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MARKET REVIEW – BIOSIMILAR MEDICINES MARKETS

POLICY OVERVIEW

2017

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Acknowledgements

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Introduction

The Biosimilar Medicines Group - Market Access Committee is pleased to present the 2017 Market Review – European Biosimilar Medicines Markets – Policy overview.

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

The 2017 Market Review covers 7 main topics: Availability, Pricing system, Tendering, Reimbursement system, Physician policies, Pharmacist policies and Patient policies. Throughout the different topics, the reader will get a clear overview of how biosimilar medicine policies are set in the reviewed countries.

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

Adrian van den Hoven
Medicines for Europe Director General

Martin Klaus
Chair of the Biosimilar Medicines Group
Market Access Committee

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Availability (1/1)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
1. For which of the following biological active substances are biosimilar medicines available (i.e. marketed) in your country? (January 2017)																															
Somatropin	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓
Epoetin	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Filgrastim	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Infliximab	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Follitropin alfa		✓		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓	✓			✓
Insulin glargine		✓		✓	✓	✓	✓	✓	✓	✓	✓		✓		✓	✓				✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Etanercept	✓	✓	✓		✓	✓	✓	✓		✓	✓		✓		✓	✓				✓	✓	✓	✓				✓	✓	✓		✓
Enoxaparin sodium								✓							✓					✓		✓								✓	
2. In which settings are the biosimilar medicines available? (H: hospital pharmacy; R: retail pharmacy; S: specialized centres; O: other)																															
Somatropin	H,R,S	H,R,S	R	H	H	H,R,S	H	H,R	H,R	H	H,R,S	H,O[1]	H	H	R	H,R[2]	R	R	H	H	H	H,R	H	H,R		H,R	H	H,R	H,R,S	H,R	H
Epoetin	H,R	H,R,S	H,R,S	H,S	H,S	H,R,S	H	H	H,R	H	H,R,S	H,O[1]	H	H	H,R	H,R[2]		R	H	H,R	H	H	H	H,R	H,R	H,R[4]	H	H,R,S	H,S	H,R	H
Filgrastim	H	H,R	H	H	H,S	H,R,S	H	H	H,R	H	H,R,S	H,O[1]	H	H	H,R	H,R[2]	H,R	R	H	H,R	H	H,R	H	H,R	H,R	H,R	H	H,R	H,S	H,R	H
Infliximab	H,R	H,R	H,R	H	H	S	H	H	H,R	H	H,R,S	H,O[1]	H	H	H,R	H	R	H	H,O[3]	H	H	H	H	H,R	S	H,R	H	H,R	H,S	H	H
Follitropin alfa		H,S		H,S	H,S	S	H	H,R	H,R	H	H,R,S	H,O[1]	H	R	R	H,R[2]	H,R	H	H	H	H,R	H,R	H,R		H,S	H,R	H	H,R			H
Insulin glargine		H,R		H	H	H,R	H	H,R	H,R	H,R	H,R,S		H	R	H,R	H,R[2]		R	H,R,O[3]	H,R	H,R	R	H,R		H,R	H,R	H	H,R	H,R,S	H,R	H
Etanercept	H,R	H,R	R	H	H	S	H	H		H,R			S	H	H,R	H		H	H,R,O[3]	H	H	H	H				H	H,R	H,R,S		H
Enoxaparin sodium															H,R							H,R								H,R	H

(1) Sick funds pharmacies are supplying all high-cost (and oncology) medicines, including biosimilar medicines in Greece. There are 27 sick funds pharmacies in Greece covering 98.2% of Greek citizens
(2) For epoetin, filgrastim, follitropin alfa and insulin glargine only a minor part in retail pharmacy
(3) POYC scheme: supply of tender products to outpatients from retail pharmacies
(4) Dyalisis centers get the product from local retail pharmacy if they are not part of the hospital

