biosimilar medicines

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MARKET REVIEW – EUROPEAN BIOSIMILAR MEDICINE MARKETS

POLICY OVERVIEW

2023

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ACKNOWLEDGEMENTS

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The Biosimilar Medicines Group Market Access Committee is pleased to present the 2023 Market Review – European Biosimilar Medicine Markets – Policy overview.

The purpose of this Market Review is to provide a general overview of the policies that are currently in place for biosimilar medicines in the different European countries allowing the reader to get a clear understanding. The 2023 Market Review covers the following policy areas: Availability of biosimilar medicines, Pricing & Reimbursement systems, Procurement of biosimilar medicines, prescribing & dispensing policies, and information & education policies.

The European countries covered in this edition of the Market Review are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Switzerland, Sweden and United Kingdom.

Adrian van den Hoven
Medicines for Europe Director General

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A growing opportunity for patients with over **100 new biologic medicines** opening to biosimilar competition by 2030

A considerable opportunity for European healthcare budget: a **$40BN** market will **open to competition** between 2024-2029

Healthcare systems in Europe are facing huge challenges that threaten the access, affordability, and quality of healthcare. Multiple factors such as a growing and ageing population, increased disease burden, the introduction, and the high cost of innovative medicines, as well as the recovery from the covid-19 pandemic have put pressure on healthcare systems across Europe forcing policymakers to adjust healthcare spending. Biologic medicines have accounted for an important and growing part of the pharmaceutical budget in recent years and will represent 35% of spending globally by 2027[1]. Moreover, new biologic medicines are often launched at very high prices. Since the first biosimilar medicine approval in Europe in 2004, biosimilar medicines have provided more than 1 million patient treatment years[2] of safe clinical experience. Access to biologic standards of care has expanded for all biologic therapies where a biosimilar medicine is available, thanks to dynamic competition on the market between the available equivalent versions of a given reference medicine.

The overall biosimilar opportunity is set to increase by 5-fold by 2026 in Europe, compared to the period 2016-2021, with a potential value of €17.7bn[3]. Today, with an average relief of €4.47Bn provided annually on the European pharmaceutical spending, biosimilar medicines competition forms an important pillar of European healthcare systems equilibrium and a necessary enabler to patient access to biologic medicines.

An ambitious and focused set of well identified policy improvements at EU and national levels will be needed to make the best of an unprecedented wave of biologic medicines losing exclusivity by 2030. This report provides an overview of the market policies that currently underpin those opportunities and explores proposals on how to improve them for more patient access to medicines.

RESOURCES:
Medicines for Europe key figures on biosimilar medicines, 2022

(1) The global use of Medicines 2023: Outlook to 2027. IQVIA institute for Human Data Science, January 2023.
(2) EMA press release 'Biosimilar medicines can be interchanged' (19 Sept 2022) https://www.ema.europa.eu/en/news/biosimilar-medicines-can-be-interchanged
(3) IQVIA The Global Use of Medicines 2023 https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2023

AVAILABILITY

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
1. For which of the following biological active substances are biosimilar medicines available in your country? (Since)																												
Adalimumab	3/1/2019	10/1/2018	10/22/2018	12/1/2018		8/1/2018	10/1/2018	1/1/2019	✓	11/1/2018	11/15/2018	5/25/2020	✓	3/5/2019	10/1/2018	4/1/2019	1/7/2019	1/1/2019	✓	1/1/2019	3/22/2017	3/28/2019	3/1/2019	11/1/2018	4/13/2018	1/1/2019	✓	✓
Bevacizumab	7/1/2020	9/1/2020	9/28/2020	9/1/2020		8/1/2020		1/1/2021	✓	6/7/2020	7/7/2020	7/2/2021	✓	3/14/2019	6/1/2020	3/1/2022	10/1/2020		✓	1/1/2021	1/15/2018		4/1/2020		9/27/2019	1/1/2020	✓	✓
Enoxaparin Sodium	10/1/2018	8/1/2020		12/1/2019		9/1/2019			✓	9/22/2018	8/10/2016	7/2/2021	✓		12/1/2017	9/1/2018		1/1/2021	✓	11/1/2016	9/15/2016				2/20/2018	1/1/2020	✓	✓
Epoetin	6/1/2010	9/1/2008	9/26/2016	7/1/2013		9/1/2010	12/1/2010		✓	7/30/2008	9/3/2007	11/16/2012	✓		2/1/2009		6/1/2015	1/1/2016	✓	3/1/2008	8/28/2007	2/23/2010	10/1/2010	10/1/2008	2/18/2008	1/1/2009	✓	✓
Etanercept	7/1/2017	9/1/2016	6/19/2020	8/1/2017		6/1/2016	2/1/2016	1/1/2017	✓	10/3/2016	11/10/2016	12/20/2017	✓	3/9/2022	10/1/2016	4/1/2020	12/1/2016	1/1/2017	✓	7/1/2016	1/14/2016	2/20/2018	2/1/2020	7/1/2018	2/25/2016	1/1/2018	✓	✓
Filgrastim	5/1/2009	2/1/2010	8/15/2011	12/8/2023		4/1/2010	2/1/2017	10/1/2008	✓	3/7/2010	3/1/2008	11/16/2012	✓	3/15/2023	6/1/2009	1/1/2009	6/1/2015	1/1/2009	✓	1/1/2008	2/6/2009	2/16/2010	3/1/2009	7/1/2009	9/25/2008	1/1/2009	✓	✓
Follitropin Alfa	7/1/2021		5/08/2015	2/1/2016		4/1/2015	7/1/2016	10/1/2016	✓	5/16/2015	2/1/2013	2/19/2016	✓		4/1/2015	8/1/2015			✓	7/1/2015	9/27/2013		10/1/2013		6/23/2023	1/1/2018	✓	✓
Infliximab	10/1/2017	4/1/2015	1/30/2014	5/1/2015		12/1/2013	3/1/2015	4/1/2014	✓	12/24/2014	2/1/2013	6/15/2015	✓		2/1/2015	1/1/2018	3/5/2018	1/1/2014	✓	1/1/2014	9/10/2013	2/11/2015	10/1/2015	7/1/2019	3/25/2014	1/1/2016	✓	✓
Insuline aspart				9/1/2015					✓	3/15/2021	7/1/2021		✓	3/7/2022		8/1/2017			✓	3/1/2021							✓	✓
Insuline aspart protamine																												✓
Insulin glargine	9/1/2021	6/1/2016	5/20/2022	9/1/2015		8/1/2015	9/1/2015		✓	1/20/2016	2/1/2014	2/19/2017	✓		2/1/2016	1/1/2016	12/1/2016		✓	1/1/2019	9/9/2014	2/9/2021	3/1/2015		1/23/2016	1/1/2015	✓	✓
Insulin Lispro				1/1/2017					✓		2/1/2017		✓		1/1/2018	2/1/2017				11/1/2017							✓	✓
Pegfilgrastim	3/1/2019	4/1/2019	3/1/2019	1/1/2019		7/1/2014	12/1/2018	1/1/2019	✓	11/22/2018	2/1/2018	5/25/2020	✓		2/1/2019	1/1/2019	3/3/2019		✓	11/1/2018	9/21/2018	5/8/2018	3/1/2019	2/3/2019	10/31/2018	1/1/2019	✓	✓
Rituximab	1/1/2018	11/1/2017	11/1/2018	8/1/2018		2/1/2018	7/1/2018	1/1/2019	✓	11/01/2017	2/1/2017	5/25/2020	✓	3/11/2012	9/1/2017	2/1/2019	9/2/2018	1/1/2020	✓	9/1/2019	2/17/2017	11/13/2018	8/1/2018	10/1/2018	4/7/2017	1/1/2018	✓	✓
Somatropin	9/1/2009	4/1/2014	5/28/2021	2/1/2015		5/1/2010	7/1/2006	4/1/2013	✓	01/07/2008	2/1/2006	2/19/2016	✓		3/1/2007	8/1/2012	6/1/2015	1/1/2016	✓	1/1/2007	4/20/2017	2/21/2006		2/1/2008	1/6/2016	1/1/2010	✓	✓
Teriparatide	1/1/2020		3/31/2021	11/1/2019		8/1/2020			✓	8/28/2019	2/1/2019	1/29/2021	✓		9/1/2019	10/1/2022	10/1/2019	1/1/2021				2/22/2022	9/1/2019		8/1/2018	1/1/2019	✓	✓
Trastuzumab	1/1/2018	8/1/2018	8/2/2018	8/1/2015		3/1/2015	5/1/2018	1/1/2019	✓	8/15/2018	2/1/2018	5/25/2020	✓	3/5/2021	9/1/2018	12/1/2020	10/1/2018	1/1/2021	✓	7/01/2018	11/15/2017	11/20/2018	11/01/2018		5/28/2018	1/1/2019	✓	✓

