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

AUGMENT Biosimilars
Country fiche BELGIUM

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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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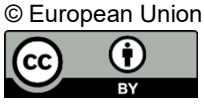

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Annex 7.2

AUGMENT Biosimilars country fiche: Belgium 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:

Joël Daems, Rijksinstituut voor Ziekte- en Invaliditeitsverzekering - Institut national d'assurance maladie-invalidité (RIZIV-INAMI) / National Institute for Health and Disability Insurance

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1 Summary of biosimilar policies and practice in Belgium 2025

Key stakeholders

In Belgium, the Federaal Agentschap Geneesmiddelen en Gezondheidsproducten / Agence Fédérale des Médicaments et des produits de Santé (FAGG-AFMPS) implements the regulatory provision regarding biosimilars, quality assurance and pharmacovigilance, whereas the decision of inclusion into reimbursement lists of biosimilars and the production of prescribing guidelines for biosimilars is the responsibilities of National Institute for Health and Disability Insurance (INAMI / RIZIV).

Major biosimilar policies and practices

For biosimilar medicines in the outpatient and inpatient sectors entering the market there is a price link. Since the 1st January 2024, prices of biosimilars, when admitted onto the reimbursement list, take into account:

- the reference price system, with a 26,60% reduction in reimbursement price comparing to the reference originator biological,
- the price reduction in place for older medicines, foreseen after several years of reimbursement status ("old cliff") or earlier, simultaneously with the reference price system

The reference originator biological will have a similar price than the biosimilar after the application of the reference price system.

These measures are applied at the ATC 5 level in the outpatient and inpatient sectors. Biosimilars are included in the positive list with percentage-based co-payments in the outpatient sector. Lower co-payments and spending caps are in place for low-income patients.

Tendering is applied for biosimilars in the inpatient sector, covering all off-patent biologics, and conducted at the hospital or hospital group level.

At the inpatient level, biosimilars are included in hospital formularies following a positive outcome of the public tendering procedure. Hospitals receive 85% reimbursement for biologics when reference price system is applied. Some older biologics are included in prospective hospital budgets, independent of consumption or price.

HTA is systematically applied for biosimilar medicines in both outpatient and inpatient settings, with a specific shorter process for biosimilars.

Impact analysis

Mandatory price reductions lowered reimbursement costs for both the originator and the biosimilar(s), but no further non-mandatory price erosion occurred. Gain-sharing models in the outpatient sector had a limited impact on biosimilar uptake, with no clear effect on treatment costs due to mandatory price reductions. Financial incentives for physicians led to modest increase in market shares.

Barriers, facilitators and good practice examples

Delays in tendering due to various hospital-level challenges (e.g., waiting for more competitors, discounts from originators). Tenders are defined at the hospital level or hospital group level with varying criteria. New tendering rules for biologicals to increase competition have been introduced in 2023, and may serve a facilitator. Limited involvement of health professionals in defining tender criteria, causing uncertainty.

Lack of incentives for health professionals, procurers or patients to prescribe, dispense, use or purchase biosimilars. There are no quotas for biosimilars. Quotas for ~~low-price medicines~~ generics exist in hospital and outpatient settings but are not ~~monitored or~~ linked to penalties/rewards.

Limited communication and support from public authorities and scientific associations. No systematic integration of biosimilars into clinical guidelines. No structured pre-launch planning for biosimilars before patent expiration.

Influence of the strong originator pharmaceutical industry, impacting policy decisions.

Recent developments

Standardisation of hospital tendering processes since 2023 to improve procurement efficiency. The Royal Decree of 13 September 2023 introduced new public procurement rules to foster competition in Belgium’s biologic medicines market, aiming to reduce barriers to biosimilar entry

Highlights and learnings

Belgian Competent Authority & Federal Ministry of Health have implemented policy measures with some success, such as position statements on switching and substitution of biosimilars, and educational activities to raise awareness among healthcare professionals.

