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MARKET REVIEW – EUROPEAN GENERIC MEDICINES MARKETS

POLICY OVERVIEW

2016

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Introduction

The Generic Medicines Group Market Access Committee is pleased to present the 2016 Market Review - European Generic Medicines Markets - Policy overview.

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

The 2016 Market Review covers 7 main topics: Pricing systems, Retail tendering, Hospital tendering, Reimbursement systems, Physician incentives, Pharmacist incentives and Patient incentives. Throughout 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 the Medicines for Europe National Associations and, if not available, Member Companies.

Adrian van den Hoven
Medicines for Europe Director General

Michele Uda
Chair of the Generic Medicines Group
Market Access Committee

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Pricing Systems (1/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
What kind of pricing system is in place for (reimbursed) generic medicines?																								
Free pricing						✓[1]			✓					✓[2]							✓[3]			✓[4]
Price regulation	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	✓	

(1) Although it is a free pricing system, a tenderling-like system is in place (auction every 2 weeks).
(2) Although free pricing there is a maximum price by legislation
(3) Free pricing in theory but the price will have to be approved by TLV (pricing authority) for reimbursement purposes. At launch, the generic medicine price cannot exceed the price of the reference product. After 6 months, the reference product has to decrease its price by approximately 65% to keep reimbursement status. This new price (-65%) becomes the new maximum price for generic medicines

(4) Free pricing for unbranded generic medicines: manufacturers can freely decide on the price (scheme M) of the unbranded generic medicines without exceeding the price of the reference product (for the first 2 years). The government will subsequently set a reimbursement price which can change every quarter, based on the quarterly information from the manufacturers on net generic medicines' income revenues and volumes of transactions together with a pharmacy margin. Price regulation for branded generic medicines: branded medicines faill into the government' price control mechanism PPRS (voluntary or statutory agreement)

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Pricing Systems (2/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
If there is price regulation, prices are set based on:																								
External reference pricing			✓[1]	✓	✓[2]					✓					✓	✓[3]	✓[4]	✓[5]	✓[6]				✓[7]	
% below originator price	48%[8]	54-60%[9]	30%	30%	32%		50%	60%[10]		33%	40%	60%	20%		25%	50%	35%	35%		40%		10-60%[11]		
Maximum price		✓			✓		✓																	
Negotiable			✓[12]					✓																
What are the key parameters considered when prices are set	13	13	14	15			13			13					16	17	18		19			20		

(1) Referenced to the lowest price in the basket of reference countries
(2) Based on the average of the three lowest priced products in the EU
(3) Maximum price established by referencing to 3 countries (France, Slovakia and Spain)
(4) Reference to the lowest price in 12 EU countries
(5) EU reference price = average of 3 lowest ex-factory prices within 26 EU countries (except Malta and Slovakia)
(6) The price of the generic medicine must be at least 30% below the average generic price in 3 reference countries (Austria, France and Germany)
(7) Generic medicines prices may be up to 60% below the price of the reference product. The generic medicine price is set by referencing to the lowest price (in €) among 5 countries (France, Greece, Italy, Portugal and Spain)
(8) The first generic medicines has to decrease its price by 48%. The second generic medicine has to decrease its price by another 15% (-56% in total) while at the same time the reference product has to decrease its price by 30%. The third generic medicine has to decrease it price by another 10% (-60% in total) and after 3 months, all generic medicines and the reference product have to decrease their price to this level (-60%)
(9) Price decrease depening on reimbursement category: -60% (category A) or -54% (category B)
(10) Mandatory price reduction of 60% for the generic medicine and at the same time the originator medicine has to decrease its price by 20%
(11) Mandatory price decreases depending on the market volume of the reference product prior to patent expiry
(12) Some generic medicines are subject to negotiation for additional discounts (not mandatory) when applying for reimbursment
(13) Price of the reference product
(14) Lowest price in referenced countries. Negotiation on further price decreases by health insurance funds
(15) Price of the reference product if it is already reimbursed, otherwise the average price of reference countries (Czech Republic, Italy and Slovenia with France and Spain as back-up countries)
(16) Prices in referenced countires, prices of substitutes and patient co-payment
(17) The maximum price is established through external reference pricing. For reimbursement purposes, the price should be at least 50% below the price of the reference product but this can even to up to 80%
(18) The price is based on which criteria generates the lowest - either through external reference pricing or 35% below the price of the reference product
(19) 30% below average price through external reference pricing
(20) Price of reference product which is subject to external reference pricing (9 countries)
(21) Cost of goods including cost of innovation, extra value created for patients and reduced health service costs such as preventing future illness