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
2. In which setting, or settings, are the biosimilar medicines available? (H: Hospital pharmacy - S: Specialised centres - R: Retail pharmacy - O:Other)																												
Adalimumab	H,R	H,R	H,R,S	R		H,S	H	R	R	R	H,R,S	H,S	R	S	H	H,R	R	H	H	H	H	R	S,R	R	H	H,S	R	H,S
Bevacizumab	H	H	H	H		H,S		H	H	H,S	H,R,S	H,S	H	S	H	H,R	H		H	H	H		H		H	H,S	H	H
Enoxaparin Sodium	H,R	H,R		H,R		O			H,R	R	H,R,S	H,R	H		H,R,S	H,R		H,R	H	H,R	H,R				H	H,S	H,R	H
Epoetin	H,R	H	H,R	H,S		O	H		R	R	H,R,S	H,S	R		H,S		R	H	H	H	H	R	H,R	H,R	H	H,S	R	H
Etanercept	H,R	H,R	H,R	H,R		H,S	H	R	R	R	H,R,S	H,S	R	S	H	H,R	R	H	H	H	H	R	S,R	R	H	H,S	R	H
Filgrastim	H,R	H	H,R	H		S	H	H	H,R	R	H,R,S	H,S	R	S	H	H,R	R	H	H	H	H	H,R	H,R,S	H,R	H	H,S	H,R	H
Follitropin Alfa	H,R		H	H		H,S	H	R	R	R	H,R,S	H,S	H		H	H,R			H	S,R	H,R		H,S		H	H,S	H	H
Infliximab	H,R	H,R	H,R,S	H		H,S	H	H	H,R	H,S	H,R,S	H	H		H	H,R	R	H	H	H	H	R	H,S	H	H	H,S	H,R	H
Insuline aspart				H					R	R	H,R,S		R	S		H,R			H	R							R	H
Insuline aspart protamine																			H									H
Insulin glargine	H,R	H,R	H,R,S			O	H		R	R	H,R,S	R	R		H	H,R	R		H	H,R	H,R	R	H,R,S		R	H,S	R	H
Insulin Lispro				H					R		H,R,S		R		H	H,R			H	H,R							R	H
Pegfilgrastim	H,R	H	H	H		O	H	H	H,R	R	H,R,S	H,S	R		H,R	H,R	R		H	H	H	R	R	H,R	H	H,S	H	H
Rituximab	H	H	H,R	H		H,S	H	H	H	H,S	H,R,S	H	H	S	H	H,R	H,R	H	H	H	H	H,R	H,R	H	H	H,S	H	H
Somatropin	H,R	H,R	H,R,S	H,R		O	H	R	R	R	H,R,S	H	H		H,R	H,R	R	H	H	H	H,R	R		R	H	H,S	R	H
Teriparatide	H,R		H,R	H		O			R	R	H,R,S	S	H		H,R	H,R	R	H	H			R	H,R		H	H,S	R	H
Trastuzumab	H	H	H	H		H,S	H	H	H	H,S	H,R,S	H,S	H	S	H	H,R	H,R	H	H	H	H	H,R	H		H	H,S	H	H
Comments	1					2																						

(1) "In the outpatient sector, costs are covered by social insurance if the corresponding biosimilars are included in the positive list (reimbursement code). These biosimilars are dispensed via the public pharmacy. They can also be procured inpatient by the hospital pharmacy, but this is the exception. Biosimilars that are predominantly used in hospitals are also procured there. They are only available via the public pharmacy in rare exceptional cases."
(2) Other biosimilar medicines have special method of reporting to health insurance companies or have special conditions of reimbursement

In the EU, biosimilar medicinal products can only be placed on the market after they have been authorised by the European Commission following a recommendation by the European Medicines Agency (EMA). Marketing authorisations are granted in accordance with common EU rules intended to ensure the quality, safety, and efficacy of medicines. Member States are responsible for setting the price and reimbursement of medicines in view of promoting the health of their citizens and the financial sustainability of their social security systems.

Therefore, the highly regulated pricing and reimbursement rules in Europe fall under the responsibility of the Member States.