2 Key data regarding biosimilars in Belgium

First biosimilar medicine launched (i.e. brought on the market):
Somatropin, 2007

Source: GaBI Journal, 2012

Number of the **biosimilars marketed**:
16 molecules with biosimilars available, as of March 2025
47 biosimilars (per trade name), as of March 2025
Source: RIZIV-INAMI 2024

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

19,7 % in volume in year 2023 (41,3 % in hospital and 11,0 % in officina)
Volume is defined in DDD, share of market for available biologic pharmaceuticals

42,4 % in value in year 2023 (54,8 % in hospital and 28,9 % in officina)
Value is defined in public pharmaceutical expenditure, share of market for available biologic pharmaceuticals

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

Source: Sciensano, KCE, INAMI/RIZIV 2024

Key national publicly accessible sources reporting data on biosimilars

- Répertoire Commenté des Médicaments https://www.cbip.be/fr/chapters/6, includes prices by molecule, but no information is available on uptake, volume or value shares.
- https://www.belgiqueenbonnesante.be/metadata/hspa/2024/E4.pdf, report produced in 2024, only includes data up to 2021.
- MORSE-rapport | RIZIV

3 Stakeholders involved in and targeted by biosimilar policies in Belgium

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Legislator	Ministry of Social Affairs and Public Health (Federal) Ministry of Welfare, Public Health and Family (Flanders) Ministry of Health, Equal Opportunities, and Womens' Rights (Walloon Region) Ministry of Health (Brussels Region) Ministerium für Familie, Soziales, Wohnen und Gesundheit (German-speaking Region) Santé publique, Sécurité de la Chaîne alimentaire et Environnement / Federal Public Service Health, Food Chain Safety and Environment	Prepares legislation	Ministre des Affaires sociales et de la Santé publique (2016)
National regulatory authority	L'Agence fédérale des médicaments (AFMPS) / Federal Agency for Medicines and Health Products	Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance	Kurki et al. (2021) AFMPS (2023) AFMPS (2018)
Pharmaceutical pricing authority	Federal Public Service (FPS) Economy https://economie.fgov.be/en	Implements pricing legislation regarding biosimilars, decides on the maximum prices	FPS (2019)
Pharmaceutical reimbursement authority	National Institute for Health and Disability Insurance (INAMI / RIZIV)	Decides on inclusion of biosimilars into reimbursement lists. Produces prescribing guidelines for biosimilars, responsible for prescription quotas	INAMI (2019b) INAMI (20118) INAMI (no year)
Procurement agency	Central Purchasing Body (Federal Public Service Public Health FPS / FOD) Regional Purchasing Bodies: e.g. MercurHosp, HospiLim)	Involved in tenders and procurement procedures	FPS (2019)
HTA agency / body	Scientific Institute of Public Health (WIV-ISP) Federaal kenniscentrum voor de gezondheidszorg (KCE) / Belgian Health Care Knowledge Centre	Scientific advice on healthcare topics, generally proposed by public authorities. Regarding biosimilars, KCE produced a specific report examining the reasons why biosimilars have still not made a breakthrough in our country. RIZIV-INAMI: HTA on all molecules which will be included in the reimbursement system (CTG-CRM)	Lepage-Nefkens et al. (2013) KCE (2013)

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
National competition authority	Autorité Belge de la Concurrence / Belgische Mededingingsautoriteit / Belgian Competition Authority	Enforcement of the competition law, anti-trust cases	
Doctors	*Represented by:* Association Belge des Syndicats Médicaux (ABSyM) Ordre de Medecins https://ordomedic.be/fr	Inform patients and Medical Societies in disease areas with biologics use	ABSyM (2018)
Nurses	*Represented by:* Federatie van Beroepsverenigingen van Verpleegkundigen (ACN/AFN) / Belgian Federation of Professional Nursing Associations	Informing patients	
Community pharmacists	*Represented by:* Association Pharmaceutique Belge (APB)/Belgian Pharmaceutical Association *Pharmacy society:* Orde der Apothekers – Ordre des Pharmaciens/Belgian Order of Pharmacists	Inform pharmacists and patients about medicines	
Hospital pharmacists	*Represented by:* Belgian Association of Hospital Pharmacists (AFPHB/VZA) Association Francophone des Pharmaciens Hospitaliers de Belgique (AFPHB) / Belgian Association of Hospital Pharmacists[3]	Support procuring medicines, inform patients / health professionals / procurers	
Patient organisations	*Represented by:* Vlaams Patiëntenplatform (VPP) / Flemish Patients' Platform List patient organisations: Diabetes Liga vzw / Diabetes League Association Crohn-RCUH Belgique / Belgian Crohn and Colitis Association Association de l'Hémophilie - Hemofilievereniging (AHVH) Kom op tegen Kanker / Stand up to Cancer Belgium ReumaNet vzw / RheumaNet Rare Disorders Belgium (RDB)	Information sharing within the specific patient organisation	ReumaNet (2015)

