biosimilar medicines

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2025 Market Review Biosimilar Medicines Markets

POLICY OVERVIEW

COUNTRY	NATIONAL ASSOCIATION/COMPANY	CONTACT PERSON
Austria	BiVÖ - Biosimilarsverband Österreich	Wolfgang Andiel
Belgium	Medaxes	Nele D' Haeze
Belgium	Sandoz	Maria Jose Gomez Silva
Bulgaria	BGPHARMA	Evgeni Tassovski
Croatia	Croatian Employers' Association – Pharmaceutical Industry Association	Mirela Gudan
Czech Republic	Czech association of pharmaceutical companies	Jana Benová
Denmark	IGL	Peter Jørgensen
Estonia	Sandoz	Kristel Aver
Finland	Finnish Generic Pharmaceutical Association	Heikki Bothas
France	GEMME	Alexandre Soufer
Germany	Pro Generika (AG Pro Biosimilars)	Frank Wittkemper
Greece	Pan Hellenic Association of Pharmaceutical Industry	Mark Ollandezos
Hungary	Hungarian Association of Generic Pharmaceutical Manufacturers and Distributors	Katalin Berta
Ireland	Celltrion Healthcare	Michael Comerford
Italy	Egualia	Daniela Blasio
Latvia	Sandoz	Dagnija Poreitere
Lithuania	Sandoz	Laisvida Krusiene
Luxembourg	Gedeon Richter Plc	Alexandrosz Czira
Malta	Gedeon Richter Plc	Alexandrosz Czira
Netherlands	Bogin	Jean Hermans
Norway	Farma Norge	Kjetil Berg
Poland	Polish Association of Employers of the Pharmaceutical Industry	Grzegorz Rychwalski
Portugal	EQUALMED	Ana Valente
Romania	APMGR	Valentina Baicuianu
Slovakia	GENAS	Michaela Palágyi
Slovenia	Sandoz	Mojca Tramsek
Spain	Sandoz	Jesus Vidart Anchia
Sweden	FGL: The Association for Generic Pharmaceuticals and Biosimilars in Sweden	Tobias Cassel
Switzerland	Intergenerika	Lucas Schalch
UK	Medicines UK	Robert Russellpavier

Availability

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
1. For which of the following biological active substances are biosimilar medicines available in your country? (Since)																													
Adalimumab	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
NEW Aflibercept																				✓					✓			✓	
Bevacizumab	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
NEW Denosumab																				✓					✓			✓	✓
NEW Eculizumab	✓	✓	✓					✓	✓	✓	✓			✓			✓		✓	✓	✓	✓			✓	✓		✓	✓
Enoxaparin Sodium	✓	✓			✓			✓	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	
Epoetin Alfa	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Epoetin Zeta	✓			✓		✓		✓	✓	✓	✓	✓		✓		✓				✓		✓			✓	✓		✓	
Etanercept	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Filgrastim	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Follitropin Alfa	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓		✓		✓		✓	
Infliximab	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Insuline aspart								✓	✓	✓					✓	✓		✓	✓	✓	✓				✓			✓	
Insuline aspart protamine																				✓									
Insuline glargine	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓		✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Insulin Lispro								✓		✓				✓	✓				✓	✓	✓				✓			✓	✓
NEW Natalizumab						✓		✓	✓	✓				✓					✓	✓		✓			✓	✓	✓	✓	✓
NEW Omalizumab	✓																			✓					✓	✓			
NEW Pegfilgrastim	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
NEW Ranibizumab		✓			✓	✓	✓	✓	✓	✓					✓	✓				✓	✓			✓			✓		✓
Rituximab	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Somatropin	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
Teriparatide	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	
NEW Tocilizumab	✓			✓	✓	✓	✓	✓	✓	✓			✓		✓	✓			✓	✓	✓	✓		✓	✓	✓		✓	✓
Trastuzumab	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
NEW Ustekinumab	✓	✓	✓	✓	✓		✓	✓	✓	✓			✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓

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2. In which setting, or settings, are the biosimilar medicines available? (H: Hospital pharmacy - S: Specialised centres - R: Retail pharmacy - O:Other - A:All Settings)																													
Adalimumab	A	H,R	A	R,H	H,S	H	R	R	A	A	A	R,	H,R,	A	R	A		H	H	A	H	H	R	S,R	R	H	A	H,R	H
Aflibercept																				A									
Bevacizumab	H	H	H	H	H,S	H	H	H	H,S	A	H,	S	H	H,R		H			H	A	H	H	H	H	H	H	A	H	H
Denosumab																				A					H,R				H
Eculizumab	H	H	H					H	H,S	A	H			H,S					H	A	H	H			H	H		S	H
Enoxaparin Sodium	A	H,R			R			H,R	A	A	A	S		H,S		H		H,R	H	A	R	H,R			R	R	A	H,R	
Epoetin Alfa	A	H	H,S	H,S	O	H		R	A	A	S	R		H,R		A		H	H	A	H	H	R	H,R	H,R	H	A	R	
Epoetin Zeta	A			H,S		H		R	H,R	A	S	R		H,R		A				A		H			H,R	H	A	R	
Etanercept	A	H,R	H,S	H,R	H,S	H	R	R	A	A	S	R	H,R,	H,S,R	R	A		H	H	A	H	H	R	S,R	R,H	H	A	R	H
Filgrastim	A	H	H,,S	H	O	H	H	H,R	A	A	S	R	H,R,	H,R	R	A			H	A	H	H	H,R	A	H,R	H	A	S,R	H
Follitropin Alfa	A		H	H	H,S	H		R	A	A	R	R		H,S	R	A			H	A	S,R	H,R		H,S		H		S	
Infliximab	A	H,R	H,S	H,R	H,S	H	H	H,R	H,S	A	H,S	S	A	H,S	R	A		H	H	A	H	H	R	H,S	H	H	A	S	H
Insuline aspart								H,	R,H						R	A			H	A	R				R			S	
Insuline aspart protamine																				A									
Insuline glargine	A		H,R,S	R	O	H		H,	R,H	A	R	R		H	R	A			H	A	R	H,R	R	H,S,R	R	R		A,R	R
Insulin Lispro								H,		A				H	R				H	A	R				R			A,R	H
Natalizumab						H		H	H,S	A				H,S					H,R	A		H			H	H		R	H
Omalizumab																				A					H	H			
Pegfilgrastim	A	H	H,S	H	O,R	H	H	H,	A	A	S	R		H,R	R	A			H	A	H	H	R	R	H,R	H	A	H	H
Ranibizumab		H		H	H,S	H	H	H	H	A				H,S	H	A				A	H			S	S		A		H
Rituximab	H	H	H,S	H	H,S	H	H	H	H,S	A	H	S	H,R,	H,S	H	A		H	H	A	H	H	H,R	H,R	H	H	A	H	H
Somatropin	S	H,R	H,S	H,R	O,R	H	R	R	R,H	A	R	R		H,R	R	A			H	A	H	H,R	R		R,H	H	A	R	H
Teriparatide	A		H,S	R	O,R	H	H	R	R	A	S	R	H,R	H,R	R	A		H	R	A		R	R	H,R	R		A	R	
Tocilizumab	A			H,R	H,S		H	H	H,S	A			H,R		R	A			H	A	H	H		A	H,R			S	H
Trastuzumab	H	H	H	H	H,S	H	H	H	H,S	A	H	S	H,	H		A		H	H	A	H	H	H	H	H	H	A	H	H
Ustekinumab	A	A	H,S	H,R	H,S		A	H	H,S	A			H,R	H,S	R	A			H	A	H	H	R	A	H,R			R	H
Comments											(1)					A		(2)		A	(3)								

(1) The 34 EOPYY pharmacies are considered as Specialized Centres. Available in all settings : Refers to medicines that start at the hospital however the therapy may be completet via the EOPYY pharmacies. EOPYY is considering the possibility to send High Cost Medicines from its pharmacies to the private pharmacies that the patients may request.
(2) Not confirmed
(3) Teriparatide and Epoetin Zeta are not reimbursed