The most common types of policies to set the prices of biosimilar medicines are:

- **External reference pricing:** An approach where the price of a medicine is set according to the benchmark prices for the same or similar type of medicine in comparable countries previously defined in the policy. Usually, policymakers adjust prices over time depending on the changes available in the countries used as reference[1] and apply different formulas to calculate this price.
- **Set % below originator price**: Type of policy where the price of a medicine should be below a previously determined specific percentage, having as a starting point the price of the originator medicine. (e.g. Companies should set the price 30% below the price of the originator medicine).
- **Reference groups**: When applied, prices are set according to the prices of a previously determined group of medicines (e.g., average price of medicines with the same type of active substance-ATC-5).
- **Maximum price**: Policy where generic medicines cannot be higher than a predefined maximum price.
- **Negotiation**: When this policy is applied, the price of a biosimilar medicine is negotiated between the company and the payers.

Current pricing policies, aimed at constantly lowering medicine prices, result in market concentration and health inequalities. External reference pricing is not a proper tool to ensure competitive pricing in the off-patent market, therefore, different strategies that ensure long term healthy competition for biosimilar medicines should be promoted to address the market challenges.

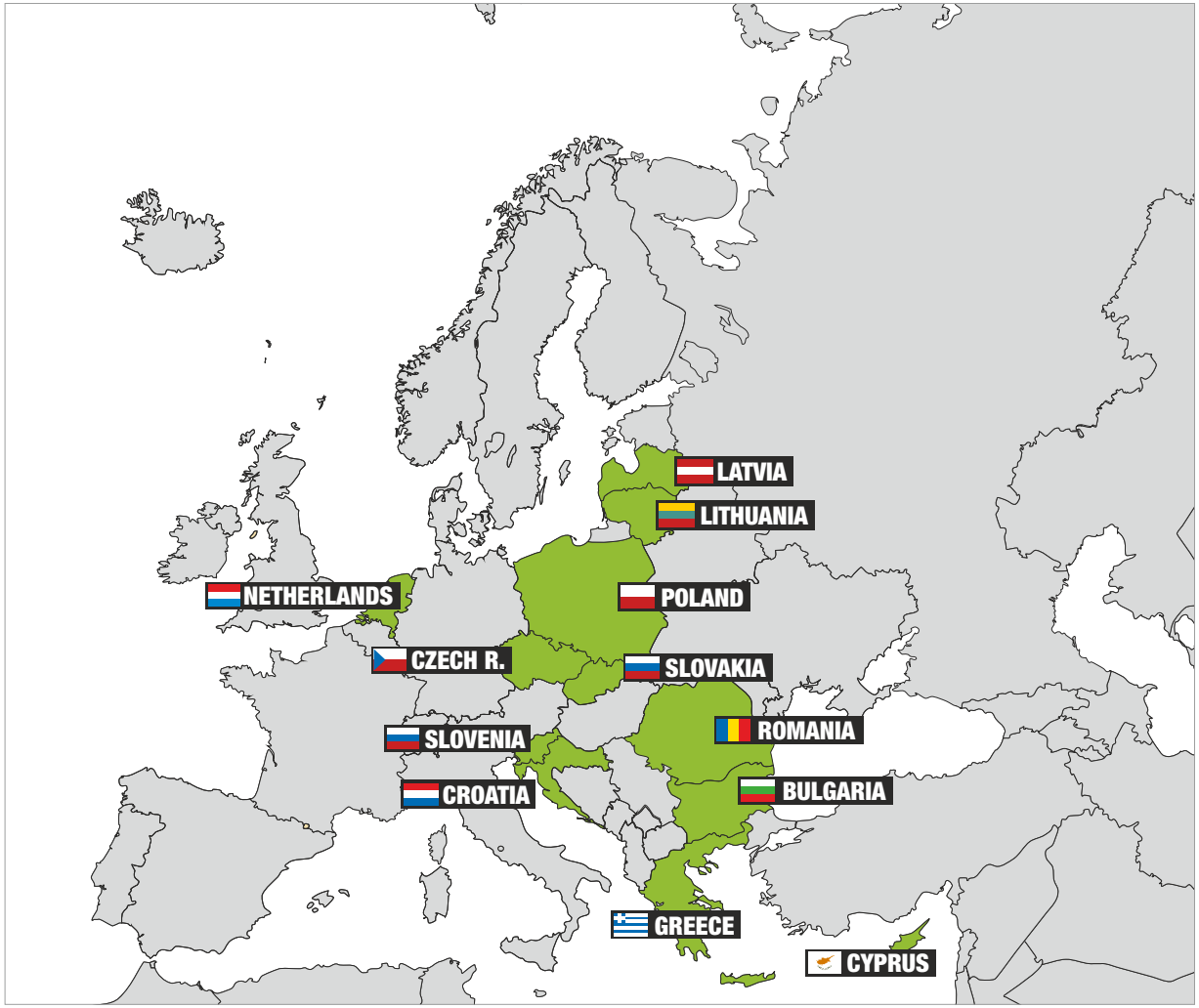
RESOURCES:
Medicines for Europe's position on ERP

(1) Guidelines Review Committee. (2020, September 28). WHO guideline on country pharmaceutical pricing policies. https://who.int/publications/i/item/9789240011878

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
3.What kind of pricing system is in place for biosimilar medicines (reimbursed)?																												
Free pricing							✓											✓									✓	✓
Regulated pricing	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		
Comments	1																											
4.Which criteria is used to set the prices?																												
External reference pricing			✓	✓	✓	✓						✓				✓	✓		✓	✓		✓	✓	✓				
Set % below originator price	✓		✓			✓		✓	✓	✓			✓	✓	✓	✓	✓			✓	✓	✓	✓	✓		✓		
• Percentage below originator price	38%		20%			30%		30%	30%	40%			30%	50%	20%	30%	15%			25%	20%	20%	25%	32%		25%		
Maximum price																	✓		✓			✓		✓	✓			
Negotiation										✓	✓	✓		✓	✓				✓	✓				✓				
Other		2													5b		6					9						
Comments						3					4	4b	5						7		8		10					

(1) Biosimilars reimbursement pricing is governed by the General Social Security Act (ASVG).
(2) Price decrease from -35,8% to -47,18%
(3) In case of 1st Biosimilar medicine - need of 30% reduction of originator price. Other biosimilar medicines can set price based on similar medicine (already reimbursed) or ERP
(4) Open house contracts, reference price.
(4b) To receive reimbursment status without negotiations, a biosimilar medicine needs to be priced below the original price
(5) 2. gen -20%, 3. gen -10%
(5b) Percentage of discount depends on the average public expenditure of originator in the last three years
(6) Ranking system
(7) Hospital groups negotiate the price
(8) 20% or 30% if Market share ≥5%
(9) Yearly price revision
(10) Regulated price reduction -25% below originator price for biosimilar entry including External reference pricing for biosimilars

