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MARKET REVIEW – EUROPEAN GENERIC MEDICINE MARKETS

POLICY OVERVIEW

2020

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Introduction

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

The European countries covered in this edition of the market review are: Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Netherlands, Poland, Portugal, Romania, Slovakia, Spain, Sweden, Turkey, UK.

The 2020 Market Review covers 8 main topics: Pricing systems, Control of Excessive Spending, Retail tendering, Hospital tendering, Reimbursement systems, Physician incentives, Pharmacist incentives and Patient incentives. Through the different topics, the reader will get a clear overview of how generic 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 generic medicines. The information gathered in this document has been sourced from both the Medicines for Europe National Associations and Member Companies.

Adrian van den Hoven
Medicines for Europe Director General

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Pricing Systems (1/3)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
1. What kind of pricing system is in place for generic medicines (reimbursed)?																						
Free pricing					✓			✓														✓[3]
Price regulation	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓[1]	✓[2]	✓	✓	✓	✓	✓	✓	
2. If there is price regulation, which criteria are used to set the prices																						
External reference pricing			✓	✓[6]					✓[9]		✓[11]		✓	✓[14]	✓[16]	✓[18]	✓[19]	✓[20]			✓[22]	
% below originator price	✓[4]	✓	✓(30%)	✓(40%)		✓(50%)[7]	✓(60%)		✓(35%)	✓(40%)[10]	✓(60%)	✓(>20%)[12]	✓(70%)		✓(25%)	✓(50%)	✓(35%)	✓[23]	✓(40%)			
Maximum price				✓									✓	✓	✓							
Negotiation													✓		✓							
Other		✓[5]						✓[8]					✓[13]	✓[15]	17					✓[21]		

(1) In the Netherlands we have regulations from the Government and we also have reimbursement and tendering systems from health insurance companies.
(2) A detailed regulatory framework was introduced in 2012 in the Reimbursement Act.
(3) The primary care market is a system of free pricing, with the Government able to intervene and direct prices where competition is not working in the interests of the taxpayer. The secondary care system is a tender system. Scotland, Wales and Northern Ireland follow the UK government system of pricing and reimbursement and have made only minor adjustments to date.
(4) 1st -50%, 2nd -18% below 1st, 3rd -15% below 2nd. 3 months after 3rd generic entry, prices of predecessors must decrease to the price of the 3rd
(5) Generics undergo a patent cliff; percentage depends on age of molecule and reimbursement category and varies between a 54% and 60% price decrease
(6) Based on the average of the three lowest priced products in the EU
(7) 40% if the product includes a device (e.g. an inhalator)
(8) Tender system, discounts by law, Internal reference pricing
(9) Price of the originator is set as the average of the two lowest prices among eurozone countries
(10) Stepped pricing system: first generic has to be priced 40% lower than the originator, followed by 20%, 10%, 5%, 5%, 5%.
(11) Reference countries: Austria, Belgium, Denmark, Finland, France, Germany, Netherlands, Spain, UK, Greece, Italy, Portugal, Sweden and Luxemburg
(12) Balduzzi Decree: voluntary and automatic method to determine the price of a new generic
(13) Base price, Maximum co-payment level for patient, 20% of the annual recipe price level
(14) Reference countries: Belgium, France, Norway, United Kingdom
(15) Reimbursement of the generic molecule based mediate prices
(16) Reference countries: All EU/EFTA countries (limit base is set within therapeutic reference group)
(17) Maximum price cannot be higher than 1) the equivalent setting the limit base 2) the cheapest equivalent if the limit base is set by a medicine with another active substance. The limit base is set within limit groups (therapeutic reference groups).
(18) Reference countries: Spain, France, Italy, Slovenia
(19) Reference countries: Bulgaria, Czech Republic, Slovakia, Poland, Lithuania, Hungary, Italy, Austria, Spain, Greece, Belgium, Germany
(20) Reference countries: all EU countries
(21) The reimbursed price will have to be approved by TLV (pricing agency). When generic medicines enter the market, they can be the same price as the originator or lower. If price competition starts (prices drop by more than 70% with competition) the originator must lower their price by approximately 65% 6 months after patent expiry (if they want to remain reimbursed - if they skip reimbursed). That price (-65%) will be the maximum price for generics. If not reimbursed, the pricing is free.
(22) The price of the generic medicine is set by referencing the lowest price (in €) among 5 countries: France, Greece, Italy, Portugal, Spain
(23) 1st -45%; 2nd -10%; 3rd - 5%

