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

AUGMENT Biosimilars
Country fiche BULGARIA

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augment biosimilars

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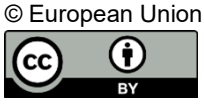

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Annex 7.3

AUGMENT Biosimilars country fiche: Bulgaria 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:

Manoela Manova, Национален съвет по цени и реимбурсиране на лекарствени продукти / National council of prices and reimbursement of medicinal products (NCPRMP)

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1 Summary of biosimilar policies and practice in Bulgaria 2025

Key stakeholders

Key stakeholder groups for biosimilar availability, access and affordability are the Ministry of health (MoH), National council of prices and reimbursement (NCPR) of medicinal products, National health insurance fund (NHIF), physicians, pharmacists, and patient's advocacy groups.

Major biosimilar policies and practices

Bulgarian market is oriented towards low priced medicines, applicable also to biosimilars. Prices of biosimilars are set below 80% of originator price. NHIF reimbursed the low price per defined daily dose (DDD) per INN. HTA is not required for biosimilars. Hospitals organise tenders with single winner with lowest prices.

Physicians can prescribe under INN but rarely does so. They also can mark substitution option on the prescription.

Impact analysis

The major impact from the applied policy measures is reported in the decreasing prices of biosimilars and/or originators, and increased consumption.

Barriers, facilitators and good practice examples

Key barrier is the lack of supporting policy, clearly stated compulsory INN prescribing. Educational programs for physicians, pharmacists and patients are scarce.

Facilitators are the requirements for low-cost tender for inpatient, internal referencing which creates stimulus for low priced medicines prescribing, as well as internal referencing within the positive drug list.

Recent developments

The only recently introduced change is the possibility physicians to allow substitution by marking the prescription, but the electronic system does not support such possibility.

Highlights and learnings

There is a need of active, systematic and regular educational activities for authorities, patients, physicians, and pharmacists about the value and benefits of biosimilars. There is also a need for generic medicines policy which include biosimilars.

2 Key data regarding biosimilars in Bulgaria

First biosimilar medicine launched (i.e. brought on the market):
eopetin alfa (Binocrit®) in 2016
Source: Annex 1 of the national council of prices and reimbursement (Comment: electronic information about the positive drug lists is available since 2016 therefore we cannot date biosimilars entrance before 2016)

Number of the **biosimilars marketed**:
22 molecules (INNs) are with biosimilars available, as of July 2025
38 trade names out of 89 authorised trade names as of July 2025

Source: PDL. NCPR www.ncpr.bg

Biosimilar market shares in 2023 (or latest available data):
1.35 % **in value** in 2023
Value is defined as **share of public pharmaceutical expenditure**

Market to which the biosimilar market shares data relate to: **total public reimbursed market (outpatient and hospital, public sector only)**

Source: National health insurance fund (www.nhif.bg)

3 Stakeholders involved in and targeted by biosimilar policies in Bulgaria

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Министерство на Здравеопазването / Ministry of Health	Prepares legislation, issue health policy strategy, issue national health programs	There is no national program for biosimilar medicines
National regulatory authority	(Изпълнителна агенция по лекарствата) / Bulgarian drug agency	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance, control storage and dispensing of all medicines including biosimilars, permits parallel trade for important medicines part of which biosimilars	There are no publications on biosimilar medicines.
Pharmaceutical pricing authority	Национален съвет по цени и реимбурсиране на лекарствени продукти / National Council on Prices and Reimbursement of Medicinal Products (NCPRMP)	Implements pricing legislation regarding biosimilars, decides on the prices, include in the positive drug list, decide on the level of reimbursement, perform HTA, monitors the therapeutic effect of the new molecules with insufficient efficacy evidence, publish pharmacotherapeutic guidelines.	National positive drug list HTA guidelines Pharmaco-therapeutic guidelines
Pharmaceutical reimbursement authority	Национална здравно осигурителна каса / National health insurance fund	Negotiate discounts with MAHs, pay for outpatient and inpatient reimbursable medicines, calculate deductibles in case of budget overspend, publish monthly information on reimbursed volumes and values of all reimbursed medicines.	Information for the reimbursed medicines Information for budget overspend
Procurement agency	Агенция за обществени поръчки / Public procurement agency	Involved in tenders and procurement procedures. In the case of hospital tenders, hospitals are obliged to announce PPA in advance for the value of tender if it is above 450 mill Euro.	
HTA agency / body	Национален съвет по цени и реимбурсиране / National council of prices and reimbursement of medicinal products	Contributes to setting prices and reimbursement level for all reimbursed products and performs HTAs.	The biosimilars are not an object of HTA if originator is already included in the PDL. Ministry Council decree for Regulation on prices and reimbursement of medicinal products № 97/19.04.2013
National competition authority	Комисия за защита на конкуренцията / Commitee for the protection of competition	Enforcement of the competition law, anti-trust cases	