Pricing & reimbursement system

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3. What kind of pricing system is in place for biosimilar medicines (reimbursed)?																													
Free pricing						✓												✓										✓	✓
Regulated pricing	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		
Comments																		(1)			(2)			(3)					
4. Which criteria is used to set the prices?																													
External reference pricing			✓	✓	✓						✓				✓	✓	✓	✓	✓		✓		✓	✓	✓				
Set % below originator price	✓	✓	✓	✓	✓		✓	✓	✓			✓	✓	✓	✓	✓					✓	✓	✓	✓		✓	✓		
Percentage below originator price	38%		20%	20%	30%		30%	30%	30 - 40%			30%	45%	20%	30%						25%	20%	80%	25%	-	30%	10 - 35%		
Maximum price																✓			✓	✓	✓		✓				✓		
Negotiation									✓	✓			✓							✓	✓				✓				
Other																✓							(16)						✓
Comments	(4)	(5)			(6)				(6b)	(7)	(8)	(9)	(10)			(11)	(12)	(13)	(14)			(15)					(17)		(18)

(1) The IRP system in the public sector encompasses originator drugs, generics, and biosimilars. In the private sector, all medicines sold in community pharmacies are potentially subject to the voluntary IRP scheme.
(2) First generic/biosimilar applying for reimbursement must have lower price – at least 25% (mandatory, according to reimbursement law) in comparison to current price of the only one product being reimbursed
(3) Regulated price reduction -25% for biosimilar entry to the market/reimbursement list. External reference pricing is valid for biosimilars as well
(4) Retail segment: Biosimilars Reimbursement Price Regulation: The first Biosimilar must be priced 38% below the original brand. The second Biosimilar must be 15% below the first, and the third Biosimilar must be 10% below the second. The original brand must reduce its price by 30% three months after the first Biosimilar enters the market. Three months after the third Biosimilar enters, all products must match the third Biosimilar's price. Subsequent Biosimilars must be slightly cheaper than the lowest-priced existing Biosimilar.
(5) Price setting biosimilar is 26,60% lower than the reference product. When the biosimilar is available on the market, the 'biocliff' will be applied and the originator has the same price decrease to arrive at the same price level
(6) 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
(6b) 40% is for retail, 30% in hospital setting (if the drug has a regulated price).
(7) Internal reference pricing, rebate contracts (mainly Open House), choose 1 of 4 lowest price
(8) Average of the 2 different lowest prices at the Eurozone
(9) First- 30% than -10% than -10%
(10) Different pricing model for Hospital and community dispensed meds
(11) Ranking system may be applied for interchangeable molecules
(12) Lux does not have a formalised HTA process and does not set domestic practices for medicines on sale. Instead, Lux imports all medicines, and these are sold at the price set by the COO. The Lux legislation merely caps the ex-manuf price of the medicines at that approved in the COO.
(13) Although the regulations do not define biosimilars, it may be deduced that the same rule applies to this category of drug.
(14) Hospital groups negotiate the price
(15) 20% or 30% if Market share ≥5%
(16) Yearly price revision
(17) At launch a minimum of 20% difference is mandatory. The discounts are based on the turnover, for below 8 mln CHF the discount is 20%, between 8-16 it is 25%, 16-25 it is 30% and finally over 25 mln it is 35%. After the 3-years price review a minimal price difference of 10% is possible and discounts are calculated as follows: turnover, for below 8 mln CHF the discount is 10%, between 8-16 it is 15%, 16-25 it is 15% and finally over 25 mln it is 20%.
(18) Suppliers mustn't sell above their maximum sale price that they have agreed with Government in what are largely hospital tenders.

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NEW **5. How often are prices adjusted in your country?**																													
months	3-24	1	6 -24	6	12		4	12	24	6-12	12		12	24	3	6		6	6		3	12	12	12	6		36		
Comments:		**(1)**				**(2)**		**(3)**	**(4)**	**(5)**				**(6)**			**(7)**					**(8)**	**(9)**	**(9b)**			**(10)**		**(10b)**
NEW **6. When price adjustments occur, can prices be revised upward, or only downward?**																													
Prices can only decrease								✓			✓		✓			✓						✓	✓				✓		
Prices can increase and decrease	✓																			✓			✓						
In theory, prices can increase, but in practice, they rarely do	✓	✓	✓	✓	✓		✓		✓	✓					✓		✓	✓	✓		✓			✓	✓				
Other	**(11)**	**(11b)**						**(12)**	**(13)**					**(14)**			**(16)**	**(16)**			**(17)**	**(18)**		**(19)**			**(20)**		**(21)**

(1) In theory, prices can be adjusted every month. Normally, the price of a biosimilar will only change if concrete saving measures are put in place, the conditions of reimbursement change (if the targeted population is bigger, the price will decrease) of when a biosimilar company asks for a voluntary price decrease.
(2) Free pricing in Denmark, changes in pricing vary greatly according to the setting.
(3) There are two public prices in Finland. Max reimbursed price which is determined by authority (PPB) and in-market prices which are determined by competition. Price and Reimbursement decision from PPB is usually valid 24 months. When applying renewal, the price can in theory either increase or decrease but in practice the max reimbursed price can only stay the same or decrease. In-market prices can be changed bi-weekly and these can decrease or increase but not increase over max reimbursed price.
(4) At hospital level : 24 and 48 months after initial pricing. At retail level: 24 months, then 18 months later, based on market share evolution between the reference biologic and its biosimilars. Outside of these schedules, price revisions may also occur when market conditions change (e.g., volume shifts, entry of new competitors, European price comparisons)
(5) Active: manufacturer can change price every 14 days, but different effects will work (additional rebates, price moratorium, patient copayment can occur) Passive (by system): Internal reference pricing (Festbeträge): about every 6-12 month"
(6) In Italy, the revision of drug prices follows specific procedures established by the Agenzia Italiana del Farmaco (AIFA). For class C medicines, the price can be increased every two years, precisely in January of odd-numbered years. For class A and H medicines, reimbursed by the National Health Service (SSN), prices can be revised through negotiations between pharmaceutical companies and AIFA, often on the occasion of new tenders or the entry of new competitors on the market.
(7) at launch or event driven only
(8) once a year.
(9) Every year as per legislation, but in reality, every 2 years or more. In 2024 generics and biosimilars were exempted from price correction. It applied to originator medicines only. We are advocating for benefiting of exemption in 2025 as well.
(9b) Monthly for the reimbursed drugs more than 36 month, and plus 6 monthly for the reimbursed drugs to 36 months.
(10) Unless not defined differently by product when the initial price is negotiated
(10b) Most biosimilars are hospital supplied. Here, tender prices are fixed, often the tender duration is 18-24 months.
(11) Retail reimbursement prices are regulated as described in chapter 4. Mandatory price cuts in accordance with this regulation must be made within 3 months. Once all stages of the regulation have been completed, prices must be reduced every two years to a maximum range of +20% above the cheapest Biosimilar with the same active ingredient ("priceband-regualtion"). The period for Hospital tender-like procurements is usually 12 months.
(11b) Prices will only increase after a specific procedure, launched by the company, to get a price increase (with specific arguments why it's necessary).
(12) When a biosimilar enters the market, its maximum reimbursable price is set at 30% below the originator's price prior to patent expiry. One year later, the maximum price for both the originator and its biosimilars is reduced to 75% of the maximum price of the biosimilars. In-market prices can be changed bi-weekly and these can decrease or increase but not increase over max reimbursed price.
(13) prices generally decrease, but there are exceptions in rare cases under very specific conditions. Not sure if it has been the case for biosimilars.
(14) In Italy, medicines price adjustments can occur either upwards or downwards, depending on market conditions and negotiations between pharmaceutical companies and AIFA. However, in practice, it is more common to observe price reductions, especially following the entry of new biosimilars on the market, which increase competition and help reduce costs for the SSR (Regional Health Service- Servizio Sanitario Regionale).
(15) IRP Inflation, price increase with 5% happens sometimes but generally decreasing trend
(16) As in general happens with IRP prices
(17) Reimbursement for the drug is valid for 2 or 3 years after which the price is negotiated (downwards only). It is possible to apply for price increase during the decision but the process is demanding.
(18) However, prices for medicines up to €16 have increased in the last 3 years.
(19) During the external referencing there is no possibility to increase the price, even the average of the 3 lowest EU prices is higher, than the drug price in SR.
(20) Discounts vary from 10 - 20% based on the turnover. Less than 8mln CHF the discount is 10%, between 8-25 it is 15% and over 25 it is 20%
(21) Tender prices are largely fixed.