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Pricing Systems (2/3)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
3. What are the key parameters considered when prices are set:	1	2	3	4		5		6	7	8	9	10	11	12	13	14	15	22	16		17	
4. If external reference pricing is used in pricing decisions, what does it indicate?																						
Price for originators									✓					✓		✓		✓	✓		✓	
Price for generics			✓				✓		✓[18]					✓			✓	✓			✓[18]	
Benchmarking with other countries			✓	✓			✓				✓		✓	✓	✓			✓				
Other																						
5. If external reference pricing influences price of generic medicines, what formula is applied:																						
Lowest price in reference countries			✓										✓	✓	✓		✓				✓	
Average price of reference countries											✓					✓		✓				
Other				20			21		✓[18]				✓						✓			

(1) Price of reference product or already launched Gx at the time of entry into reimbursement code
(2) Legal price decreases when first generic enters the market. Prices of other generics in other cases
(3) External reference pricing and 30% below originator price
(4) Three lowest priced products in the EU
(5) Price of the reference product
(6) If a reference price exists, the originator price, benchmark of other generic companies
(7) The average of the 2 lowest prices of the reference product in the Eurozone.
(8) Daily cost of treatment, which is based on the manufacturer price
(9) Generic price must be 60% below originator price. For ERP: average of the basket countries
(10) Annual average value of the total public expenditure in the three years preceding the request for P&R
(11) Base price, Patient co-payment level
(12) Government regulation ERF
(13) The stance of the Economic Commission, price competitiveness, the recommendations of the president of the Agency for HTA and Tariffs, especially the result of an analysis of the cost to health effect ratio. Final price decision of the Ministry of Health should take into account the balance of interests of service recipients and manufacturers or distributors of medicines, the payment ability of the entity obliged to finance healthcare services from public funds and the applicant's scientific, research and investment activity related to health protection in the territory of Poland and in other member states of the EU or member states of EFTA. In fact, these criteria are marginalised in the process
(14) Price of the reference product
(15) Reference countries, reference product
(16) Originator price
(17) Lowest price referenced in the basket of reference countries
(18) ERP is indirectly used for generics, since the price is set at 65% of the reference product price
(19) The price of the generic medicine may be up to 60% of the price of the reference product
(20) Average price of three lowest priced products in the EU
(21) Formula is not specifically defined. Modalities may vary on a case-by-case basis
(22) Reference price calculated as an average of 3 lowest prices within 28 EU countries including Slovakia. In SK is defined 3 level entry for Gx: 1st Gx minus 45% of originator price; 2nd Gx minus 10% and 3rd GX minus 5%

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Pricing Systems (3/3)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
6. Is the application for P&R of a generic medicine a:																						
Single process	✓		✓			✓	✓			✓	✓	✓			✓		✓	✓	✓	✓		
Separate processes		✓		✓				✓	✓					✓		✓[1]					✓	
7. On average, how long does it take for a generic medicine to receive its P&R approval from the day of application? (In days)	135-150[1]	60	30	60	[2]	22	60	[4]	180[3]	30	60-90	120		90	180	30-45	120-180	90-120	30	30	90	
8. After being listed, how long does it take for a generic medicine to be available in the hospital?	[5]	[6]	[7]	[8]			[9]	[10]	[11]	[12]	[13]	[14]		[15]	[16]		[17]	[18]	[19]	[20]	[21]	
9. What are the causes of the delay between the generic medicine listing and the hospital availability?	[22]	[23]	[24]	[25]		[26]				[27]	[28]	[29]		[30]	[31]		[32]		[33]		[34]	

(1) Lead time from application to effective entry in the reimbursement list
(2). In Denmark there is free pricing on medicines (so no "P") and reimbursement is not a precondition for being launched on the market.
(3) Pricing: 30-90 days from pricing application; Reimbursement: 60-180 days from reimbursement application (the reimbursement procedure is initiated after the generic has received a price)
(4) 14 days for price approval, but 1,5 years for approval of reimbursement
(5) Generic medicine can be launched in hospital immediately after granted marketing authorisation, no reimbursement necessary. Limiting factor: outpatient prescription after discharge not possible
(6) Depends on necessity of tender which is decision by individual hospital and based on volume of medicines needed which triggers the appropriate tender level
(7) 15 days after posting on the positive list, the Health Fund accepts it and tenders may be held
(8) Immediately
(9) When the next tender process is opened
(10) 0 days
(11) Immediately
(12) Promptly after official price comes into effect
(13) Immediately
(14) 60 days
(15) 2-5 days
(16) 90 days
(17) Depends on the hospital tender
(18) Immediately
(19) Days
(20) After the patent expires
(21) Once listed, it can be marketed immediately
(22) No delay, but no outpatient prescription possible
(23) Originator exclusivity contracts that are being concluded just before end of exclusivity. Contracts valid for 4 years.
(24) Tender time - 30 - 60 days
(25) Delay is not necessary
(26) Tender period
(27) Patent protection, company decision
(28) Supply
(29) The authorities don't open the tender within 60 days
(30) Sometimes hospital reimbursement
(31) Public tender procedures
(32) Hospital tender
(33) None
(34) Tender procedures

