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MARKET REVIEW – EUROPEAN GENERIC MEDICINE MARKETS

POLICY OVERVIEW

2023

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ACKNOWLEDGEMENTS

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

The purpose of this Market Review is to provide a general overview of the policies that are currently in place for Generic Medicines in the different European countries allowing the reader to get a clear overview on how generic medicines policies are set in the reviewed countries. The 2023 Market Review covers the following policies: Pricing & Reimbursement systems, Control of excess spending, Generic medicines substitution and Procurement of medicines.

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

Adrian van den Hoven
Medicines for Europe Director General

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In the EU, medicinal products can only be placed on the market after they have been authorised by the European Commission or the competent national authorities. Marketing authorisations are granted in accordance with common EU rules intended to ensure the quality, safety, and efficacy of medicines. Member States are responsible for controlling the prices and reimbursement of medicines in view of promoting the health of their citizens and the financial sustainability of their social security systems.
Therefore, pricing and reimbursement rules in Europe fall under the responsibility of the Member States. The pharmaceutical market in each Member State is highly regulated.

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

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

- Current pricing policies, aimed at constantly lowering medicine prices, result in market concentration, and consequently medicines shortages and health inequalities.
- External reference pricing is not a proper tool to ensure competitive pricing in the off patent market
- Highly resilient and future-proof strategies should be promoted to counteract rising inflation and address market challenges

RESOURCES:
Medicines for Europe paper new pricing models
Medicines for Europe position on ERP

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

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
1. What kind of pricing system is in place for generic medicines (reimbursed)?																												
Free pricing							✓											✓										✓
Regulated pricing	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
Comments	1					2		3																		4		

(1) Generic reimbursement pricing is governed by the General Social Security Act (ASVG).
(2) "In general, all reimbursed medicines are regulated. There can be exceptions - list of ATC group stated in MoH decree. These ATC groups are deregulated - meaning that the product has to declare a maximum price (increase one time per quarter, decrease every month).
General rules for listing ATC group as deregulated:
- at least 4 brands in ATC group and specific route of administration
- public interest"
(3) Reimbursed prescription drug prices are nationally regulated to ensure optimal pricing. The prices of over-the-counter and non-discounted medicines are not regulated, their pricing is free
(4) The pricing is dependent on the originators

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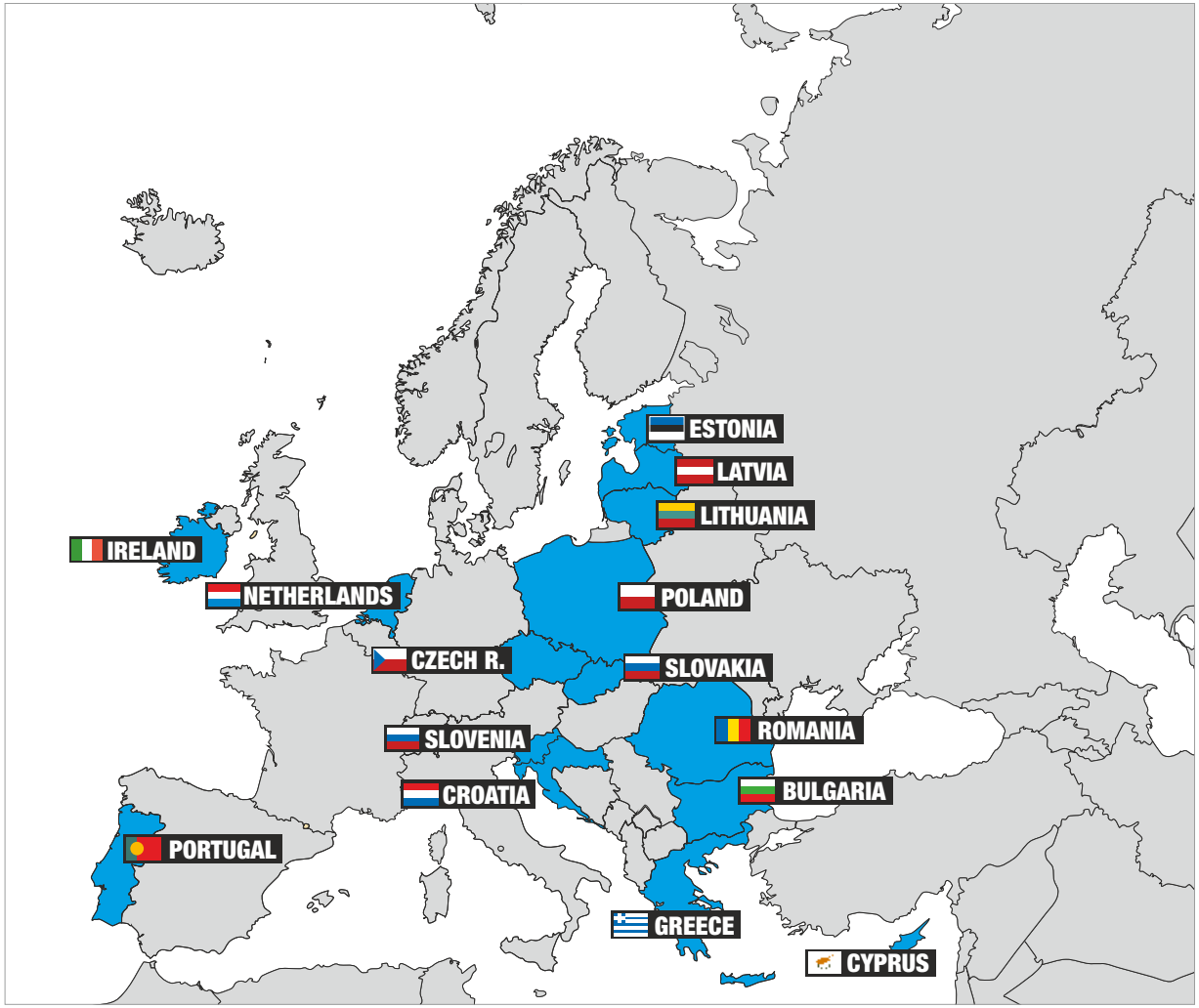
2.Which criteria is used to set the prices?																												
External reference pricing			✓	✓	✓	✓		✓				✓		✓		✓	✓		✓	✓	✓	✓	✓	✓				
Set % below originator price	✓	✓	✓		✓	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓			✓	✓	✓	✓	✓	✓			
Percentage below originator price	50%		30%		80%	40%		30%	50%	60%		35%	40%	60%	20%	30%	30%			25%	50%	65%	49%	68%	40%			
Maximum price			✓																✓	✓		✓		✓			✓	
Negotiation										✓				✓					✓	✓				✓				
Other											5								8							9	10	
Comments	1	2						3	4				6		7													