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Pricing Systems (1/2)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
3. How is the price of biosimilar medicines determined?																															
Free pricing							✓[1]				✓[2]																	✓[5]			✓
Price regulation	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓[3]	✓	✓	✓	✓	✓	✓[4]	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	
4. If there is price regulation, which criteria are used to set the prices?																															
External reference pricing		✓	✓	✓	✓	✓						✓[10]	✓	✓[11]			✓	✓		✓[16]		✓	✓	✓[20]	✓	✓				✓	
% below originator price	38%[6]	7,5%		15%		30%		15%	30%	- [9]			30%		42%[12]	- [13]	30%	30%[14]				25%[18]	20%	20%	25%[21]	32%			25%		
Maximum price						✓								✓[11]						✓	✓[17]					✓					
Negotiation		✓[7]	✓	✓		✓							✓	✓[11]		✓		✓							✓		✓				
Other				✓[8]															✓[15]				✓[19]		✓						
5. Is a marketing autorisation necessary to apply for a price of a biosimilar medicine?																															
Yes	✓	✓	✓	✓	✓	✓	✓[22]	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓[24]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	n.a.
No											✓[23]																				n.a.

(1) Prices are set through the normal tender system
(2) There is a "Festbetragsgroup" for epoetin (price fixed) and somatropin (no price fixed). Also for infliximab there is one in development
(3) Yearly blind biosimilar licit; specialized centralized tender for 12-24 months
(4) Tender, based on lowest price
(5) Free pricing but the price has to be approved by the government (TLV) for reimbursement purposes. In retail setting, the price of the biosimilar medicine cannot exceed the price of the originator. In hospital setting, tenders decide the price.
(6) 1st biosimilar -38%, 2nd -15%, 3rd -10%. The originator biological has to decrease its price by -30% once the biosimilar enters the market
(7) In practice: a combination of the above indicated criteria leads to price decreases of more than 30% compared to the initial price of the originator
(8) The national fund calculates prices, the lowest price is the internal pricing level
(9) The details are currently being negotiated. At this moment, there is no general price discount required, it is negotiated case by case with CEPS
(10) The average of the 3 lowest prices in a reference basket of 22 EU countries
(11) For high cost medicines there is a special approval process
(12) Originator biological obliged to lower price by 30%
(13) The % of discount depends on the average public expenditure of originator in the last three years. Generally speaking the level of discount is around 20% (depenging also on the different strenght and dosages).
(14) First biosimilar medicines -30%, second -10%, third -10%
(15) See previous question
(16) Average of prices per INN of BE, DE, FR and UK
(17) Price of the originator medicines is the maximum price
(18) Prices in reference countries and substitutes are taken into account. -25% is the minimum discount
(19) The biosimilar medicine must be 20% lower priced than the reference product for P&R purposes; aferwards there is a negotiation (tender) which drives the prices further down
(20) Minimum price of 12 EU countries
(21) Central purchasing system on top. In addition to that there is Reimbursement Law 363/2011 under revision with proposal to have -30% for the 1st biosimilar, additional -5% for 2nd and an additional -5% for 3rd biosimilar medicine
(22) Yes, but possible to submit to tender before MA. However, necessary to have MA before start of contract.
(23) Free pricing & reimbursement beginning with day one = market entry
(24) Usually no application for biosimilar medicines necessary if the orginator is already on the market

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Pricing Systems (2/2)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
6. Is the application for pricing and reimbursement of a biosimilar medicine:																															
A single process	✓		✓	✓		✓	n.a.[1]	✓	✓		n.a.				✓	✓			n.a.[3]	✓		✓						✓	✓		n.a.
Separate processes		✓			✓		n.a.[1]			✓	n.a.	✓	✓	✓			✓[2]	✓	n.a.[3]		✓		✓	✓	✓[4]	✓	✓			✓	n.a.
7. On average, how long does it take for a biosimilar medicine to receive its P&R approval from the day of application (in days)?																															
	180[5]	180	90	180	90[6]	60	n.a.	180	119	?	n.a.	270[7]	90	60[8]	-	120[9]	90	90	n.a.[10]	30-60	30-90	60	120-180[11]	120	120[12]	180	-	45	90	-[13]	n.a.