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Control of Excessive Spending (1/3)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
10. Which of the following measures are applied in your country in case of excess spending in pharmaceutical budget?																						
Mandatory discounts/rebates								✓(6% for gx)	✓(14-30%)[2]					✓							✓[4]	✓[5]
Clawback (Can include payback schemes)		✓	✓			✓	✓		✓[12]	✓		✓	✓	✓	✓		✓	✓				
Other		✓[1]								✓[3]						✓						
None	✓			✓	✓						✓								✓	✓		
11. If clawback/payback is applied, how Is the target spending determined:																						
Global pharmaceutical target budget		✓[6]	✓												✓		✓					
Segmented pharmaceutical target budget									✓[13]			✓	✓									
Pharmaceutical expenditure growth rate			✓				✓								✓							
Other						✓[7]				✓[8]				✓[9]	✓			✓[10]				✓[11]

(1) Tax on total sales + negotiated and modulated price decrease
(2) Mandatory discounts/rebate for pharmaceutical companies range from 14% to 30% over the ex-factory price. The rebate applies per brand, to all reimbursed products (outpatient and hospital), on a quarterly basis. It is calculated by a logarithmic formula which factors the product's sales and characteristics.
(3) Tax on medical representatives, price-volume agreements
(4) In case of budget excess, the Social Security Institution would choose to increase the discounts of medicines, but this is not mandatory.
(5) None to manufacturers. The Government may carry out analysis and question why an unbranded medicine is at the price it is. After investigation, it may direct the price downwards and/or refer the matter to the competition authorities; The Government can take money out of the pharmacy margin which is the reimbursement price that the Government pays to community pharmacists to cover the cost of the medicine and a top-up is applied to enable them to operate. The reimbursement tariff is nearly double the UK actual sales price for unbranded medicines. A cap exists for branded generics as part of a branded medicines system. They are treated in the same way as patented products. Participants contribute to the difference annually between the annual cap and the actual amount, depending on how much their NHS sales are.
(6) The percentage includes an aggregated set of taxes and paybacks
(7) The payback was part of the governmental savings plan on reimbursed outpatient pharmaceuticals
(8). Clawback + Savos tax (payback) + tax on medical representatives
(9) Depends on the negotiations/tenders of the health insurer
(10) Base for payback is sum of sale of Product for 12 months before observing period. Ministry of Health SR takes a budget on each product reimbursed over 1,5 mio €. All sales over budget are considered as paybacks to HICs.
(11) Unbranded generics do not face a control to their pricing, they are regulated by pricing; with the Government having the ability to intervene where it believes competition is not working adequately to regulate the price. For branded generics, they are captured by a cap and the difference between the actual amount is paid back to the Government. This is part of the schemes for branded medicines, which primarily capture patented products.
(12) Payback for MAHs (the term clawback is used) applies in addition to rebates, on a semester basis, as the difference between the incurred expenditure and the corresponding budget ceilings (outpatient and hospital). Clawback is applied as a compulsory horizontal measure - not on a brand specific basis within the frame of MEAs, or within the overall context of an MoU, affecting disproportionately generics net prices, distorting competition and threatening their viability. The increasing cost of the new medicines, combined with the low annual budget ceilings, has led to the escalation of clawback from 78 mn. € in 2012 to ~1,2 bn € in 2019. Rebate and clawback in 2019 accounted for ~40% of the medicines ex-factory prices on average.
(13) Segmented pharmaceutical target budget: Retail vs hospital.

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Control of Excessive Spending (2/3)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
12. How much of the budget overrun is paid back by the pharmaceutical industry?		[1]	[2]				0,50%		100%[24]			[3]		0%	50%		[4]					[5]
13. How is the clawback/payback calculated?																						
Based on market share						✓			✓			✓										✓[11]
Based on revenue		✓	✓				✓															✓[11]
Based on growth			✓						✓						✓			✓				
Other		✓[6]								✓[7]			✓[8]	✓[9]	✓[10]		✓					
14. What is the percentage of the clawback/payback applied to the base selected above?		[12]	[13]				[14]		[15]	[16]		[17]	[18]	[19]			[20]					[21]
15. Is there a differentiated clawback/payback for generic medicines?																						
Yes									✓[22]					✓			✓					
No		✓	✓[23]			✓	✓	✓		✓		✓	✓		✓			✓				✓