(1) "1st generic medicine: -50% of the reference drug. 2nd generic medicine: -18 % of 1st generic medicine 3rd and subsequent generic medicine: -15% of previous generic medicine. Reference drug must reduce its price by -30% after three months from the introduction of the 1st generic medicine. After introduction of 3rd generic medicine, all medicines (original and all already reimbursed generic medicines) must reduce to 3rd generic medicine price.
Regulation as of 1/1/2024: -48% / -15% / -10%. Ox -30% after 3 months and analog further reduction to 3rd Gx price.
Further regulation: ""Price band"": max. price difference of drugs with the same active ingredient: +20% above the respective cheapest. Price basis: price of the key strength (the most frequently prescribed dose strength). Excluding products below prescription fee.
As of 1.1.2024: Level pricing at the lowest price can be enforced by the authorities by procedure."
(2) Set% below price originator depending on the type of reimbursement category and turnover of originator
(3) Generic product entry into reimbursement requires 30% lowering of price vs originator. Next entry -10%
(4) 50 % for most, 40 % for products with a device
(5) Rebate Contract, Price Freeze, Internal Reference Price
(6) Following the percentage of the generic already on the market (40% - 20% -10% -5% - 5% -5%)
(7) Balduzzi Decree voluntary and automatic method to determine the price of a new generic
(8) Tendering system by health insurers and hospitals
(9) The cheapest third of all the drugs with same INN is relevant, 10% higher is then the maximal price that can be charged
(10) The reimbursed price will have to be approved by TLV (pricing agency). When Generics enter the market, they can have the same price as the originator or lower. If price competition starts (price drops of more than 70% by competition) the originator must lower their price by approximately 65% 6 months after patent expiry (if they want to stay reimbursed - if they skip reimbursement, that price (-65%) will be the maximum price for generics (and originators). If the product is not reimbursed, there is free pricing

COUNTRIES USING ERP



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

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
3. Countries using external reference pricing as criteria to set the prices																													
Bulgaria		■								■		■			■	■	■						■	■	■	■			
Croatia						■				■					■										■	■			
Cyprus	■	■					■			■	■	■			■							■				■		■	
Czech Republic		■		■			■		■	■	■		■	■	■	■	■		■		■	■		■	■	■		■	
Estonia[1]	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■		■	
Greece	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■		■	
Ireland	■			■			■			■		■	■			■		■				■			■		■	■	
Latvia						■	■	■					■				■				■		■	■					
Lithuania[2]	■	■	■		■	■	■	■	■	■		■	■	■	■	■	■		■	■	■	■		■	■	■	■	■	■
Netherlands		■								■										■									■
Poland	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■		■	
Portugal										■					■										■	■			
Romania	■	■	■			■		■				■			■		■				■			■		■			
Slovakia	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■		■	
Slovenia	■									■	■																		