Stakeholder	Name in local language and English translation & URL	Role with regard to biosimilars	Publications by this stakeholder group
Consumer organisations	Test-Santé		Test-Santé (2018) Test-Santé (no year)
Biosimilar industry	*Represented by:* Medaxes - Association for accessible medicines	Produces and supplies biosimilars, promotes the uptake of biosimilar medicines	Medaxes (2022) Medaxes (no year)
Generic industry	*Represented by:* Medaxes - Association for accessible medicines	Produces and supplies generics, promotes the uptake of generics	Medaxes (2022)
Pharmaceutical industry in general	*Represented by:* Association générale de l'industrie du Médicament (Pharma.be) / Belgian Pharmaceutical Industry Association		Pharma.be (2022) Pharma.be(2024) Pharma.be (2022a) Medaxes
Pharmaceutical industry for new biological medicines	*Represented by:* Fédération belge des industries chimiques et des sciences de la vie (Essencia)		Pharma.be
Pharmaceutical industry biosimilars		Biosimilars	Medaxes

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

4 Biosimilar policies and practices in Belgium

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

4.1 Pricing and procurement policies 2025

Biosimilar price link

A **biosimilar price link** is in place.	Yes
It applies for the following situations:	For biosimilar medicines in the outpatient and inpatient sectors entering the market
Price reduction of the first biosimilar compared to the reference product	26,60 % + the price reduction applied for older medicines (if not already applied). Following biosimilar availability and reimbursement for one month.
Price reduction of the second, third and further biosimilars	Same extent of price reduction for all biosimilars, up to 52,29% of the reference product.
Price reduction for the reference product	26,60 % + the price reduction applied for older medicines (if not already applied). Following biosimilar availability and reimbursement for one month.
Any further specificities	Introduced in 2024
Generic price link	Yes The price reduction is 51.52% for essential medicines (Category A) and 44.75% for other reimbursed medicines (Category B), when the active ingredient has been reimbursed for more than 12 years (from 61.22 to 68.49% before that deadline for Category A, from 55.80 to 64.09% before that deadline for Category B).

Source: PPRI 2025, Vogler et al. 2024, Gerkens et al. 2020

External price referencing

External price referencing is applied for biosimilars.	No
If yes, it is applied for the following situations:	N/A
Any specificities	
External price pricing is in place for other medicines than biosimilars.	Yes, namely: in-patent medicines only

Source: PPRI 2025, Kanavos P, Fontrier AM, Gill J, Kyriopoulos 2017

Tendering

Some (or all) biosimilars are procured through tendering (or tendering-like) processes.	Yes
If yes, the scope with regard to the care sector:	Inpatient sector only
Tendering biosimilars in the inpatient sector	
Scope of biological medicines tendered	All medicines
Institutional framework	Conducted by hospitals and hospital procurement groups.
Information available on procurement procedures and practices	Tenders are performed at the level of hospitals or hospital groups, with criteria that may vary but usually include criteria other than prices. A Royal Decree was issued in September 2023 banning specific criteria, such as efficacy, safety, and quality, which is guaranteed by the EMA market authorization. Tendering is compulsory within 9 months after the biosimilar approval. New tendering rules for biosimilar tendering in hospitals were released in 2023, for details see chapter 8.
Tendering biosimilars in the outpatient sector (or tendering-like policies)	
Scope of biological medicines tendered	None
Institutional framework	
Information available on procurement procedures and practices	
Generics are tendered (or procured through competitive tendering-like policies).	Inpatient: Yes, for most hospital products a tendering process is implemented Outpatient: No

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Vogler et al. 2024; Moorkens et al. 2022; Barbier et al. 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	A 26.6% decrease in the reimbursement price is applied on the reimbursement basis of the reference drug + the price reduction applied for older medicines (if not already applied).
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 other medicines than biosimilars), and how those medicines are clustered?	Yes ATC 5 cluster