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7. Countries used for external reference pricing																													
Austria											✓					✓	✓				✓		✓	✓	✓				
Belgium			✓		✓						✓					✓	✓		✓		✓		✓	✓					
Bulgaria											✓					✓					✓		✓	✓					
Croatia					✓						✓					✓					✓			✓					
Cyprus											✓					✓					✓			✓					
Czech Republic				✓							✓				✓	✓					✓		✓	✓					
Denmark					✓						✓				✓									✓					
Estonia											✓				✓	✓					✓			✓					
Finland					✓						✓					✓					✓			✓					
France			✓		✓						✓					✓	✓	✓	✓		✓			✓	✓				
Germany					✓						✓					✓	✓				✓		✓	✓	✓				
Greece			✓								✓					✓					✓		✓	✓					
Hungary					✓						✓				✓	✓					✓		✓	✓					
Iceland																					✓								
Ireland					✓						✓					✓					✓			✓					
Italy			✓	✓	✓						✓					✓					✓		✓	✓					
Latvia			✓		✓						✓				✓	✓					✓			✓					
Lichtestein																					✓								
Lithuania			✓		✓						✓										✓		✓	✓					
Luxembourg											✓										✓			✓					
Malta											✓					✓					✓			✓					
Netherlands					✓						✓										✓			✓					
Norway																			✓		✓								
Poland					✓						✓					✓					✓		✓	✓					
Portugal					✓						✓					✓		✓			✓			✓					
Romania			✓								✓				✓	✓					✓			✓					
Slovakia			✓		✓						✓				✓	✓					✓		✓						
Slovenia			✓	✓	✓						✓					✓					✓			✓					
Spain			✓		✓						✓					✓		✓			✓		✓	✓					
Sweden					✓						✓										✓			✓					
United Kingdom																		✓	✓										

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
8.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)	(4)						(5)	(6)				
9.What formula is used when applying external reference pricing?																													
Lowest price in reference countries			✓												✓				✓		✓								
Average price of reference countries				✓	✓																			✓	✓				
Other					(7)						(8)					(9)	(10)	(12)					(14)	(15)	(16)				
Any additional comments:								(7b)									(11)		(13)										
NEW **10. Is a MA necessary to apply for the pricing of biosimilar medicines?**																													
Yes	✓		✓	✓	✓			✓	✓		✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	
No																													
11.The application for pricing & reimbursement is a:																													
Single process	✓		✓		✓	✓	✓	✓				✓		✓	✓	✓	✓	✓			✓		✓	✓		✓	✓	✓	
Separate process (One process for pricing and a separate process for reimbursement)		✓		✓					✓		✓								✓			✓			✓				
Comments					(17)			(17b)			(18)								(19)										

(1) ERP is used for all price settings (originator and biosimilar medicines) and for reimbursement. Only for 1st biosimilar - see previous comments - need of 30 % reduction from originator price
(2) Not further detailed in
(3) Not further detailed in the legislation only applies ERP in general
(4) In the first instance, there is an attempt to derive an average price in each of the tiers; if this is possible, then the mean of the three averages is used
(5) Basket of all EU countries
(6) Reference pricing is basis for maximum allowed price calculation. Maximum allowed price is basis for negotiation for reimbursed price confirmation.
(7) Average of the 3 lowest price in reference basket
(7b) Most often PPB tries the price to be average of other countries but local price level affect also pricing.
(8) Average of the two lowest different prices in the Eurozone
(9) Average of 5 lowest prices in reference countries
(10) Cannot exceed price in the COO that is, from which imported)
(11) In Lux the legislation specified that ex-manufacturer prices of medicines sold cannot exceed the ex-manufacturer price approved for them in the COO. However, this is not considered by the authorities as an IRP mechanism per se
(12) In the first instance, there is an attempt to derive an average price in each of the tiers; if this is possible, then the mean of the three averages is used
(13) The Netherlands calculate with the wholesaler buying price from Norway and not the pharmacist selling price
In the Netherlands the distribution fee is a fix fee and is placed under the pharmacist prices and this gives in combination with the price law extra price pressure
(14) Lowest price within basket or average of the lowest 3 from the basket for essential medicines
(15) Average of the three 3 lowest prices
(16) 92% of median of highest and lowest biosimilar price in reference countries (FR, AT, DE)
(17) There should be one application for P&R. Biosimilar has 2 possibilities for setting price and reimbursement: 1) external referencing (general process) - longer process. 2) process of similar product - faster process - new product ask for price and reimbursement of already reimbursed product (with same active substance...)
(17b) Evaluation by the HTA is no longer requested for biosimilars, which have the same reimbursement as the originator product. We have 1 single application to the Pricing committee (CEPS).
(18) Separate and sequential
(19) But a biosimilar in NL is automatically reimbursed

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12. 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	141	120	60	105	60	1	60	31	176	14	180	90	60	2	45	120	1	1	1	60	100	30	90	120	180	90	60	90	(1)
NEW **13. Is a MA necessary to apply for reimbursment of biosimilar medicines?**																													
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
No										✓																			✓	✓
14. After being listed, how long does it take for a biosimilar medicine to be available in the hospital? (In days)																													
days		274	30	1	1	1	15	1	1	1	30	7	1	90	45	1	1	1	1	30	14	1		1	1	1	1	2	
Comments	(2)																						(3)						(3b)
15. Are biosimilar medicines included in internal reference pricing systems for reimbursement purposes?																													
Yes	✓		✓	✓	✓		✓	✓		✓		✓			✓	✓			✓	✓	✓	✓	✓	✓	✓	✓			
No		✓				✓			✓		✓			✓			✓	✓										✓	✓	✓
Comments		(4)											(5)			(6)		(7)												
16. How is the reference group established?																													
By active substance (ATC-5)	✓		✓	✓				✓	✓	✓		✓	✓		✓	✓			✓	✓		✓	✓	✓	✓				
By pharmacological class (ATC-4)				✓			✓			✓						✓				✓						✓			
By therapeutic class (ATC-3)				✓						✓		✓								✓									
Other					✓													(9)			✓								
Comments					(8)																(10)								
17. 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				✓						✓																			
Comments				(11)	(12)			(13)		(14)													(15)						

(1) Companies must notify Government within an intention to launch and propose a maximum selling price no less than 28 days from launch.
(2) In principle as soon as the product is marketed. Prerequisites are MA, availability and the hospital procurement process. Lead-times are inhomogeneous and depend on individual hospitals or hospital groups.
(3) If a tender is won, delivery at first order
(3b) Biosimilar medicines don't need a reimbursement price.
(4) The answer is provided from the point of view that there is no comparison between molecules within the same therapeutic area
(5) The current agreement is due for renew in 2025
(6) Either ERP or internal referencing pricing applies depending on which is lower
(7) No reimbursement system in Malta
(8) 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).
(9) Either ATC-5 or ATC-4 applies, may differ molecule by molecule
(10) By create Limit Group (with the same international name or other international names but similar therapeutic effect and similar mechanism of action)
(11) based on internal rulebook or by decisions made by national committee for drugs.
(12) Reference price is lowest price from ERP (all EU members states) of any medicine listed on the reference group.
(13) Reference price is the lowest priced substitutable product + 0,5 EUR (several medicines can be reimbursed simultaneously).
(14) price of lowest 3rd of substances
(15) Lowest priced biosimilar medicine because currently they are on C list only