(1) European Union member states, especially Latvia, Lithuania and Slovakia.
(2) Countries in EURIPID database

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
4. What is determined using external reference pricing?																												
Price for originators (ERP is indirectly applied to generics as it is used to determine the price of originators, which ultimately influences the price of generics)					✓			✓				✓									✓							
Price for generics (ERP is directly applied to generics)			✓			✓											✓					✓		✓				
Benchmarking with other countries				✓										✓		✓	✓		✓	✓			✓					
Comments						1													3									
5. What formula is used when applying external reference pricing?																												
Lowest price in reference countries			✓																	✓		✓						
Average price of reference countries				✓	✓	✓		✓						✓							✓			✓				
Other																6	7						9					
Comments						4						5							8									

(1) ERP is used for all price settings (originator and generics) and for reimbursement.
(2) And benchmarking with other countries
(3) In the Netherlands it is necessary to pay a so called distribution fee to the wholesaler. That is part of the reference price, hence the Dutch net prices are much lower than stated in the pricelist
(4) Average of the 3 lowest prices
(5) Average of the two lowest different prices from the Eurozone countries
(6) Not higher as second lowest. Not higher as in other Baltic countries (Latvia, Lithuania)
(7) 5 lowest prices of INN from EURIPID
(8) Lowest price is the price in the pricelist and the product does not have to be on the market
(9) The average of the three (3) lowest EU prices

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6.Is the application for pricing & reimbursement of a generic medicine a:																												
Single process	✓		✓			✓		✓	✓				✓		✓	✓				✓		✓	✓			✓	✓	
Separate process (One process for pricing and a separate process for reimbursement)		✓		✓	✓					✓	✓	✓		✓			✓		✓		✓			✓	✓			
Comments						1																						
7.On average, how long (in days)? does it take for a generic medicine to receive its P&R approval from the day of application?																												
Days	135	90	30	120	90	60		30	21	94	14	150	45	30	90	45	30		1	100	30	90	120	90	30	30	30	
Comments																			2									
8.Is a marketing authorization necessary to apply for reimbursement of generic medicines?																												
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
No											✓							✓											
Comments	3							4			5							6										

(1) "There should be one application for P&R.
Generic has 2 possibilities for setting price and reimbursement:
1. external referencing (general process) - longer process
2. process of similar product - faster process - new product asks for price and reimbursement of an already reimbursed product (with same active substance)"
(2) The reimbursement of generics is fast, however, the Dutch Z-index system causes delays and is open for changes once a month, therefore, sometimes it can take max 6 weeks before a product is visible on the market
(3) "Basic requirements for P&R:
Marketing Authorisation
Publication in the List of Goods"
(4) To increase attractiveness of market and competition, authorities have set a simplified MAH process to attract parallel trade import into the country. Ordinary MAH is 210 days, while simplified MAH is only 30 days. Prerequisite for submission of a simplified MAH process is to already be registered as ordinary MAH in Estonia.
(5) If there is marketing authorisation, the manufacturer can set the price
(6) No reimbursement system in Malta

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9.Is there a reference pricing reimbursement system (like j umbo groups) for generic medicines in your country?																												
Yes		✓	✓	✓		✓			✓		✓	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓	✓			
No	✓				✓		✓	✓		✓						✓		✓								✓	✓	✓
Comments								1																				
10.How is the reference group established?																												
By active substance (ATC-5)		✓		✓					✓		✓		✓	✓	✓		✓		✓		✓	✓	✓		✓			
By pharmacological class (ATC-4)			✓								✓	✓	✓															
By therapeutic class (ATC-3)				✓							✓									✓				✓				
Other						✓																						
Comments						2			3			4	5						6									

(1) It is INN based reference pricing for generic medicine
(2) Reference groups are based on therapeutical interchangeability medicines and similar clinical effect. There is a MoH decree on reference groups (several ATC7 in one reference group).
(3) Groups are established by similar pack sizes
(4) "ATC-4 with the application EDQM criteria (form, dosage, release, strength and indication)
Generics of all high-cost medicines (Law 3816) are grouped in ATC-5 category."
(5) Some jumbo groups exist based on ATC-4
(6) ATC5: Active substance, pack size, then dosing and formulation (Berekening maximumprijzen | Prijsvorming | Farmatec).