COUNTRIES USING ERP



How to read: The rows represent the countries that use ERP and the columns represent the countries used as reference (countries included on the basket for ERP)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
5. Countries used for external reference pricing																													
Bulgaria		■								■		■			■	■	■						■	■	■	■			
Croatia						■				■					■										■	■			
Cyprus	■	■					■			■	■	■			■							■				■	■		
Czech Republic		■		■			■		■	■	■		■	■	■	■	■		■		■	■		■	■	■		■	
Greece	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■		■	
Latvia						■	■	■								■	■				■	■		■					
Lithuania	■	■	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■			■	■	■	■	■	■			
Netherlands		■								■										■									
Poland[1]	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Romania	■	■	■								■	■			■		■				■	■		■		■			
Slovakia	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■	■	■	
Slovenia	■									■	■																		

(1) Plus Iceland and Lichtenstein

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
6.What is determined using external reference pricing (ERP)?																												
Price for originators (ERP is indirectly applied to generics as it is used to determine the price of originators, which ultimately influences the price of generics)																	✓		✓									
Price for Biosimilars (ERP is directly applied to Biosimilars)			✓		✓	✓						✓								✓		✓						
Benchmarking with other countries				✓												✓							✓	✓				
Comments						1																	2	3				
7.What formula is used when applying external reference pricing?																												
Lowest price in reference countries			✓																✓	✓				✓				
Average price of reference countries				✓	✓	✓																						
Other						4						5				5b	6					7	8					

(1) ERP is used for all price settings (originator and biosimilar medicines) and for reimbursement.
(2) Basket of all EU countries
(3) Reference pricing is basis for maximum allowed price calculation. Maximum allowed price is basis for negotiation for reimbursed price confirmation.
(4) Average of the 3 lowest price in reference basket
(5) Average of the two lowest different prices in the Eurozone
(5b) Not higher as in other Baltic countries nor higher as second lowest in reference countries
(6) Average of 5 lowest prices of 5 EU countries
(7) Average of the lowest 3 prices from the basket
(8) Average of the three (3) lowest prices

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
8.The application for pricing & reimbursement is a:																												
Single process	✓		✓			✓	✓	✓	✓				✓	✓	✓	✓	✓	✓		✓		✓	✓		✓	✓	✓	✓
Separate process (One process for pricing and a separate process for reimbursement)		✓		✓	✓					✓	✓	✓							✓		✓			✓				
Comments												1																
9.On average, how long (in days) does it take for a biosimilar medicine to receive its P&R approval from the day of application ?																												
days	135	120	60	120	90	60	1	90	58		14	220	45	60	90	45	90	1	1	180	30	90	120	140	120	30	90	1
10.After being listed, how long does it take for a biosimilar medicine to be available in the hospital? (In days)																												
days	1	365	30		1	1	1	90	1		14	90	1	60	60	1	30	1	1	30	6	30	121	365	10	14	1	1
Comments				2											2b													3
11.Are biosimilar medicines included in internal reference pricing systems for reimbursement purposes?																												
Yes	✓		✓	✓		✓		✓			✓	✓	✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓			
No		✓			✓		✓		✓	✓					✓			✓								✓	✓	✓
Comments	4																	5										

(1) Separate and sequential
(2) Depends on the tender for the originator which is in place at the time of the biosimilar medicine entrance.
(2b) On average 60 days, but it really depends on regional authorities
(3) Once a medicine has it's market authorization, it can be sold to hospitals out of contract if there is demand or companies can wait until the next regional tender

(4) The originator biologic product is the reference price
(5) No reimbursement system in Malta

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
12.How is the reference group established?																												
By active substance (ATC-5)	✓		✓	✓				✓				✓	✓	✓		✓	✓		✓		✓	✓	✓	✓				
By pharmacological class (ATC-4)													✓												✓			
By therapeutic class (ATC-3)				✓																								
Other						✓					2							No		5								
Comments						1						3						4		6								
13.On what basis is the internal reference price established?																												
Average price of medicines														✓														
Average price of biosimilar medicines											✓														✓			
Lowest priced medicine			✓										✓			✓												
Lowest priced biosimilar medicine	✓							✓				✓										✓						
External reference pricing is used						✓													✓	✓			✓	✓				
Other																	10				10b							
Comments	7			8		9											11			12								

(1) Reference groups are based on therapeutical interchangeable medicines with similar clinical effect. There is MoH decree on reference groups (several ATC7 in one reference group).
(2) Three groups of reference price groups
(3) The single buyer (EOPYY) buys only the product with the cheapest price and therefore all similar products are forced to lower their price at the level of the lowest
(4) No reimbursement system in Malta
(5) by create Limit Group
(6) Drug with the same international name or other international names but similar therapeutic effect and similar mechanism of action is eligible for a limit group using the following criteria: The same indications or uses for which they are reimbursed; similar efficacy.
Limit group composition is decided by Ministry of Health.

(7) 1st Biosimilar medicine price is referenced to the Originator
2nd Biosimilar medicine price is referenced to the 1st Biosimilar medicine
3rd Biosimilar medicine price is referenced to the 2nd Biosimilar medicine"
(8) 5% volume market share in the therapeutic group for the respective time period for retail biosimilar medicines
(9) Reference price is lowest price from ERP (all EU members states) of any medicine listed on the reference group.
(10) ERP and IRP
(10b) % below originator price
(11) Lowest price from ERP or IRP
(12) EXF price, taking into account the number of DDD/PDD in the unit package, may not be higher than: 75% of the EXF price of the only reimbursable equivalent in the indication; EXF price of the counterpart setting the limit base, or EXF price of the the cheapest equivalent if the basis of the limit in the given limit group is determined by a drug with a different active substance.