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18. For which active substances is the internal referencing pricing system used?																													
Adalimumab	✓		✓	✓	✓		✓	✓		✓		✓	✓		✓	✓			✓	✓	✓	✓	✓	✓		✓			
Aflibercept																✓				✓									
Bevacizumab			✓		✓								✓		✓				✓	✓	✓	✓		✓		✓			
Denosumab																				✓						✓			
Eculizumab																			✓	✓						✓			
Enoxaparin Sodium	✓				✓			✓							✓				✓	✓	✓	✓				✓			
Epoetin	✓		✓		✓			✓				✓	✓						✓	✓	✓	✓	✓	✓		✓			
Etanercept	✓		✓	✓	✓		✓	✓		✓		✓	✓		✓				✓	✓	✓	✓	✓	✓	✓	✓			
Filgrastim	✓		✓		✓			✓				✓	✓		✓				✓	✓	✓	✓	✓	✓		✓			
Follitropin Alfa	✓		✓		✓		✓								✓				✓	✓	✓	✓		✓		✓			
Infliximab	✓		✓		✓					✓			✓		✓	✓			✓	✓	✓	✓	✓	✓		✓			
Insuline aspart				✓				✓				✓			✓				✓	✓	✓			✓					
Insuline aspart protamine																				✓									
Insuline glargine	✓		✓	✓	✓			✓				✓			✓				✓	✓	✓	✓	✓	✓		✓			
Insulin Lispro				✓				✓				✓			✓				✓	✓	✓					✓			
Natalizumab								✓					✓							✓									
Omalizumab																				✓									
Pegfilgrastim	✓		✓		✓			✓				✓	✓		✓				✓	✓	✓	✓	✓	✓		✓			
Ranibizumab					✓										✓	✓				✓	✓			✓	✓				
Rituximab			✓		✓			✓					✓		✓				✓	✓	✓	✓	✓	✓		✓			
Somatropin	✓		✓		✓		✓	✓							✓				✓	✓	✓	✓	✓			✓			
Teriparatide	✓		✓		✓			✓					✓		✓				✓	✓		✓	✓	✓		✓			
Tocilizumab	✓			✓	✓			✓					✓		✓				✓	✓	✓	✓		✓	✓	✓			
Trastuzumab			✓		✓								✓		✓				✓	✓	✓	✓	✓	✓		✓			
Ustekinumab	✓			✓	✓		✓	✓					✓		✓				✓	✓	✓	✓	✓	✓					
Comments					(1)			(2)		(3)										✓									

(1) Process is same for all reimbursed medicines (there are no difference between Gx and Biosimilar medicines)
(2) marked biosimilars are included in the reference price system; insulin glargine will be included 1.4.2025 and other long-acting insulins 1.1.2026
(3) Missing substances!!Certolizumab pegol Golimumab

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NEW **19. Are there positive and/or negative reimbursement lists for biosimilar medicines in your country?**																													
Positive list	✓	✓	✓						✓		✓	✓	✓	✓	✓		✓	✓			✓				✓		✓		
Negative list																			✓									✓	
No list		(1)		✓	✓	✓	✓	✓		✓						✓				✓		✓		✓		✓			✓
20. Is there any type of cost sharing or out-of-pocket (OOP) payment for biosimilar medicines?																													
Yes	✓	✓			✓		✓	✓		✓		✓			✓	✓					✓	✓	✓	✓			✓		
No			✓	✓		✓			✓		✓		✓	✓			✓	✓	✓	✓					✓	✓		✓	✓
Comments	(2)	(3)	(4)		(5)											(6)		(7)	(8)		(9)	(10)	(11)						(11b)
21. 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)																											✓		
Other					✓					✓																			✓
Comments					(12)			(13)		(14)						(15)					(16)			(17)					(17b)
22. Do the out-of-pocket payment schemes for biosimilar medicines differ from the reference product?																													
Yes					✓																			✓					
No	✓	✓		✓			✓	✓		✓		✓			✓	✓					✓	✓					✓		✓
Comments					(18)																			(19)					

(1) Depending on the molecule, there is an OOP or not
(2) Prescription fee per dispensed package on account of health insurance, currently EUR 7.55.
(3) Depends on the molecule
(4) 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.
(5) Copayment is legally possible, but in practice there is no biologic medicines (including biosimilars) with copayment. All biologic medicines in hospitals have prices (from tender) at or below the level of reimbursement amount.
(6) Co-payment might be applied, but in majority of cases it is covered by producers
(7) The reimbursement system does not involve any co-payments since all medicines in the positive list are 100% reimbursed to entitled patients
(8) Patients in the Netherlands pay 385 euro 'own risk' cost per year. That can include medicines but also other medical procedures/costs. Currently medicines are capped at 250 euro.
(8) "out-of-pocket payment only for medicines in pharmacies; no payment for medicines in hospitals"
(10) Only in the retail market
(11) Lowest price within INN is reimbursed in the interval of 100-120%. For medicines with higher price than 120% the difference is supported by patient
(11b) As nearly all biosimilars are up to now hospital supplied, NHS patients receive these free of charge. If prescribed in the community, patients in England of working age that work would pay a prescription charge contribution of around 12 Euros. Patients in Wales, Scotland and Northern Ireland do not pay prescription charges
(12) See previous comment
(13) The amount of reimbursement depends on the medicine you are buying and whether Kela has granted you a right to reimbursement, varying from 40% - 100%. The annual maximum limit on out-of-pocket medicine costs refers to the maximum amount that you have to pay for your medicines in one calendar year. In 2025, the annual out-of-pocket maximum is EUR 633.17. Once that is reached, you only have to pay a copayment of EUR 2.50 for each prescription medicine you buy during the rest of the year.In addition to that there is a copayment of 4,50 EUR for medicines that are (otherwise) 100 % reimbursed.
(14) 1) per pack: full price up to 5€, up to maximum of 10€ per pack for more expensive drugs. 2) if manufacturer prices above reference price, the patient pays the difference above reference price (however since lots of competitions this is rather rare or just below 5-10€).3) there can be exemptions from OOP payments (complicated)
(15) Difference above the reference price (reimbursement price)
(16) Fixed amount per pack for medicines in the pharmacy; no payment for medicines in hospitals
(17) For products where fixed co-payment is not defined by rules, then ratio between reimbursement and co-payment should be kept
(17b) As above, with nearly all current biosimilars, there is no patient payment.
(18) See previous comment
(19) MEA contracts are used by originators, contract between MoH SR and MAH concerning special price discounts. Details regarding price and amount are strictly confidential.

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23. For which active substances do out-of-pocket payment schemes apply?																													
Adalimumab	✓	✓			✓			✓		✓		✓			✓	✓								✓					
Aflibercept																✓													
Bevacizumab					✓					✓					✓	✓								✓					
Denosumab												✓				✓													
Eculizumab																✓													
Enoxaparin Sodium	✓	✓			✓			✓		✓					✓	✓					✓	✓							
Epoetin	✓				✓			✓		✓		✓				✓					✓			✓					
Etanercept	✓	✓			✓			✓		✓		✓			✓	✓								✓					
Filgrastim	✓				✓			✓		✓		✓			✓	✓								✓					
Follitropin Alfa	✓				✓					✓						✓					✓	✓		✓					
Infliximab	✓	✓			✓					✓					✓	✓								✓					
Insuline aspart				✓				✓				✓			✓	✓					✓								
Insuline aspart protamine																✓													
Insuline glargine	✓			✓	✓			✓		✓		✓			✓	✓					✓			✓					
Insulin Lispro				✓				✓		✓		✓			✓	✓					✓								
Natalizumab										✓						✓													
Omalizumab																✓													
Pegfilgrastim	✓				✓			✓		✓		✓			✓	✓								✓					
Ranibizumab		✓			✓		✓			✓					✓	✓								✓					
Rituximab					✓					✓		✓			✓	✓								✓					
Somatropin	✓				✓			✓		✓		✓			✓	✓						✓							
Teriparatide	✓				✓			✓		✓		✓			✓	✓						✓		✓					
Tocilizumab	✓				✓		✓	✓		✓					✓	✓													
Trastuzumab					✓					✓					✓	✓								✓					
Ustekinumab	✓	✓			✓		✓	✓		✓						✓													
Comments																(1)								(2)					

(1) Co-payment might be applied for any product sold in pharmacy, unless it is covered by producer
(2) This is variable item depends valid reimbursement list in specific month (revision 12x per years.

