 720/2008 for the approval of the list of reimbursed international non proprietary names, corresponding to the medicinal products that patients benefit from, with or without personal contribution, in the social healthcare security system.
Pharmaceutical pricing authority	Ministry of health	Implements pricing legislation regarding biosimilars, decides on the prices, approves prices	https://www.wolftheiss.com/insights/pricing-and-reimbursement-of-medicinal-products-in-cee-and-see/#Romania (Note: the information on this webpage is not official and not approved by the MoH)
Procurement agency	Agentia Nationala pentru Achizitii Publice/ National agency for public procurement	oversee the management of public investment and to ensure the quality of public spending.	Emergency Ordinance no. 13/2015

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
HTA agency / body	Department at the National Authority of Medicines and Medical Devices	Performs the HTA evaluation	There are 3 situations: 1. If there is no biological reference product in the reimbursement List, then the biosimilar must submit an application for HTA. 2. If there is already the reference product in the reimbursement List, then the biosimilar is included in the List without HTA evaluation. 3. If the biological refence product has a conditional decision and an MEA (cost-volume or cost-volume-result) is in place, then the MAH must submit an HTA application.
National competition authority	Consiliul ConcurenteiRomania/National competition authority	protecting and stimulating competition in order to ensure a normal competitive environment, with a view towards the consumers' interests	https://www.consiliulconcurentei.ro/en/
National patent office	Oficiul de Stat pentru Invenții și Mărci / State Office for Inventions and Trademarks	Granting and managing patents on biologic medicines	
Doctors	*Represented by: Colegiul Medicilor din România (CMR)/ Association of physicians in Romania*	Prescribe biosimilars a/o by INN. Inform patients Medical societies in disease areas with biologics use	https://www.cmr.ro/
Nurses	*Represented by: t*he National Association of Nurses from Romania], The Order of Nurses and Midwifes of Romania (OAMGMAMR)	No role with regard to biosimilars	Clocotici L. Asociaţia naţională a surorilor de ocrotire din România, cadru de acţiune pentru dezvoltarea şi afirmarea profesiei (partea I) [The National Association of Nurses from Romania, a framework for the development and the affirmation of the profession. II]. Viata Med Rev Inf Prof Stiint Cadrelor Medii Sanit. 1982 Oct;30(10):237-40.
Community pharmacists	*Represented by: Colegiul Farmacistilor din Romania / The Romanian College of Pharmacists*	Dispense medicines, inform patients, provide information	https://www.colegfarm.ro/noutati/accesarea-si-utilizarea-portalului-platformei-informatice
Hospital pharmacists	*Represented by: Asociatia Nationala a Farmacistilor de Spital din Romania (ANFSR) / The National Hospital Pharmacists Association of Romanian*	Support procuring medicines, inform patients / health professionals / procurers, establish of hospital pharmacy as a study field, which includes clinical pharmacy and pharmacy administration; educate hospital pharmacists; update legislation.	https://www.anfsr.ro/anfsr-presentation/

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Patient organisations	*Represented by:* COPAC - Coalition of Patients' Organisations with Chronic Diseases (Romania)	represent the patients' perspective in dialogues with the national decision-making and legislative authorities, at national and local level. COPAC's remit includes working towards improving access to information for patients with chronic diseases, and monitoring the implementation and performance of national programmes.	https://www.eu-patient.eu/Members/The-EPF-Members/Full-Membership/The-Coalition-of-Patients-Organizations-with-Chronic-Diseases-from-Romania/
Consumer organisations	Asociatia Pro Consumatori – APC (member of BEUC)	Protect consumers rights	https://www.apc-romania.ro/ro/search.html?srcstring=biosimilare&submit=%C2%A0
Generic industry	*Represented by: Asociatia Producatorilor de Medicamente Generice din Romania (APMGR) / Romanian Association of Manufacturers of Generics- Member organisation of Medicines for Europe*	Biosimilar producers are a member of the association and participate in information provision about the biosimilars production and dissemination	https://apmgr.org/despre-biosimilare/#date-generale
Pharmaceutical industry in general	*Represented by: Asociația Română a Producătorilor Internaționali de Medicamente (ARPIM) / Romanian Association of International Medicine Manufacturers)*- Member organisation of EFPIA	Comments on the lost loss exclusivity of biosimilar https://arpim.ro/?s=biosimilar	

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

4 Biosimilar policies and practices in Romania 2025

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

4.1 Pricing and procurement policies

Biosimilar price link

A **biosimilar price link** is in place.	Yes
It applies for the following situations:	
Price reduction of the first biosimilar compared to the reference product	20% (at 20% of the originator – Radu Ciprian Paul)
Price reduction of the second, third and further biosimilars	There is only a percentage of 20% lower that the reference product.
Price reduction for the reference product	The reference pruduct must reduce the price with 20% following the next price revision.
Any further specificities	
Generic price link	Yes, the price of the first generic is set at 35% lower than the reference product.