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
14.For which active substances is it used?																												
Adalimumab	✓		✓			✓		✓				✓	✓	✓		✓	✓		✓	✓	✓	✓		✓	✓			
Bevacizumab			✓			✓						✓		✓		✓			✓	✓	✓				✓			
Enoxaparin Sodium	✓					✓										✓			✓	✓	✓				✓			
Epoetin	✓		✓			✓						✓	✓				✓		✓	✓	✓	✓		✓	✓			
Etanercept	✓		✓			✓		✓			✓	✓	✓	✓		✓	✓		✓	✓	✓	✓		✓	✓			
Filgrastim	✓		✓			✓					✓	✓	✓	✓		✓	✓		✓	✓	✓	✓		✓	✓			
Follitropin Alfa	✓		✓			✓		✓				✓				✓			✓	✓	✓				✓			
Infliximab	✓		✓			✓					✓	✓				✓	✓		✓	✓	✓	✓		✓	✓			
Insuline aspart				✓									✓	✓		✓			✓	✓								
Insuline aspart protamine																			✓									
Insulin glargine	✓		✓	✓		✓							✓			✓	✓		✓	✓	✓	✓			✓			
Insulin Lispro				✓									✓			✓			✓	✓								
Pegfilgrastim	✓		✓			✓						✓	✓			✓	✓		✓	✓	✓	✓		✓	✓			
Rituximab			✓			✓						✓		✓		✓	✓		✓	✓	✓	✓		✓	✓			
Somatropin	✓		✓			✓		✓								✓	✓		✓	✓	✓	✓		✓	✓			
Teriparatide	✓		✓			✓						✓				✓	✓		✓			✓			✓			
Trastuzumab			✓			✓						✓		✓		✓	✓		✓	✓	✓	✓			✓			

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
15.Is there any type of cost sharing or out-of-pocket (OOP) payment for biosimilar medicines?																												
Yes	✓	✓		✓		✓			✓		✓		✓			✓	✓			✓	✓		✓					
No			✓		✓		✓	✓		✓		✓		✓	✓			✓	✓			✓		✓	✓	✓	✓	✓
Comments	1	2	3	4								5	6						7	8	9							
16.What type of cost sharing or out-of-pocket payment by patients is used?																												
Fixed amount per prescription/pack (Co-payment)	✓	✓		✓		✓			✓		✓		✓				✓						✓					
% Of cost of medicines is partially reimbursed (Co-insurance)									✓							✓				✓	✓							
Patient annual/monthly consumption (DDD)																												
Difference above reference price																												
Insurance takes effect when a certain threshold has been reached (deductible)																												
Comments						10			11														12					

(1) Prescription fee per dispensed package on account of health insurance, currently EUR 6.85
(2) Depends on the molecule
(3) Many biologic originator and biosimilar products are reimbursed at 75%. Patients do not pay out of pocket. MAH pay an additional 25% to the NHIF.
(4) Many biologic originator and biosimilar products are reimbursed at 75%. Patients do not pay out of pocket. MAH pay an additional 25%.
(5) For enoxaparin, in retail market co-payment is applied (25%)
(6) For retail products only
(7) Mostly there is NO co-payment because it is in hospital setting.
(8) Out of pocket payment if patient illness is not qualified as reimbursed indications.
(9) Only in the retail market
(10) Copayment is legally possible, but in practice there is no biologic medicines (including biosimilars medicines) with copayment. All biologic medicines in hospitals have prices (from tender) at or below the level of the reimbursement amount.
(11) There are three categories:
Basic rate of reimbursement 40%
Lower special rate of reimbursement 65%
Higher special rate of reimbursement 100%. A copayment of EUR 4.50 per medicine and per purchase is charged."
(12) For products where fixed co-payment is not defined by rules, then ratio between reimbursement and co-payment should be kept

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17.Do the out-of-pocket payment schemes for biosimilar medicines differ from the reference product?																													
Yes						✓																	✓						
No	✓	✓		✓					✓		✓		✓			✓	✓			✓	✓								
Comments																							1						
18.For which active substances is it used?																													
Adalimumab	✓	✓				✓			✓		✓		✓			✓	✓						✓						
Bevacizumab						✓			✓		✓					✓							✓						
Enoxaparin Sodium	✓	✓				✓			✓		✓					✓				✓	✓								
Epoetin	✓					✓			✓		✓		✓				✓						✓						
Etanercept	✓	✓				✓			✓		✓		✓			✓	✓						✓						
Filgrastim	✓					✓			✓		✓		✓			✓	✓						✓						
Follitropin Alfa	✓					✓			✓		✓									✓	✓		✓						
Infliximab	✓	✓				✓			✓		✓					✓	✓						✓						
Insuline aspart				✓					✓		✓		✓			✓				✓									
Insuline aspart protamine																													
Insulin glargine	✓			✓		✓			✓		✓		✓			✓	✓			✓			✓						
Insulin Lispro				✓					✓		✓		✓			✓				✓									
Pegfilgrastim	✓					✓			✓		✓		✓			✓	✓						✓						
Rituximab						✓			✓		✓					✓	✓						✓						
Somatropin	✓					✓			✓		✓					✓	✓				✓								
Teriparatide	✓					✓			✓		✓					✓	✓						✓						
Trastuzumab						✓			✓		✓					✓	✓						✓						

(1) MEA contracts are used by originators, contract between MoH SR and MAH concerning special price discounts

Many biosimilar medicines are dispensed in a hospital setting and consequently, are purchased through procurement procedures. Tendering procedures are widely used in the hospital settings and can have a national (centralised), regional or individual hospital (facility-based) scope depending on the country or region. The procurer can be a national or regional authority or health insurance fund or al hospital procurer that may procurement on behalf of an individual or a group of hospitals. Procurement can be a great policy to stimulate competition in the biologic market. However, there can also be downsides to procurement when criteria are too narrowly defined.

A recent study supported by the European Commission shows that medicine procurers are focused primarily on cost-minimisation, through price-only, single-winner tenders. This encourages bidders to offer the lowest-price possible and provides no reward for security of supply measures or environmentally sound manufacturing. This risk is compounded by mounting inflation across Europe and the increase in global production costs, leading to consolidation at all levels of the pharmaceutical supply chain.

As pointed out by the authors, the potential for substantial savings makes biosimilar medicines an attractive target for optimising procurement policies. However, barriers for more widespread use of biosimilar medicines have been identified, including practices of biological originator suppliers to disincentivise or impede procurement of biosimilar medicines and policy frameworks that do not encourage biosimilar medicines uptake. Specific aspects of biosimilar procurement include the monitoring of patent expiry to optimise timing of tenders and working with prescribers to ensure procured products are being used (e.g., through use of treatment guidelines). Lack of uptake of biosimilar medicines may be due to lack of interaction between procurers and prescribers. Procurers therefore need to work with prescribers to ensure that procured products meet the needs of patients and are being prescribed.