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11.On what basis is the reference price established?																												
Average price of medicines														✓														
Average price of generic medicines																												
Lowest priced medicine			✓						✓				✓						✓	✓		✓		✓				
Lowest priced generic medicine															✓		✓								✓			
External reference pricing						✓						✓					✓						✓					
Other		1		2							4										7							
Comments									3			5	6										8					
12.Are there positive and/or negative lists for generic medicines in your country?																												
Positive list	✓	✓	✓	✓			✓	✓		✓		✓	✓	✓	✓	✓				✓				✓			✓	
Negative List												✓		✓										✓				
No list					✓	✓			✓		✓						✓	✓	✓		✓	✓	✓		✓	✓		✓
Comments	9																		10							11		

(1) Price of the originator
(2) 5% volume market share in the therapeutic group for the respective time period
(3) The reference price is determined by adding EUR 0.50 to the retail price of the cheapest product of each reference group. Several products can be reimbursed simultaneously.
(4) Depending on the reference price level, criteria are lowest priced medicines in accordance with sold volume
(5) Average of the two lowest different prices in the Eurozone
(6) "Jumbo groups: average price of medicines
There are other requirements: reference product should have a minimum percentage of the market share"
(7) Based on the average of the 5 lowest priced medicines of the same group of active substances
(8) Basket of all EU countries, the average of the three (3) lowest EU prices
(9) "The Positive List is named ""Erstattungskodex"" (Reimbursement Code). It contains all secured suppliable drugs that may be dispensed to patients on account of healthcare providers.
There is also a negative list, which is a list of criteria for drugs that are generally not reimbursable (e.g. products that are mainly used in hospitals, or products that are not used for the sick, such as contraceptives, vitamin preparations, etc.)."
(10) The minister decides which medicines are reimbursed. This work is done by the Zorg instituut
(11) All drugs that are reimbursed are on www.spezialitaetenliste.ch

CONTROL OF EXCESS SPENDING

Policymakers apply different policies to control pharmaceutical budgets and the economic burden of healthcare. Mechanisms that can be used to control spending are different types of patient participation in the form of out-of-pocket payments. Other cost containment measures are aimed directly at the manufacturers of medicines and seek to decrease the level of spending on pharmaceutical products. Common policies are mandatory discounts and/or rebates, or clawback/payback schemes.

Clawback/payback definition: Payback/clawback policies require manufacturers to pay back a share of their revenue if a pre-specified budget ceiling for public pharmaceutical expenditure is exceeded.

Discounts, clawback and payback policies can easily be overused and severely impact the economic viability and sustainability of supply.

RESOURCES:
BGMA VPAS position

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CONTROL OF EXCESS SPENDING

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

(1) There is no obligatory co-payment for any medicines (generic included). Co-payment is subject to the market behavior of MAHs and levels of reimbursement.
(2) Every Rx medicine (applied for both- Gx and Originators) has co-payment of 2.5eur as prescription cost, this does not depend on reimbursement level
(3) Patients must pay a prescription fee per dispensed pack. For 2023, the amount is EUR 6,85
(4) Gradual reimbursement. The maximum yearly expense is EUR 600
(5) The patient always pays the part of the price of the drug that exceeds the limit of reference price. A 2.5 fixed prescription fee also applies. Then according to the severity of the disease, partial reimbursement can be applied and depending on that, an out-of-pocket cost applies- eg. 50%, 75% or 100% reimbursement with co payment of 50%, 25% and 0% accordingly
(6) "There are three categories:
Basic rate of reimbursement 40%
Lower special rate of reimbursement 65%
Higher special rate of reimbursement 100%. A co-payment of EUR 4.50 per medicine and per purchase is charged.
In 2023 the annual maximum is set at EUR 592.16 after which co-payment is EUR 2.50 for each reimbursable medicine"
(7) Regions (21) are allowed to require the payment of a "ticket" on the medical prescription or pack. 70% of the regions has a co-payment ticket.
(8) Difference between base price and reimbursement price
(9) Capped on EUR 250
(10) For products where fixed co-payment is not defined by rules, then ratio between reimbursement and co-payment should be kept
(11) The patient pays 100% of the cost up to a certain level, then 50%, 25%, 10% and finally gets all the medicines totally free (if the product is within the reimbursement system). After a 12 month period this system starts all over again.