(1) Not applicable as not necessary in Denmark as all biosimilar medicines are tender products
(2) Pricing without the reimbursement doesn' t make sense as all biological medicines, including biosimilar medicines, are purchased only through the reimbursement system. But formally these are two processes while within reimbursement application is also reimbursement price setting (single process; no possibility to obtain the reimbursement while a price is not approved)
(3) Not applicable is the originator medicines is already on the market
(4) Separate process via generic application subgroup - Biosimilar
(5) 180 days is the maximum period, no average data available
(6) Reimbursement is only obtained through public tendering
(7) 270 days from the day that the national phase (codes + blue box requirements) have been granted
(8) 180 days is the maximum
(9) 120 days on average, 90 is the minimum. It depends on the schedule of meetings of Italian medicines agency P&R committee and technical & scientific committee which are the bodies that evaluate P&R dossiers
(10) See previous question
(11) The average time varies according volume of applications and importance of the molecule for the company and NHS (e.g; insuline glargine took a much longer period than etanercept and infliximab)
(12) you are entering at the beginning of the 5th month of the process
(13) Pricing approval takes maximum 90 days. As to reimbursement, it may take maximum 9-12 months.

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Tendering (1/3)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
8. Is tendering applied to biosimilar medicines in your country?																															
Yes, retail market							✓				✓[1]							✓		✓								✓[3]			
Yes, hospital market	✓	✓	✓	✓		✓	✓	✓	✓	✓					✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
No, not at all												✓[2]																	✓		
9. If yes, what is the scope of the tenders?																															
National				✓[6]	✓		✓				✓[8]		✓	✓				✓	✓	✓[11]	✓	✓	✓		✓		✓	✓			
Regional	✓								✓[7]		✓					✓				✓							✓	✓[13]			✓[14]
Hospital		✓[1]	✓[5]	✓[6]		✓		✓	✓	✓					✓		✓[10]	✓		✓	✓	✓	✓	✓	✓	✓[12]	✓			✓	
Other																✓[9]															

(1) All biosimilar medicines are tendered and dispensed in hospitals (no retail pharmacy pick-up for patients)
(2)There are national negotiation committee in Greece asking for rebates. Biosimilar medicines belong to list of high-cost medicines for which price-volume agreements are requested by the sick funds pharmacies
(3)Retail market if the patients administrated the medicine s themselves and pick it up at the pharmacy. Hospital market if the product is administrated to the patient in the hospital
(4)Sometimes there are purchasing committees covering several hospital
(5)Still tenders are done in individual hospitals but after the expected implementation of the electronic tender system in 2017 there will be a central tender for submitting offers and then a 2 year contract for supply of all hospitals.
(6)National for filgrastim, hospital for epoetin and infliximab
(7)There are 5 big regoinal hospital tenders in Finlan
(8)In Germany there are regional and national health insurers (SHI)
(9)Group of hospitals in few cases
(10)Only filgrastim and follitropin alfa are available in the hospital setting
(11)Hospital products are tendered at regional or hospital level. A retail product can be in the "preference policy" of the health insurers, where the reach is limited for the clients of the particular health insurer
(12)In 2017 we expect to have national tenders for hospital. Until then, only at hospital level
(13)Normally it is a regional business. Since recently there is a new form of national supervision (three-party agreement) where the pricing authority is involved and provides a national recommendatoin based on price/discount
(14) 4 tender regions: South, London, Midlands and East, North

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Tendering (2/3)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
10. If yes, what is the average contract duration of the tender (in months)?																															
	12	18	12[1]	12	24	12	12[2]	12	24	~[3]	24		12-24	12[4]	12	24[5]	12-24	12	12-24	12-36	12	6-12[6]	12[7]	12	12	6	-	24		12[8]	24[9]
11. If yes, are there separate tender for naïve versus currently on treatment patients?																															
Yes		✓		✓									✓					✓		✓[14]			✓[15]			✓[16]	-				
No	✓	✓[10]	✓		✓	✓	✓	✓	✓	✓[11]	✓			✓[12]	✓	✓[13]	✓		✓	✓[14]	✓	✓		✓	✓		-	✓[17]		✓	✓
12. If yes, does the tender allow for more than one winner?																															
Yes					✓		✓[19]				✓[21]			✓	✓	✓[22]	✓[23]					✓	✓[25]		✓	✓[26]	✓				
No	✓	✓	✓[18]	✓		✓		✓	✓	✓[20]			✓					✓	✓	✓	✓[24]			✓				✓[27]		✓[28]	✓