Source: PPRI 2025

Inclusion into reimbursement and co-payments

Reimbursement in the outpatient sector	
Apart from their potential inclusion into the reference price system (see above), biosimilars are included in outpatient reimbursement (positive list).	Yes
If yes, how many and date of inclusion into reimbursement, if known)	
Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list	Outpatient care: percentage of the price. Community pharmacy: patient fixed co-payment for low-cost drugs (below 14.38 euros), with additional percentage of price for non low-cost medicines. Reduced co-payments and expenditure cap for low-income patients.
Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use	The reimbursement procedure for biosimilars is simpler and shorter (90 vs 180 days) compared to the process for reference products.
Indicate URL of outpatient positive list	
Co-payments for biosimilars for outpatient use	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 original biological (and doctors are recommended to switch)
Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use	The reimbursement procedure for biosimilars is simpler and shorter (90 vs 180 days) compared to the process for reference products.
Indicate URLs of hospital pharmaceutical formularies, if publicly accessible	URL of national hospital pharmaceutical formulary: Not publicly available
Co-payments for biosimilars for inpatient use	A fixed payment of 0.62 euros per in-patient day
<u>For medicines for inpatient use in general (other medicines than biosimilars):</u> Hospital pharmaceutical formularies Co-payments for medicines for inpatient use	A fixed payment of 0.62 euros per in-patient day

Source: PPRI 2025, Vogler et al. 2024

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))	The reimbursement of biologic medicines to hospitals is of 85% of the price when reference price system is applied. Additionally, some older products (somatropin, epoietin) are included in the prospective hospital budget for medicines, without link to consumption or prices.
Enforcement of anti-trust policies	No, but under discussion
Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines	Mix of financial and performance-based MEAs

Source: PPRI 2025, Moorkens et al. 2021a

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	
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	There is HTA process with a specific shorter process for biosimilars
If yes, in which situations and settings (outpatient and inpatient)	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	There is a specific process for biosimilar medicines.
Any specificities	

Source: PPRI 2025, KCE 2013.

4.5 Demand-side measures 2025

Doctors (and further prescribers)

Country context: Only doctors may prescribe

Prescribing and switching recommendations	
Prescribing recommendations for doctors with regard to prescription of biosimilars exist	Yes
If yes, what is recommended for naïve patients?	Recommendation to prescribe biosimilars for naïve patients
If yes, what is recommended for patients already on biologic treatment	Recommendation to switch patients for economic reasons

Prescription guidelines (including switching guidelines) were issued by	No
URL of prescription & switching guidelines	
Prescribing quota	
Prescribing quota for doctors with regard to prescription of biosimilars exist	Yes
If yes, which quota are defined for biosimilars	No quota for the moment being
Any exemptions	
Any sanctions in case of non-achievement	No
Any (financial) incentives for achieving the quota	Premiums for prescribing biosimilars, support for compliance Pilot implemented in 2019. Financial incentive paid to physicians to prescribe biosimilars adalimumab or etanercept in ambulatory care. The payment is €750, €1,000 or €1,500 depending on whether the annual target reached is 5%, 10% or 20% of prescribed adalimumab and etanercept biosimilars.
Prescribing quota were issued by	INAMI/RIZIV
URL of prescribing quota	
Prescribing quota for other non-biosimilar medicines exists	Yes, for low-price medicines
Further gain-sharing models	
Further gain-sharing models exist (beyond those mentioned above)	yes
If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced)	Hospitals only receive 85% of the price of the reference product when a biosimilar is available, and older biosimilar medicines are included in the prospective hospital budget without any cost sharing. No gain sharing in outpatient settings.
Publicly accessible information	Zoekmodules SSP - bijgewerkt op
INN prescribing	
In general, prescribing by INN is place (information not focused on biologics)	Yes, indicative
If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions	No exemption for biologicals: biologics and biosimilars may be prescribed by INN
Further measures targeted at doctors	
Information materials for doctors	Absence of systematic information or support material, no update of guidelines to incorporate biosimilars or switching practices (with the exception of an initiative in 2018 at hospital level, by the national medicines agency).
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, Moorkens et al. 2021a, Moorkens et al. 2021b Barbier et al. 2022

Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense

Substitution policies	
(Automatic) substitution for biosimilars	No, not allowed
If yes, for which biologic substances and under which prerequisites?	
If yes, since when, and when was it extended? (process of implementation)	