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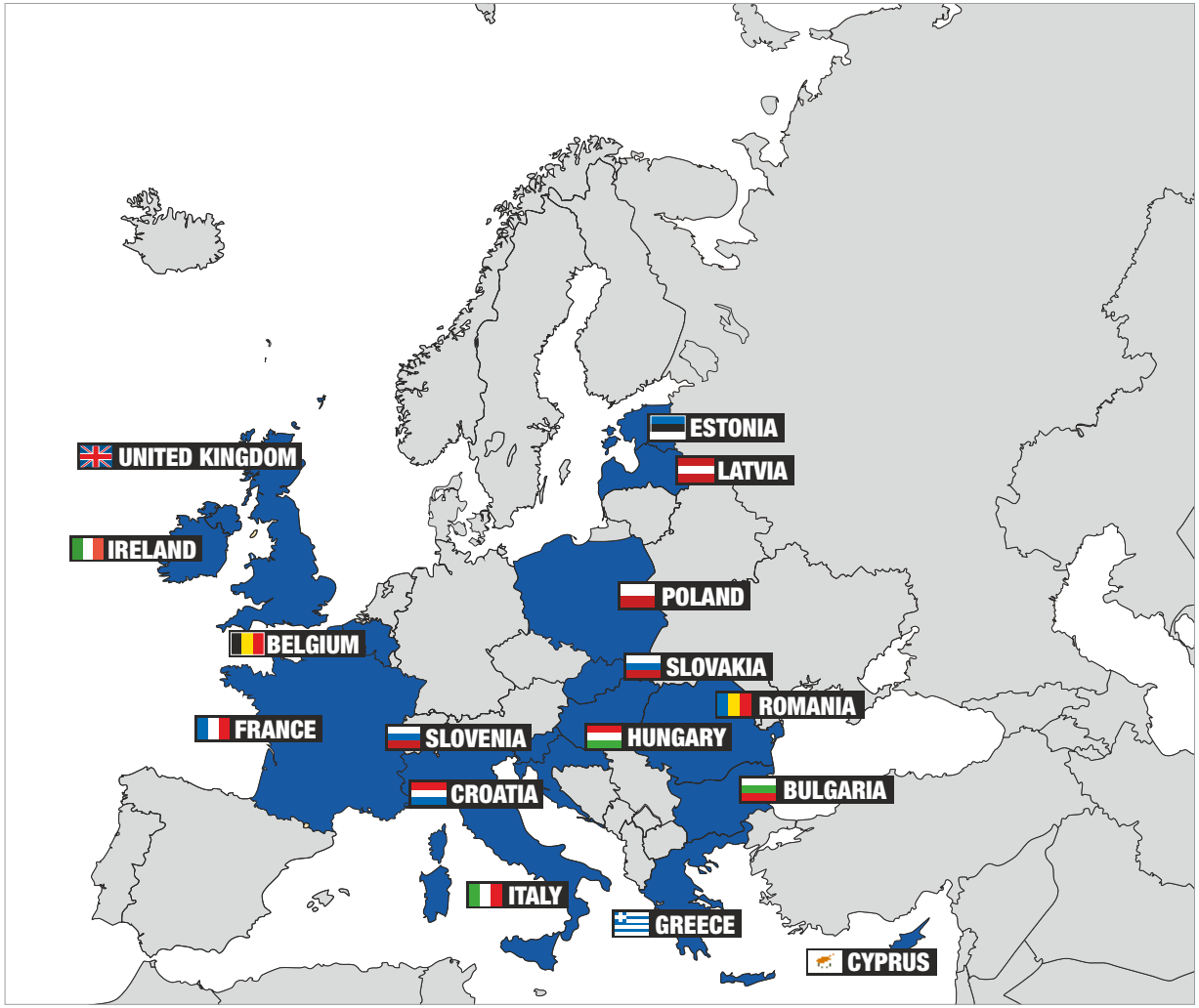
15.Do the out-of-pocket payment schemes for generic medicines differ from the reference originator medicines?																												
Yes					✓							✓		✓	✓					✓			✓					
No	✓	✓	✓	✓			✓	✓	✓		✓		✓			✓	✓		✓		✓	✓		✓		✓	✓	
Comments					1										2					3			4					
16.Which of the following measures are applied in your country in the case of excess spending in the pharmaceutical budget?																												
Mandatory discounts/rebates				✓								✓		✓														
Percentage applied for mandatory discounts/rebates					35%							35%		30%														
Clawback/payback		✓	✓	✓	✓			✓		✓		✓	✓	✓	✓	✓				✓		✓	✓	✓				✓
Other					5																	6						
None of the above	✓					✓	✓		✓		✓						✓	✓	✓		✓				✓	✓	✓	
Comments	7			8		9		10					11				12		13		14		15					16