Control of Excess Spending

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
NEW **24. Which of the following measures are applied to biosimilar medicines when the pharmaceutical spending exceeds the budget? (Select all that apply)**																													
Manadatory price reductions and rebates (%)										✓	✓														✓				
Please specify percentge:											(1)									25%									
Clawback/payback mechanisms		✓	✓	✓					✓		✓	✓		✓	✓				✓		✓		✓						✓
Biosimilar medicines are exempted													✓																
Other	✓				✓	(4)	✓	✓								✓	✓	✓	✓			✓		✓		✓	✓	✓	
Comments	N/A	(2)			(3)		(5)	(6)								(7)	(8)		(9)		(10)	(11)		N/A		None	(12)	N/A	(12b)
NEW **25. If you mentioned that clawback/payback is applied how is the target spending specified?**																													
Global pharmaceutical target budget		✓																			✓								
Pharrma expenditure growth rate			✓						✓					✓															
Segmented pharma target budget (specify)									✓		✓	✓			✓														
Specify percentage:											(14)	(15)											15%						
Other		(13)		✓											(16)								(17)						(17b)
NEW **26. How is the clawback/payback calculated?**																													
Based on market share											✓			✓	✓														
Based on revenue		✓		✓					✓																				
Based on growth			✓						✓																				
Other												✓									✓								✓
Comments												(18)									(19)								(20)

(1) -13,3% from ex-f, plus rebate 14% - 30%
(2) Clawback not specifically for the biologicals/biosimilars, but they are included
(3) Other (Please specify) - Biosimilars are in majority reimbursed in specific centres - so they have specific conditions in the contract with health insurance companies
(4) No budget
(5) Nothing
(6) Finland doesn't have a set pharmaceutical budget
(7) After first biosimilar of the particular molecule enters the reimbursement system, no specific measures to control the budget apply
(8) Not specified
(9) The Health Insurer agrees with the hospitals a maximum reimbursement prices, lower than the public prices. This max reimbursement price is not a public price. In the retail market the HIC applies preference policy
(10) applies only to medicines in pharmacies
(11) Extraordinary Contribution for the Pharmaceutical Industry (14,3)% in hospital and 2,5% in retail.
it applies to all biosimilar sales and it is not linked to an excess spending of the pharmaceutical budget.
(12) No plan at all so far.

(12b) Biosimilars must pay a clawback of between 10-35% on sales depending the level of reduction vs the originator list price pre loss of exclusivity.
(13) Percentages are decided by the General Council
(14) Different budgets for all hospital medicines and high cost medicines from EOPYYs own pharmacies
(15) Based on the net of the extra governmental spending **(overrun)** on reimbursed pharmaceuticals compared to what has been budgeted for the calendar year on the Jan 1 of the respective year. Clawback is calculated based on the % of reimbursement share of MAH
(16) Based on INN used for treatment on some dg
(17) Clawback applied to all medicines, 15% for generics and biosimilars and 25% for innovative medicines.
(17b) It is a fixed clawback irrespective of Government pharmaceutical spending levels.
(18) % of reimbursement share of MAH
(19) Only for products in the pharmacy whose value for the limit group is increasing. The payback depends on the product's share in the limit group and amounts to 50% of the calculated value
(20) Only for products in the pharmacy whose value for the limit group is increasing. The payback depends on the product's share in the limit group and amounts to 50% of the calculated value.

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
NEW **27. What is the percentage of the clawback/payback applied to the base selected above?**																													
%		4%	100%	12%					0%		50%	20%		2%	1%						50%								10-35%
NEW **28. Is there a differentiated clawback/payback for biosimilar medicines compared to the originator?**																													
Yes																													✓
No		✓	✓	✓					✓		✓	✓		✓	✓						✓								
NEW **29. What percentage of the budget overrun is paid back by the pharmaceutical industry?**																													
%		100%	100%	0%					(1)		100%	100%		50%	1%						50%								N/A
NEW **30. Has the budget overrun increased, decreased, or remained the same over the past few years?**																													
Increased			✓						✓		✓										✓		✓						✓
Decreased												✓		✓															
Remained the same																													
I don't know			✓	✓											✓														
NEW **31. Do you have any opportunities to give feedback on government decisions concerning the pharmaceutical budget?**																													
Public consultations														✓															✓
Advisory boards or committees											✓			✓															
Industry feedback sessions		✓	✓											✓	✓														✓
Healthcare provider consultations				✓										✓															
No formal feedback mechanisms									✓		✓	✓									✓		✓						
Other		(2)																					(3)				(4)		

(1) Contribution rate for pharma industry depends on the overspend.
(2) Medaxes is not member of the General Counsel (pharma.be - the originator association is)
(3) We give feedback in our meetings with stakeholders and in our communication with media
(4) In CH there is no pharmaceutical budget so far

Hospital tendering

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
32. Is there a tendering system in place for biosimilar medicines in the hospital market?																													
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
No										✓	✓						✓												
Comments				(1)											(2)			(3)											
33. What is the scope of the tenders?																													
National			✓	✓			✓					✓				✓		✓	✓	✓	✓	✓	✓	✓		✓			✓
Regional	✓					✓		✓	✓					✓					✓							✓		✓	✓
Hospital (individual or group)	✓	✓	✓		✓		✓		✓				✓		✓	✓					✓	✓	✓	✓	✓	✓	✓		
Other																													
Comments													(4)						(5)					(6)					
34. Which body is in charge of the tendering system?																													
National government			✓	✓	✓									✓		✓		✓			✓	✓	✓			✓			✓
Regional government						✓								✓												✓		✓	
Health insurance funds				✓			✓					✓												✓					
Group of hospitals	✓	✓			✓		✓	✓	✓					✓					✓		✓		✓				✓		
Individual hospitals	✓	✓	✓		✓		✓		✓						✓	✓					✓	✓	✓	✓	✓		✓		
Other(Please specify)						(7)							(8)			(9)				(10)							(11)		
NEW **35. To whom are tenders applied?**																													
all pharmaceuticals			✓	✓	✓	✓	✓	✓	✓			✓	✓			✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
Off-Patent	✓	✓												✓															
Other please specify																													

(1) Tenders are on brand level (full ATK, so each biosimilar wins with their price)
(2) Just for starting therapy in some hospitals
(3) Procurement of medicines in the public sector mostly consists of a price-driven system which is based on tenders. The cheapest option that fits the technical specifications in the tender is opted for and the tender value is published"
(4) some tenders are run at hospital level and other are run centrally by the HSE on behalf of a hospital or group of hospitals in a region
(5) We have one national hospital buying group (academic centres) and a few regional buying groups
(6) Initiated by General Insurance Company - state owned
(7) Amgros.
(8) v - all of the above
(9) Central Purchasing Organization (CPO)
(10) All hospitals
(11) Pharmacy groups

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
36. How are tendering contracts awarded?																													
By active substance	✓	✓	✓			✓		✓	✓			✓	✓	✓	✓	✓					✓	✓	✓		✓	✓	✓	✓	✓
By therapeutic indications																													
Other				✓	(2)		✓											✓	✓					✓					
Comments				(1)		(3)	(4)									(5)		(6)	(7)	(8)	(9)			(10)					(10b)
37. What is the average contract duration of the tender? (In months)																													
months	12	24	24	12	36	12	24	24	24			24	24	36	12	12		12	24	24	24	12	12 - 48	24	12	48	12	48	18-24
Comments		(11)											(12)										(13)						
38. Are there separate tenders for naïve versus currently on treatment patients?																													
Yes																													
No	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Comments		(14)			(15)							(16)						(17)											
39. Does a single tender allow for more than one winner?																													
Yes						✓			✓				✓	✓						✓	✓	✓			✓	✓		✓	✓
No		✓		✓	✓		✓	✓				✓				✓		✓	✓				✓	✓			✓		
If Yes, provide more details		(18)		(19)		(20)							(21)	(22)				(23)	(24)	(25)	(26)			(27)				(28)	(29)

