generic medicines

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2025 Market Review Generic Medicines Markets

POLICY OVERVIEW

ACKNOWLEDGEMENTS

COUNTRY	NATIONAL ASSOCIATION/COMPANY	CONTACT PERSON
Austria	OeGV - Österreichischer Generikaverband	Wolfgang Andiel
Belgium	Medaxes	Antoon Daneels
Bulgaria	BGPHARMA	Evgeni Tassovski
Croatia	Croatian Employers' Association – Pharmaceutical Industry Association	Mirela Gudan
Cyprus	Remedica	Andreas Hadjipanayis
Czech Republic	Czech association of pharmaceutical companies	Jana Benová
Denmark	IGL	Peter Jørgensen
Estonia	Sandoz	Roland Lepik
Finland	Finnish Generic Pharmaceutical Association	Heikki Bothas
France	GEMME	Alexandre Soufer
Germany	Pro Generika	Frank Wittkemper
Greece	Pan Hellenic Association of Pharmaceutical Industry	Mark Ollandezos
Hungary	Generic Association	Dora Oros
Ireland	Medicines For Ireland	Paul Neill
Italy	Egualia	Camilla Faletra
Latvia	Egis Pharmaceuticals PLC & Sandoz	Aranka Bonyhadi/ Dagnija Poreitere
Lithuania	VGA	Darius Sinkevicius
Luxembourg	Sandoz	Aline Lescrauwaet
Malta	Sandoz Hellas	Eleni Armelidou
Netherlands	Bogin	Jean Hermans
Norway	Farma Norge	Kjetil Berg
Poland	Polish Association of Employers of the Pharmaceutical Industry	Grzegorz Rychwalski
Portugal	EQUALMED	Ana Valente
Romania	APMGR	Valentina Baicuianu
Slovakia	GENAS	Michaela Palágyi
Slovenia	Sandoz d.d./Lek	Katarina Puh/ Mojca Tramsek/ Damjan Draskovic
Spain	AESEG	Maria Álvarez Fernández
Sweden	FGL: The Association for Generic Pharmaceuticals and Biosimilars in Sweden	Kenneth Nyblom
Switzerland	Intergenerika	Lucas Schalch
UK	Medicines UK	Robert Russellpavier

Pricing & reimbursement system

	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
1. What kind of pricing system is in place for generic medicines (reimbursed)?																														
Free pricing							✓												✓												
Regulated pricing	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Comments	(1)					(2)		(3)			(4)					(5)				(6)		(7)						(8)		(8b)
NEW **2. How often are prices adjusted in your country (months)?**																														
Months	24	12	24	12	12	36		3	3	12	4	12	3	1	24	3-12	6	6		6	60	3	3	12	12	2	12	12	36	18-24
Comments																(9)									(10)			(10b)		(10c)
NEW **3. When price adjustments occur, can prices be revised upward, or only downward?**																														
Prices can only decrease												✓	✓				✓						✓		✓		✓	✓		
Prices can increase and decrease	✓	✓	✓					✓										✓			✓			✓					✓	✓
In theory, prices can increase, but in practice, they rarely do	✓			✓	✓	✓		✓		✓	✓			✓		✓				✓		✓			✓	✓		✓		
Other									(15)						✓					(21)										
Comments	(11)				(12)	(13)		(14)				(16)		(18)	(19)			(20)		(22)		(23)			(24)		(25)	(26)		(27)

