biosimilar medicines

better access. better health.

MARKET REVIEW – BIOSIMILAR MEDICINE MARKETS

POLICY OVERVIEW

2020

biosimilar medicines
better access. better health.

Acknowledgements

Country	National Association / Member Company	Contact Person
Austria	Biosimilars Association Austria	Dr. Sabine Möritz-Kaisergruber
Belgium	Medaxes	Pieter Boudrez
Bulgaria	BGPharmA	Evgeni Tassovski
Croatia	Sandoz	Branka Ahel & Nikolina Bičanić
Czech Republic	CAFF	Martin mátl
Denmark	IGL	Peter Jorgensen
Estonia	Sandoz	Kristel Aver
Finland	FGA	Heikki Bothas
France	GEMME	Alexandre Soufer
Germany	Pro Generika	Frederike Voglsamer
Hungary	GE	Alexandra Csihi
Ireland	Mylan Ireland	Anastasia Papavassiliou
Italy	Egualia	Stefano Ilacqua
Latvia	Sandoz	Dagnija Poreitere
Lithuania	VGA	Mindaugas Grinevicius
Netherlands	Bogin	Martin Favie
Poland	PZPPF	Grzegorz Rychwalski
Portugal	Apogen	Ana Valente & Fernanda Aleixo
Romania	Sandoz	Dragos Toma
Slovakia	GENAS	Michaela Palagyi
Slovenia	Association of manufacturers of medicinal products in Slovenia	Katja Razinger
Spain	BioSim	Encarnación Cruz Martos
Sweden	FGL	Kenneth Nyblom
Switzerland	Sandoz	Daniel Sarbach
Turkey	IEIS	M. Vedat Egilmez & Aysu Ozel
UK	BBA	Ania Swirski

2020 Market Review | European Biosimilar Medicine Markets – Policy Overview | Authors: Diogo Piedade, Market Access Manager - Heleen Verhelst, Junior Market Access Officer
Credit photos: Fotolia | Graphic Design: José Antonio García Sánchez | Issued in March 2021 Belgium | Medicines for Europe – Biosimilar Medicines Group | Rue d'Arlon 50 B-1000 Brussels Belgium

Introduction

The Biosimilar Medicines Group - Market Access Committee is pleased to present the 2020 Market Review – European Biosimilar Medicine Markets – Policy overview.

This year, the European countries covered in the market review are: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

The 2020 Market Review covers 8 main topics: Availability, Pricing system, Retail tendering, Hospital tendering, Reimbursement systems, Physician-related topics, Pharmacist-related policies and Information and education. Throughout the different topics, the reader will get a clear overview of how biosimilar medicine policies are set in the reviewed countries.

This document will be distributed to Medicines for Europe members as well as to external stakeholders working in the field of biosimilar medicines. The information gathered in this document has been sourced from the Medicines for Europe National Associations and Member Companies.

Adrian van den Hoven
Medicines for Europe Director General

Table of contents

biosimilar medicines
better access. better health.

Availability (1/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
1. For which of the following biological active substances are biosimilar medicines available in your country? (Since)																										
Adalimumab	✓ Nov 2018	✓ Nov 2018	✓ Oct 2018	✓ Dec 2018	✓ Oct 2018	✓ Oct 2018	✓ Jan 2019	✓ Dec 2018	✓	✓ 2019	✓	✓ Nov 2018	✓ Oct 2018	✓	✓ Dec 2018	✓	✓ Jan 2019	✓ Nov 2018		✓ Mar 2019	✓ Nov 2018	✓ Apr 2018	✓ Dec 2018	✓ Nov 2019	✓	✓ Dec 2018
Bevacizumab		✓ Sep 2020							✓	✓ Jul 2020	✓		✓ Jun 2020			✓				✓ Apr 2020	✓ Oct 2020			✓ Jul 2020		
Enoxaparin Sodium	✓ Jun 2018	✓ Aug2020							✓	✓ 2016	✓		✓ Dec 2017			✓	✓ Nov 2016					✓ Feb 2018		✓ Aug 2020	✓	
Epoetin	✓ Dec 2018	✓ Aug 2007	✓ Jul 2013	✓ Jul 2013	✓ Dec 2010	✓		✓	✓	✓ 2007	✓		✓ Feb 2009		✓ Jan 2010	✓	✓[2] 2007	✓ Jan 2008	✓ 2010	✓ Oc 2010	✓ Oct 2008	✓ Feb 2008	✓	✓ Jul 2009	✓	✓
Etanercept	✓ Jan 2017	✓ Jan2016		✓ Aug 2017	✓ Aug 2016	✓ Feb 2016	✓ Jan2017	✓ Feb 2018	✓	✓ 2016	✓	✓ Dec 2015	✓ Oct 2016	✓	✓ Dec 2016	✓	✓ Jul 2016	✓ Jan 2017	✓ 2017	✓ Feb 2020	✓ Jul 2018	✓ Feb 2016	✓ Apr 2016	✓ Jul 2018		✓ Feb 2016
Filgrastim	✓ Dec 2018	✓ Sep 2008	✓ Aug 2011	✓ Apr 2012	✓ Mar 2010	✓ Feb 2017	✓ Nov 2008	✓	✓	✓ 2008	✓	✓ Nov 2008	✓ Jun 2009	✓ Mar 2009	✓ Jan 2009	✓	✓[2] 2009	✓ Feb 2009	✓ 2009	✓ Mar 2009	✓ Jul 2009	✓ Mar 2009	✓	✓ Nov 2019	✓	✓
Follitropin Alfa	✓ Jul 2014	✓ Sep 2013	✓ May 2015	✓ Feb 2016	✓ Nov 2015	✓ Jul 2016		✓	✓	✓ 2013	✓	✓ Aug 2018	✓ Apr 2015	✓ Aug 2015	✓ Aug 2015	✓	✓ Jul 2015	✓ Jul 2015		✓ Oct 2013	✓ Sep 2015	✓ Jun 2014	✓	✓ Nov 2018		✓
Infliximab	✓ Apr 2015	✓ Sep 2013	✓ Nov 2013	✓ May 2015	✓ Dec2013	✓ Mar 2015	✓ May 2014	✓	✓	✓ 2013	✓	✓ Nov 2013	✓ Feb 2015	✓ Jan 2014	✓ Aug 2014	✓	✓ Jan 204	✓ Nov 2013	✓ 2016	✓ Oct 2015	✓ May 2015	✓ Mar 2014	✓	✓ Jan 2016	✓	✓ Feb 2015
Insulin glargine	✓ Apr 2015	✓ Sep 2014	✓ Aug 2015	✓ Sep 2015	✓ Jul 2015	✓	✓ Jun 2015	✓	✓	✓ 2014	✓	✓ Sep 2017	✓ Feb 2016	✓ Jan 2016	✓ Dec2016	✓	✓ Sep 2015	✓ Jan 2017		✓ Mar 2015	✓ Mar 2016	✓ Jun 2016	✓	✓ Sep 2015	✓	✓ Sep 2015
Insulin Lispro	✓ Dec 2017							✓	✓	✓ 2017	✓		✓ Jan 2018	✓ Dec2017			✓ Nov 2017									
Pegfilgrastim	✓ Nov 2018	✓ Apr 2019		✓ Jan 2019	✓ Dec 2018	✓	✓ Mar 2019	✓	✓	✓ 2018	✓	✓ Nov 2018	✓ Feb 2019	✓		✓	✓ Nov 2018			✓ Mar 2019	✓ Feb 2018	✓ Oct 2018	✓ Dec 2018	✓ Nov 2019		
Rituximab	✓ Sep 2017	✓ Aug 2018	✓ May 2018	✓ Feb 2018	✓ Apr 2018	✓	✓ feb 2019	✓	✓	✓ 2017	✓	✓ Jun 2017	✓ Sep 2017	✓	✓ Oct 2018	✓	✓ Sep 2019	✓ Jun 2017	✓ 2018	✓ Aug 2018	✓ May 2018	✓ Apr 2017	✓ Jul 2018	✓ Sep 2018	✓	✓ Apr 2017
Somatropin	✓ May 2006	✓ Apr 2006	✓ Feb 2015	✓ Jan 2015	✓ Oc 2010	✓	✓ Apr 2013	✓	✓	✓ 2006	✓	✓ Feb2015	✓ Mar 2007	✓ Jan 2009	✓ May 2014	✓	✓[2] 2006	✓ Dec 2014	✓ 2018		✓ Apr 2010	✓ Feb 2014	✓	✓ May 2015	✓	✓
Teriparatide				✓ Nov 2019					✓	✓ 2019	✓		✓ Sep 2019						✓ 2009	✓ Sep 2019	✓ Dec 2019	✓ Jun 2003		✓ Sep 2019		
Trastuzumab	✓ May 2018	✓ Sep 2018	✓ Aug 2018	✓ Dec 2018	✓[1]	✓	✓ Feb 2020	✓	✓	✓ 2018	✓	✓ Jul 2018	✓ Sep 2018	✓	✓ Oct 2018	✓	✓ Jul 2018	✓ May 2018		✓ Nov 2018	✓ Nov 2018	✓ Apr 2018	✓	✓ Oct 2019	✓	✓ Mar 2018