(1) Usual time for contract in a hospital tender is 12 months. In some rare cases certain hospitals sign contracts for 24 or 36 months. With the new electronic tender system in 2017 the duration will be 24 months plus 12 months in addition in case there is a need of prolongation.
(2) National tender authority (AMGROS) has been adjusting tender openings to meet entrance of new biosimilar medicines
(3) Varies per hospital
(4) Can be up to 48 months
(5) with a possible extension of 24 months
(6) Depends on product and therapeutic program
(7) The national tender can be renewed up to 36 months
(8) Generally 12 monhts but in case the medicines would be needed immediately, public hospital can conclude contracts for 1 months or etc.
(9) 24 months on a 6 monthly rolling basis between regions
(10) The latest communication by the Minister of Health promotes 1 parcel in tenders for both naïve and on treatment patients
(11) Previously tenders were separate but since the adoption of the 2017 budget law (LFSS) allowing interchangeability tenders will be in 1 lot
(12) The switch needs to get an approval according to clinical evaluation
(13) No more separate tenders since the adoption of the new procurement law in December 2016
(14) "Preference policy" can distinguish naïve vs currently on treatment
(15) Only at hospital level
(16)In current tenders there is 33% for biological medicine, 33% for biosimilar medicine and 33% not defined (it could be either biological or biosimilar). The future tenders are likely not to be separate
(17) Usually not. There was one tender for infliximab which was split between naïve and currently on treatment patients.
(18) Only the product that offers the lowest price will win the tender. With the new electronic tender platform in 2017 the intention is to have 2 winning distributors
(19) Yes, but in practice VERY strong steering to winner (i.e. lowest priced product)
(20) There can be exceptions
(21) Health insurers (SHI) have open-house tenders with a fixed rebate open to all companies with the molecule
(22) Since the adoption of the new prodrement law in December 2016 mandatory tenders with 3 preferred products in case of ≥ 3 competitors. In case of < 3 competitors, free to use single- or multi-winner tender.
(23) Hospitals are obliged to purchase the cheapest available product at a moment of order
(24) All products are allowed to be prescribed but the lowest priced is recommended by the government
(25)The selection is by the type of patients, being one supplier per type of patients (naïve or established patients)
(26)In the future 2 providers will be obliged
(27) Usually not (see previous question)
(28) Consortiums are allowed

Tendering (3/3)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
13. If yes, do tender contracts have to be re-opened once biosimilar medicines enter the market?																															
Yes, immediately after the marketing autorisation of the biosimilar medicine																											✓				
Yes, a couple of months after the marketing autorisation of the biosimilar medicine																✓[8]															
No	✓[1]	✓[2]	✓	✓	✓	✓[3]	✓[4]	✓	✓[5]	✓	✓[6]		✓	✓[7]	✓		✓	✓	✓[9]	✓	✓[10]	✓	✓[11]	✓	✓	✓		✓[12]		✓	✓

(1) Tenders will be opened in case of significant market change
(2) From a legal point of view it should be applied. In reality it is not the case (yet). in the latest communication by the Minister of Health, the hospitals were urged to start the tender process as quickly as possible after patent expiry of the originator biological
(3) Not obligatory but usually re-opened after 4-5 months
(4) Not formally but the national tender authority (AMGROS) is normally very effective and makes sure that old contracts expire whenever biosimilar medicines enter the market
(5) Decided on case by case by each regional area
(6) There is no obligation to re-open the contracts but the health insurers (SHI) open the tender with market entry of the first biosimilar medicine
(7) Tenders tend to be for shorter period if biosimilar medicines are entering the market in near future
(8) Since the adoption of the new procurement law in December 2016, obligatory to re-open contracts within 60 days after market entry (communication by MAH that the prodct is available for purchase)
(9) A new tender is published only after the old one expires. The originator tenders are usually negotiated tenders with expiry date soon after biosimilar medicines are expected to become available
(10) New biosimilar medicines entering the market can be included
(11) Although not followed by hospitals and national formulary, we have a legal document that allows the entrance of a biosimilar medicie if it complies with tender conditions (i.e. lower price)
(12) Tender can be re-opened if it is written in the contract (not always the case)