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Doctors	*Represented by:* Български лекарски съюз / Bulgarian physicians union Medical societies: There are medical societies for every clinical specialty. The important input is having Rheumatologists society, Gastroenterologists society, Dermatology society etc.	Prescribe biosimilars. Inform patients Medical societies in disease areas with biological use. Scientific societies create therapeutic guidelines, participate as experts in HTA process, participate in the committees for defining suitable patients for biological therapy.	
Nurses	*Represented by:* Българска асоцияция за професионалистите по здравни грижи / Bulgarian association of the health care professionals	Informing patients, educating on appropriate application.	
Community pharmacists	*Represented by:* Български фармацевтичен съюз / Bulgarian Pharmaceutical Union	Dispense medicines, inform patients	
Hospital pharmacists	*Represented by:* Българска асоциация на болничните и клинични фармацивти / Bulgarian association of the hospital and clinical pharmacists	Support procuring medicines, inform patients / health professionals / procurers, dispense biosimilars for in and some outpatients.	
Patient organisations	*Represented by:* Национална пациентска организация / National patient's organisation Асоциация на пациентите с онкологични заболявания / Association of oncology patients Национален алианс на хората с редки болести / National alliance of people with rare diseases	Patient organisations in diseases with particular biologics use a/o organisations with specific advocacy or education work on biosimilars, advocate for patients' rights, organise education for patients.	
Consumer organisations	Национална асоциация за защита на потребителите / National association of consumer protection	Control medicines prices at retail and wholesale level, including those of biosimilars.	
Generic industry	*Represented by:* Българска генерична фармацевтична асоциация / Bulgarian generic pharmaceutical association	Represent interests of generic including biosimilars producers on the Bulgarian market	
Pharmaceutical industry in general	*Represented by:* Асоциация на научноизследователските фармацевтични производители в България (ARPharM) / Association of research and innovative pharmaceutical companies	Represent interests of the innovative biological companies	

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

4 Biosimilar policies and practices in Bulgaria 2025

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

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 and aiming to be included into the outpatient reimbursement list, the price is set at 80% from the manufacturer price of the product with the same INN and dosage form, already included in the PDL.
Price reduction of the first biosimilar compared to the reference product	80%
Price reduction of the second, third and further biosimilars	There is no defined price reduction for subsequent biosimilars.
Price reduction for the reference product	During the entrance in the reimbursement list of the new biosimilar with low price than already approved it became a reference for all other and NHIF is paying at the lowest price per INN.
Any further specificities	No
Generic price link	The NHIF is reimbursing the lowest price per INN.

Source: PPRI 2025

External price referencing

External price referencing is applied for biosimilars.	Yes, the lowest manufacturer price of the same medicinal product out of 10 reference countries.
If yes, it is applied for the following situations:	For biosimilar medicines in the outpatient and inpatient sectors entering the market.
Any specificities	
External price pricing is in place for medicines other than biosimilars.	Yes, for all prescription medicines.

Source: PPRI 2025

Tendering

Some (or all) biosimilars are procured through tendering (or tendering-like) processes.	Yes
If yes, the scope with regard to the care sector:	Inpatient sector only. Every state and municipality hospital should procure medicines via open tender procedure with single tender winner chosen on the basis of lowest price per bid.
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All off-patent and patented biological medicines, supplied to state or municipality hospitals.
Institutional framework	Conducted by hospitals after preliminary notification of the procurement agency for the value and scope of the tender if it is above 450000 Euro.

Information available on procurement procedures and practices	Single winner tenders at lowest proposed price that should not be higher than the maximum wholesale price set through the regulation. The applicable law of the Law for public procurement. It does not distinguish medicines from other goods.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	No such
Institutional framework	
Information available on procurement procedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: No Outpatient: No

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.	Yes
If yes, how many and under which specifications	All generics, including biosimilars are paid at the lowest price per DDD within the same INN (ATC 5 level). If the National council of prices and reimbursement decide it can create groups at ATC4 level and again choose the lowest price per DDD as reference. Such group exists for erythropoietin.
If publicly accessible, indicate URL of RPS list	https://portal.ncpr.bg/registers/pages/register/archive.xhtml
When were the first biosimilars included in the reference price system?	Electronic information has been available since 2016 for epoetin alfa (Bimatocrit)
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 in general, but there are some medicines clustered at ATC 4

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, only medicines included in the PDL are reimbursed.
If yes, how many and date of inclusion into reimbursement, if known)	22 molecules (INNs) are with biosimilars available, as of July 2024 38 trade names out of 89 authorised trade names as of July 2024
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	Usually at 100% (there are also 75% and till 50% available)
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	If the originator or other biosimilar is already included in the PDL the inclusion of the new one is shorter, based only on application and price proposal.