(1) The cheapest generic has zero co-payment. The difference in Euro for all other generics and Originator with Higher w/s prices, are paid by the patient as co-payment
(2) In addition, the difference between the Reference Price and the public price of the product sold by the pharmacist has to be paid, all over the country, by the patient if he doesn't accept the substitution with generic
(3) In the pharmacy list, there is co-payment for all medicines, in drug programs (hospital) there is no co-payment
(4) MEA contracts are used by originators, contract between MoH SR and MAH concerning special price discounts. Conditional reimbursement (valid untill the end of July 2022)
(5) Above 10 Euros there is a rebate of 35% , from 10-5 euros a rebate of 30%, from 5-3 Euros 22% and below 3 euros 12%
(6) Clawback is capped and differentiated (25% innovative. 20% imported generics, 15% locally produced). It is applied on the quantities sold in the reimbursement system
(7) There are no such regulations for generic medicines. Only for certain patent-protected originals.
(8) Only for some generic medicines, not for all. Usually for those that enter some financial agreements where originator already had an agreement in place before generics entered
(9)In general, there is no obligatory payback. In individual cases (especially for highly innovative products under patent protection) there could be agreement between MAH and health insurance companies for payback - these agreements can be part of budget impact analyses (in case budget impact or CUA unacceptable before agreement). But it is up to MAH and health insurance companies as to what is real form and amount of payback in these agreements.
(10) Clawback is based on the contract with the government and usually related to originators and bio products.
(11) "There are several clawbacks:
1: 20-28% of the reimbursement must be paid by the MAH. 2: 10% of the reimbursement where there is no competitor. 3: rep fee. 4: price-reimbursement agreement. 5: clawback for excess spending (all excess spending is paid by the MAHs based on their market share in reimbursement)"
(12) Applied for originators only
(13) There are pre-access negotiations with the government for products above 20 MIO per year or if for 50.000 per patient then 10 mio per year, but that is for new specialty products
(14) "Extraordinary Contribution for the Pharmaceutical Industry: 14.3% in hospital and 2.5% in the retail market.
This applies to all generic sales and it is not linked to an excess spending of the pharmaceutical budget"
(15) National legislation defines clawbacks, but it is not implemented in practice
(16) For medicines marketed with a brand name, which includes branded generics and branded for commercial. It does not apply to unbranded generics.

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
17. How is the target spending determined when clawback/payback is applied?																													
Global pharmaceutical target budget		✓								✓			✓							✓									
Segmented pharmaceutical target budget (e.g., hospital vs retail or innovator vs off-patent)					✓										✓														
Pharmaceutical expenditure growth rate			✓																										✓
Other				1	2			3				4		✓		5						5.1	6	7					
Comments																													7.1
18.How is the clawback/payback calculated?																													
Based on market share					✓					✓		✓	✓		✓	✓						✓							
Based on revenue		✓						✓															✓	✓					✓
Based on growth			✓							✓										✓			✓						
Other				8						9				✓															
19.What is the percentage of the clawback/payback applied to the base selected above?																													
Percentage		4%	100%	5-20%				1%		60%		Not fixed	1%	12%	1%	100%				100%		20%		1%					26.% and 27.5%
Comments				10	11							12											Not defined						13

(1) Spending in the respective therapeutic area
(2) It is applied to all products except the innovator products
(3) Yearly sales are determined in contract with government. It's not a specific percentage
(4) "The total budget is divided into two channels i.e. Hospitals and Outpatient. In 2022, the outpatient budget was split further into 2 sub - budgets : (a) Retail (reimbursed products provided through the private pharmacies) and (b) High cost medicines mainly provided through EOPYY (the main SSF) owned pharmacies"
(5) According to specific contract descriptions. Yearly overspend of specific INN and/or diagnosis
(5.1) The clawback is capped and differentiated: - 25% innovative, - 20% imported generics, - 15% locally produced
(6) Base for payback is sum of sale of the product for 12 months before observing period. MoH SR takes a budget on each product reimbursed over 1,5 mio EUR. All sales over budget are considered as paybacks to HCIs
(7) Clawback only applied to originators
(7.1) If the actual branded medicines expenditure goes above the allowed amount, sellers of branded generics pay a percentage of their national health system revenues so the industry pays for any overspend.
(8) Either as a fixed % of the healthcare expenditure or as the difference between the planned budget and expenditure for the respective time period
(9) The calculation is based on market share and growth (70% and 30% respectively)
(10) It is different for every product
(11) There is no fixed percentage of the clawback/payback applied. It depends on the excess budget locked each year.
(12) The clawback percentage is not fixed as it depends on the excess over the budget limit. e.g. for 2021, the clawback was ~27% on average over the ex-f price for the EOPYY outpatient channel. This, combined with the compulsory rebate (ranging from 14 - 30% ; average 2021 : 17%) results in a total burden (rebate & clawback) of 44% on average. Please note that in 2022 an extra rebate of 5% was introduced for the products included in positive list clusters with annual sales (of the total cluster) > 20 mn EUR
(13) 26.5% in the voluntary branded scheme, 27.5% in the shadow statutory scheme

COUNTRIES USING CLAWBACK



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CONTROL OF EXCESS SPENDING

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
20.Is there a differentiated clawback/ payback for generic medicines compared to the originator?																												
Yes								✓												✓		✓		✓				
No		✓	✓	✓	✓					✓		✓	✓	✓	✓	✓							✓					✓
Comments		1						2							3									4				
21.What percentage of the budget overrun is paid back by the pharmaceutical industry?																												
Percentage		4%	100%		1%			1%		60%		100%	100%	10%	50%	100%				17%		20%	Not defined	1%				25%
Comments					It is not constant																							

(1) The clawback % varies from year to year
(2) Generics are not under clawback as the cost containment is covered by INN's quarterly price referencing system. Generics might be subject to clawback for rare diseases and biosimilars
(3) The only difference is that generics and off-patent medicines don't contribute to overspending of innovative products
(4) No clawback on generics

Generic medicine substitution policies aim to provide physicians and pharmacists with incentives to prescribe (in the case of physicians) and dispense (in the case of pharmacists) generic medicines which will ultimately provide patients access to medicines and at the same time use economic resources wisely.