(1) Despite two products being on the list of reimbursed medicines, Trastuzumab is not yet available on CZ market.

(2) The date of introduction of biosimilar medicines containing epoetin, filgrastim and somatropin cannot be determined precisely. These medicines were available on the market before 2012.

biosimilar medicines
better access. better health.

Availability (2/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
2. In which setting, or settings, are the biosimilar medicines available? (H: Hospital pharmacy - S: Specialised centres - R: Retail pharmacy)																										
Adalimumab	H,S,R	H,R	H,R	R	H,S,R	H	R	R	H	H,S,R	H,S	R	H	R	R	H	H	H		H,S,R	R	H	R	H,S,R	H	H
Bevacizumab		H					H		H	H,S,R	H,S	H	H	R		H		H		H,S	H			H,S,R		
Enoxaparin Sodium	H,S,R	H					H		H	H,S,R	H,R	H,R	H,S,R	H,R		H,R	H,R	H,R				H,R		H,S,R	H,S,R	
Epoetin	H,S	H	H,S	H,S	H,R	H	H	H,R	H,R	H,S,R	H,R	H,R	H,S,R	H,R	R	H,R	H,S	H	R	S,R	H,S,R	H	H,R	H,S,R	H,S,R	H
Etanercept	H,S,R	H,R		H,R	H,S	H	R	R	H,R	H,S,R	H,S	H,R	H	R	R	H	H	H	R	H,S,R	R	H	R	H,S,R		H
Filgrastim	H,S,R	H	H	H	H,R	H	H	H,R	H,R	H,S,R	H,R	H,R	H,R	H,R	R	H,R	H,R	H	H,R	H,R	H,R	H	H,R	H,S,R	H,R	H
Follitropin Alfa	H,S	H	H	H	H,S,R	H		R	H,R	H,S,R	H,S,R	H	H,R	R	R	H,R	S,R	H,R		H,S	H,R	H,R		H,S,R		H
Infliximab	H,S,R	H	H,S,R	H	H,S	H	H	H	H	H,S,R	H,S	H,R	H	R	R	H	H	H	R	H,S	H	H	H	H,S,R	H,R	H
Insulin glargine	H,S,R	H,R	H,R		H,R	H	R	R	H,R	H,S,R	H,R	H,R	H,R	R	R	H,R	H,R	H,R		H,S,R	R	H,R		H,S,R	H,R	H
Insulin Lispro	H,S,R			H			R	R	H	H,S,R	H,R	H,R	H	R			H,R				R					
Pegfilgrastim	H,S,R			H	H,R	H	H	R	H	H,S,R	H,R	R	H,R	R		H,R	H	H	H,R	R	H,R	H	H	H,S,R		
Rituximab	H,S,R	H	H,R	H	H,S	H	H	H	H	H,S,R	H,S	H	H	R	H	H	H	H	H,R	H,S,R	H	H	H	H,S,R	H	H
Somatropin	H,S,R	H	H,R	H,R	H,S,R	H	R	R	H,R	H,S,R	H,S,R	R	H,R	R	R	H	H,R	H,R	R		R	H	R	H,S,R	H,R	H
Teriparatide				H					H	H,S,R	H,R	R	H,R	R				H,R			R	H,R		H,S,R		
Trastuzumab	H,S	H	H	H	H,S	H	H	H	H	H,S,R	H,S	H	H	R	R	H	H	H		H	H	H	H	H,S,R	H	H,S

biosimilar medicines
better access. better health.