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Pricing Systems (3/3)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
Is the application for P&R of a generic medicine																								
Single process	✓			✓		✓	✓	✓	n.a.		✓	✓	✓		✓						✓	✓		n.a.
Separate processes		✓	✓		✓				n.a.	✓				✓		✓[1]	✓	✓	✓	✓			✓	n.a.
On average, how long does it take for a generic medicine to receive its P&R approval from the day of application (in days)?	120-180	60	30-45	120	75	14-28	23	300	0[2]	180-270	30	50	180	30	60[3]	20	90-120	90-180[4]	90	14[5]	30	30	90[6]	0[7]

(1) The processes are separate but are performed subsequantial by the same entity (green pass for generic medicines)
(2) Not applicable as no application is necessary
(3) 60 days is the practice for products that have reimbursed substitutes. It takes around 180 days if no substitutes are reimbursed as an HTA assessment is necessary
(4) The process of categorisation differs whether the reference product is already listed for reimbursement:

- the medicine has the same strength of active substance as it is listed in the Categorisation list of the reimbursed medicines, it means it is P&R submission to existing Reference group in the Categorisation list of reimbursed medicines - the process takes 3-4 months
- the medicine has not the same strength of active substance as it is listed in the Categorisation list of the reimbursed medicines, or it is a new fixed combination, or it is original, it means it is P&R submission to new Reference group in the Categorisation list of reimbursed medicines - the process takes 5-6 months

(5) Automatic if the price is at least 40% below the price of the reference product
(6) If the applicant is applying for a first price submission, it is concluded within 90 days. Any subsequent submissions are concluded in 10 days
(7) No application is necessary. Reimbursement prices are updated quarterly based on the manufacturers every quarter on the basis of the manufacturer's sales and volume data. If an unbranded generic medicine tis launched, a temporary reimbursement price is set until they have a quarter's sales and volume data from generic manufacturers and a permanent reimbursement price is set

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Retail Tendering (1/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
Is there a tendering system in place for generic medicines in the retail market	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No	Yes	No	No	No	No	No	Yes[1]	No	No	No	No
If yes, what is the geographical scope of the tenders																								
National						✓			✓					✓										
Regional									✓											✓				
Other																								
If yes, which body is in change of the tendering system?																								
Government (national/regional)						✓[2]														✓[3]				
Health insurance funds									✓					✓										
Other														✓[4]										
If yes, are tendering contracts awarded by:																								
Active substance						✓			✓					✓						✓				
Group of active substances									✓															
Therapeutic indications																								
Other																								

(1) Only in the region of Andalucia
(2) National government
(3) Regional government
(4) Since recently also wholesalers have started tendering

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Retail Tendering (2/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
What is the average contract duration of the tender?						14 days			2 years					2 years						2 years				
After granting the tender, are prices subject to change until the next tender?						No			Yes					No						No				
Is there an agreed minimum or maximum volume as a result of winning the tender?						Yes			No					No						Yes[1]				
Are factors other than the lowest price taken into account when determining the winner of the tender?						No			No					No						No[2]				
Is the tender bidding process a sealed bid procedure? (competitors are not aware of how much other competitors are bidding)						Yes			Yes					Yes						Yes				
Are competitors bidding in the tendering procedure allowed to be informed of the other competitors bidding in the procedure?						No			No					No						No				
Is the winning price from the tender transparent to other competitors?						Yes			No					Yes/No[3]						Yes[4]				

(1) The winning company, in a theoretical point of view, must assure no shortages for 2 years according with the volume estimated by the Andalucian government
(2) The criterium is not the lowest price but the maximum discount over national official price by presentation inside Andalucia But the criterium is not lowest price, is maximun discount over national official price by presentation and province inside os CCAA
(3) There are 2 systems in the Netherlands: one where the company has to offer a price, which is public or another one where the company has to offer a discount on the price, which is confidential
(4) Andalucia publishes on the official website the prices of the winning medicine, the discounts in % and the company name by presentaion and province inside Andalucia