RESOURCES:
Medicines for Europe Position paper on best procurement practices

PROCUREMENT OF MEDICINES - HOSPITAL TENDERING

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
19.Is there a tendering system in place for biosimilar medicines in the hospital market?																												
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
No											✓															✓		
Comments																1							2					
20.What is the scope of the tenders?																												
National			✓	✓	✓		✓	✓		✓		✓	✓				✓	✓		✓	✓		✓		✓			✓
Regional									✓	✓		✓			✓										✓		✓	✓
Hospital (individual or group)	✓	✓	✓	✓	✓	✓		✓		✓				✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓			
Comments																							3					
21.Which body is in charge of the tendering system?																												
National government		✓	✓	✓	✓							✓			✓		✓	✓			✓				✓			✓
Regional government							✓					✓			✓										✓		✓	
Health insurance funds					✓			✓					✓						✓				✓		✓			
Group of hospitals	✓	✓				✓			✓	✓					✓				✓			✓						
Individual hospitals	✓	✓	✓	✓		✓		✓		✓				✓		✓	✓		✓	✓	✓	✓	✓	✓	✓			
Other															4													

(1) Just for starting therapy in some hospitals
(2) Tendering system used partially only
(3) Initiated by General Insurance Company - state owned
(4) the national specialized tender agency can develop a tender, for those regions not able to perform on their own

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
22.How are tendering contracts awarded?																												
By active substance	✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓		✓	✓
By therapeutic indications													✓					✓										
Other						1											3											
Comments							2																3b					
23.What is the average contract duration of the tender? (In months)																												
months	12	48	24	12	24	36	12	24	24	12		30	12	12	36	12	12	24	12	24	12	18	24	12	48		48	24
24.Are there separate tenders for naïve versus currently on treatment patients?																												
Yes					✓								✓															✓
No	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Comments																												4
25.Do tender contracts have to be re-opened once biosimilar medicines enter the market?																												
Yes-Immediately after market authorisation of the biosimilar medicine																					✓							
Yes-A couple of months after the marketing authorisation of the biosimilar medicine	✓			✓					✓						✓													
• Number of months	5								6						2													
No		✓	✓		✓	✓	✓	✓		✓		✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓
Comments										7								8									9	10

(1) Inpatient care - MoH and the antimonopoly body prefer to tender by active substance and this process is increasingly used (but some hospitals prefer to tender by specific brand, especially in biological treatments).
(2) Plus indications
(3) By brand name
(3b) Selection process of distributors by the selected Brand (concrete product)
(4) Not always, it is a choice of the purchasing authority on behalf of the national health service.
(5) 3 to 6
(6) This differs between areas and molecules. Tenders are usually re-opened shortly after patens expiry.
(7) It can be reopened if there is a drop in the price
(8) Only when the next tender is due for publication
(9) Often it happens and regions plan for the entrance of biosimilar medicines
(10) They will join the next available tender

PROCUREMENT OF MEDICINES - HOSPITAL TENDERING

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
26.Is there an agreed minimum or maximum volume as a result of winning the tender?																												
Minimum volume												✓	✓			✓												
Maximum volume			✓		✓												✓	✓		✓	✓							✓
None	✓	✓		✓		✓	✓	✓	✓					✓	✓				✓				✓	✓	✓		✓	✓
Comments																								1				2
27.After granting the tender, are prices subject to change before the next tender?																												
Yes			✓	✓						✓					✓	✓				✓		✓		✓	✓		✓	✓
No	✓	✓			✓	✓	✓	✓	✓			✓	✓	✓			✓	✓	✓		✓		✓					
Comments																								3	4			5
28.Is the winning price from the tender transparent to other competitors?																												
Yes		✓	✓	✓	✓	✓		✓	✓			✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	
No	✓						✓			✓				✓					✓									✓
29. Does a single hospital tender contract allow for more than one winner?																												
Yes							✓					✓			✓									✓	✓			✓
No	✓	✓	✓	✓	✓	✓		✓	✓	✓			✓	✓		✓	✓	✓	✓	✓	✓	✓	✓				✓	
Comments							6					7	8		8b													
30.Are factors other than the lowest price considered when determining the winner of the tender?																												
Yes		✓			✓		✓		✓	✓		✓						✓		✓					✓		✓	✓
No	✓		✓	✓		✓		✓					✓	✓	✓	✓	✓		✓		✓	✓	✓	✓				
Comments		9										10						11		12								13

(1) There are penalties for non-supplied volume.
(2) Normally there is no guaranteed volume
(3) Only for reference price changing. The discount remains fixed.
(4) The duration of spanish tenders is 4 years but every year authorities do an extension and in some regions they for a new price if the manufacturer wants to continue
(5) Price review mechanisms half way through the tender (12 months)
(6) Not all tenders allow more than one winner
(7) The three lowest bidders are awarded with percentages of 50%, 30% and 20% respectively of the tender volume
(8) It is up to the hospitals to decide the number of winners but usually is one
(8b) By law is mandatory from 2017 the use of framework agreements in public procurement procedures, when there are more than three biosimilar medicines; these framework agreements must involve all economic operators owning medicines based on the same active ingredient.
(9) But not always, sometimes only price is considered
(10) Quality criteria for the supplier are applied
(11) Tender specifications
(12) According to polish procurement law, price can't be the only factor in the winning criteria. Usually other factors are as well (eg. payment terms). Price has the highest weight.
(13) Social value criteria is being established and KPIs around supply performance exist

The uptake of biosimilar medicines can be lower in the retail setting than in the hospital setting due to the absence of clear guidance for prescribers or absence of appropriate gain sharing measures. This constitutes a challenge for biologic therapies that are dispensed mainly outside the hospital setting, including medicines that can be self-administered by patients. Hence, promoting and increasing the uptake of biosimilar medicines in the retail setting represents a huge opportunity for biosimilar medicines to contribute to the improvement of patient access to biologic therapies, the reduction of equity gaps across Europe and support the sustainability of the healthcare budget. Some countries are considering the introduction of biologic pharmacy substitution to increase the use of biosimilar medicines or to make additional budget savings. This currently applies in France for some molecules and requires a communication between the pharmacist and the treating physician. More recently, Norway introduced a similar provision. Germany has a law to authorise biologic substitution, but this is not yet enacted in practice and could be delayed for the most commonly used biosimilar medicines. The same situation applies in Finland where a law was adopted and came into force in January 2023. Sweden is evaluating a law on biologic substitution.