Pricing Systems (1/5)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
3. What kind of pricing system is in place for biosimilar medicines?																										
Free pricing						✓				✓		✓											✓			✓
Price regulation	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓[1]	✓	✓	✓[2]	✓[3]	✓	✓[4]	✓	✓	
4. If there is price regulation, which criteria are used to set the prices?																										
External reference pricing	✓		✓	✓[6]	✓[7]									✓		✓	✓[11]	✓[13]	✓[14]	✓[15]	✓[17]	✓[19]			✓[22]	
% below originator price	✓ 38%	✓[5] 35,8%	✓ 20%	✓ 20%	✓ 30%		✓ 30%	✓ 30%	✓ 40%		✓[9] 30%		✓[10] 20%	✓	✓ 15%		✓ 25%	✓ 20-30%	✓ 20%	✓[16]	✓ 32%			✓ 25%		
Maximum price	✓								✓[8]								✓					✓[20]	✓[21]			
Negotiation	✓						✓						✓				✓					✓[20]	✓[21]			
Other							Tender price								23		12				✓[18]					

(1) Price regulations apply only to reimbursed products. For non-reimbursed products, prices are free. A detailed new regulatory framework was introduced in 2012 in the Reimbursement Act. Biosimilar medicines are treated like generic medicines throughout the pricing process.
(2) The reference price is the average of the 3 lowest within 28 EU countries. In SK, there is a defined 3 level/step entrance of biosimilar drugs: 1st Biosimilar minus 25%, 2nd Biosimilar minus 5%, 3rd Biosimilar minus 5%.
(3) Pricing regulation in Slovenia applies only to those medicinal products that are financed with public revenues. With the pricing regulations, the Maximum Allowed price (MAP) is defined, which is the starting point for negotiations with National Health insurance institute to obtain reimbursed price. Only MAP price without VAT (Wholesaler's price - the price from Wholesaler to Pharmacy) is officially published.
(4) There is free pricing, but if you want to be within the reimbursement system, the price will have to be approved by TLV (agency). When the Bios/Gx enters the market, they can have the same price as the originator or lower. If only hospital use, there is a normal tender (with free pricing).
(5) Average level of price is between 35,8% to 45,53% lower.
(6) The maximum price is 100% of the average comparative price (PUC) in reference countries and reference countries are Slovenia, Italy, Czech Republic + Spain and France.
(7) Reference countries: the EU except for BG, EE, LU, DE, AT, RO, GR, CY, MT
(8) Maximum price is only applicable at hospital level
(9) Stepped pricing system in the case of biosimilar products: 1st biosimilar must be priced 30% lower than the originator product; 2nd and 3rd biosimilar - 10%; then below the cheapest
(10) % discount depends on the average public expenditure of originator in the previous three years. The price level below the originator is generally around 20% (depending also on the different strength and dosages). These are the list prices, then the tender path starts at regional level
(11) All EU/EFTA countries
(12) Biosimilar medicines are treated like generic medicines throughout the pricing process. Price requirements are the same as for generics: where another biosimilar is reimbursed for a given indication, the maximum price cannot be higher than 1) the equivalent setting the limit base or 2) the cheapest equivalent i the limit base is in a given limit group, set by a medicine with another active substance. The limit base is set within limit groups (therapeutic reference groups).
(13) Reference countries: Spain, France, Italy, Slovenia
(14) Reference countries: Czech Republic, Bulgaria, Hungary, Slovakia, Austria, Belgium, Italy, Lithuania, Germany, Greece, Spain
(15) Reference countries: 28 EU countries, including Slovakia
(16) 3 step entrance of biosimilar medicines: 1st biosimilar minus 25%, second minus 5%, third minus 5%
(17) Reference countries: Austria, France, Germany
(18) 8% below the lowest Sandoz biosimilar. 32% below originator price is used only if there are no Sandoz biosimilars marketed in reference countries. So far, this criterion has not been used for Sandoz biosimilars.
(19) Reference countries: France, Italy, Portugal
(20) The price is set by the Interministerial Pricing Commission (CIPM). They have to negotiate with the company for a price below the originators' price, taking European prices (France, Italy, Portugal) into account. The price set is a maximum price for biosimilars used in hospitals.
(21) Maximum price only for retail. For hospital use, there is no maximum price. If the product group is very costly for society, it is negotiated (Three party agreement). This is valid for less than 2% of the volume of the total market but includes big products such as Humira / Adalimumab.
(22) Reference countries: France, Greece, Italy, Portugal, Spain
(23) Price tendering in reimbursement list based on group or INN

Pricing Systems (2/5)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
5. What are the key parameters considered when prices are set?																										
	1	2	3	4	5			6			7	8	9				10	11	12	13	14	15	16		17	
6. If external reference pricing is used in pricing decisions, what does it indicate:																										
Price for originators	✓			✓					✓									✓		✓	✓	✓	✓		✓	
Price for biosimilars	✓		✓	✓														✓	✓[19]	✓	✓	✓	✓		✓	
Benchmarking with other countries	✓		✓[20]	✓	✓									✓		✓	✓[18]			✓						
Other																										