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Hospital Tendering (1/4)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
Is there a tendering system in place for generic medicines in the hospital market																								
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
No												✓												
If yes, what is the geographical scope of the tenders																								
National			✓[1]	✓		✓				✓	✓					✓[2]	✓[3]		✓				✓	✓
Regional	✓						✓		✓				✓				✓[3]				✓			✓
Hospital (individual or group)		✓	✓[1]	✓	✓			✓	✓	✓			✓	✓	✓	✓	✓	✓		✓		✓	✓	
If yes, which body is in charge of the tendering system?																								
Government (national/regional)			✓			✓				✓			✓			✓			✓		✓		✓	✓
Health insurance funds				✓						✓	✓													
Hospitals (individual/group)	✓	✓	✓	✓	✓		✓[4]	✓[5]	✓	✓				✓	✓	✓[6]	✓	✓		✓		✓	✓	

(1) For certain groups of medicines there are national tenders, for the other medicines it is the responsibility of individual hospitals
(2) For certain medicines, national l tenders are used to select 3-5 suppliers after which hospitals (individual or group) can launch a new tender to select on supplier out of the 3-5
(3) For some national health programs the medicines can be tendered at national/regional level
(4) Hospital districts are responsible for tenders
(5) A new system of territorial hospital groups (Groupement hospitalier territorial) has been introduced recently by law
(6) For certain medicines, national l tenders are used to select 3-5 suppliers after which hospitals (individual or group) can launch a new tender to select on supplier out of the 3-5

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Hospital Tendering (2/4)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
The tenders are applied to:																								
Total pharmaceutical market		✓	✓		✓	✓	✓	✓	✓[1]	✓	✓						✓		✓		✓		✓	✓
Off-patent market	✓			✓									✓	✓		✓[2]						✓		
Other															✓[3]			✓		✓				
If yes, are tendering contracts awarded by:																								
Active substance	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Group of active substances							✓		✓		✓			✓			✓			✓[4]	✓		✓	
Therapeutic indications							✓		✓		✓			✓			✓							
Other																								
What is the average contract duration of the tender? (months)	12	-[5]	-	12	12	12[6]	24	24-36	12	12	12-24		24[7]	12	24-36	-[8]	12	12-24	6	12-24	24	12[9]	12	18-24
After granting the tender, are prices subject to change until the next tender?	No	No	No	No	Yes	No	No	No	Yes	No	No		No	Yes	No	Yes	No	No	No	No	No	No	Yes	Yes

(1) There can be exceptions which are at the discretion of the hospital/hospital groupthere are exceptions: this can be at the discretion of the hospital/hospital group
(2) Total pharmaceutical market by legislation but in practice only off-patent market
(3) Responsibility of hospital
(4) There is a therpaeutical equivalents model (group of active substances) in Andalucia and Valencia
(5) Specified in the technical specification of the contracts
(6) Can be extended
(7) Can be extended for another 2 years
(8) Hospitals 3 months; national tenders 12-24 months
(9) Estimation as no contractual details are made public

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Hospital Tendering (3/4)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
Is there an agreed minimum or maximum volume as a result of winning the tender?	No	No	Yes	No	No	Yes[1]	No[2]	Yes[3]	Yes[3]	Yes[4]	Yes[5]		No	No	No	Yes[6]	Yes[4]	Yes[7]	No	No	No	Yes[4]	No	No
Are factors other than the lowest price taken into account when determining the winner of the tender?	Yes	Yes	Yes	No	No	No	Yes[8]	Yes	Yes[9]	No	No		Yes	No	Yes	No	Yes	No	No	No	Yes	Yes[10]	Yes	Yes[11]
If yes, which of the following factors is 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	✓	✓	✓					✓	✓				✓				✓					✓		
Other			✓[12]				✓[13]														✓[14]	✓[15]		