Any specificities	
URL of underlying law	
Generic substitution in place	Yes, 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	Biological and biosimilar medicinal products | FAMHP
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 information available
If yes, provide URL of most common materials	
If yes, key producers of education measures	
Information events for patients (e.g., seminars, trainings)	No information available
If yes, key providers of educational events	
Gain-sharing models	
Gain-sharing models for patients	No information available
If yes, pls. describe	
Publicly accessible information	

Source: PPRI 2025

5 Impact of biosimilar policies and practices in Belgium

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 Belgium

Outcome indicator	Caused by	Findings	Publication
Savings for the public payer	mandatory price reductions	This article looked at the evolution in volumes and costs of the relevant products in the market. Reimbursement costs decreased due to mandatory price reductions. No further non-mandatory price erosion occurs after the application of these mandatory price reductions	Vandenplas et al. 2021
Savings for the public payer	Gain-sharing models in the outpatient sector	Limited impact in the biosimilars uptake and led to fewer than expected etanercept biosimilar dispensing. It was not possible to attribute any effect on treatment cost to policy interventions due to the mandatory price reductions for biosimilars and originators after 12 years of reimbursement.	Vandenplas et al. 2023
Savings for the public payer	Gain-sharing models -financial incentives to physicians	Physician incentives of €750, €1,000 or €1,500, depending on the annual target reached: 5%, 10% or 20% of prescribed adalimumab and etanercept biosimilars. Small effect, with 7.1% and 16.5% market shares for adalimumab biosimilars and of etanercept biosimilars, respectively.	Car et al. 2023, Moorkens et al. 2020
More patients treated	Prescribing quotas in hospitals	Increases in biosimilar uptake. This effect was stronger for filgrastim biosimilars than for epoetin biosimilar	Vandenplas et al. 2023
Biosimilar uptake	information campaign on biosimilars in hospitals	Significant impact on quarterly epoetin biosimilar uptake but limited and only temporary impact on filgrastim biosimilar uptake.	Vandenplas et al. 2023

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 Belgium

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

Tenders are often only initiated long after a biosimilar enters the market. Moorkens et al. (2021a) attribute this to five possible factors: "a) tenders require considerable time efforts from hospital pharmacists, b) hospitals might initially wait until more players can offer a bid, c) the innovator's reach and possible benefits to hospitals can play a role in the lack of willingness to open a tender when the biosimilar enters, d) legally correct new exclusivity contracts with potentially substantial discounts are concluded just before biosimilars enter the market, and f) discounts are given on subcutaneous alternatives, limiting the need for a new contract on the intravenously administered biosimilar product". Moreover, each hospital or hospital group establishes its own tender process, which increases the burden for hospitals. Additionally, each hospital or group of hospitals applies different criteria, some of which favour the originator product (Moorkens et al. 2021a). For instance, hospitals may seek scientific support, such as grants or conference funding, or request complimentary supplies through medical need programs, which are exclusively available for the original brand-name product (Moorkens et al. 2021a). Health professionals may not be involved in defining the tender criteria, contributing to raising doubts about the selected pharmaceuticals.

Financial barriers

Lack of incentives for health professionals, procurers or patients to prescribe, dispense, use or purchase biosimilars (no gain-sharing); biosimilar prices are considered as too low or too static by suppliers (with risk of suppliers leaving the market). Gain-sharing for hospitals exists but is not transparent for healthcare professionals, who do not benefit financially from the savings (by contrast, switching implies time and effort that are not financially compensated). Quotas for low-price medicines exist but are not monitored, neither associated to penalties or rewards.

Evidence and communication-related barriers

It appears that communication on biosimilars is very limited. First, guidelines are not systematically updated to incorporate biosimilars, or to orient switching practices. Second, information and support are lacking from public authorities, medical or scientific associations on biosimilars. Third, even if some recommendations have been provided in hospital settings, the application of recommendations is not subject to support or monitoring. No such recommendations exist in the outpatient sector. Finally, there is insufficient preparation for the potential entry of biosimilars before patent expiration. Authorities and procurers could make greater use of horizon scanning to anticipate the expiration of patents and other exclusivity rights associated with originator biologicals. This would also enable them to better estimate the timing and number of biosimilars expected to receive regulatory approval from the European Medicines Agency and identify which are likely to enter the Belgian market (Moorkens

et al., 2021a). Preparation for the entry of biosimilars could also involve stakeholder discussions on the potential benefits of biosimilars, the development of management strategies for their adoption and uptake, and the implementation of concrete plans to facilitate this transition (Moorkens et al., 2021a).