(1) Originator is the reference
(2) Legal price decreases, sometimes deviations are discussed referring to European benchmarks but rarely sustained
(3) For retail, see above. For hospitals: tender
(4) Maximum allowed price
(5) Three lowest priced products in the EU
(6) Price of the originator
(7) Daily cost of treatment, which is based on the manufacturer price
(8) Price of originator, HSE guidance, Price of competitor biosimilars
(9) Annual average value of the total public expenditure in the three years preceding the request for P&R.
(10) The stance of the Economic Commission, price competitiveness, the recommendations of the president of the Agency for HTA and Tariffs, especially the result of an analysis of the cost to health effect ratio. Final price decision of the Ministry of Health should take into account: the balance of interests of service recipients and manufacturers or distributors of medicines, the payment ability of the entity obliged to finance healthcare services from public funds and the applicant's scientific research and investment activity related to health protection in the territory of Poland and in other member states of the EU or member states of EFTA. In fact, these criteria are marginalised in the process.
(11) Reference product
(12) The lowest price considering both criteria
(13) Reference price is average of 3 lowest within 28 EU countries. The 3 step entrance of biosimilar drugs: 1st Biosimilar minus 25%, 2nd Biosimilar minus 5%, 3rd Biosimilar minus 5%.
(14) Reference price
(15) European prices, expenditure on R&D, administration and the economic and financial situation of the company
(16) Price of competitors
(17) Referenced to the lowest price in the basket of reference countries
(18) Application for reimbursement should contain information concerning reimbursement of the medicinal product in all member states of the EU or member states of the EFTA with an indication of the reimbursement level, reimbursement terms and conditions and restrictions, including detailed information on any risk sharing instruments executed or information on the absence of such restrictions or such instruments, the maximum and minimum net selling price obtained in particular member states of the EU or member states of the EFTA as part of financing from the public funds of those states in the year before the application, information on rebates, discounts or pricing agreements.
(19) The lowest price from the reference basket (question 4) is used to establish the price for both originals and biosimilars. For biosimilars, the lowest price from the basket is compared also with 80% from the originator price in Romania and the lowest value is selected.
(20) Romania, France, Latvia, Greece, Slovakia, Spain, Belgium, Poland, Hungary, Italy

Pricing Systems (3/5)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
7. If external reference pricing influences price of biosimilar medicines, what formula is applied:																										
Lowest price in reference countries			✓														✓	✓ for hospital	✓		✓				✓	
Average price of reference countries	✓			✓												✓		✓ for retail		✓						
Other					✓[1]									✓								✓[2]	✓[3]			
8. Is a marketing authorisation necessary to apply for a price of biosimilar medicine?																										
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	
No										✓													✓			
9. If yes, the pricing application:																										
Starts simultaneously with the marketing authorisation process and ends before the marketing authorisation is granted																										
Starts simultaneously with the marketing authorisation process and ends after the marketing authorisation is granted																✓							✓			
Starts after the marketing authorisation process is initiated and ends before the marketing authorisation is granted																										
Starts after the marketing authorisation process is initiated and ends after the marketing authorisation is granted													✓													
Starts only after the marketing authorisation is granted	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓		✓	✓	✓	✓	✓	✓		✓	✓	

(1) Average price of the three lowest priced products in the EU
(2) Generally, 20% - 30% discount over the originator price. Recently, the MoH is taking the real price of the originator in Spanish hospitals into account to set the price.
(3) Only compared with domestic prices, not compared to prices in other countries.

Pricing Systems (4/5)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
10. Is the application for pricing and reimbursement of a biosimilar medicine:																										
A single process	✓		✓			✓		✓			✓	✓	✓			✓	✓	✓	✓[2]	✓	✓		✓	✓		
A separate procedure		✓[1]		✓	✓				✓						✓			✓			✓	✓[3]			✓	
11. On average, how long does it take for a biosimilar medicine to receive its P&R approval from the day of application (in days)?																										
	180	120	30	90	75	/		46	/	0	30	90	180	45	60	[1]	180[4]	30	180-240	120	120	210	60	50	180-270[5]	
12. After being listed, how long does it take for a biosimilar medicine to be available in the hospital?																										
	6	7	8	6	6	6		/	9	0	10	11	12		/	18	13	6	14	15	6	16	17	18	6	

(1) 2 separate government organisations: FPS economy and Nihdi
(2) If the INN is already reimbursed, the reimbursement for the biosimilar is granted automatically. If there is no reimbursement for the INN, an HTA dossier must be submitted and approved, which is a separate process.
(3) Spain does not have reimbursement like other countries but has funding. The administration sets the maximum price they are willing to pay for the drug.
(4) 180 days is the maximum time for the Ministry of Health to consider the P&R application and issue a refund decision (positive or negative). If the data required to examine the application needs to be supplemented, the running of the period will be suspended until the day the data is supplemented or until the time limit for supplementing the application passes. As the Ministry of Health is interested in the reimbursement of generics (it allows for cost containment) the real terms may be lower than the ones set by law. Information on average time of reimbursement for generics is not available (they do not need assessment of the Agency for Health Technology Assessment and Tariffs, so there is no information on the reimbursement application submission date). In practice, the time to consider an application for a biosimilar /generic medicine depends on: 1) the number of all reimbursement applications submitted to the MoH, 2) the result of price negotiations with the Economic Commission (positive EC opinion speeds up the further processing of the application).
(5) Pricing approval takes a maximum of 90 days. For reimbursement, there are several parameters to be considered (such as being the first biosimilar, local production etc.) but it generally takes 3-6 months.
(6) Immediately
(7) Depends on tender
(8) After tender - 30-45 days
(9) When the next tender process is open
(10) Promptly after official price comes into effect, except in the case of patent protection for the original drug. However, for tender products: a tender procedure is necessary and only the winner can be available in hospitals
(11) Depending on the formulary committee to approve
(12) 60 days, but depends on the Regional authorities
(13) Depends on the organisation of public tenders
(14) Until the first tender
(15) Depending on the molecule and central purchasing process (approximately 6 months)
(16) No data
(17) When you have a price and MA
(18) 1 day

Pricing Systems (5/5)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
13. What are the causes of the delay between the biosimilar medicines listing and the hospital availability?																										
	1	2	3	4	5	6		/	7	/	8	9	10		/	/	11	4	4	12	4	13	14	14	4	

(1) Negotiations
(2) Tenders, exclusivity contracts
(3) Timing of tenders and possible complaints
(4) Tender
(5) Hospital decision
(6) Efficient tender system
(7) Timing of tender procedures
(8) Patent protection, lack of tender
(9) All Biosimilars are available for hospitals after P&R. Depends on hospital formulary committee approval
(10) The Regional Authorities do not open the tender within 60 days
(11) Public tender procedures
(12) Central purchasing process organised by Health Insurance Companies
(13) Regional level
(14) No delay

biosimilar medicines
better access. better health.