(1) The buyer is not obliged to acquire the whole agreed volume and is allowed to request for more without changes to the price. If the winning manufacturer cannot supply, he is subject to penalties which can be quite severe
(2) The hospital district give estimates on earlier consumptions but these are not binding
(3) Varies according to each tender
(4) Minimum volume
(5) Minimum & maximum volumes
(6) The agreed volumes are binding in the hospital setting
(7) Can be but not necessarily
(8) Hospital disctricts have different criteria but price is the most important factor
(9) Only in some cases
(10) Usually an internal expert team looks at the presentation (galenics, packaging) and decides on whom to invite for the offer
(11) If more medicines have offered the same price (on 2 decimals) the medicine with multipl distribution channels is preferred
(12) Condition of payment
(13) Some regions also include environmental criteria
(14) Environmental impact and corporate responsibility
(15) Galenics

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Hospital Tendering (4/4)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
Is the tender bidding process a sealed bid procedure? (competitors are not aware of how much other competitors are bidding)	Yes	Yes	Yes	Yes	No[1]	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Are competitors bidding in the tendering procedure allowed to be informed of the other competitors bidding in the procedure?	No	No	No	No	No	No	No	No	No	No	No		No	No	Yes	Yes	No	No	Yes	No	No	No	No	No
Is the winning price from the tender transparent to other competitors?	Yes	Yes	No	No	Yes[2]	Yes	Yes	Yes	Yes/No[3]	Yes	No		Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	No

(1) Depends on the type of the tender
(2) Transparent for offical public tenders
(3) Depends on the tender

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Reimbursement Systems (1/4)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
Is a marketing autorisation necessary to apply for reimbusement of generic medicines	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Do you have a reference pricing reimbursement system fro generic medicines?	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No[1]	Yes	Yes	No[2]	No	Yes	No
If yes, how is the reference group established?																								
By active substance (ATC-5)		✓	✓	✓			✓	✓	✓		✓	✓	✓		✓	✓	✓		✓	✓			✓	
By pharmacological class (ATC-4)									✓					✓										
By therapeutic class (ATC-3)				✓	✓						✓								✓					
Other															✓[3]									

(1) Extra for generic medicines, but for all reference or reimbursement group
(2) Depends on what is meant with reference price. The retail market is by some people called "tender-like market" while other say the lowest price is the 'reference price'. All pharmacies must dispense the product with the lowest price. If the patient wants another
(3) Jumbo groups

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Reimbursement Systems (2/4)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
If yes, based on what is the reference price established?																								
Average price of medicines												✓		✓										
Average price of generic medicines								✓[1]											✓					
Lowest priced medicine			✓		✓[2]		✓				✓		✓[3]				✓[4]		✓				✓	
Lowest priced generic medicine																								
Other		✓[5]		✓[6]			✓[7]		✓[8]		✓[9]				✓[10]	✓[11]				✓[12]			✓	

(1) Based on the lowest priced generic medicine (= average price as there is just one common price for generic medicines)
(2) Lowest priced in EU countries
(3) The lowest public price on the market for the same active substance, strenght, dosage form and pack size
(4) For most groups the lowest priced medicine but for for certain national health programs the reference price is 120% of lowest priced medicine
(5) Based on the maximum price for generic medicines (= price reduction compared to the reference product: -54% for cat B and -60% for cat A medicines)
(6) Based on the lowest priced medicine with 5% volume market share in the last three months
(7) Reference prices are set every three months. The reference price is the lowest price for a certain substitutable product and pack size, which is available for the whole period of three months. All medicines wit a price corridor ot the lowest price medicine + €1.50 (€2 for medicines that cost over €40) are fully reimbursed. The difference above this corridor has to be paid by the patient. Companies can change their prices every 2 weeks
(8) Based on the lowest third priced generic medicine
(9) Market share requirements
(10) The price of similar stock keeping unit (dosage, package, active substance) in other countries through external reference pricing
(11) The price is decided based on the average of the five lowest priced medicines of the same group of active substances (homogeneous group). The price is reviewed every 3 months (12) The reference price is set at the level of the lowest priced generic
(12) The reference price is set at the level of the lowest priced generic medicines in the reference group. Patients are not allowed to pay the difference between the reference price and the actual price, which creates an incentive for all medicines, including off-patent originator medicines, to be priced at the same level
(13) 15 groups by active substance are reimbursed at the lowest price within each group. Products in other groups are reimbursed up to 10% of the lowest unit price within the group

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Reimbursement Systems (3/4)