(1) On brand level
(2) 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).
(3) Plus indications
(4) Price
(5) Concrete brand is awarded as a tender winner
(6) not specified
(7) Both, by active substance and by therapeutic indications. Depends per tender, mainly if there are left indications under patent
(8) Multiple factors: Price 25%, Environment 30%, other factors like supply security and stock level are also considered
(9) For some products, it is possible to vary the indications between products. In such cases, the tender conditions may also specify an indication
(10) Selection process of distributors by selected Brand (concrete product).
(10b) Awards are broken down by pack size, form, strength within that.
(11) max 48 months
(12) the contract usually included a option of 12 -24 month extension
(13) It is dependent on the therapeutic area. Longer contracts are usually the ones organised by hospitals and not the Ministry of Health, and they can be a barrier for entry to market for biosimilar medicines
(14) not sure
(15) In some molecules there is still an attempt by some hospitals to divide the contracts into two parts - for naive and on-treatment patients (with a preference for the original treatment for on-treatment patients). But the MoH and the antitrust authority are increasingly pushing for to stop this splitting.
(16) It was used to be, but not common and there is no separate naive tender at the moment
(17) not specified
(18) One winner per hospital, but the winner can be different in different hospitals
(19) ach brand wins as tender groups are on brand level and full ATK
(20) Some do, some don't
(21) This is not a common practice.
(22) In Italy, Law 232/2016 defines a multi-winner framework agreement
(23) not specified
(24) Hospital purchasing groups try to avoid all tenders appointing to the same supplier
(25) Multiple winners is a possibility, but does not always apply
(26) There are tenders where the contract is divided into packages. Then there is one winner for each package.
(27) Only one winner, without any volume guarantees for winner.
(28) In rare instances there is one winner.
(29) Yes, unless the market is very small.

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
40.Is there an agreed minimum or maximum volume as a result of winning the tender?																													
Minimum volume															✓	✓							✓						
Maximum volume			✓				✓		✓			✓				✓						✓	✓						
None	✓	✓		✓	✓	✓		✓					✓	✓				✓	✓	✓	✓			✓	✓	✓	✓	✓	✓
Comments				(1)			(2)		(2b)							(3)		(4)	(5)			(6)		(7)		(8)		(9)	(10)	
NEW **41. If there is an agreed minimum or maximum volume as a result of winning the tender, is there flexibility to adjust this volume during the contract period?**																													
Yes							✓																✓				✓		
No			✓						✓			✓											✓		✓				✓
Other																(11)													
42. After granting the tender, are prices subject to change before the next tender?																													
Yes		✓	✓	✓					✓					✓	✓			✓			✓		✓			✓		✓	
No	✓				✓	✓	✓	✓				✓	✓			✓			✓	✓		✓		✓	✓	✓		✓		
Comments		(12)		(13)	(14)													(15)			(16)		(17)					(18)	
43. Is the winning price from the tender transparent to other competitors?																													
Yes		✓	✓	✓	✓		✓	✓				✓		✓	✓						✓	✓		✓	✓	✓		✓	
No	✓					✓			✓				✓			✓		✓	✓	✓							✓		✓

(1) Tender volumes are approximated.
(2) does not apply to every tender.
(2b) Minimum volumes are informative but not binding, maximum volumes are.
(3) Minimum volumes are also indicated in the tender agreement
(4) not specified
(5) There is volume tendering but no agreements on minimum or maximum offtake
(6) contracts define delivery quantities in accordance with demand
(7) Minimum and maximum volumes are stipulated in the contract, however hospitals order based on their needs and there is no enforcement of these limits. If lower volumes or no volume is requested there is no way for companies to request compensation
(8) There are penalties for non-supplied volume.
(9) No binding volume fixed in tenders, most of the time they simply announce the quantities they have been using the year before
(10) No volume commitments in Swedish tenders
(11) Limited flexibility
(12) If price decreases are put in place by the government, the price of the biological product in the tender can change
(13) There can be price adjustment at any time of tender from any of competitors
(14) It depends on contract conditions - it's on contract parties.
(15) Price-driven tenders
(16) a change in price may result from a change in the financing limit
(17) Prices can only decrease during the contract. Generally, for centralised tenders which last for 2 years there is another round of bids after 1 year and prices can decrease/the supplier can be changed.
(18) It's not mandatory but it's a possibility

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
44. Are factors other than the lowest price considered when determining the winner of the tender?																													
Yes, always		✓						✓	✓											✓	✓					✓	✓	✓	
In specific circumstances	✓	✓				✓							✓						✓										
No			✓	✓	✓		✓					✓		✓	✓	✓		✓				✓	✓	✓	✓				✓
Comments/If answered ' Yes/In specific circumstances' please describe the factors and their weight	(1)	(2)			(3)	(4)		(5)					(6)						(7)	(8)	(9)		(10)					(11)	
NEW **45. What is the lead time from the contract being signed until the first supply of medicine is expected (in months)?**																													
In months	2	0	1	1	2	1	1	1	1			1	2	2		2		1	6	9	1	(11)	(12)	(13)	1	0,5	3 - 6	4	(13b)
NEW **46. Do you have any opportunities to give feedback when the tender is being designed?**																													
Yes						✓	✓	✓						✓					✓	✓	✓		✓			✓		✓	✓
Other stakeholders are consulted but not the industry			✓																										
No	✓	✓		✓	✓				✓			✓	✓			✓		✓				✓		✓	✓		✓		
47. 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								(16)						2															
No	✓		✓	✓	✓		✓		✓			✓	✓		✓	✓		✓		✓	✓		✓	✓	✓		✓	✓	
Comments	(14)	(15)						(17)	(18)			(19)	(20)					(21)			(22)		(23)			(24)		(25)	(26)

(1) Other criteria were applied only in very few cases. E.g. a plan to ensure availability was required.
(2) Not always, depending on the situation. The ease of use can also play a role
(3) We are working on changing this practice (MEAT criteria).
(4) Varies
(5) Quality aspects are taken into account. The weight depends on both the substance and the procurement ring.
(6) this is the most common practice
(7) There are sometimes availability, product specific or ESG criteria in the tenders, but there are no weighting given to the criteria so its not clear how much it counts
(8) Multiple factors: Price 25%, Environment 30%, other factors like supply security and stock level are also considered
(9) Price may not be the only factor, which is determined by law. The most common other criterion is payment terms
(10) Generally minimum prices is considered, however there are hospitals who organize tenders for innovation only (although with patent lost)
(11) Price is the deciding factor but there are other qualitative criteria.
(12) Few days
(13) specifically defined by contracts
(13b) Variable, several weeks to months.
(14) Not mandatory. Driven by hospital pharmacist, when significant savings are expected
(15) within 9 months after the arrival and reimbursement of the first biosimilar, the tender must be put in place **(15)** This differs between areas and molecules. Tenders are usually re-opened shortly after patens expiry.
(16) This differs between areas and molecules. Tenders are usually re-opened shortly after patens expiry
(17) It is common that tender contracts are re-opened, but it varies between different procurement rings.
(18) It can be reopened if there is a drop in the price
(19) No obligation to re-open the tender, but usually HA opens it quickly after the appearance of the first biosimilars
(20) but this is common practice.
(21) Only when the next tender is due for publication
(22) The entry of biosimilars lowers the funding limit. If the original drug does not reduce the price a new tender is opened.
(23) Previously in centralised contracts there was a clause allowing the tender to be reopened when a biosimilar entered the market. However, this did not work as originators sued the Ministry of Health, and blocked any new bids during the trial, so in the end, in practice the tender could only be reopened after the current contract expired. Currently most tenders happen at hospital level and there is no such clause to reopen it when a biosimilar enters the market.
(24) Depends on the molecule, if there will be more than one, in 3 months we have the first tender, if not maybe will not any tender.
(25) Not mandatory, there is a paragraph in the tender contract that states that tenders can be reopened when a biosimilar enters the market, this paragraph is rarely used
(26) The NHS purchasing authority will broadly plan a tender to coincide with known loss of exclusivity dates.