Source: PPRI 2025, Vogler et al. 2025; Radu et al. 2018

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 sector entering the market
Any specificities	Basket of 12 reference countries, lowest price is taken in consideration
External price referencing is in place for other medicines than biosimilars.	Yes, for all prescription-only medicines, both in inpatient and outpatient sector

Source: PPRI 2025; Radu et al. 2018

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 hospitals, National Agency for Public Procurement (ANAP), and the Ministry of Health
Information available on procurement procedures and practices	Award criteria include Price, Environmental factors, Security of supply, since in some cases the Most Economically Advantageous Tender (MEAT) award criteria is applied
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	No scope. The reference reimbursed price for community pharmacies is already settled by the CNAS.
Institutional framework	
Information available on procurement procedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes Outpatient:

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

4.2 Reimbursement policies

Reference price system

Biosimilars are included into the reference price system (RPS) applied in the outpatient sector.	Yes
If yes, how many and under which specifications	Yes, there are 6 sub-lists - sub-list A=90% public reimbursement of the reference price; Sub-list B=50% public reimbursement of the reference price •Sub-lists C (C1, C2, and C3) =100% public reimbursement of the reference price •Sub-list D=20% public reimbursement of the reference price; Sub –list E= 50% or 100% reimbursement of the reference price
If publicly accessible, indicate URL of RPS list	http://www.cnas.ro/category/lista-medicamentelor.html
When were first biosimilars included in the reference price system?	n/a

Any further specificities	The public stakeholders involved in the introduction, moving, or delisting of a medicine at INN level within the reimbursement list are the National Drug Agency through the HTA Unit, the MoH, and the Specialty Commission of the MoH
In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are 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)	Yes, there are 6 sub-lists - sub-list A=90%publicreimbursement of the reference price; Sub-list B=50%publicreimbursement of the reference price •Sub-lists C (C1,C2, andC3) =100% public reimbursement of the reference price •Sub-list D=20% public reimbursement of the reference price Sub-list E=50% or 100% reimbursement of the reference price
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	The extent to reimbursement rates applicable to biosimilars is 100%, 90%, 50%.
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	There is no difference between the inclusion in reimbursement of biosimilars and generics.
Indicate URL of outpatient positive list	
Co-payments for biosimilars for outpatient use	If the reference price calculated per therapeutic unit is lower than the retail price per therapeutic unit, the insured person bears the difference (out-of-pocket 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 (100% for essential medicines for chronic conditions and life-threatening diseases, 90% for medicines for severe conditions that require long-term treatment, and 50% for medicines for less severe conditions or those that are considered supplementary. - Percentage co-payments
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
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	No.
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	No
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, Ministry of Health Order No. 861/2014 regarding the approval of criteria for evaluation of medical technologies, the documents to be submitted by solicitants, the process and the methodology used to assess the drugs and the new indications to be included on the list, and the criteria for exclusion of drugs from the list, published in Romanian Official Gazette No. 557/28.07.2014

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))	There is a clawback applicable also for biosimilars. The clawback tax could potentially distort competition, as the percentage of the tax is calculated based on the growth of the market, as opposed to that of each relevant company (the actual contribution being calculated by applying that percentage to the revenues from reimbursed medicines of each MAH). The matter has also attracted criticism from the EU Commission with respect to one of the criteria used for applying different tax levels. The clawback tax is already differentiated from Q3 2023. Biosimilar drugs -15% compared to 25% for innovative drugs under patent protection.
Enforcement of anti-trust policies	2 trials and penalties to Roche for strategies to delay the market of biosimilar molecules and creation of barriers to market entry, with foreclosing effects, hindering the prescription of biosimilar products and placing an additional financial burden on healthcare reimbursement budget, the Roche product being reimbursed at a higher level than the biosimilar. In January 2020, the Romanian Competition Authority fined Roche Romania €3.4 million for abusively implementing a strategy to prevent sales of cheaper alternatives to Erlotinib. During 2017, Roche's practice was manifested in the context of participating in the centralized public procurement for medicines containing the substances Rituximab and Trastuzumab, within the national oncology program, as well as in 47 tenders organized at hospital level for the supply with the same medicines. Roche eliminated its competition in tenders, because the distributors were not able to participate in these procedures under reasonable conditions, which would ensure them to carry out their activity effectively (profitably). At the same time, this strategy was motivated by the intention to delay and hinder market access of similar variants competing with Roche products, containing the substances Rituximab and Trastuzumab (Mabthera and Herceptin). For this practice, Roche was fined with 44,168,105 lei (9.47 million Euro).
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Mix of financial and performance-based MEAs