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Reimbursement Systems (1/1)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
14. Is a marketing autorisation necessary to apply for reimbursement of biosimilar medicines?																															
Yes	✓	✓	✓	✓	✓	✓	✓[1]	✓	✓	✓	n.a.[2]	✓	✓	✓	✓	✓	✓	✓	n.a.[3]	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	n.a.
No											n.a.[2]								n.a.[3]		✓[4]										n.a.
15. Are biosimilar medicines included in internal reference pricing systems for reimbursement purposes?																															
Yes	✓		✓[5]					✓			✓[6]	✓[7]	✓					✓		✓	✓		✓		✓	✓	✓			✓[8]	
No		✓		✓	✓	✓	✓		✓	✓				✓	✓	✓	✓		✓			✓		✓				✓	✓		✓
- If yes, for which active substances? (Jan 17)																															
Somatropin	✓		✓					✓			✓	✓						✓		✓			✓			✓				✓	
Epoetin	✓		✓					✓			✓	✓	✓					✓		✓			✓		✓	✓				✓	
Filgrastim	✓		✓					✓				✓	✓					✓		✓			✓		✓	✓				✓	
Infliximab	✓		✓					✓				✓								✓			✓		✓					✓	
Follitropin alfa								✓				✓	✓							✓	✓		✓		✓						
Insulin glargine								✓					✓							✓	✓		✓		✓		✓[9]			✓	
Etanercept	✓		✓					✓												✓			✓								
Enoxaparin sodium								✓												✓										✓	

(1) Reimbursement not needed as biosimilar medicines are tender products in hospital
(2) No application for reimbursement needed
(3) No application for reimbursement necessary for biosimilar mediciness if the orginator is already on the market
(4) Hospital products are not reimbursed, DRG payment system
(5) Internal referencing is done on INN groups level and is based on the product with lowest price. This means that everyone in this group has to sell at one price to keep the 100% reimbursement (valid for both retail and hospital level)
(6) Epoetin (price fixed) and somatropin (no price fixed). In development for infliximab
(7) Biological and biosimilar medicines are clustered together, however each one has its own reference price
(8) Reference groups are based on active substance, form and dosage according to SSI Communique on Healthcare Practices. Medicines are reimbursed up to 10% above the lowest unit price within the group.
(9) Only for retail market

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Physician Policies (1/3)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
16. Is INN prescribing allowed in your country? (chemical and/or biological medicines)																															
Yes		✓	✓	✓	✓	✓	✓[1]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
No	✓																											✓			
17. If INN prescribing is allowed: - is there a specific guideline/ policy excluding biological medicines?																															
Yes		✓[2]		✓			✓		✓	✓[3]	✓[4]	✓	✓		✓	✓			✓		✓		✓[2]	✓[7]	✓[8]		✓			✓		✓
No			✓		✓	✓		✓						✓			✓	✓[5]		✓[6]		✓				✓				✓	
18. If INN prescribing is allowed and biological medicines are not excluded: - is it applied to biological medicines?																															
Yes								✓[10]						✓			✓[11]	✓[12]												✓	
No			✓[9]		✓	✓																✓[13]				✓[14]					
19. Are measures in place supporting the prescription of biosimilar medicines?																															
Yes, legislative measures								✓	✓			✓						✓													
Yes, recommendations		✓					✓		✓	✓	✓	✓	✓			✓			✓	✓	✓	✓	✓	✓		✓	✓	✓			✓
No			✓	✓	✓	✓								✓	✓		✓								✓				✓	✓	