Retail tendering (1/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
14. Is retail tendering applied to biosimilar medicines?																										
Yes										✓						✓		✓								
No	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓
15. If yes, what is the scope of the retail tenders?																										
National																										
Regional																		✓								
Other										1						✓2		✓3								
16. If yes, which body is in charge of the retail tendering system:																										
National government																		✓								
Regional government																										
Health insurance funds										✓						✓										
Other																3		3								
17. If yes, what is the average contract duration of the retail tender (in months)?																										
										24						12-24		/								
18. If yes, are there separate tenders for naïve versus currently on threatment patients?																										
Yes																✓										
No										✓								✓								

(1) Number of persons insured by the specific sick fund
(2) Hospitals and healthcare insurers
(3) Hospital

Retail tendering (2/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
19. If yes, does a single retail tender contract allow for more than one winner?																										
Yes										✓						✓										
No																		3								
20. If yes, how are retail tendering contracts awarded? By:																										
Active substance										✓						✓		✓								
Group of active substances																										
Therapeutic indications																										
Other																										
21. Do tender contracts have to be re-opened once biosimilar medicines enter the market?																										
Yes - Immediately after the marketing authorisation of the biosimilar medicine																										
Yes - A couple of months after the marketing authorisation of the biosimilar medicine																										
No										✓						✓		✓								
22. Are factors other than price taken into account when determining the winner of the tender?																										
Yes																		✓								
No										✓						✓										

(1) Not applicable for retail market

Retail tendering (3/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
23. If price is not the single factor, what is the range of weight given to price when determining the winner of a tender?																										
Minimum (%)																										
Maximum (%)																		Almost 100%								
24. If yes, which of the following factors is taken into account?																										
Costumer service																										
Ongoing patient support																										
Local manufacture																										
Most complete range of indications																										
Proven track record of ability to supply																		✓								
Patient registry																										
Environmental aspects																										
Condition of payment																		✓								
Formulation																		✓								
Aggregation (of packs)																										
Corporate responsibility																										
Other																		✓								

biosimilar medicines
better access. better health.

Hospital tendering (1/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
25. Is hospital tendering applied to biosimilar medicines?																										
Yes		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓			✓	✓	✓	✓	✓[7]	✓	✓	✓	✓	✓	✓
No	✓									✓[1]				✓	✓											
26. If yes, what is the scope of the hospital tenders?																										
National				✓		✓	✓				✓						✓[2]	✓				✓			✓	
Regional								✓				✓	✓				✓[2]					✓	✓			✓
Hospital (individual or group)		✓	✓	✓	✓		✓		✓		✓	✓	✓			✓	✓	✓	✓	✓	✓	✓		✓	✓	
Other																										
27. If yes, which body is in charge of the hospital tendering system:																										
National government				✓							✓							✓				✓	✓		✓	✓
Regional government						✓							✓									✓	✓			
Health insurance funds			✓				✓				✓															
Group of hospitals		✓			✓		✓	✓	✓			✓				✓				✓		✓		✓	✓	
Individual hospitals		✓		✓	✓		✓		✓		✓	✓					✓	✓	✓	✓	✓	✓		✓	✓	
Other		[3]											[4]				✓									
28. If yes, what is the average contract duration of the hospital tender (in months)?																										
		48[5]	6-12	12	12	12	12-24	48	24		12	12	24			12-24	12-24	12	24	12	12	variable	48	24	12	[6]

(1) In Germany, there are no tenders in the hospital market but individual contracts between the companies and the hospitals / purchasing associations.
(2) Since 2018, the law allows regional and national tenders for hospital products. The law gives the right to conduct regional or national tenders to the President of the NHF and Directors of NHF's voivodship branches. But as yet it has not been used.
(3) Purchasing groups for hospitals
(4) national specialised tender agency
(5) 48 (or 2y+1y+1y)
(6) 2 years awarded on a 6 monthly rolling basis
(7) Only 10% of hospitals, depending also on molecule (e.g. there are some hospitals tenders for filgrastim).

biosimilar medicines
better access. better health.

Hospital tendering (2/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
29. If yes, are there separate tenders for naïve versus currently on treatment patients?																										
Yes											✓					✓						✓				
No		✓	✓	✓	✓	✓	✓	✓	✓			✓	✓				✓	✓	✓	✓	✓		✓	✓	✓	✓
30. If yes, does a single hospital tender contract allow for more than one winner?																										
Yes				✓									✓					✓			✓	✓		✓		✓
No		✓	✓		✓	✓	✓	✓	✓		✓	✓				✓	✓		✓	✓			✓		✓	
31. If yes, how are hospital tendering contracts awarded? By:																										
Active substance		✓	✓		✓	✓	✓	✓	✓		✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Group of active substances											✓	✓										✓	✓		✓	
Therapeutic indications						✓					✓	✓									✓		✓			✓
Other				✓[1]																						
32. Do tender contracts have to be re-opened one biosimilar medicines enter the market?																										
Yes - Immediately after the marketing authorisation of the biosimilar medicine																										
Yes - A couple of months after the marketing authorisation of the biosimilar medicine								✓					✓[1]													
No		✓	✓	✓	✓	✓	✓		✓		✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

(1) Within 60 days after market entry (communication by the company that the product is available for purchase.)
(2) Branded name

biosimilar medicines
better access. better health.