Source: PPRI 2025; Radu et al. 2018; Bondoc & Asociatii 2025, Consiliul concurentei, 2020

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	

Source: PPRI 2025

Health technology assessment

HTA is applied for biosimilar medicines	Yes
If yes, in which situations and settings (outpatient and inpatient)	outpatient and inpatient For biosimilar medicines aiming to be included into the reimbursement list there are 3 situations: 1. If there is no biological reference product in the reimbursement List, then the biosimilar must submit an aplication for hta. 2. If there is already the reference product in the reimbursement List, then the biosimilar is included in the List without hta evaluation. 3. If the biological refence product has a conditional decision and a MEA (cost-volume or cost-volume-result) is in place, then the MAH must submit an HTA application.
Differences in criteria and processes of HTA for biosimilars compared to other medicines	If there is no biological reference product in the reimbursement List, then the biosimilar must submit an aplication for HTA. If the biological refence product has a conditional decision and a MEA (cost-volume or cost-volume-result) is in place, then the MAH must submit an HTA application. – but the evaluation only counts the price.
Any specificities	

Source: PPRI 2025

4.5 Demand-side measures

Doctors (and further prescribers)

Country context: Only doctors may prescribe

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes
If yes, what is recommended for naïve patients?	Recommendation to prescribe biosimilars for naïve patients. Except in patient-specific medical situations when the physician may recommend the reference biologic
If yes, what is recommended for patients already on biologic treatment	Recommendation that doctors should consider switching within 12 months after a biosimilar medicine was added to the reimbursement (reference price) list (according to a 2023 framework)
Prescription guidelines (including switching guidelines) were issued by	
URL of prescription & switching guidelines	

Prescribing quota	
Prescribing quota for doctors with regard to prescription of biosimilars exist	Yes, according to a 2023 Framework doctors should prescribe biosimilars (either to naïve patients or switching within 12 months after a biosimilar was included in the reimbursement list) to at least 50% of patients
If yes, which quota are defined for biosimilars	
Any exemptions	
Any sanctions in case of non-achievement	No. Only one guide document on interchangeable prescribing of biosimilars.
Any (financial) incentives for achieving the quota	No at this moment
Prescribing quota were issued by	
URL of prescribing quota	
Prescribing quota for other non-biosimilar medicines exists	Physicians are recommended to prescribe biosimilars to at least 50% of patients
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	No
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 may not be prescribed by INN
Further measures targeted at doctors	
Information materials for doctors	Guidance document on interchangeable prescribing of biosimilars issued by CNAS
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

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense / pharmacists and in a few cases also other health professionals 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, indicative
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	No
If yes, provide URL of most common materials	
If yes, key producers of education measures	
Information events for patients (e.g., seminars, trainings)	No
If yes, key providers of educational events	
Gain-sharing models	
Gain-sharing models for patients	No
If yes, pls. describe	
Publicly accessible information	No

Source: -

5 Impact of biosimilar policies and practices in Romania

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 Romania

Outcome indicator	Caused by	Findings	Publication
Savings for the public payer	Budget impact analysis of interchanging between originator and biosimilar	Total cost savings achieved if interchanging between originator infliximab and biosimilar infliximab was allowed from 6 months after the initiation of the treatment in 80% of the patients over the 3 years were estimated to €8.0 and 16.9 million, respectively, in the CEE countries, namely Bulgaria, the Czech Republic, Hungary, Poland, Romania, and Slovakia	Brodszky et al. 2016
Therapeutic efficacy and patient safety	Non-medical switch	53 patients with inflammatory bowel disease (IBD) were switched from the original Adalimumab to a biosimilar based on the recommendation of the National Insurance House. Six and twelve months after the switch, there were no significant differences observed in fecal calprotectin (FC) and C-reactive protein (CRP) levels. Only one patient needed a change in their biological treatment due to a clinical and biological loss of response.	Spataru et al. 2024
Net price reduction	Competitor entrance	Net price reduction from average price of the countries in scope 1 year before first biosimilar entry for insulin glargine	IQVIA 2020
More patients treated	Competitor entrance	Change in biologic volume since biosimilar entry for insulin glargine	IQVIA 2020
More patients treated	No specific policy mentioned	Romanian Registry of Rheumatic Diseases (RRBR) RRBR data from 2022 confirm the market rise of biosimilars in RA, but also physicians' prudence in prescribing them to highly active cases. In the Romanian RA cohort, biosimilars are overall more effective in holding remission than originators	Popoviciu et al. 2023
More treatment options in the reimbursement list	Biosimilar entrance	Volume change of treatment days following introduction of biosimilar 152%	IQVIA 2017