(1) Legally allowed but not applied in practice
(2) The Medicines Agency stronly advices not to prescribe by INN for biological medicines
(3) Prescriptions for biologicals must indicate brand name + INN
(4) Each biological product has to be clearly identifiable: INN + product name + batch number
(5) INN prescribing obligatory for all medicines and not allowed to add brand name. For biological medicines it is allowed to add brand name
(6) Allowed in retail pharmacy, not allowed in hospitals
(7) Biological medicines are obliged to be prescriber with brand name
(8) Drug Law 362/2011: there is an exact list of molecules which cannot be described by INN
(9) Because of reimbursement purposes, all biological medicines are prescribed by brand name
(10) Mandatory INN prescription, also for biological medicines
(11) INN prescription is the required standard. Brand name is allowed only for patients already on treatment (on reimbursed prescription) receiving a particular brand for the same diagnosis in past. The same rules apply for chemical and biological medicines
(12) Decision of physicians to add brand name or not
(13) INN prescribing is possible for biological medicines but generally the brand name is used
(14) INN prescribing is not excluded for biological medicines but in practice all biological medicines are only prescribed by brand name

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Physician Policies (2/3)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
20. Do the supportive measures differentiate between treatment naïve patients and patients currently under treatment?																															
Yes								✓			✓[1]	✓				✓[2]		✓	✓[3]	✓[4]				✓		✓	✓	✓[6]			✓
No		✓					✓		✓	✓			✓								✓	✓	✓[5]					✓			
21. If supportive measures are in place, which kind of policies?																															
Prescribing guidelines							✓		✓[9]			✓				✓		✓	✓	✓			✓				✓[13]	✓[14]			✓
Electronic prescribing								✓	✓[10]			✓[10]						✓[11]			✓			✓[10]		✓[10]					
Target agreement (i.e. quota)											✓					✓						✓	✓								
Gainsharing systems		✓								✓	✓					✓					✓										✓
Prescription audits		✓						✓				✓				✓		✓								✓					
Health insurance fund visits											✓							✓				✓				✓					
Direct financial incentives										✓																					✓
Direct financial restrictions												✓							✓												
Information/education materials/trainings		✓[7]					✓[8]	✓	✓	✓	✓					✓							✓			✓					✓
Other																					✓[12]										

(1) Some policies do differentiate, others not
(2) Many decrees of regional authorities provide recommendations for naïve patients. The adoption of the new procurement law will change the framework for recommendations in the future
(3) Usually yes but biosimilar medicines are still a new concept in Malta and policies and measures vary depending on the product
(4) Guidelines state the there is no problem for naïve patients, for patients on treatment, monitoring is required when switching patients to biosimilar medicines, as for all biological medicines
(5) The recommendations recognise that originator and biosimilar medicines are equivalent so the switch is possible and recommended. However, the clear message is to start naïve patients with biosimilars
(6) For some biosimilar medicines (epoetin and infliximab), in some tender regions there are recommendations (guidelines) to start with naïve patients and to avoid switching
(7) The Medicines Agency will initiate an information campaign and recently highlighted that there is no increased risk when switching to biosimilar medicines
(8) Information to patients has been developed in co-operation with relevant patient organisations
(9) Since 1 January 2017, there is a decree that obliges physicians to prescribe the least expensive product if comparable products are available of a biological medicine. A medical justification is neede when the physician wants an exemption on this rule. Each prescription counts for one year.
(10) (allows also brand-name prescribing)
(11) (only allows INN prescribing)
(12) Most biosimilar medicines are hospital products, the tender body recommends the use of the lowest-priced product and provides documentation for the products
(13) In particular for naïve patients
(14) Local guidelines within a specific tender region

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Physician Policies (3/3)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
22. Which of the above supportive measures have been the most effective in increasing the medical use of biosimilar medicines?																															
		1					2	3			4	5				6		7	8			9	10	11		12	_	13			14

(1) Too early to assess, probably gainsharing and tendering in 1 parcel
(2) Two: Guidelines and reccomendations for RADS (Council on the use of expensive medicines) and the information from the Medines Agency to patients and to HCP's
(3) INN prescription
(4) Target agreements (information, consultation, targets)
(5) Direct financial restrictions
(6) Prescribing guidelines
(7) Prescription audit
(8) Financials - cost saving to government
(9) Target agreements
(10) Too soon to evaluate
(11) None
(12) Health insurance fund visits
(13) Guidelines
(14) Gainshare agreements and metrics once finalised and published at a national level