Reimbursement in the outpatient sector	
Indicate URL of outpatient positive list	https://portal.ncpr.bg/registers/pages/register/archive.xhtml
Co-payments for biosimilars for outpatient use	The NHIF is paying at the lowest price per defined daily dose (DDD) per INN and the rest is co-paid by the patient even if the reimbursement level is 100%.
For medicines for outpatient use in general (other medicines than biosimilars) Positive list for medicines in general Percentage reimbursement rates are in place Co-payments for reimbursable outpatient medicines	Annex 1 of the positive drug list includes all medicines for outpatients' care reimbursed by the NHIF. Medicines are reimbursed 100%, 75% or to 50% (25% or 50%). The NHIF is paying at the lowest price per defined daily dose (DDD) and the rest is co-paid by the patient even if the reimbursement level is 100%. If the medicine is reimbursed 100% the price is set at the wholesale level and pharmacies receive a fixed prescription fee.
Reimbursement in the inpatient sector	
Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level	Yes, additionally to the originator.
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	Annex 2 of the positive drug list includes medicines for hospitals. They are supplied via tenders and hospitals are buying the lowest priced medicines. Physicians are prescribing available medicines in the hospital. The hospital can create internal pharmaceutical formulary but it should not include medicines outside of the national PDL (Annex 2). The hospital formulary if any is oriented towards the medicines suitable for hospital profile.
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	www.ncpr.bg
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 any medicines for inpatient use

Source: PPRI 2025

4.3 Specific pricing, procurement and funding policies

Application of special pricing, procurement and reimbursement models for biosimilars (e.g., delinkage / subscription-model, management-entry agreements (MEA))	No, only price discounts are negotiated between NHIF and marketing authorisation holders. According to regulations a price discount of 10% is mandatory but companies can negotiate higher than that.
Enforcement of anti-trust policies	No
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Yes, HTA assessment for new INNs in the PDL, MEAs (usually only discounts are negotiated) and NCPR can decide to monitor the therapeutic effect for newly included into the PDL medicines.

Source: PPRI 2025

4.4 Supportive tools and practices for policy-makers

Horizon scanning

Public authorities or public payers use a horizon scanning system to identify loss of exclusivity (patent expiry) of biologics	No
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	No, if there is a product with the same INN included in the PDL
If yes, in which situations and settings (outpatient and inpatient)	If biosimilar applies before the originator for inclusion in the PDL it will be an object of HTA because the INN is not included. Only if medicine can prove well established use (more than 12 years in EU) it is not an object of HTA.
Differences in criteria and processes of HTA for biosimilars compared to other medicines	No
Any specificities	No

Source: PPRI 2025

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes, for high-cost medicines for which there are available therapeutic alternatives physicians are encouraged to prescribe less costly alternative.
If yes, what is recommended for naïve patients?	Prescribing of so-called high-cost medicines (many biologicals fell within this category) is allowed after a decision of medical committee from specialists which is issuing a protocol renewed on a yearly basis. Committee have to choose the most cost-effective alternative if there are therapeutic alternatives available. The latter concerns naive patients. NHIF should issue a list of therapeutic alternatives. In the case of biosimilar products, the committee may recommend them.
If yes, what is recommended for patients already on biologic treatment	As stated, NHIF pays the lowest price per DDD per INN and if patient cannot cover the co-payment physician can switch but there is no written evidence about.

Prescribing and switching recommendations	
Prescription guidelines (including switching guidelines) were issued by	NCPR is issuing the so-called pharmaco-therapeutic guidelines for disease areas (e.g. neurology, rheumatology etc.). The guidelines recommend pharmacotherapy under INN but there are no special recommendations for prescribing biosimilars. When prescribe reimbursed medicines physicians have to comply with the pharmaco-therapeutic guidelines.
URL of prescription & switching guidelines	https://ncpr.bg/bg.html
Prescribing quota	
Prescribing quota for doctors with regard to prescription of biosimilars exist	No
If yes, which quota are defined for biosimilars	
Any exemptions	
Any sanctions in case of non-achievement	No
Any (financial) incentives for achieving the quota	
Prescribing quota were issued by	
URL of prescribing quota	
Prescribing quota for other non-biosimilar medicines exists	No
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)	Physicians can prescribe by INN or indicate at the prescription that substitution is allowed but this practice is not supported by the electronic system due to separate code for every medicine.
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	No
Further measures targeted at doctors	
Information materials for doctors	Physicians use the pharmaco-therapeutic guidelines and price list of PDL (www.nhif.bg)
Information events for doctors (e.g., seminars, trainings)	Usually, scientific societies organise such events but not regularly and not systematically.
Involvement of doctors in switching studies that evaluate clinical outcomes of a switch	No