(1) Depends on negotiation next to payback, legally fixed to be 2,5% of total budget for medicines
(2) So far 10% of the cost of molecules without generic competition - still subject to a decision
(3) 50% for hospital channel / 100% for retail channel
(4) Depends on expenditure value/CB capped and differentiated
(5) NA for unbranded medicines. It is forecast to be high 9% in 2021 for branded products, to increase in subsequent years.
(6) Payback on revenue, clawback max 2,5% of medicines budget
(7) Based on the amount of reimbursement
(8) Financial and clinical results are evaluated
(9) Fixed percentage 2,5 - 5% depending on HCI
(10) The share of the reimbursement value in the total reimbursement value of products reimbursed in a given limit group, which exceeded the budget
(11) This only applies to branded generics
(12) 11,15% of revenue
(13) 10% for single source products
(14) 3 possible contribution rates (50%, 60%, 70%) are legally applicable depending on the level of revenue. The payback can't exceed 10% of the total revenue of the company.
(15) 80% from market share and 20% from growth
(16) 20% and 10%
(17) Hospital -7,18% / Retail +5,15%
(18) % is calculated on an individual case
(19) 2,5 - 5%
(20) Quarterly calculated/15%/20%
(21) 12% for branded generics, but this is likely to rise steeply
(22) Generics and off patents are exempted from Growth (effective from July 2020)
(23) So far there is none for generic, but a payback of growth is envisaged
(24) The budget excess refers to retail prices so MAHs are burdened with the amount that corresponds to the distribution channel.

Rebate – clawback for generic medicines in Greece

The payback mechanism - called "clawback" - was introduced in 2012 for all out patient reimbursed medicines while in 2016, it was also applied to the hospital medicines. The mechanism provides budget ceilings for the outpatient and inpatient expenditure and any excess should be returned to the State by the MAHs. In parallel, a mandatory logarithmic rebate was set for all reimbursed medicines on a brand basis, currently ranging from 14% to 30% of their ex-factory value.

Multiple factors (e.g., low annual budget limits; delays and/or lack of measures to rational prescribing and use), led to an escalation of the clawback, from 78 mn € in 2012 (budget ceiling: 2,880 mn €) to ~790 mn € in 2019 (budget ceiling: 1,945 mn €) for the outpatient sector. If the hospital clawback is also considered, the total clawback in 2019 was ~1.2 bn €

Total rebates and clawbacks in 2019 were ~1.9 bn €, corresponding to over 40% of the medicines ex-factory prices on average. In practice, the industry finances 1 in 3 medicines reimbursed by SSFs (1 in 2 for hospitals).

The ever-increasing clawback burdens generics by affecting their net prices and by distorting competition. This, combined with the lack of incentives to promote generics use, explains why Greece still presents the lowest generic penetration among EU countries (~24% in volume).

Definitions Clawback – Payback

Payback policies require manufacturers to pay back a share of their revenue if a pre-specified budget ceiling for public pharmaceutical expenditures is exceeded. Note that sometimes clawback is used instead of payback.

Clawback policies are usually applied to pharmacies. Clawbacks capture discounts on either the dispensing fees of pharmacies or discounts on medicine purchases by pharmacies. The rationale of clawback mechanisms is to seize these discounts, which increase pharmacies' profit, and to pass them on as income/revenues to the public payer.

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Retail Tendering (1/3)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
16. Is there a tendering system in place for generic medicines in the retail market?																						
Yes								✓						✓				✓	✓			
no	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓	✓	✓			✓	✓	✓
17. If yes, what is the geographical scope of the retail tenders?																						
National														✓				✓				
Regional																			✓			
Other								✓[1]						✓[2]								
18. If yes, which body is in charge of the retail tendering system?																						
National government																						
Regional government																			✓			
Health insurance funds								✓						✓				✓				
Other														✓[3]								
19. If yes, how are retail tendering contracts awarded? By:																						
Active substance								✓						✓				✓	✓			
Group of active substances																						
Therapeutic indications																						
Other																						

(1) Number of persons insured by the specific sick fund
(2) Tendering is done by the 4 main health care insurers (private companies)
(3) hospital groups

Retail Tendering (2/3)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
20. What is the average contract duration of the tender?								2 years						12-24 months				2 years	2 years			
21. Does a single tender contract allow for more than one winner?																						
Yes								✓											✓			
no														✓				✓				
22. Is there an agreed minimum or maximum volume as a result of winning the tender?																						
Minimum volume																			✓			
Maximum volume																		✓				
None								✓						✓								
23. After granting the tender, are prices subject to change beore the next tender?																						
Yes																		✓				
no								✓						✓					✓			
24. Is the tender bidding process a sealed bid procedure? (competitors are not aware of how much other competitors are bidding)																						
Yes								✓						✓					✓			
no																		✓				