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

(1) Called 'Répertoire' of generic medicines
(2) Called 'Spezialitätenliste'
(3) Not specifically for generic medicines but there is a list of categories of products that are not reimbursable
(4) Regional formularies which list medicines that cannot be prescribed
(5) Reference groups are divided into partially and fully reimbursed
(6) Patients are not allowed to pay the difference between the reference price and the actual price. In that case, only medicines that are priced at the level of the reference price are reimbursed. As a consequence, almost all medicines, including the off-patent
(7) Usually generic medicines are only partially reimbursed (25-75%) but since recently generic cardiovascular medicines are 100% reimbursed
(8) The co-payment is about 10-20% of the price of the individual medicine
(9) The patient has to pay the difference between the lowest price medicine and the actual price if this price exceeds 5% of the lowest price
(10) 10% of the retail price (minimum €5, maximum €10)
(11) The patient pays 100% of the cost up to a certain level, then 50%, 25%, 10% and finally gets medicines free if the product is within the reimbursement system. After a 12 month period this system starts again. Since Oct 2002 there is generic substitution.
The pharmacy must susbstitute to the lowest priced product and only the lowest priced medicine is reimbursed. The patient can request a higher priced medicine but needs to pay for the price difference (even if the patient has already reached the level where
he gets the medicines for free)
(12) Pensioners pay 10% and employees pay 20% of the expense of their medicines. Besides this, for each prescription all patients pay a fee depending on the number of boxes they have been prescribed.

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Reimbursement Systems (4/4)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
Does the patient co-payment differ for generic medicines when compared to the reference originator medicine?	No	Yes[1]	Yes	No	No	No	Yes[2]	No	Yes	No	Yes/No[3]	Yes[4]	Yes/No[5]		No	Yes/No	No	No[7]	No		No	Yes/No[8]	No	

(1) The co-payment for originator medicines is higher than that for generic medicines
(2) If the patient chooses to buy a more expensive (usually originator) medicines that is not within the price corridor, the patient has to pay the difference
(3) This depends on the price of the individual medicine
(4) If the patient insists on receiving the reference originator medicine which is more expensive than the generic medicine he has to pay the different then they pay the difference
(5) This depends on the region. If the patient insists on receiving the reference originator medicine which is more expensive than the generic medicine then he has to pay the difference
(6) This depends on on how much the price of the medicine is above the reference price
(7) Reimbursement is per SDD within reference group, the same for reference and generic medicines. The level of co-payment depends on the strategy, whether the reference product decreases its final price or not
(8) This is dependent on the price of the medicine

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Physician Incentives (1/1)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
Is INN prescribing allowed in your country?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Is there legislation/recommendation to prescribe generic medicines by INN																								
Recommendation				✓			✓		✓[1]			✓		✓[2]	✓				✓	✓[4]		✓		✓
Legislation		✓[5]	✓[6]		✓[6]	✓[7]		✓		✓[8]	✓[9]		✓			✓	✓	✓[3]					✓[10]	
Are physicians encouraged to prescribe generic medicines?	Yes	Yes	No	Yes	No	Yes	Yes[11]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No[12]	Yes	Yes	
By prescribing guidelines	✓	✓		✓		✓		✓		✓		✓	✓	✓		✓	✓		✓	✓				✓
By electronic prescribing	✓			✓		✓		✓	✓	✓	✓[13]		✓	✓		✓	✓		✓	✓			✓	
By medicine database							✓	✓											✓				✓	
By prescription audits		✓		✓					✓	✓		✓							✓					
By health insurance fund visits	✓			✓					✓					✓					✓					
By financial incentives		✓		✓				✓						✓					✓	✓[14]				✓
By financial restrictions				✓		✓			✓				✓						✓			✓		
By information/education campaigns		✓										✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		
Other																		✓						

(1) Recommended by health insurance funds and some regional physician associations
(2) The recommendation is strictly observed by physicians and monitored by health insurers
(3) Physicians can still write the brand name between brackets
(4) All prescriptions for cute treatments and chronic treatment for naïve patients must be with INN
(5) Legally allowed but not actively promoted (less than 10%)
(6) Legally allowed but not applied in practice
(7) Legislation to allow INN prescribing but still a lot of brand-name prescribing as pharmacists anyhow have to dispense the lowest priced medicine
(8) With exceptions
(9) Currently suspended
(10) Permitted but not compulsory
(11) Very little encouragement at the moment
(12) No real incentives, and since the pharmacists substitute the product anyway the prescription of the doctor does not matter that much
(13) Currently suspended
(14) only in a few cases