Hospital tendering (3/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
33. Are factors other than price taken into account when determining the winner of the tender?																										
Yes		✓						✓	✓			✓					✓[1]	✓				✓	✓	✓	✓	
No			✓	✓	✓	✓	✓				✓		✓			✓			✓	✓	✓					✓[2]
34. If price is not the single factor, what is the range of weight given to price when determining the winner of a tender?																										
Minimum (%)		50%						40%	NA			60%					60%					variable	40%	75%		
Maximum (%)		90%						60%	NA			100%					99%	almost 100%				variable	100%	90%		
35. If yes, which of the following factors is taken into account?																										
Costumer service		✓						✓				✓						✓				✓		✓		
Ongoing patient support		✓										✓										✓				
Local manufacture												✓												✓	✓	
Most complete range of indications		✓						✓				✓											✓	✓		
Proven track record of ability to supply		✓							✓			✓						✓				✓	✓	✓	✓	
Patient registry																		✓				✓				
Environmental aspects								✓	✓			✓										✓	✓			
Condition of payment		✓										✓					✓					✓				
Formulation		✓										✓						✓				✓	✓			
Aggregation (of packs)									✓			✓												✓		
Corporate responsibility		✓																				✓	✓			
Other		✓[3]						✓[4]									✓[5]						✓[6]			

(1) In fact, the price is the most important factor. Recently, new mechanisms ("correction factors") have been introduced in the reimbursement system, that have strengthened the role of the lowest price as a criterion when determining the winner of the tender. The purpose of the "correction factors" launch was to encourage hospitals to buy the cheapest available therapies in exchange for additional, increased financing for healthcare services related to drug administration. The range of correction factors is determined by the President of the NHF

(2) The BBA position is that focus should be on the full value proposition of different products, including services and support and not just price.
(3) Innovation
(4) safety, effectiveness, usability
(5) safety, effectiveness, usability, delivery terms
(6) Product range, artwork readability

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
36. Is a marketing authorisation necessary to apply for reimbursement of biosimilar medicines?																										
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
No										✓																
37. If yes, the reimbursement																										
Starts simultaneously with the marketing authorisation process and ends before the marketing authorisation is granted																✓										
Starts simultaneously with the marketing authorisation process and ends after the marketing authorisation is granted																✓										
Starts after the marketing authorisation process is initiated and ends before the marketing authorisation is granted																										
Starts after the marketing authorisation process is initiated and ends after the marketing authorisation is granted																										
Starts only after the marketing authorisation is granted	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
38. Are biosimilar medicines included in internal reference pricing systems for reimbursement purposes (e.g. Festbetrag)?																										
Yes		✓	✓							✓	✓	✓		✓	✓		✓	✓		✓		✓			✓	
No	✓			✓	✓	✓	✓	✓	✓				✓			✓			✓		✓		✓	✓		✓

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
39. If yes, how is the reference group established?																										
By active substance (ATC-5)		✓	✓							✓	✓	✓		✓	✓		✓	✓		✓		✓			✓	
By pharmacological class (ATC-4)										✓		✓			✓											
By therapeutic class (ATC-3)												✓														
Other																	✓[1]									
40. If yes, on what basis is the reference price established?																										
Average price of medicines																		✓								
Average price of biosimilar medicines										✓																
Lowest priced medicine											✓			✓	✓							✓			✓	
Lowest priced biosimilar medicine		✓[2]	✓				✓																			
External reference pricing			✓	✓	✓									✓				✓								
Other																	✓[3]			✓[4]						

(1) In Poland the therapeutic reference pricing (TRP) is implemented through limit groups. Drugs with the same international name or with different international names but a similar therapeutic effect and mechanism of action are classified to the same limit group (if they have similar effectiveness and the same indications for use, for which they are reimbursed). Within the group a common financing limit is set. The common financing limit performs two functions - determines the maximum funding level (the NHF does not reimburse cost above the limit), as well as sets the threshold price for therapeutic competitors applying for entry into the reimbursement system (if the active substance is the same). Most often in open pharmacies the financing limit is set at the cheapest drug whose cumulative share (expressed in daily defined doses) is 15% of the sales in the group. The exception is price limit indicated by the first equivalent.
(2) CRM tries to lower the price even after legal price decrease, for example in case biosimilar can be positively discriminated for a financial incentive
(3) Price of the only equivalent reimbursed for a given indication (no higher than 75% of the original drug price) or 2) Maximum price in the case of another (second, third or subsequent) equivalent reimbursed for a given indication no higher than: a) of the equivalent setting the limit base or b) of the cheapest equivalent if the limit base in a given limit group is set by a medicine with another active substance)
(4) Average of three lowest prices. Basket is 28 EU countries.

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
41. If yes, for which active substances?																										
Adalimumab		✓		✓			✓							✓	✓		✓	✓		✓		✓			✓	✓
Bevacizumab		✓										✓		✓				✓		✓						
Enoxaparin Sodium		✓												✓			✓					✓			✓	
Epoetin			✓	✓							✓			✓	✓		✓	✓		✓		✓			✓	
Etanercept		✓		✓			✓			✓				✓	✓		✓	✓		✓		✓				
Filgrastim		✓	✓	✓						✓	✓			✓	✓		✓	✓		✓		✓			✓	
Follitropin Alfa			✓											✓	✓		✓	✓		✓		✓				
Infliximab		✓	✓	✓						✓		✓		✓	✓		✓	✓		✓		✓			✓	
Insulin glargine		✓		✓			✓							✓	✓		✓	✓		✓		✓			✓	
Insulin Lispro							✓							✓			✓	✓								
Pegfilgrastim		✓		✓							✓			✓			✓	✓		✓						
Rituximab		✓	✓	✓								✓		✓			✓	✓		✓		✓			✓	
Somatropin			✓	✓			✓							✓	✓		✓	✓				✓			✓	
Teriparatide														✓				✓		✓		✓				
Trastuzumab		✓	✓	✓								✓		✓	✓		✓	✓		✓		✓			✓	
42. Is there patient co-payment for biosimilar medicines?																										
Yes		✓	✓				✓	✓		✓	✓				✓		✓	✓[1]	✓			✓	✓	✓	✓	
No				✓	✓	✓			✓			✓	✓	✓		✓				✓	✓					✓

(1) Only in retail

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
43. If yes, for which active substances?																										
Adalimumab		✓	✓				✓	✓		✓					✓								✓	✓	✓	
Bevacizumab										✓														✓		
Enoxaparin Sodium										✓	✓						✓					✓		✓	✓	
Epoetin										✓	✓				✓			✓	✓[1]					✓	✓	
Etanercept		✓					✓	✓		✓					✓				✓				✓	✓		
Filgrastim										✓	✓				✓		✓		✓				✓	✓	✓	
Follitropin Alfa										✓	✓				✓		✓	✓				✓		✓		
Infliximab			✓							✓					✓				✓					✓	✓	
Insulin glargine							✓			✓	✓				✓		✓					✓		✓	✓	
Insulin Lispro							✓			✓	✓						✓							✓		
Pegfilgrastim										✓									✓					✓		
Rituximab										✓									✓					✓		
Somatropin							✓			✓	✓				✓			✓	✓				✓	✓	✓	
Teriparatide										✓	✓							✓				✓		✓		
Trastuzumab										✓					✓									✓	✓	

(1) It might appear for any of the existing INN, but usually the companies are covering the co-payment. The Romanian government covers 120% of the cheapest drug.