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Pharmacist Policies (1/2)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
23. Is there a general legal provision which allows substitution of medicines at the level of retail pharmacies? (i.e. without consulting the prescriber)																															
Yes			✓[1]			✓	✓	✓	✓	✓	✓	✓[2]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓[3]	✓	✓	✓	✓	✓	✓	
No	✓	✓		✓	✓																										✓
24. If yes, is substitution also legally allowed for biological medicines (including biosimilar medicines) at the level of retail pharmacies? (i.e. without consulting the prescriber)																															
Yes						✓		✓		✓[4]							✓[6]	✓		✓		✓	✓[8]							✓	
No			✓				✓		✓		✓[5]	✓	✓	✓	✓	✓			✓		✓[7]			✓	✓	✓[9]	✓	✓	✓			
25. If yes, is substitution also applied to biological medicines (including biosimilar medicines) at the level of retail pharmacies? (i.e. without consulting the prescriber)																															
Yes								✓									✓[10]	✓				✓									✓[12]	
No						✓				✓										✓[11]			✓									

(1) Substitution is only allowed in case of INN prescribing
(2) Only for medicines in retail pharmacy with generic alternatives, not allowed for high-priced medicines (including biosimilar medicines)
(3) Only for small molecules
(4) The law allows substitution for naïve patients but is not applicable as the implementing decree has not been published yet
(5) Substitution at retail level is only allowed for biosimilar medicines coming from the same cell line and production site
(6) The same rules apply for chemical and biological medicines
(7) Only medicines on the substitution list are eligible, biological medicines are not included
(8) The law does not exclude substitution but also does not support
(9) Interchangeable list of medicines not applicable to biological medicines
(10) For INN prescriptions, the pharmacist has to dispense the lowest priced product. For brand name prescriptions, pharmacists should inform about the alternatives. The same rules apply for chemical and biological medicines
(11) If the prescription is by INN, the pharmacist is allowed to substitute. However, it is agreed in the field that this is not applied to biological medicines. The preference policy by health insurers is usually only applied to naïve patients and not to patients already on treatment
(12) Practices Communique clearly provides that substitution shall apply if the relevant medicines are in the same equivalent group.

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Pharmacist Policies (2/2)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
26. If substitution (at retail level) is legally allowed and applied to biological medicines: - for which kind of patients is it allowed?																															
Treatment naïve patients																	✓	✓				✓								✓	
Patients currently under treatment																	✓	✓				✓								✓	
Other																															
- Do physicians explicitly need to give permission for it?																															
Yes																															
No																	✓	✓				✓								✓	
- Can physicians prevent it?																															
Yes																	✓	✓				✓								✓	
No																															
- Are pharmacists obliged to inform their patients?																															
Yes																	✓	✓[1]				✓								✓	
No																															
- Can patients refuse it?																															
Yes																	✓	✓				✓								✓	
No																															

(1) The pharmacist must provide all the options, patients can choose

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Patient Related Incentives (1/3)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
27. Has there been information/ educational material developed on biosimilar medicines targeted at patients in your country?																															
Yes		✓		✓			✓		✓	✓[1]	✓	✓	✓			✓		✓		✓		✓	✓				✓		✓[4]	✓	✓[5]
No	✓		✓		✓	✓		✓						✓	✓		✓[2]		✓		✓			✓	✓[3]	✓		✓			
28. If yes, in which form have they been rolled out?																															
Handbooks										✓						✓		✓		✓		✓					✓			✓	
Videos							✓																							✓	
Campaigns																✓				✓											
Leaflets		✓		✓			✓			✓	✓		✓			✓		✓		✓		✓	✓								
Seminars, conferences or workshops		✓		✓					✓		✓	✓				✓		✓		✓		✓	✓								✓
Websites		✓		✓			✓		✓		✓					✓				✓		✓	✓				✓		✓		
Apps																															
Other		✓[6]																					✓								