Source: PPRI 2025

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense

Substitution policies	
(Automatic) substitution for biosimilars	If the physician stated that the substitution is allowed pharmacists can apply but as stated, electronic system does not support. Also, the regulation of prescribing and dispensing of medicines states that if the medicine is prescribed under a trade name the same product should be dispensed.
If yes, for which biologic substances and under which prerequisites?	It is possible for all biosimilars if the physician stated substitution permitted.

If yes, since when, and when was it extended? (process of implementation)	Since the changes in the regulation of prescribing and dispensing of medicines in 2019
Any specificities	
URL of underlying law	regulation № 4 /4 March 2009 for the conditions and order of prescribing and dispensing of medicinal products, last amended State gazette 68/ 13 August 2024
Generic substitution in place	Yes, indicatively see above
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)	The same as physicians not regularly

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: PPRI 2025

5 Impact of biosimilar policies and practices in Bulgaria

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 Bulgaria

Outcome indicator	Caused by (specify policy, if applicable)	Findings	Publication (citation or URL)
Savings for the public payer	Hypothetical interchangeability (A budget impact model for biosimilar infliximab for Crohn diseases)	Calculate a 3-year, prevalence-based budget impact analysis and state that if interchanging not allowed savings will be €8 million.	Brodszky V, Rencz F, Pentek M, Baji P, Lakatos PL, Gulacsi L. A budget impact model for biosimilar infliximab in Crohn's disease in Bulgaria, the Czech Republic, Hungary, Poland, Romania, and Slovakia. Expert Rev Pharmacoecon Outcomes Res. 2016;16(1):119–125. doi: 10.1586/14737167.2015.1067142
Savings for the public payer	External reference pricing and internation reference reimbursement	58 biosimilars for 16 reference products authorized for sale on the European market by the end of 2019 were available on the national market. Prices of the observed bDMARD decreased by 17% down to 48%. Significant price decreases were noted upon biosimilar entrance onto the market. In total, the reimbursed expenditures for the whole therapeutic group steadily increased from 72 to 99 million BGN. Utilization changed from to 0.5868 to 2.7215 defined daily dose (DDD)/1000inh/day. The study shows that the entrance of biosimilars in the country is relatively slow because only half of the biosimilars authorized in Europe are reimbursed nationally. Introduction of biosimilars decreases the prices and changes the utilization significantly but other factors might also contribute to this.	Tachkov K, Mitkova Z, Boyadzieva V, Petrova G. Did the Introduction of Biosimilars Influence Their Prices and Utilization? The Case of Biologic Disease Modifying Antirheumatic Drugs (bDMARD) in Bulgaria.Pharmaceuticals (Basel). 2021 Jan 14;14(1):64. doi: 10.3390/ph14010064
Savings for the public payer	External reference pricing and internation reference reimbursement	Authorized-for-sale, biosimilar insulins at the European level were compared with those on the national market. Prices and utilization were compared in value, number of defined daily dose (DDD), and DDD/1000 inh/day. Almost all types of insulins possessed biosimilars, and even more than one on the European market, but only two were found to be available and reimbursed on the national market. The total number of reimbursed INNs was 11, and for seven of them, changes in reference price per DDD were found. The highest price decrease was observed for insulin (price per DDD decline from 2.77 to 2.22 Bulgarian Leva (BGN)). The total expenditure for insulin increased from 68 to approximately 72.8 mil BGN (34 to approximately 37 mil Euro). The utilization in DDD/1000/inh/day decreased from 16.12 to 15.31.	Tachkov K, Mitkova Z, Milushewa P, Petrova G. Biosimilar Insulins and Their Impact on Prices and Utilization of Insulins in Bulgaria. *Healthcare*. 2021; 9(6):697. https://doi.org/10.3390/healthcare9060697
Savings for patients and payer	External reference pricing and internal reference reimbursement	The access for treatment is evaluated as the availability of the product on the market and the prices level. The prices data was obtained from the official web pages of the responsible institutions up to date December 2017. The results show that four out of all six INNs have authorized biosimilars in EMA. Despite its earlier authorization biosimilar	Manova M, Savova A, Vasileva M, Terezova S, Kamusheva M, Grekova D, Petkova V, Petrova G. Comparative Price Analysis of Biological Products for Treatment of Rheumatoid Arthritis. Front Pharmacol.