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Pharmacist Incentives (1/1)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
Is generic medicines substitution legally allowed?	No	No[1]	Yes	No	Yes[2]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes[3]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Are there recommendations to substitute generic medicines?	No	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No
If substitution is allowed:																								
Do physicians explicitly need to give permission?			No		No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes
Can physicians prevent it?			Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes
Are pharmacists obliged to inform the patient?			Yes		Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Can patients refuse?			Yes		Yes	Yes	Yes	Yes[4]	Yes[4]	Yes	No	Yes	No	Yes[5]	Yes	Yes	Yes	Yes	Yes	Yes	Yes[4]	Yes	Yes	No
Has it led to an increased use of generic medicines?			?[6]		No	Yes	Yes	?	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No

(1) Substitution is mandatory in case of antibiotics and antimycotics. In that case, the pharmacist has to dispense the lowest priced medicine
(2) The system equalised the reimbursement conditions for originator medicines so in practice there is no difference between the originator and generic medicine
(3) With limited efficiency
(4) Patients can refuse. They will have to pay the different and also be subject to 'tiers payant contre génériques': they will be exempted from the system of direct payment by the health insurance funds to the pharmacists (known as the 'tiers-payant') but will have to pay the full amount of the price of the medicine and will have to recover this cost from their health insurance fund
(5) Patients can refuse it but have to pay the difference (and in case that the medicine is included in a preference policy the medicine will be 0% reimbursed)
(6) Too early to tell as generic substitution was only introduced in June 2016

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Patient Incentives (1/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
Have there been information campaigns targeting patients to inform them about generic	Yes	Yes	Yes	No	No	Yes	No	Yes	No	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No
If yes, in which form have they been rolled out?																								
TV campaign		✓						✓		✓		✓	✓		✓	✓								
Radio		✓								✓		✓	✓		✓	✓								
Leaflets	✓	✓	✓					✓		✓		✓	✓		✓	✓	✓			✓	✓	✓		
Seminars & conferences	✓		✓							✓		✓	✓		✓					✓				
Websites			✓									✓	✓		✓	✓	✓			✓				
Advertising								✓		✓		✓				✓	✓							
Other						✓[1]		✓[2]																

(1) Through education by healthcare professionals
(2) Public letter to the Minister of Health in the press

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Patient Incentives (2/2)

Country	Austria	Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
If yes, what was the message of the campaign?																								
Quality	✓	✓	✓					✓		✓		✓	✓			✓	✓			✓	✓	✓		
Safety	✓	✓	✓					✓		✓		✓	✓			✓	✓			✓	✓			
Value	✓		✓			✓		✓		✓		✓			✓		✓			✓	✓	✓		
Sustainability	✓		✓			✓						✓	✓			✓	✓			✓				
If yes, who organised these campaigns?																								
Pharmaceutical industry	✓		✓					✓		✓		✓	✓		✓		✓					✓		
National authorities		✓				✓		✓[1]		✓		✓	✓			✓	✓[2]	✓		✓	✓	✓		
If yes, have the information campaigns led to an increased use of generic medicines?	No	No data	No data			No data		No		No		Yes	Yes		Yes	Yes	No data			Yes	No	Yes		

(1) Two step campaign in 2016 targeting heath professionals and the general public conducted by the authorities
(2) National authorities joined the information campaigns set-up by pharmaceutical industry

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The Generic Medicines Group is a sector group of Medicines for Europe, representing the generic medicines developers and manufacturers, which provide high-quality cost-competitive medicines to millions of patients in Europe and around the world. Over 350 manufacturing and research & development sites across Europe produce your essential medicines, employ over 160.000 employees and invest up to 17% of their turnover into R&D activities. Generic medicines account today for 56% of all dispensed medicines but for only 22% of the pharmaceutical expenditure in Europe. In other words, generic medicines only account for 4% of total healthcare costs. Without generic medicines, Europe would have had to pay €100 billion more in 2014 to get the same level of access to treatment as we have today. The European generic medicines industry vision is to provide sustainable access to high quality medicines for all patients, based on 5 important pillars: patients, quality, value, sustainability and partnership.

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