Reimbursement Systems (5/5)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
44. If yes, which of the following is the co-payment based on?																										
Patient monthly/annual consumption (DDD)																	✓									
Fixed amount per prescription							✓				✓															
% of cost of medicines (partially reimbursed)		✓	✓					✓			✓						✓	✓				✓		✓		
Difference above reference price											✓				✓		✓		✓							
Other		✓[1]								✓[2]							✓[3]						✓[4]	✓[5]	✓[6]	
45. If yes, does the co-payment differ for biosimilar medicines when compared to the reference product?																										
Yes											✓				✓		✓[7]		✓					✓[8]		
No		✓	✓					✓		✓								✓				✓	✓		✓	

(1) With maximum depending on the class the biosimilar is in
(2) 10% of retail price, but min 5 euro, max 10 euro
(3) Reimbursement Act provides four categories of a patient's co-payment: free of charge (to the limit), fixed fee, 30% (to the limit) and 50% (to the limit). MoH gives a category for each drug during the P&R process. Biosimilar / generic and original medicines have the same category, if they are reimbursed in the same clinical indications. At the time of buying the drug at the pharmacy - reimbursement is given by NHF up to the limit, which is set for each drug (depends on price of drug being the limit base in given group and the amount of the active substance in the SKU). While a patient's co-payment consists of two parts: a payment to the limit (based on the category specified by the MoH) and difference in price of the drug and the limit for it.
(4) The patient pays 100% of the cost up to a certain level, then 50%, 25%, 10% and finally gets all the medicines totally free (if the product is within the reimbursement system). After a 12 month period this system starts all over again. Does not matter if it concerns Biological or Chemical products.
(5) Capped at CHF 700,- p.a.
(6) For chronic diseases, if there is a health report from a healthcare organisation, then there is no co-payment. Otherwise, the pensioners pay 10% and employees pay 20% of the expense of their medicines. Besides this, for each prescription all patients pay a fee depending on the number of boxes they have been prescribed.
(7) The patient's co-payment (to drugs within one limit group) depends on the official prices and the price-to-limit ratio. If the price of a biosimilar / generic medicine differs from the price of the original medicine, then the co-payment of the patient is also different.
(8) It depends on the product price

Physician-related topics (1/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
46. Is INN prescribing legally allowed in your country? (for biological medicines)																										
Yes					✓		✓		✓		✓			✓	✓		✓	✓							✓	✓	
No	✓	✓	✓	✓		✓		✓		✓		✓	✓			✓			✓	✓	✓	✓	✓			✓
47. Are there recommendations to prescribe biological medicines by INN?																										
Yes														✓	✓		✓							✓		
No	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓					✓		✓					✓	
48. If INN prescription is legally allowed for biologic medicines:																										
Physicians are obliged to prescribe only by INN														✓												
Physicians can prescribe only by brand name					✓						✓															
Physicians can prescribe only by brand name under certain exceptions																										
Physicians are obliged to prescribe by both INN and brand name									✓						✓		✓[2]	✓						✓[1]	✓	
49. Are there measures in place supporting the prescription of biosimilar medicines?																										
Yes, legislative measures		✓						✓	✓		✓				✓											
Yes, recommendations	✓	✓		✓		✓		✓	✓	✓			✓	✓				✓			✓	✓				✓
No			✓		✓		✓					✓				✓	✓		✓	✓			✓	✓	✓	

(1) Free to choose.
(2) Physicians may prescribe by INN or brand name or by both. The NHF has recently introduced financial incentives that should increase the INN prescriptions in hospitals. These tools enable hospitals to obtain a higher rate of settlement for non-drug health services after purchasing the drug with a correspondingly lower price. This solution increases the use of biosimilar medicines and dissemination of the view that biosimilar medicine can (shall) be treated in the same way as originals.

Physician-related topics (2/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
50. Do the supportive measures differentiate between treatment naïve patients and patients currently under treatment?																										
Yes				✓									✓		✓[1]			✓[2]			✓	✓				✓
No	✓	✓				✓		✓	✓	✓	✓			✓					✓							
51. Which supportive measures are in place?																										
Prescribing guidelines	✓			✓				✓		✓					✓			✓				✓				✓
Electronic prescribing									✓		✓		✓	✓	✓			✓				✓				
- Only allows INN prescribing														✓			✓									
- Allows also brand name prescribing									✓		✓			✓	✓			✓				✓				
Voluntary target agreements		✓								✓												✓				
Compulsory prescription targets (i.e. quotas)									✓[3]	✓	✓							✓								
Benefit-sharing agreements									✓[4]				✓					✓								✓
Prescription audits	✓	✓								✓								✓								
Health insurance fund visits	✓									✓											✓					✓
Direct financial incentives		✓							✓									✓								
Direct financial restrictions										✓								✓								
Information/education materials/training	✓	✓				✓		✓		✓			✓	✓				✓				✓				✓
Other				✓													✓[6]	✓[5]								

(1) The cheapest product in the group should be prescribed to new patients
(2) Recommending the use of biosimilars for new patients. Switching from reference product to biosimilar if this has economic advantages (most cost-effective option)
(3) Quotas only exist for insulin at retail level
(4) Benefit-sharing agreements are currently being experimented at regional level
(5) Since 2016, there are signed annual contracts with the health units for which the minimum of 20% MS of biosimilar are a goal, with sharing of benefits (25% - 15% of gains) or penalty of a maximum of 3% of total financial amount for the health unit if the goal is not achieved. Benchmarking every 3 months and the market shares / hospital are published.
(6) Physicians may prescribe by INN or brand name or by both. The NHF has recently introduced financial incentives that should increase the INN prescriptions in hospitals. These tools enable hospitals to obtain a higher rate of settlement for non-drug health services after purchasing the drug with a correspondingly lower price. This solution increases the use of biosimilar medicines and dissemination of the view that biosimilar medicine can (shall) be treated in the same way as originals.