Outcome indicator	Caused by (specify policy, if applicable)	Findings	Publication (citation or URL)
		adalimumab is not present. Differences in manufacturers' prices of reference biological products in selected countries in comparison with the lowest manufacturer price are higher with 22 to 69% while the retail prices between 62 and 95%. Manufacturers' prices differ between 26 and 75%, while retail prices differ between 40 and 92% for biosimilars. Comparison of the differences between manufacturer prices of reference biological product and biosimilars shows 36% difference for etanercept, 39% for rituximab, and 31% for infliximab, while at retail level the differences are 11, 86, and 143%, respectively. Introduction of biosimilars on the national markets led to significant decrease in reimbursed prices paid by public funds and thus might benefit the patients' access to biological therapy. The decrease of prices after biosimilars entrance on the market is not as notable as for commodity generics.	2018 Sep 20;9:1070. doi: 10.3389/fphar.2018.01070. PMID: 30294275
More patients treated (Patients access)	Biosimilars reimbursement policy and procedures	The reimbursed biosimilars for hospitalized patients in Bulgaria were 14 (26.42%) in 2018 and 29 (40.85%) in 2019. The ambulatory patients' access to biosimilars was relatively low – 15 out of 71 (21.13%) in 2019. The dynamics in the number of reimbursed biosimilars within the 6-month period showed remarkable increase – almost 2 times. The average time to include in the PDL is approximately 3 years after marketing authorization through centralized procedure. The longest time passed for inclusion of Somatropin (9 years) and the shortest - for infliximab, trastuzumab and insulin glargine.	Tamer J, Grozev J, Kamusheva M, Petrova G. ACCESS OF BULGARIAN PATIENTS TO BIOSIMILAR MEDICINES. VALUE IN HEALTH - NOVEMBER 2019, S787

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 Bulgaria

Legal barriers

Lack of clear rules for INN prescribing, or substitution, as well as lack of obligation for biosimilars prescribing for naive patients.

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

Lack of clear policy for biosimilars uptake, lack of implementation plans; lack of accountability of stakeholders; parallel exports. To overcome the negative consequences of the parallel export Bulgarian drug agency is issuing a list of medicines with shortages and wholesalers could not export those medicines.

It could potentially be considered as a barrier that biological therapy prescribing is approved by a medical committee of 3 specialists in the therapeutic area, which issued protocol for biological therapy, renewed on a yearly basis. To be allowed to receive biological therapy patients have to comply with previously stated disease severity criteria.

Financial barriers

Lack of incentives for health professionals to prescribe or dispense biosimilars, tenders are single winner and if originator propose low price this could let to decrease of the biosimilars uptake.

Evidence and communication-related barriers

Lack of evaluation studies of biosimilar policies, lack of switching studies (or their limited dissemination), limited outreach of communication activities to effectively reach the target groups; lack of follow-up monitoring; lack of guidance of the national regulatory authority for procurement or prescribing, switching and use of biosimilars; lack of information materials and educational programs.

Policy-related barriers

INN prescribing for biologicals or biosimilar substitution is not encourage; pricing through biosimilar price link policy is the only clearly stated in the regulation requirement. Lack of enforcement of anti-trust measures, limited experience and knowledge of policy-makers and/or procurer to implement biosimilar policies or conduct strategic procurement.

Stakeholder-related barriers

Limited knowledge and acceptance about biosimilars on behalf of patients; limited collaboration between doctors and pharmacists.

Any other barriers

In general, biosimilars are not a policy issue in Bulgaria.

7 Facilitators and good practice examples in Bulgaria

Internal reference pricing and payment at the lowest price create stimulus for prescribing and dispensing of biosimilars. It is a physician's decision to prescribe either original or biosimilar. Usually, physicians are concerned by the cost of therapy, due to patients' financial capabilities and whenever appropriate prescribe low priced medicines.

Recent development in the Regulation for prescribing and dispensing of medicines necessitate in case of available therapeutic alternatives to be prescribed less costly once which also concerns and biosimilars.

Less stringent requirements for HTA of biosimilars compared to biological medicines supports faster uptake.

8 Developments in Bulgaria

Recent changes

The only recently introduced change is the possibility physicians to allow substitution by stating in the prescription, but the electronic system does not support such possibility.

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NHIF	National health insurance fund inpatient medicines reimbursement https://www.nhif.bg/bg/nzok/hospital-medicine
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