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22. Is generic medicines substitution legally allowed?																												
Yes		✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
No	✓		✓	✓																								
Comments				1			2	3																		4		
23.Are there recommendations to substitute generic medicines?																												
Yes		✓			✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓		✓		✓		✓			✓	✓	✓
No														✓		✓		✓		✓		✓		✓	✓			
Comments		5				6	7	8							9	10			11							12		
24.Which statement describes pharma-ceutical substitution in your country?																												
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					✓	✓	✓		✓	✓		✓	✓					✓		✓	✓			✓		✓	✓	✓
Other																								16				
Comments									13						14				15							17	18	19

(1) The only situation when pharmacists can substitute the prescribed product is if it is out of stock on the market and then the pharmacist can dispense any product with the same or lower price. Otherwise substitution is not allowed
(2) It's mandatory
(3) There is INN prescription with substitution in pharmacies.
(4) There is even an incentive at pharmacy level (interesting for pharmacist to switch short term to generics), however margins are lower for low cost treatments, therefore not interesting for long term Patients to switch them
(5) There is an obligation to substitute with the economically most advantageous medicine
(6) If there are more medicines in the same ATC-7 group, then the pharmacist has to offer the medicine with the lowest co-payment.
(7) By law
(8) According to the framework, pharmacists should offer patients the cheapest medicine, or the ones within the reference price limit
(9) There is an obligation to substitute with the most economically advantageous medicine
(10) INN prescription for reimbursed medicines
(11) There is a guideline for pharmacists on how to substitute because some therapies should not be substituted.
(12) Allowed and mandatory
(13) Patients who refuse substitution will have to pay the difference to the reference price
(14) Physicians are obliged to prescribe INN for naïve patients
(15) Dutch MEB: Responsible switching guideline (orange and red products). List is included as pdf
(16) Pharmacists may substitute
(17) Physicians do this often for therapies where they do not want to have a switch due to medical reasons such as special indications like CNS
(18) If the prescriber refuses, the patient will be fully reimbursed. If the patient refuses to substitute, the patient will not be reimbursed at all (needs to pay the full price)
(19) Physicians can prevent it by selecting a specific brand which the pharmacist has to dispense.

Tender procedures are widely used in the hospital setting in most European countries. The organisation of tenders varies and can have a national (centralised), regional or individual hospital (facility-based) scope. The procurer can be a national or regional authority or health insurance fund or an individual hospital procurer (on behalf of an individual or a group of hospitals).

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

RESOURCES:
Medicines for Europe Position paper on best procurement practices

PROCUREMENT OF MEDICINES
Hospital tendering

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

(1)They tender in groups and when a company bids the lowest price it is not possible to know which products have been bought by the hospitals, but if products are not in stock then there is a fine
(2) Tenders for national level are carried out by EKAPY, a body under the supervision of the Ministry of Health
(3) Clusters of regions tendering together

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PROCUREMENT OF MEDICINES
Hospital tendering

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
28.To whom are the tenders applied?																													
All pharmaceuticals	✓		✓	✓	✓	✓	✓	✓	✓		✓		✓	✓			✓	✓	✓	✓	✓			✓			✓	✓
Off-patent pharmaceuticals		✓								✓		✓			✓								✓					
Other																												
Comments						1																						
29.How are tendering contracts awarded?																													
By active substance	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓		✓	✓			✓	✓
By therapeutic indications					✓		✓											✓		✓								✓
Other						✓											3											
Comments						2												4										
30.What is the average contract duration of the tender? (in months)																													
Months	12	48	24	12	12-24	36	12	12	24	12	12	24	12	12	36		12	24	12 or 24	24	12		12	12			24	24
Comments																			5									
31.Does a single tender contract allow for more than one winner?																													
Yes		✓								✓	✓	✓		✓					✓	✓	✓			✓				✓
No	✓		✓	✓	✓	✓	✓	✓	✓				✓		✓		✓	✓					✓				✓	
Comments	6	7										8									9							

(1) No hospital in the Czech Republic is able to tender all medicines. The average of pharmaceuticals bought in tenders is between 50-75 %, cheap medicines and medicines for the public part of the hospital pharmacy are often bought directly without tender.
(2) "Inpatient care - MoH and the antimonopoly body prefer to tender by active substance and this process is being increasingly used (but some hospitals prefer to tender by specific brand, especially in biological treatments).
Outpatient care (public part of hospital pharmacy) - mainly tender by specific brands."
(3) By brand name
(4) By therapeutic indications – in selected cases only
(5) Each group makes its own rules
(6) Only exceptionally
(7) It is allowed but seldom used
(8) The three lowest bidders are awarded with percentages of 50%, 30% and 20% respectively of the tender volume
(9) At hospital level (individual or group) it's not allowed more than one winner.