RESOURCES:
Biosimilar medicines Group (Medicines for Europe) policy recommendations on uptake of biosimilar medicines in the retail market

PROCUREMENT OF MEDICINES - RETAIL TENDERING

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
31.Is there a tendering system in place for biosimilar medicines in the retail market?																												
Yes											✓								✓				✓					
No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓	✓	✓	✓
Comments											1																	
32.What is the scope of the tenders?																												
National																			✓				✓					
Regional																			✓									
Hospital (individual or group)																												
Other											2																	
Comments																							3					
33.Which body is in charge of the retail tendering system?																												
National government																												
Regional government																												
Health insurance funds											✓								✓				✓					
Other																												

(1) As OpenHouseContracts
(2) Number of patients insured by the specific sick fund
(3) Organised by General Insurance Company (VSZP) - state owned

PROCUREMENT OF MEDICINES - RETAIL TENDERING

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
34.How are retail tendering contracts awarded?																												
By active substance											✓								✓				✓					
Group of active substances																												
Therapeutic indications																												
Other																												
Comments																							1					
35.What is the average contract duration of the tender? (In months)																												
months											24								24				36					
36.Are there separate tenders for naïve versus currently on treatment patients?																												
Yes																			✓									
No											✓												✓					
37.Do tender contracts have to be re-opened once biosimilar medicines enter the market?																												
Yes-Immediately after market authorisation of the biosimilar medicine																			✓									
Yes-A couple of months after the marketing authorisation of the biosimilar medicine																												
• Number of months																												
No											✓												✓					

(1) only one winner with the lowest price

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
38.Is there an agreed minimum or maximum volume as a result of winning the tender?																												
Maximum volume																						✓						
Minimum volume																						✓						
None											✓								✓				✓					
Comments																						1						
39.After granting the tender, are prices subject to change before the next tender?																												
Yes																												
No											✓								✓				✓					
40.Is the winning price from the tender transparent to other competitors?																												
Yes											✓												✓					
No																			✓									
Comments											2																	
41.Are factors other than the lowest price considered when determining the winner of the tender?																												
Yes																												
No											✓								✓				✓					

(1) No commitment/pemaltyto comply with min/ max quantity
(2) In the Open House System

In the European Union, the EMA and the HMA (Heads of Medicines Agencies) have clarified in a statement that biosimilar medicines are equivalent therapeutic options (to the corresponding originator medicine) available for physicians and patients to choose from HMA and EMA consider that once a biosimilar is approved in the EU it is scientifically interchangeable, which means the biosimilar can be used instead of its reference product (or vice versa) or one biosimilar can be replaced with another biosimilar of the same reference product.

Physician-led switching is the common implementation tool in the EU for biosimilar medicines to enter patients' treatment pathways: physicians benefit from broader therapeutic options and more patients can access biologic medicines, at times earlier in the treatment pathway, where medically appropriate, when e.g., access restrictions have been lifted or reimbursement policies expanded.

RESOURCES:
Positioning statements on physician-led switching for Biosimilar medicines in Europe, 2021
Medicines for Europe Biologic pharmacy substitution position paper, 2020

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
42.Which statement(s) best describes biologic medicine switching practice, with the involvement of a clinical decision-maker, in place for biosimilar medicines in your country?																												
It only applies to treatment naïve patients		✓		✓	✓				✓			✓	✓		✓	✓								✓	✓	✓		
It applies to all patients	✓						✓							✓				✓	✓	✓	✓		✓				✓	✓
Physicians can opt out	✓		✓							✓	✓	✓	✓		✓		✓			✓		✓				✓		✓
Physicians can only opt out after justification	✓					✓		✓	✓																			
Patients can opt out						✓					✓	✓								✓		✓				✓		✓
Comments	1																2											
43.Are there incentives for prescribers or patients to use biosimilar medicines?																												
Yes										✓				✓	✓													
No	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Comments																		3	4									
43b. what type of incentives																												
Type of incentives										5				6	7													
44.How should prescribers prescribe biological medicines by law in your country?																												
By INN (non-proprietary name)												✓		✓		✓		✓								✓		
By Trade name (incl invented name)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Comments								7b												8								

(1) There is no obligatory switch, there are rules for an economic prescribing, but in practice the decision is left to the physician.
(2) Unless it is regulated by ranking
(3) It depends on the awarded biosimilar in the national tender
(4) All benefits for the use of biosimilar medicines are for the hospital or due lower cost for the health insurance company
(5) Remuneration based on the public health objectives for physicians
(6) EUR 500 to hospitals for each new start and switch to biosimilar medicines
(7) there are some recommendations and supportive measures (electronic prescribing; financial restrictions and benefit-sharing agreements; information / educational materials / training)or regional decree
(7b) In retail market by brand
(8) INN prescriptions are possible but it is only margin of all prescriptions

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45.Which statement(s) best describes physician led biological medicine switching practices in your country?																												
Physicians often tend to switch from biologic to biosimilar medicines for all type of patients							✓		✓		✓								✓	✓							✓	✓
Physicians often tend to switch from biologic to biosimilar medicines only for currently on treatment patients																												
Physicians often tend to start treatment with biosimilar medicines in naïve patients	✓	✓			✓			✓	✓		✓	✓			✓						✓			✓	✓	✓		✓
Physicians don't tend to switch regularly from biologic to biosimilar medicines in any kind of patients	✓		✓	✓								✓	✓		✓	✓	✓					✓	✓	✓	✓	✓		
Other						1												2										
Comments																	3			4			5			6		
46.Is biological medicine substitution, at the level of retail pharmacies, legally allowed? (i.e. without consulting the prescriber)																												
Yes								✓		✓						✓		✓	✓	✓								
No	✓	✓	✓	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓		✓				✓	✓	✓	✓	✓	✓	✓	✓
Comments									7	8		9				10				11								

(1) In the Czech Republic almost all biologic treatments are initiated and administered in hospitals (biologic medicines are not prescribed by prescription and patients do not pick them up at the pharmacy, but are administered directly in hospitals), hence, the use of the medicine is often decided by hospital management according to which medicines have won the tender
(2) Switching is done at a national level depending on the tender award
(3) Unless it is obliged to prescribe a biosimilar by ranking rules for naive patients
(4) Deciding factors are:
- product's availability in the hospital (if originator is present or only biosimilar)
- patient's co-payment in pharmacy"

(5) There are differences in Biosimilar medicines' prescription affinity by different specialist groups (e.g. Derma, Gastro, – used to prescribe biologics from originators)
(6) Biosimilars medicines penetration rate is low in Switzerland
(7) There's an ongoing legislative chance possibly entering into force in 2024.
(8) Substitution is authorized for two molecules: Filgastrim and Pegfilgastrim
(9) It is allowed in EOPYY owned pharmacies for naive patients
(10) Not applied in practice
(11) The possibility to replace a reimbursable drug: containing the same active substance dose, pharmaceutical form, not covered by reimbursement: containing the same active substance, dose, pharmaceutical form - drug issued with 100% patient payment