Physician-related topics (3/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
52. Which of the above supportive measures have been the most effective in increasing the medical use of biosimilar medicines?																										
	1			2		3		none	4	5	/		6		7			All sets			/	8				9

(1) Prescribing guidelines
(2) No big impact
(3) Education of patients and doctors
(4) Measures are too recent to evaluate their effects
(5) Compulsory prescription targets
(6) Financial restrictions and benefit share agreements
(7) The cheapest product in the group should be prescribed to new patients
(8) Training and information to physicians
(9) Commissioning Framework for Biological Medicines including biosimilar medicines

Pharmacist-related policies (1/1)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
53. Is biologic medicines substitution, at the level of retail pharmacies, legally allowed? (i.e. without consulting the prescriber)																										
Yes					✓									✓	✓		✓	✓[3]							✓	
No	✓	✓	✓	✓		✓	✓	✓	✓[1]	✓[2]	✓	✓	✓			✓		✓[3]	✓	✓	✓	✓	✓	✓		✓
54. Is there a specific legal provision which allows substitution of biosimilar medicines at the level of retail pharmacies? (i.e. without consulting the prescriber)																										
Yes					✓												✓[4]									
No	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
55. If substitution (retail level) is legally allowed:																										
It is not enforced or applied in practice					✓									✓												
It only applies to treatment naïve patients																										
It only applies to existing patients																										
Physicians need to explicitly give permission																										
Physicians can prevent it					✓									✓			✓									
Pharmacists are obliged to inform the patient					✓												✓	✓								
Pharmacists are obliged to substitute																	✓									
Patients can refuse					✓									✓			✓	✓								

(1) Substitution is authorised by law, but non-applicable because the implementation decree has not yet been adopted.
(2) GASV-law: It will be allowed in 2022
(3) Theoretically it is allowed, but it does not happen in reality. This is not incentivised by the Government.
(4) Pharmacists are obliged to propose a cheaper medicine

Information and education (1/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
56. Is there an identified need for information targeting patients or healthcare professionals about biosimilar medicines?																										
Yes	✓[1]	✓[2]	✓[3]	✓[4]	✓	✓[5]	✓	✓[6]	✓[7]	✓		✓[8]		✓	✓[9]		✓[10]	✓[11]	✓	✓	✓	✓[12]	✓	✓[13]	✓	✓
No											✓		✓			✓										
57. Have there been information campaigns targeting patients or healthcare professionals to inform them about biosimilar medicines?																										
Yes	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓	✓				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
No									✓[14]		✓			✓	✓	✓										
58. If yes, in which form have they been rolled out?																										
Handbooks				✓	✓		✓			✓		✓	✓				✓	✓			✓	✓		✓	✓	✓
Videos	✓	✓						✓		✓		✓	✓					✓			✓	✓			✓	✓
campaigns	✓	✓		✓			✓			✓		✓	✓					✓	✓	✓						✓
Leaflets	✓	✓	✓	✓	✓	✓	✓			✓		✓	✓				✓	✓	✓	✓				✓	✓	
Seminars, conferences or workshops	✓	✓	✓	✓	✓		✓	✓	✓	✓			✓				✓	✓	✓	✓	✓	✓		✓		
Training or continuous professional development for healthcare professionals				✓	✓	✓	✓	✓					✓					✓	✓	✓	✓	✓		✓		
Websites	✓	✓	✓		✓	✓		✓		✓		✓	✓				✓	✓	✓		✓	✓	✓	✓		✓
Apps													✓													
Other												✓[15]								✓[15]						

(1) pharmaceutical industry
(2) Medaxes + nihidi taskforce
(3) manufacturers of biosimilars
(4) Healthcare fund, MAH, Agency for Medicines
(5) Patient organisations, doctors, medicines agency, etc
(6) Finnish Medicines Agency
(7) industry/authorities
(8) Relevant stakeholders, including HSE and HCPs
(9) Industry
(10) Patient's Rights Ombudsman, Associations of pharmaceutical companies, patient groups, clinical experts
(11) Authorities, industry and patients
(12) physicians, authorities, companies
(13) Sandoz
(14) no wide information campaings
(15) media

Information and education (2/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Hungary	Ireland	Italy	Latvia	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
59. If yes, who developed the material/events?																										
Patient associations		✓		✓		✓				✓		✓	✓				✓							✓		✓
Medical societies				✓			✓	✓				✓	✓				✓	✓				✓				
Authorities				✓		✓		✓				✓	✓				✓	✓		✓			✓			
Biosimilar medicines industry	✓	✓	✓	✓	✓		✓		✓	✓		✓	✓				✓	✓	✓	✓	✓	✓		✓	✓	
Originator medicines industry									✓								✓									
Collaborative (multi-stakeholder) effort												✓	✓					✓		✓		✓				✓
Other										✓[1]								✓[2]							✓	

(1) pro generika
(2) professional societies

biosimilar medicines

a medicines for europe sector group

The Biosimilar Medicines Group is a sector group of Medicines for Europe representing the leading companies developing, manufacturing and/or marketing biosimilar medicines across Europe. With more than 10 years of positive patient treatment experience and over 30 products successfully launched, today biosimilar medicines provide a huge opportunity to deliver significantly improved access to modern therapies for millions of European patients in both chronic and acute care. Our members bring competition to the biological medicines market, thereby increasing access to highly innovative treatments to patients, in Europe and around the world, and supporting the sustainability of the European healthcare systems.

The Medicines for Europe vision is to provide sustainable access to high quality medicines for all patients, based on 5 important pillars: patients, quality, value, sustainability and partnership. For more information, please follow us at www.medicinesforeurope.com and on Twitter @biosimilarsEU.

Medicines for Europe
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11 - F: +32 (0)2 736 74 38
info@medicinesforeurope.com
www.medicinesforeurope.com
@medicinesforEU