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PROCUREMENT OF MEDICINES
Hospital tendering

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
32.Is there an agreed minimum or maximum volume as a result of winning the tender?																												
Minimum volume								✓					✓				✓											
Maximum volume			✓		✓							✓					✓	✓			✓							✓
None	✓	✓		✓		✓	✓		✓	✓	✓			✓	✓				✓	✓			✓	✓			✓	
Comments								1											2					3				3.1
33.After granting the tender, are prices subject to change before the next tender?																												
Yes			✓	✓				✓		✓					✓		✓			✓				✓				✓
No	✓	✓			✓	✓	✓		✓		✓	✓	✓	✓				✓	✓		✓		✓				✓	
Comments						4		5											6					7			8	
34.Is the winning price from the tender transparent to other competitors?																												
Yes		✓	✓	✓	✓	✓	✓	✓	✓			✓	✓		✓		✓	✓		✓	✓		✓	✓			✓	
No	✓									✓	✓			✓					✓									✓
Comments						9																	10					

(1) It's set as a desired volume, but not limited to this number only and hospitals have the right to exceed this volume
(2) It is tendered on volume but in practice the manufacturer cannot rely on this
(3) Minimum usually not defined but fines might be enforced for stock outs. Sometimes maximum volume is defined.
(3.1) Volumes provided but not guaranteed
(4) It depends on contract conditions
(5) For this, so called mini tenders can be announced, to check if prices are lower or new competitors enter
(6) Companies cannot change with the increase of inflation, if a product is out of stock there is a fine
(7) Only due to reference pricing change
(8) If a company lowers the pharmacy price, the tender price must follow down but not up
(9) Contract parties can agree that specific price is subject to trade secret and will not be publically available.
(10) Only applies to General Insurance Company (VSZP)

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
35.Are factors other than the lowest price considered when determining the winner of the tender?																												
Yes		✓					✓		✓	✓		✓						✓										✓	✓
No	✓		✓	✓	✓	✓		✓			✓		✓	✓	✓		✓		✓	✓	✓		✓	✓				
Comments		1									2	3						4											5

(1) It can be price-only as well
(2) Only in one case. There was one tender with ecological and regional factors
(3) The primary criteria to "win" a tender is based on the lowest price. However, there are prerequisites to participate in the tender bidding such as quality criteria regarding the supplier, i.e. proven record of supply and ISO certification and active MA in the country
(4) Tender specifications
(5) Introduction of "social value" weighting and KPIs on supply performance

PROCUREMENT OF MEDICINES
Retail tendering

In some European countries, namely the Czech Republic, Germany and the Netherlands, tendering is also applied in the retail market.

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
36.Is there a tendering system in place for generic medicines in the retail market?																												
Yes						✓					✓								✓									
No	✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Comments						1							2															
37.What is the geographical scope of the retail tenders?																												
National																												
Regional																												
Hospital (individual or group)																												
Other						3					4								5									
Comments																												
38.Which body is in charge of the retail tendering system?																												
National government																												
Regional government																												
Health insurance funds											✓								✓									
Group of hospitals																												
Individual hospitals																												
Other																												
Comments						6													7									

(1) "There are specific situations in the retail market - several pharmacy chains have a majority in the market share and hundreds of independent pharmacies. Pharmacy chains provide their own tenders according to their own policies (it´s not public procurement)."
(2) Special binding system
(3) Based on the owner of the pharmacy (pharmacy chains)
(4) Number of people insured by the specific sick funds
(5) Health insurers
(6) Based on the owner of pharmacy (pharmacy chains)
(7) Tenders methods differs for each health insurer

PROCUREMENT OF MEDICINES
Retail tendering

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
39.How are retail tendering contracts awarded?																												
By active substance											✓								✓									
Group of active substances																												
By therapeutic indications																												
Other						1																						
Comments																												
40.What is the average contract duration of the tender? (in months)																												
... Months											24								24									
41.Does a single contract tender allow more than one winner?																												
Yes											✓																	
No																			✓									
42.Is there an agreed minimum or maximum volume as a result of winning the tender?																												
Minimum volume																												
Maximum volume																												
None											✓								✓									
43.After granting the tender, are prices subject to change before the next tender?																												
Yes																												
No											✓								✓									

(1) It depends on the pharmacy chain - mainly by active substance or specific brand

Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	UK
44.Is the winning price from the tender transparent to other competitors?																												
Yes																												
No						✓					✓								✓									
45.Are factors other than the lowest price considered when determining the winner of the tender?																												
Yes																												
No						✓					✓								✓									

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