Policy-related barriers

A policy-related barrier to biosimilar uptake is the practice of originator companies offering substantial discounts and extending exclusivity agreements just before patent expiration. Indeed, while hospitals are financially incentivized to issue tenders to reduce costs, this strategy allows originator companies to bypass the administrative burden of initiating a tender process, ultimately limiting biosimilar market entry (Moorkens et al. 2021a).

Tenders for biosimilars are often delayed after market entry due to several factors, including the time-intensive process for hospital pharmacists, hospitals waiting for more competitors to bid, and the influence of originator manufacturers offering incentives pharmaceuticals (Moorkens et al. 2021a). The decentralized nature of the tendering process, with each hospital or hospital group setting its own criteria, further complicates procurement and can favour originator products. Some hospitals prioritise factors like scientific support or complimentary supplies available only for brand-name products. Furthermore, the exclusion of health professionals from tender decision-making may contribute to uncertainty about the selected pharmaceuticals (Moorkens et al., 2021a).

Stakeholder-related barriers

The innovation-oriented environment in Belgium due to a large pharmaceutical R&D footprint acts as a barrier, as policy is impacted by decision-makers care not to affect the sector, mainly dominated by the originator industry (Moorkens et al. 2021a).

7 Facilitators and good practice examples in Belgium

Policy measures enacted primarily by the Belgian Competent Authority and the Federal Ministry of Health have shown positive, however limited, impact in increasing biosimilar uptake (e.g. position statement on switching and substitution of biosimilars, educational activities raising awareness for biosimilars and involving multiple stakeholders, establishment of prescription targets, regular monitoring of biosimilar uptake).

In recent years, measures have been implemented to enhance the tendering process. For instance, in 2016, the government recommended including a clause in contracts that allows hospitals to terminate agreements early and initiate new tenders when alternative options become available (Moorkens et al., 2021a). This provision helps prevent hospitals from being disadvantaged by originator companies' strategies, such

as offering significant discounts or extending exclusivity agreements just before patent expiration.

The Royal Decree of 13 September 2023 introduced new procurement rules to boost competition in Belgium's biologic medicines market and facilitate biosimilar adoption (Van Bael & Bellis, 2023). It mandates hospitals to launch public tenders within nine months of a biosimilar's reimbursement unless justified, with oversight from the National Institute for Health and Disability Insurance and the Belgian Competition Authority. It also limits supply contracts to a maximum of four years and bans tendering criteria that restrict competition, such as requiring prior market presence, requesting unrelated services, or linking discounts to exclusive contracts (Van Bael & Bellis, 2023). These measures aim to prevent favouritism toward originator biologics and promote fair market conditions.

8 Developments in Belgium

Recent changes

In 2023, Belgium changed some biosimilar tendering rules (Van Bael & Bellis, 2023). The Royal Decree of 13 September 2023 introduced new public procurement rules to foster competition in Belgium's biologic medicines market, aiming to reduce barriers to biosimilar entry. It enforces three key changes:

- **Mandatory Public Tendering** – Hospitals must launch a public tender within nine months of the reimbursement and availability of the first biosimilar for a given biological medicine. Any exception must be justified to the National Institute for Health and Disability Insurance, which may escalate cases to the Belgian Competition Authority for further scrutiny. Additionally, all new biological medicine contracts from 2 October 2023 must include a termination clause to allow for new tenders when required.
- **Limited Contract Duration** – The decree caps supply contracts from public tenders at two years, with a possible extension of one additional year if no new biosimilars are reimbursed in the first two or three years after the first biosimilar enters the market. The total contract duration cannot exceed four years.
- **Restrictions on Anti-Competitive Criteria** – The decree prohibits certain tendering criteria that could hinder biosimilar competition. These include requiring prior market presence or minimum turnover, requesting unrelated additional services (such as R&D sponsorship), assessing efficacy and safety (as these are already evaluated by the EMA), mandating clinical switching data, linking discounts to multiple awarded lots when competition is limited, bundling different administration routes in a way that limits competition, and creating contractual ties with other medicines.

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