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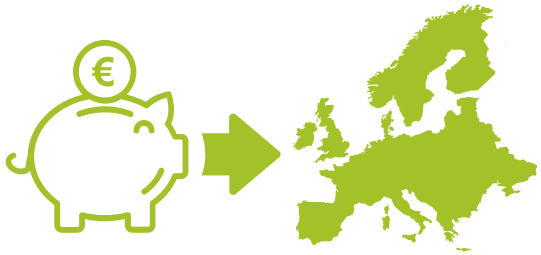
47.Which statement(s) best describes the substitution of biosimilar medicines at retail pharmacies in your country?																												
It is not enforced or applied in practice																		✓										
It applies to certain molecules/medicines/setup										✓									✓									
It is only applied to treat naïve patients																												
It applies to all patients										✓						✓			✓	✓								
Physicians need to explicitly give permission										✓																		
Physicians can opt out										✓																		
Pharmacists are obliged to inform the patient																			✓	✓								
Pharmacists are obliged to inform the prescriber								✓																				
Pharmacists are obliged to substitute																			✓									
Patients can opt out																												
Comments																				1								
48.Are there incentives for pharmacists to substitute biosimilar medicines?																												
Yes																			✓									
No								✓		✓						✓		✓		✓								
48b. What type of incentives																												
Type of incentives																			2									

(1) Pharmacists are obliged by law to inform the patient that the cheapest equivalent is available.
(2) Hospital pharmacy get a margin.

Biosimilar medicines have provided a wide range of direct and indirect benefits to patients, healthcare professionals and the healthcare system in general. These medicines allow patients to have access to safe and effective biologic standards of care and at the same time enable significant pharmaceutical budget relief. In addition, they allow for a broadening of the number of patients treated, as well as for changes in patient treatment paradigm with opportunities for earlier treatment, where medically appropriate. There have also been benefit-sharing models allowing for part of the savings generated to be reinvested in providing better care and / or additional health products or services to patients. In order to sustainably deliver on this access promise, it is important that all actors involved are empowered through accurate information and educational efforts including patients, healthcare professionals (EC/EMA guide for healthcare professionals), payers and policymakers.

RESOURCES:
Biosimilar medicines group (Medicines for Europe) Biosimilar medicines reading list

Since biosimilar medicines have been available, healthcare systems were able to reinvest **€18BN**
total savings across Europe (2021)



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49.Is there an identified need for information targeting patients or healthcare professionals about biosimilar medicines?																												
Yes	✓	✓		✓	✓	✓	✓			✓	✓	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓		✓	✓		✓
No			✓					✓	✓							✓		✓						✓			✓	
Comments																			1							2		
50.Have there been information campaigns targeting patients or healthcare professionals to inform them about biosimilar medicines?																												
Yes	✓	✓		✓	✓		✓		✓	✓	✓			✓	✓		✓		✓		✓	✓	✓	✓		✓	✓	✓
No			✓			✓		✓				✓	✓			✓		✓		✓					✓			
Comments										3			4															5
51.Which types of healthcare professionals have been consulted for information campaigns targeting healthcare professionals?																												
Physician specialists	✓			✓	✓		✓		✓	✓	✓						✓		✓		✓	✓		✓		✓		✓
Nurses	✓				✓						✓						✓		✓					✓		✓		✓
Hospital pharmacists	✓				✓		✓			✓	✓				✓				✓		✓			✓		✓		✓
General practitioners	✓						✓		✓	✓	✓								✓									
Pharmacists	✓																		✓					✓				
Other		6																					7				8	

(1) With new treatment indications
(2) Knowledge of Biosimilars medicines in Switzerland is very low
(3) Only for physicians in connection with the incentive mechanisms for the prescription of biosimilar medicines
(4) Only companies do it to HCPs
(5) Historically yes but not now
(6) FAMHP campaign focussed on patients mainly with spillover to all HCPs
(7) INEKO analysis of the outcomes and its recommendations were shared with MoH SR in order to increase Biosimilar awareness within all experts (HCPs, patient organisations, Insurance companies etc.)
(8) Civil servants in regions

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52.In which form(s) have they been rolled out?																												
Handbooks											✓			✓	✓		✓		✓		✓	✓		✓		✓		✓
Videos									✓		✓			✓	✓		✓				✓			✓				✓
Media campaigns		✓		✓			✓				✓			✓	✓							✓	✓			✓		✓
Leaflets	✓	✓					✓		✓		✓				✓		✓				✓	✓	✓					✓
Seminars, conferences or workshops	✓			✓					✓		✓				✓		✓		✓		✓	✓	✓	✓		✓	✓	✓
Training or continuous professional development for healthcare professionals					✓		✓								✓		✓		✓		✓			✓		✓		✓
Websites	✓	✓		✓			✓		✓		✓				✓		✓		✓		✓		✓	✓		✓		✓
Apps							✓				✓				✓									✓				✓
Other										1																		
53.Who developed the material?																												
Patient associations	✓						✓				✓				✓						✓							✓
Medical societies	✓						✓				✓				✓				✓		✓							
Authorities	✓	✓		✓			✓		✓	✓					✓				✓		✓						✓	✓
Biosimilar medicines industry	✓			✓	✓						✓			✓	✓		✓		✓		✓	✓	✓	✓		✓		✓
Originator industry	✓																											
Collaborative (multistakeholder) effort	✓						✓								✓		✓		✓		✓					✓		
Other																					2		3					
54.Example of a campaign targeting patients or healthcare professionals to inform them about biosimilar medicines																												
Example	4	5		6	7				8					9	10				11		12	13		14		15		16

(1) The information is communicated during the discussions relating to the financial incentive mechanisms for prescription
(2) Professional Societies
(3) EMA guidelines
(4) The Biosimilars Association, together with the regulatory authority, has produced a patient information document that is available in several languages and is also used for doctors.
(5) FAMHP information campaign on biosimilars
(6) A day seminar organized by biosimilar medicines industry
(7) HCP training for the correct use of Somatotropin, in addition to correct use and replacement of Somatotropin Pen.
(8) Finnish Medicines Agency has sent a letter to chief physicians.
(9) Medicines for Ireland campagins
(10) https://www.youtube.com/watch?v=xNML1NT_r-4&t=92s
(11) https;//www.medicijngebruik.nl/scholing/e-learning/4508/biosimilars-in-de-eerste-lijn
(12) INFARMED's video about Biosimilar Medicines and INFARMED 's Informative Session on Biosimilar Medicines
(13) Leaflet developed based on EMA guide endorsed by NIH, MOH, NDA
(14) IBD and pregnancy
(15) Biosimilar.ch, a website from trade association Intergenerika.ch
(16) Biosimilar medicines education, often working with the national service to inform healthcare professionals about biosimilar medicines entitled: What is a biosimilar medicine?

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.

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