Retail Tendering (3/3)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
25. Are competitors bidding in the tendering procedure allowed to be informed of the other competitors' bidding in the procedure?																						
Yes																						
no								✓						✓				✓	✓			
26. Is the winning price from the tender transparent to other competitors?																						
Yes																		✓	✓			
no								✓						✓[1]								
27. Are factors other than the lowest price taken into account when determining the winner of the tender?																						
Yes																						
No								✓						✓				✓	✓			
28. If price is not the single factor, what is the range of weight given to price when determining the winner of a tender?																						
Minimum (%)																						
Maximum (%)																						

(1) Minority of tenders are based on the lowest price in the national price list, then visible. Not in sealed bid ones.

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Hospital Tendering (1/5)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
29. Is there a tendering system in place for generic medicines in the hospital market?																						
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
No																						
30. If yes, what is the geographical scope of the tenders?																						
National	✓				✓[6]				✓	✓			✓			✓	✓				✓	
Regional						✓			✓			✓		✓						✓		✓[2]
Hospital (individual or group)	✓	✓	✓	✓			✓	✓		✓	✓	✓	✓	✓	✓[1]	✓	✓	✓	✓		✓	
Other																						
31. If yes, which body is in charge of the tendering system?																						
National government									✓	✓			✓			✓	✓				✓	✓[3]
Regional government												✓								✓		
Health insurance funds			✓										✓									
Group of hospitals	✓	✓		✓		✓	✓	✓		✓		✓		✓				✓			✓	
Individual hospitals		✓	✓	✓			✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	
Other	[4]				[7]				[5]													

(1) The law gives possibility to conduct regional and national tenders for hospital products, but has not yet been used.
(2) Volume is grouped together nationally, and contracts may then be awarded to an English region. Although one supplier can serve the entire national volume if there are no other tenders, or it is significantly cheaper than its competitors. In Scotland, Wales, Northern Ireland, a single contract covers the whole country.
(3) A central purchasing agency groups demand and organises tenders. Lots for the country are then awarded on a regional basis.
(4) Federal Procurement Agency
(5) EKAPY
(6) Normally national, but some tenders can be regional.
(7) Amgros is a national tender organization, but is run by the regions and operates on their behalf.

Hospital Tendering (2/5)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
32. If yes, the tenders are applied to:																						
Total pharmaceutical market	✓		✓	✓	✓	✓		✓			✓		✓	✓	✓	✓	✓			✓	✓	✓
Off-patent market	✓	✓					✓		✓			✓		✓								
Other										[1]								✓	[2]			
33. If yes, how are tendering contracts awarded? By:																						
Active substance	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	
Group of active substances	✓	✓		✓		✓				✓				✓	✓					✓	✓	
Therapeutic indications				✓	✓	✓		✓							✓					✓		
Other														✓					[3]			
34. What is the average contract duration of the tender? (in months)	12-24	48	6-12	12-48	12	24	24	12	24	12	24	24		12	12-24	3-12	12-24	12	Depends	24	12	12-18
35. Does a single tender contract allow for more than one winner?																						
Yes	✓								✓	✓		✓[4]				✓			✓			✓
No		✓	✓	✓	✓	✓	✓				✓			✓	✓		✓	✓		✓	✓	
36. Is there an agreed mimimum or maximum volume as a result of winning the tender?																						
Minimum volume							✓			✓							✓					
Maximum volume			✓				✓		✓	✓		✓			✓	✓	✓					
None	✓	✓		✓	✓	✓		✓			✓			✓				✓	✓	✓	✓	✓

(1) Top of the hospital medicines
(2) By products
(3) Presentation
(4) Some regional systems allow more than one winner (framework agreement), but this is not the general case

Hospital Tendering (3/5)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
37. After granting the tender, are prices subject to change before the next tender?																						
Yes	✓[1]		✓	✓			✓[2]		✓						✓	✓	✓	✓		✓		✓[3]
No		✓			✓	✓		✓		✓	✓	✓		✓					✓		✓	
38. Is the tender bidding process a sealed bid procedure? (competitors are not aware of how much other competitors are bidding)																						
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
No																	✓					
39. Are competitors bidding in the tendering procedure allowed to be informed of the other competitors' bidding in the procedure?																						
Yes	✓																					
No		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
40. Is the winning price from the tender transparent to other competitors?																						
Yes			✓		✓	✓	✓			✓		✓			✓	✓	✓	✓		✓	✓	
No	✓	✓		✓				✓	✓		✓			✓					✓			✓

(1) After a freeze period (mutually agreed), price increases are possible
(2) It is possible for some products in the case where CEPS decides to lower the price.
(3) Only if a price increase application is made, and is successful.