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 Romania

Legal barriers

There is still no evidence whether these changes in the regulation for initiating therapy of naïve patients with biosimilars are vital in the practice. There is no possibility for automatic substitution by pharmacists.

Currently, there is no evidence in general to confirm whether practices implemented in other countries that encourage initiating therapy with biosimilars in naïve patients are essential in practice. Additionally, automatic substitution by pharmacists is not permitted in Romania.

For 5 INNs for which the threshold of market penetration of biosimilar products at Q1 2021 was below 30% (Adalimumabum, Etanerceptum, Teriparatidum, Rituximabum 100 mg and 500 mg and Insulinum Glargine), at CNAS level, quarterly consumption analyses were conducted so that at Q3 2024 compared to Q3 2023 (1 year after implementation):

- The number of patients who benefited from treatment (regardless of the pre-prescribed drug- reference biologic or biosimilar) increased by about 10%- The number of patients who received treatment with biosimilar drugs increased by about 36%.- Of the total patients on treatment, approximately 66% are on biosimilar treatment in Q3 2024 (with variations by INN ranging from 50.77% to 96%)- the average quarterly average cost/patient on treatment with one of the 5 INNs (irrespective of the drug prescribed) showed that, on average, it decreased by about 5% (with variations by INN ranging from -20% to +2%)

Source: European Biosimilar Medicine Markets – Policy overview, 2023; National Health Insurance House validation

Financial barriers

Claw backs are charged from pharmaceutical companies for both originator medicines (so-called type I, 25% from the sales value) as well as generics and biosimilars (type II, 15%).
This is considered by stakeholders as a financial burden on pharmaceutical companies.

Evidence and communication-related barriers

A survey on the patients' knowledge on biosimilars in Romania found out that there is still a significant information gap concerning biosimilars in patient population. The majority of them confide the treatment responsibility to their physicians, most concerns coming from adverse event occurrence (Source: Cobilinschi et al. 2020).

Policy-related barriers

Either INN prescribing of biologics and biosimilars nor biosimilar substitution is allowed, which may act as barrier to biosimilar uptake.

Significant delays in HTA approval by NAMMD (in some cases, exceeding the legal deadline by more than one year) are susceptible to creating a discriminatory regime for companies with products delayed under HTA assessment compared to competing medicines that are already under reimbursement.

Centralised, national tenders organised by the MOH with a period of approximately two years are susceptible to foreclosing the market for new products (generics, biosimilars) that enter the market after the finalisation of the tender in question.

According to consultancies, the clawback tax is also potentially distorting competition, as the percentage of the tax is calculated based on the growth of the market, as opposed to that of each relevant company (the actual contribution being calculated by applying that percentage to the revenues from reimbursed medicines of each MAH).
Source: Bondoc & Asociatii 2024

Treatment guidelines were reported to not provide clear guidance to physicians on switching decisions.

Stakeholder-related barriers

Limited knowledge of patients, see above the study that showed significant knowledge gaps of patients regarding biosimilars. The study also concluded that shared-decision principle is more of a myth since most Romanian patients rely entirely on their physician for prescribing the most appropriate product.

7 Facilitators and good practice examples in Romania

The Romanian National Competition Authority took antitrust action against a pharmaceutical company by conducting two trials and imposing penalties for practices that delayed biosimilar market entry and increased healthcare costs through competitive barriers and higher product pricing.

Recently approved changes in legislation regarding the biosimilar swich and transfer of patients are a positive policy sign for enlarging the biosimilar market.

8 Developments in Romania

Recent changes

A 2023 framework introduced targets in biosimilar prescribing, to be reached through naïve patients or switching.

Plans or under discussion

Evidently there is a willingness to enlarge the educational activities, biosimilars switch etc. and further organisational actions are needed by authorities and healthcare professionals to achieve desired results.
Source: Cobilinschi et al. (2020)

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