(1) At hospital level
(2) Producers of originator biological medicines (usually through patient association web pages/materials) had been publishing the opinion that biosimilar medicines are different, and that substitution is not acceptable. No patient materials from the government side
(3) No general educational material developed by the association GENAS, just by MAH´s by their initiative linked to MAH
(4) Very scarce availability
(5) NHS England has established a sub-group focused on developing education and communication materials for professionals and patients.
(6) Newsletters

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Patient Related Incentives (2/3)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
29. If yes, who developed the material/events?																															
Patient associations		✓					✓			✓	✓	✓				✓													✓		
Medical societies		✓								✓	✓					✓		✓		✓											
Authorities		✓[1]		✓			✓		✓	✓		✓				✓[3]				✓			✓				✓				✓
Biosimilar medicines industry		✓		✓						✓	✓		✓			✓		✓		✓			✓				✓			✓	✓[7]
Originator medicines industry											✓					✓		✓				✓	✓								
Other										✓[2]						✓[3]				✓[4]			✓[5]							✓[6]	
30. Is there patient co-payment for biosimilar medicines?																															
Yes	✓[8]	✓[9]	✓[10]				✓[11]	✓[12]	✓[13]		✓			✓[14]			✓[15]	✓[16]			✓[17]		✓[18]		✓[19]		✓[20]	✓[21]	✓		
No				✓	✓	✓				✓		✓	✓		✓	✓			✓	✓		✓		✓		✓				✓	✓

(1) According to the 2017 budget plan, the Medicines Agency should initiate an information campaign on biosimilar medicines
(2) Hospital boards
(3) Regional authorities
(4) An initiative group consisting of all stakeholders, exclusding the pharmaceutical industry and the medicines agency
(5) European Commission and other stakeholders
(6) Pharmaceutical Manufacturers Association of Turkey
(7) NHS England has established a sub-group focused on developing education and communication materials for professionals and patients
(8) Epoetin, Etanercept, Filgrastim, Infliximab & Somatropin. Fixed prescription fee regardless of the price of the product
(9) Etanercept, infliximab and somatropin (free for children, dependent on use for adults)
(10) for etanercept and infliximab. Reimbursement of biologicals (including biosimilars) in rheumatoïd arthritis is 75%, which implies a co-payment for patient. There are cases that a company decides to cover this patient co-payment by providing additional discounts
(11) For all products in pharmacies, for none in hospitals
(12) Enoxaparin sodium, follitropin alfa and insulin glargine
(13) Co-payment depends on indication
(14) follitropin alfa and insulin glargine
(15) Enoxaparin sodium, filgrastim, infliximab and somatropin. somatropin, filgrastim, infliximab, enoxaparin sodium. For infliximab, for some diagnosis group 100% reimbursement; for some 75%. For the rest of biosimilar medicines, co-payment is related to a price difference with reference product (the cheapest)
(16) Filgrastim, follitropin alfa, insulin glargine and somatropin. Usually the co-payment is compensated by pharmacy/wholesaler/MAH
(17) Follitropin alfa & insulin glargine
(18) Follitropin alfa & insulin glargine. Co-payment only at retail market, hospital 100% free for patients
(19) *epoetin, filgrastim, infliximab, follitropin alfa, insulin glargine - There is the reference pricing system in place and also Biosimilar can be with copayment in case the othe MAH will reduce the price - which becomes to be reference price.
(20) Insulin glargine
(21) Only if the patient gets the product in the retail pharmacy

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Patient Related Incentives (3/3)

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

(1) It is not a fixed amount or %, but is dependent on how much medicines the patients uses within 12 months
(2) 10% of the price, but minimum 5€ and maximum 10€
(3) Reference product (not explicitly means originator product) is without co-payment, all others which do have a higher price are with respective co-payment. There might be a different cluster for biosimilar medicines
(4) With a maximum limit
(5) The patient pays 100% of the cost up to a certain level, then 50%, 25%, 10% and finally gets all medicines totally free (if the product is within the reimbursement system). After a 12 month period this system starts all over again
(6) 10% co-pay but this is capped at CHF 800.- per annum (co-payment ends beyond this amount)
(7) Depends on price vs. reference price

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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, biosimilar medicines provide today 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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