Hospital Tendering (4/5)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
41. Are factors other than the lowest price taken into account when determining the winner of the tender?																						
Yes		✓			✓	✓	✓		✓	✓	✓				✓[1]					✓	✓	
No	✓		✓	✓				✓				✓		✓		✓	✓	✓	✓			✓
42. If price is not the single factor, what is the range of weight given to price when determining the winner of a tender?																						
Minimum (%)		50%			35%	40%	/		/	90%					60%					40%		
Maximum (%)		100%			100%	60%	/		/	100%					99%					100%		

(1) New mechanisms (correction factors) were introduced in the reimbursement system, that strengthened the role of the lowest price as a criterion taken into account when determining the winner of the tender.

Hospital Tendering (5/5)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
43. If yes, which of the following factors are taken into account?																						
Customer service		✓				✓			✓		✓											
Ongoing patient support		✓							✓													
Value added presentation					✓																	
Local manufacture		✓																			✓	
Most complete range of indications		✓									✓											
Quality		✓					✓				✓											
Proven track record of ability to supply		✓					✓		✓		✓									✓	✓	
Environmental aspects						✓														✓		
Condition of payment		✓								✓					✓							
Formulation											✓											
Aggregation		✓					✓															
corporate responsibility		✓																		✓		
Local distance from supplying warehouse		✓																				
Safety, usability, effectiveness					✓	✓																
Delivery terms, invoicing terms															✓							
Product range, Label readability																				✓		

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Reimbursement Systems (1/4)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
44. Is a marketing authorisation necessary to apply for reimbursement of generic medicines?																						
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	
No													✓									✓[1]
45. Do you have a reference pricing reimbursement system for generic medicines?																						
Yes		✓	✓	✓		✓		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	
No	✓				✓		✓						✓							✓[2]		✓
46. If yes, how is the reference group established?																						
By active substance (ATC-5)		✓	✓	✓		✓		✓	✓	✓		✓		✓	✓	✓	✓	✓	✓		✓	
By pharmacological class (ATC-4)								✓	✓													
By therapeutic class (ATC-3)				✓				✓		✓	✓						✓	✓				
By similar therapeutic effect and a similar mechanism of action															✓							

(1) A marketing authorisation is needed to market a product, but reimbursement is not linked to this.
(2) Depends on the definition of "reference pricing". Sweden had a reference price system between 1994-2002. From Oct 2002 there is generic substitution. The pharmacy must change a product to an equal product (same substance) with the lowest price. Only the lowest price is reimbursed. So in a way the lowest price can be defined as a "reference price".

Reimbursement Systems (2/4)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
47. If yes, on what basis is the reference price established?																						
Average price of medicines										✓				✓								
Average price of generic medicines									✓[4]								✓					
Lowest priced medicine				✓		✓[1]				✓				✓			✓	✓	✓		✓[2]	
Lowest priced generic medicine			✓									✓										
External reference pricing			✓								✓											
First generic is based on originator, following generics are referenced to the already available generics		✓																				
Lowest ex factory price			✓																			
Lowest priced product + €0,50						✓																
Based on the average of the 5 lowest priced medicines of the same group of active substances																✓						
Depending on the reference price level: criteria are lowest priced medicines in accordance of sold volumes								✓														
Other															[3]							

(1) Reference price groups are set every three months. The reference price group is based on the lowest priced product + €0,50. All products within that price range are fully reimbursed.
(2) Groups by active substances are reimbursed up to 10% of the lowest unit price in the group
(3) A) Price of the only equivalent reimbursed for a given indication (no higher than 75% of the original drug price) or B) Maximum price in the case of another equivalent reimbursed for a given indication no higher than: a) of the equivalent setting the limit base or b) of the cheapest equivalent if the limit base in a given limit group is set by a medicine with another active substance
(4) Weighted average DTC of the lowest priced generics in the cluster.