Retail tendering

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
48. Is there a tendering system in place for biosimilar medicines in the retail market?																													
Yes										✓									✓					✓			✓		
No	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓		✓	✓
Comments										(1)							(2)							(3)					
49.What is the scope of the tenders?																													
National										✓									✓					✓					
Regional										✓																			
Other																											✓		
Comments																			(4)					(5)			(6)		
50.Which body is in charge of the retail tendering system?																													
National government																													
Regional government																													
Health insurance funds										✓									✓					✓					
Other																											✓		
NEW **51. How are retail tendering contracts awarded?**																													
By active substance										✓									✓					✓			✓		
Therapeutic indications																													
Other																													
Comments																								(7)					
52. What is the average contract duration of the tender?																													
months										99									24					36			12		

(1) DE. As Open House Contracts
(2) LU. Unknown
(3) SK. Tendering system used partially only via insurance company.
(4) NL. 4 large and some small HIC
(5) SK. Organised by General Insurance Company (VSZP) - state owned
(6) CH. Pharmacy groups mainly
(7) SK. only one winner with the lowest price

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
53. Are there separate tenders for naïve versus currently on treatment patients?																													
Yes																													
No										✓									✓					✓			✓		
54. 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																													
Please specify in the comments section the number of months																													
No										✓														✓			✓		
55. Is there an agreed minimum or maximum volume as a result of winning the tender?																													
Maximum volume																													
Minimum volume																													
None										✓									✓					✓			✓		
Comments																													
NEW **56. If there is an agreed minimum or maximum volume as a result of winning the tender, is there flexibility to adjust this volume during the contract?**																													
Yes																													
No																													
Not sure																													
Comments																													
57. After granting the tender, are prices subject to change before the next tender?																													
Yes																			✓										
No										✓														✓			✓		
Comments																			(1)										

(1) Companies can ask for a price change after the first year when there are unforeseen (proven) circumstances, the HIC decide if they award the request or not

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
NEW **58. Does a single tender allow for more than one winner?**																													
yes										✓																			
No																								✓			✓		
Comments																			✓										
59. Is the winning price from the tender transparent to other competitors?																													
Yes																								✓					
No										✓									✓								✓		
Comments																													
60. Are factors other than the lowest price considered when determining the winner of the tender?																													
Yes																													
In specific circumstances																											✓		
No										✓									✓					✓					
If 'Yes/in specific circumstances' are selected mention the factors and their weight																													
61. What is the lead time from the contract being signed until the first supply of the medicine is expected? (In months)																													
months										1									6				(1)	(2)			3 - 6		
NEW **62. Do you have any opportunities to give feedback when the tender is being designed?**																													
Yes																			✓				✓						
Other stakeholders arr consulted but not the industry																													
No										✓														✓			✓		

(1) Few days
(2) 6-depends on contract

Economic Prescribing and dispensing policies

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
63. 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)				(3)							(4)						
64. Are there incentives/obligations for prescribers or patients to use biosimilar medicines?																													
Yes								✓	✓	✓			✓	✓												✓			✓
No	✓	✓	✓	✓	✓	✓	✓				✓	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	
comments		(5)																	(12)										
Type of incentives						(6)		(7)	(8)	(9)			(10)	(11)														(13)	(13b
65. How should prescribers prescribe biological medicines by law in your country?																													
By INN (non-proprietary name)											✓				✓		✓	✓		✓							✓		
By Trade name (incl invented name)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓			✓		✓	✓	✓	✓	✓	✓		✓	✓
Comments					(14)			(15)			(16)										(17)		(18)				(19)		

(1) In principle it applies to all patients (Guideline for economically prescription), however the continuation of the therapy with the same is tolerated by sick fund.
(2) In case of retail market, physicians can decide. In tender, there is only one available"
(3) Unless it is regulated by ATC-4 ranking
(4) Physicians prescribe the branded biologic. Automatic switch is not allowed in the pharmacy
(5) not anymore, but working on it in a taskforce with the NIHDI
(6) Indirectly. Help the hospital to stay within budget
(7) Obligation to prescribe the most affordable biologic medicine.
(8) Remuneration based on the public health objectives for physicians
(9) prescribers have strong recommendations (but not obligation) patients: none"
(10) The BVB list determines the available options for prescribers. Gain-Share is/was used as an incentive to encourage prescribers to select from the BVB list.
(11) there're some recommendations and supportive measures (electronic prescribing, financial restrictions and benefit-sharing agreements, information/educational materials/ training or regional decree
(12) In retail there are no reward systems for physicians or patients if they switch to a biosimilar. If HIC has designated a biosimilar in the preference policy, patients and physicians are required to follow it. Pharmacist are monitored by HIC in their compliance within the preference policy and have targets for this. If the pharmacy does not meet those targets, the pharmacy's reimbursements are at risk
(13) there is no official obligation but the decision is normally taken by clinic and doctors have to follow the decision made by the clinic
(13b) There are to be incentives for prescribers for best value biologic switching for certain high value biologics coming off patent from H2 2025.
(14) both options are legal theoretically, but in practice medical professionals prescribe by brand name
(15) In practice biologics are prescribed by trade name, but prescribing by INN is not forbidden by law.
(16) physician can prescribe with trade name up to 15% of the monthly prescription value
(17) INN prescriptions are possible but it is only margin of all prescriptions.
(18) Since August 2023 there is a 50% quota system for prescribing.
(19) Not specified by law, it can be either by the generic name or by the brand name. Usually it is done by the brand name.

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
66. 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)					✓					(4)				✓				✓						
Comments										(2)		(3)			(5)				(6)		(7)		(8)	(9)			(10)		(10b)
67. Is biological medicine substitution, at the level of retail pharmacies, legally allowed? (i.e. without consulting the prescriber)																													
Yes								✓	✓	✓					✓				✓	✓	✓						✓		
No	✓	✓	✓	✓	✓	✓	✓				✓	✓	✓	✓		✓	✓	✓				✓	✓	✓	✓	✓		✓	✓
Comments								(11)	(11b)	(12)								(13)			(14)								

(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) depends on familiarity of physician group with substances, e.g. new BS for Eye treatment --> reluctance since unknown. Oncologics very established
(3) If biologic medicines go down to the biosimilar price and available for the same co-payment for the patients, then physicians prefer more the biologic medicines.
(4) Physicians prescribe INN
(5) Pharmacies can give which reference product they prefer
(6) "In hospitals the hospital pharmacist and the prescribers often decide together how to switch from biologicals to biosimilars. Soms specialist exclude sensitive indications, such as Crohn disease. Tenders choose on lowest price.
In retail the HIC decide with preference policy if patients must switch to biosimilars and it is then mandatory.
In retail, prescribers can make an exception for patient if they add ""medical need' to the prescription. Than the pharmacy understands that this patient has a medical necessity to stay on the 'old' product. If there is a shortage and the pharmacist cannot dispense the designated product the pharmacy adds 'logistic need' and can use the same INN from an other supplier."
(7) "Deciding factors are:
- product's availability in the hospital (if originator is present or only biosimilar)
- patient's co-payment in pharmacy"
(8) Availability of switching differ from one therapeutic are to another. Now as they are obliged by the law with 50% quota there is a tendency in favour of biosimilars prescription
(9) There are differences in Biosimilar medicines' prescription affinity by different specialist groups (e.g. Derma, Gastro, – used to prescribe biologics from originators)
(10) Biosimilars medicines penetration rate is low in Switzerland
(10b) Biosimilar uptake has varied, but more recently, clinicians have switched both new and existing patients.
(11) Substitution is introduced gradually:
- 1.4.2024 enoxaparin
- 1.1.2025 all other substitutable biologic medicines apart from insulins
- 1.4.2025 insuline glargine
- 1.1.2026 other long-acting insulins
Short-acting insulins are not substitutable.
(11b) Not for all medicines.
(12) but only for parenterals used immediately by physicians
(13) "Biosimilar substitution at pharmacy level is not allowed. However, the Ministry for Health is currently dealing with switching of biologics to biosimilars on a case-by-case basis and the necessary
policy guidance is provided accordingly"
(14) The possibility to replace a reimbursable drug: containing the same active substance, dose, pharmaceutical form

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68. 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)									(2)		(3)			(5)					
69. Are there incentives for pharmacists to substitute biosimilar medicines?																													
Yes										✓									✓										
No								✓	✓						✓						✓						✓		✓
Please specify what type of incentives										(4)																			

(1) patients don't know anything about Parenterals
(2) In hospitals pharmacist decide with prescribers to switch to biosimilars. In retail, HIC designate the preferred product and then pharmacies are required to dispense it.
(3) Pharmacists are obliged by law to inform the patient that cheapest equivalent is available. Substitution of biosimilars is rather rare
(4) Procurement benefits when buying high volumes cheaper
(5) Rules defined by national Drug Law 362/2011.

Governing Policies

	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
NEW **70. Are there any ongoing political discussions or forecoming changes impacting market access we should consider? (e.g. inflation-based adjustments, supply chain cost considerations)?**																													
Yes		✓	✓	✓	✓			✓			✓		✓						✓	✓	✓	✓	✓	✓		✓	✓		✓
No	✓					✓	✓		✓	✓		✓		✓	✓	✓	✓	✓							✓			✓	
If yes, please specify		(1)	(2)	(3)	(4)			(5)			(6)		(7)						(8)	(9)	(10)	(11)	(12)	(13)		(14)	(15)		(15b)
NEW **71. Could you please share with us any other national legislation affecting market policies we should consider?**																													
Yes											✓			✓							✓		✓	✓		✓		✓	
No	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓		✓		✓			✓				✓
If yes, please specify											(16)			(17)							(18)		(19)	(20)		(21)	(22)	(23)	

(1) There is a Taskforce put in place to discuss about new incentives for biosimilars
(2) There is a rule to increase the price of pharmaceutical products every 12 months by the annual inflation rate.
(3) Supply chain cost, etc
(4) "- change of setting of price for endangered medicines (definition is not yet available)
- change of setting for Gx and Bios (in way that all Gx should have same reimbursement - there was obligation only for 1st Gx to reduce reimbursement)"
(5) Biosimilar must be priced so that its wholesale price is at most 70% of the wholesale price of the original product in order to be included in the reimbursement system. At the beginning of 2026, a law came into effect requiring that one year after the first biosimilar enters the market, the maximum wholesale price of both the original product and the biosimilar must be reduced to 75% of the price initially granted to the biosimilar.
(6) Extreme paybacks: Although biosimilars are generally cheaper from the originator, are burdened with the same clawback percentage each semester. This is because the clawback in hospital and EOPYY pharmacies channel is calculated by the company market share at the specific channel, and not to the product market share
(7) inflation, supply chain, support services, primary care-based care and treatment
(8) UWWTD, Distribution fee (wholesaler and HIC agreements, procurement guidelines, possible changes in WGP pricing)
(9) Inflation, unexpected cost (e.g. new tariffs, directives)
(10) Benefits for domestically produced medicines; List of critical medicines; Change in reimbursement regulations
(11) Reference pricing system for biological medicines for out-patient sector.
(12) "Triggered by APMGR : clawback decrease with 5% in 2025, price increase with inflation, extend essential medicines list, increase quota to 70%. Triggered by authorities: pricing legislation, critical medicines list"
(13) Related to UWWTD(EU Directive effective since 1.1.2025,which will have negative impact on generic medicines sustainability due to strict regulated pricing.
(14) Supply chain consideration, there is a project to change the public purchase law.
(15) There is a parliamentary initiative to implement criteria as from which price are not further reduced. At the same time the authority has been asked to develop a concise price increase process in case for economic reasons (e.g. inflation) certain products could be withdrawn from the market
(15b) The NHS is actively looking at policies that promote biosimilar uptake. Value-based procurement which is being implemented in hospital contracts to promote more reliable supply, may extend to biosimilars.
(16) The extreme clawbacks due to the underfinanced public system affect the Negotiation Committee decision, since the % price reduction proposed to MAHs by the Committee at least should exceed the previous year total returns. This impedes the growth of the biosimilar market
(17) law 232/106
(18) Benefits for domestically produced medicines
(19) UWWTD
(20) Drug Law362/2011 including Emergency system and Law regarding Drug reimbursement 363/2011
(21) There is a project to change the reference price system.
(22) A parliamentary initiative is asking the government to introduce a reference pricing system for generics and biosimilars, although this has been rejected by the parliament in 2022. The process is just starting and will take another 1 year to come to a conclusion
(23) there is an ongoing discussion whether pharmacy substitution for biosimilars could be a possibility foe Sweden.
There was an investigation that ended a year ago by the Medical Product Agency but no news/progress after that."

Information and education

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72. Is there an identified need for information targeting patients or healthcare professionals about biosimilar medicines?																													
Yes	✓	✓		✓	✓	✓			✓	✓	✓		✓	✓			✓	✓	✓		✓	✓	✓	✓					✓
No			✓				✓	✓				✓			✓	✓				✓					✓	✓	✓	✓	
Comments									(1)	(2)	(3)		(4)				(5)		(6)			(7)							
73. Have there been information campaigns targeting patients or healthcare professionals to inform them about biosimilar medicines?																													
Yes		✓		✓		✓	✓	✓		✓	✓		✓	✓	✓	✓			✓	✓		✓	✓	✓	✓	✓	✓		✓
No	✓		✓		✓				✓			✓					✓	✓			✓							✓	
Comments										(8)																			
74. Which types of healthcare professionals have been consulted for information campaigns targeting healthcare professionals?																													
Physician specialists				✓		✓	✓		✓	✓	✓		✓		✓				✓			✓	✓		✓	✓	✓		✓
Nurses							✓						✓						✓						✓	✓	✓		
Hospital pharmacists				✓		✓	✓		✓	✓	✓		✓	✓					✓			✓			✓	✓	✓		✓
General practitioners						✓			✓										✓								✓		
Pharmacists				✓			✓						✓						✓						✓	✓	✓		
Other		✓						✓																✓					
Comments		(9)						(10)																(11)					

(1) Yes, for healthcare professionals in TA, not comfortable with biosimilar medicines.
(2) for new physician groups there is lots of uncertainty, probably driven by Ox companies (e.g. now the ophthalmologist)
(3) At the moment there is no campaign. However there have been a campaign some 10 years ago…
(4) "In some treatment areas biosimilars are new. i.e. respiratory, ophthalmic. GP's"
(5) yes, in general
(6) With new treatment indications
(7) Authorities, Industry and Patients
(8) pro Biosimilar, the statutory health physician organisation, statutory health insurances and other stakeholders have driven campaigns (more or less)
(9) FAMHP and NIHDI campaigns
(10) information not available
(11) 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.)

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75. In which form(s) have these campaigns been rolled out?																													
Handbooks				✓						✓			✓	✓					✓			✓	✓		✓		✓		
Videos														✓								✓			✓	✓	✓		
Media campaigns		✓				✓					✓			✓									✓	✓		✓	✓		
Leaflets		✓		✓		✓	✓			✓	✓		✓	✓								✓	✓				✓		✓
Seminars, conferences or workshops				✓				✓		✓	✓		✓	✓	✓				✓			✓	✓	✓	✓	✓	✓		✓
Training or continuous professional development for healthcare professionals											✓		✓	✓					✓			✓			✓		✓		
Websites		✓				✓		✓		✓			✓	✓					✓					✓			✓		
Apps						✓								✓													✓		
Other		✓																											
Comments		(11)																											
76. Who developed the material?																													
Patient associations				✓		✓				✓			✓	✓								✓							
Medical societies				✓		✓				✓			✓	✓					✓			✓							
Authorities		✓				✓	✓	✓		✓	✓		✓	✓					✓			✓				✓			✓
Biosimilar medicines industry				✓						✓	✓		✓	✓	✓				✓			✓	✓	✓	✓	✓	✓		✓
Originator industry																													
Collaborative (multistakeholder) effort				✓		✓	✓			✓			✓	✓					✓			✓							
Other																						(12)		(13)					

(11) feedback campaign to the prescribers
(12) Professional Societies
(13) EMA guidelines

biosimilar medicines

better access. better health.

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