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Reimbursement Systems (3/4)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
48. Are there positive and/or negative lists for generic medicines in your country?																						
Positive list	✓		✓		✓		✓		✓			✓		✓	✓			✓		✓	✓	
Negative list								✓	✓													
49. Is there patient co-payment for generic medicines?																						
Yes	✓	✓	✓	✓[1]	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
No							✓															✓
50. If yes, on which of the following is the co-payment based?																						
Patient annual/monthly consumption (DDD)															✓							
Fixed amount per prescription/pack	✓[2] (€6,30)							✓[6]		✓		✓[7]										
% of cost of medicines (partially reimbursed)		✓[3]	✓[4]			✓[5]			✓	✓					✓	✓			✓			
Difference above reference price						✓				✓	✓				✓	✓	✓					
Other				[12]	✓								✓	✓[8]				✓[9]		✓[10]	✓[11]	

(1) Not mandatory. It is only the difference between price and reimbursement. In many cases generics are without co-payment
(2) Maximum co-payment: 2% of annual net-income
(3) Depending on the class of the medicine
(4) 25% reimbursement for cardio products
(5) After the deductable of €50, medicines are reimbursed either 40%, 65% or 100%
(6) 10% of the retail price, but min €5 and max €10
(7) Regions are allowed to require the payment of a 'ticket' on the medical prescription or pack. In addition the difference between the reference price and the public price has to be paid by the patient if he doesn't accept the substitution with generic
(8) Difference between the reimbursement level and the national list price list
(9) Defined fixed percentage of co-payment in the same reference group
(10) The patient pays 100% of the cost up to a certain level, then 50%, 25%, 10% and finally gets all the medicines for free. After a 12 month period, this system starts all over again
(11) Pensioners pay 10% and employees pay 20% of the expenses of their medicines. Besides this, for each prescription all patients pay a fee depending on the number of boxes they have been prescribed
(12) Difference between price and reimbursement

Reimbursement Systems (4/4)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
51. Does the patient co-payment differ for generic medicines when compared to the reference originator medicine?																						
Yes		✓[1]	✓[2]	✓[3]				✓	✓[5]		✓	✓		✓	✓			✓[6]				
No	✓				✓[4]	✓	✓			✓			✓			✓	✓		✓	✓	✓	

(1) Originators tend to ask a supplement with a maximum of €5
(2) NHIF pays % of the reference value which is the same for generics and originals
(3) co-payment depends on the difference between price and reimbursement
(4) The more expenses you have for reimbursable medicines, the more reimbursement you will receive within a period of one year. The one-year reimbursement period starts when you buy reimbursable medicine for the first time after the expiry of the preceding period. There are several reimbursement tresholds, but the co-payment cannot exceed 550 euro per year.
(5) Generics are reimbursed at the RP and copayments are calculated as 10% or 25% of the RP. Off patents are reimbursed at the reference price, so copayments are calculated as 10% or 25% of the RP plus the difference between RP and Reimb. Price.
(6) Reimbursement is defined per SDD. Co-payment is the difference between final price in pharmacy and reimbursement

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Physician Incentives (1/2)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
52. Is INN prescribing legally allowed in your country?																						
Yes		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
No	✓				✓															✓		
53. Are there recommendations to prescribe generic medicines by INN?																						
Yes							✓	✓	✓		✓	✓	✓	✓		✓		✓	✓			✓
No		✓	✓	✓		✓				✓					✓		✓				✓	
54. If INN prescription is legally allowed:																						
Physicians are obliged to prescribe by INN									✓			✓	✓	✓		✓		✓	✓			
Physicians can prescribe by brand name																		✓				
Physicians can prescribe by brand name under certain exceptions									✓								✓					
Physicians prescribe both by INN and brand name		✓	✓	✓		✓	✓	✓		✓	✓				✓						✓	✓

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Physician Incentives (2/2)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
55. Are physicians encouraged to prescribe generic medicines?																						
By prescribing guidelines	✓	✓					✓	✓	✓		✓	✓		✓		✓						✓
By electronic prescribing	✓						✓		✓	✓			✓	✓		✓			✓			✓
By medicine database	✓									✓				✓				✓				
By prescription audits	✓	✓						✓														
By health insurance fund visits	✓							✓		✓				✓				✓				✓
By financial incentives							✓			✓				✓								✓
By financial restrictions								✓	✓			✓		✓		✓						
By information/education campaigns	✓	✓					✓	✓			✓					✓		✓				
Other		1										2									3	4
56. Which of the above mechanisms have been most effective in increasing generic medicines usage?	5	6	7				8		9		10	11		12		13		14	15			16

(1) Quota cheap prescribing
(2) By law
(3) Reimbursement system supports generic medicines
(4) Doctors are taught to write by INN
(5) Medicines data base (eco-tool), education campaigns, prescribing reports and visits from SHI
(6) Prescription targets for physicians
(7) Financial incentives, restrictions, electronic prescribing
(8) Financial incentives
(9) None.
(10) Education
(11) Prescribing guidelines, Financial restrictions
(12) Software systems
(13) Electronic prescription and guidelines
(14) Health insurance companies
(15) Electronic prescription
(16) As well as prescribing incentives and doctors being taught to prescribe by INN, it is important to note that the reimbursement levels for a brand and unbranded medicine to community pharmacy are different. For unbranded medicines, pharmacists get a margin on top of the cost of the medicine. For a brand, the reimbursement is the cost of the medicine only. Hence, they only make money from generic prescribing.

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Pharmacist Incentives (1/1)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
57. Is generic medicines substitution legally allowed?																						
Yes				✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
No	✓	✓[1]	✓[2]								✓											✓[3]
58. Are there recommendations to substitute generic medicines?																						
Yes						✓	✓	✓	✓	✓		✓		✓		✓		✓		✓[4]	✓	
No		✓		✓	✓								✓		✓		✓		✓			
59. If substitution is allowed:																						
Physicians need to explicitly give permission										✓												
Physicians can prevent it				✓	✓	✓	✓	✓	✓					✓	✓	✓	✓			✓		
Pharmacists are obliged to inform the patient				✓			✓		✓	✓		✓	✓		✓	✓	✓	✓	✓		✓	
Pharmacists are obliged to substitute						✓	✓	✓						✓	✓							
Patients can refuse				✓	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓		✓	✓	
60. If substitution is allowed, has it led to an increased use of generic medicines?																						
Yes					✓	✓	✓	✓		✓		✓		✓	✓	✓	✓	✓	✓	✓	✓	
No				✓					✓				✓									
61. Does pharmacy substitution introduce distortions in pharmacists' remuneration?																						
Yes				✓[5]		✓	✓	✓	✓	✓				✓						✓[6]		
No					✓							✓			✓	✓	✓	✓	✓		✓	

(1) Antibiotics and Antimycotics: The prescriber can prescribe any antibiotic/antimycotic he/she wants (therapeutic freedom), but the pharmacist has to consider this prescription as INN, meaning the pharmacist has to deliver a medicine from the 'cheapest class'. Cheapest class' means that for a given molecule the pharmacist has to deliver a pack of a corresponding antibiotic or antimycotic that falls in the price range of the 'cheapest medicine'.
(2) Vertical integration between a manufacturer, wholesaler and chain of pharmacies stops this recommendation. The generic substitution would only benefit the pharmacists.
(3) There is no system of automatic generic substitution, though in practice, INN prescribing means that the market quickly turns generic in most cases following loss of exclusivity.
(4) Substitution is mandatory. The pharmacist can prevent it for medical reasons
(5) Remuneration of pharmacists is based on the price of the dispensed medicine. If a pharmacist dispenses cheaper medicine, he/she will have lower remuneration
(6) Pharmacists get paid 1 euro for all substitutable products

Patient Incentives (1/2)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
62. Is there an identified need for information targeting patients about generic medicines?																						
Yes	✓	✓	✓				✓		✓		✓	✓	✓	✓		✓	✓	✓				
No				✓	✓	✓		✓		✓					✓				✓	✓	✓	✓
63. Have there been information campaigns targeting patients to inform them about generic medicines?																						
Yes	✓	✓	✓				✓	✓	✓		✓	✓	✓			✓	✓	✓		✓		
No				✓	✓	✓				✓				✓	✓				✓		✓	✓
64. If yes, in which form have they been rolled out?																						
TV campaign		✓	✓				✓		✓		✓	✓	✓			✓						
Radio		✓					✓				✓	✓	✓			✓						
Leaflets	✓	✓	✓				✓	✓			✓	✓				✓		✓		✓		
Seminars & conferences		✓	✓									✓	✓				✓	✓				
Websites		✓	✓				✓					✓	✓			✓	✓	✓		✓		
Advertising																✓						
Information posters	✓																					
Press releases																	✓					
Information on the pharmacies																				✓		

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Patient Incentives (2/2)

Country	Austria	Belgium	Bulgaria	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Lithuania	Netherlands	Poland	Portugal	Romania	Slovakia	Spain	Sweden	Turkey	UK
65. If yes, what was the message of the campaign?																						
Quality	✓	✓	✓				✓	✓			✓	✓				✓	✓	✓		✓		
Safety	✓	✓	✓				✓	✓	✓		✓	✓				✓	✓	✓		✓		
Value	✓		✓				✓	✓	✓		✓						✓	✓		✓		
Sustainability	✓		✓								✓	✓				✓	✓	✓				
Other													✓									
66. If yes, who organised these campaigns?																						
Pharmaceutical industry			✓								✓	✓				✓	✓	✓				
National authorities		✓					✓		✓		✓	✓	✓			✓		✓		✓		
SHI	✓																					
Sick funds								✓														
National associations												✓										
GENAS																		✓				
67. If yes, have the information campaigns led to an increased use of generic medicines?																						
Yes	✓		✓				✓	✓			✓	✓				✓	✓					
No									✓				✓					✓		✓		

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