(1) Generic reimbursement pricing is governed by the General Social Security Act (ASVG).
(2) In general all reimbursed medicines are regulated. There can be exception - list of ATC group stated in MoH decree. These ATC groups are deregulated - it means that product has to announce maximum price (increase onetime per quarter, decrease every month). General rule for listing ATC group as deregulated:- at least 4 brands in ATC group and specific route of administration - public interest (very vague term)
MoH decree is going to be updated by spring 2025
(3) Reimbursed prescription drug prices are nationally regulated. (The prices of over-the-counter and non-discounted medicines are not regulated, their pricing is free.) The list of reimbursed medicinal products is amended regularly, once per quarter (on 1 January, 1 April, 1 July and 1 October), simultaneously with the adjustment of reference prices.The patient has to pay a prescription fee of 3.5 euros for each prescription medicine.
(4) 2 systems (in addtion) with each covering 100% of Gx. 1. rebate contracts <-> obligation for pharmacist to choose one of the 4 cheapest drugs (no rebate contract). 2. price freeze vs. internal reference pricing
(5) Generic price regulation: International Reference Pricing (IRP) Mandatory price cut vs originator
(6) In the NL we have a pricelaw (WGP 1996) with reference country prices to France, Belgium, UK and Norway. Due the choice of NOT EU countries we cannot compare prices but we compare exchange rates. By choosing opportunistic price-lists in the reference countries, the prices in the NL are lower than ALL the reference countries. We also have a reimbursement system (GVS 1996). That works like a prices system.
(7) First generic/biosimilar applying for reimbursement must have lower price – at least 25% (mandatory, according to reimbursement law) in comparison to current price of the only one product being reimbursed
(8) The prices of reimbursed generics must be 20% to 70% lower than those of the originator product upon market entry, and 40% to 70% lower following the triennial price review of the originator, conducted every three years by the Federal Office of Public Health (FOPH). The exact percentage depends on the Swiss market volume of the INN of the originator (and co-marketing articles) for market entry and on the Swiss market volume of the INN of the originator (and co-marketing articles) as well as generics for the triennial price review.
(8b) UK has freedom of pricing with unbranded generics, and for branded generics and biosimilars, there is a limit agreed with Government as to how much can be charged to pharmacists and hospitals.
(9) The National Health Service shall make changes in the list of reimbursable medicinal products which cause a change in the reference price for medicinal products and medical devices included in List A of reimbursable medicinal products four times a year - on 1 January, 1 April, 1 July and 1 October. Yearly review by international reference pricing, the prices in reference countries must be submitted to the National Health Service electronically every year by February 1.
(10) Monthly for the reimbursed drugs more than 36 month, and plus 6 monthly for the reimbursed drugs to 36 month.
(10b) In case of Switzerland every 36 months as part of the triennial price review. Ther regular price review which is done by the FOPH takes place all 3 years for one third of the product categories. So finally every product list reviewed every three years. But there is obviously a review every years taking place for ⅓ of all products which are included in the reimbursement list.
(10c) Drug sale prices in primary care can vary daily, but in hospital sales there are tenders, and these contracts usually last for 18-24 months.
(11) Three months after the first generic drug enters the market, the original brand-name drug must lower its price. When the third generic drug enters, all reimbursed generics and the original brand-name drug must match its price after three months. The MAH can apply for a price increase, which the reimbursement authority may approve for medical necessity or sustainable supply. After a price increase, prices are frozen for 24 months. Price decreases can occur at any time. Every two years, the Priceband-Regulation sets prices to a maximum of 20% above the cheapest product with the same API, with the lower threshold being the ex-factory value of the prescription fee.
(12) Prices in Cyprus are affected from reference countries and based on a basket of reference countries which are Expensive countries (Austria, Germany, Denmark), Middle countries (Belgium, Spain, Italy, Sweden) and cheeps countries (France, Greece, Portugal)
(13) Prices changes depend on external reference prices so if there is increase of price there could be increasing of Czech maximum price
(14) No legislative restrictions for price increase, but in practice rare occasions authorities agree with price increases; these are mostly related to limited competition and supply issues.
(15) Rerefence prices are set every three months. The maximum reimbursement prices cannot be increased in practice.
(16) In 2024, an ad-hoc increase was decided for a ~100 old products, that were on the verge of withdrawal due to the continious price decreases and the extreme clawbacks.
(18) Industry agreement in place that outlines downward only pricing policy - there is a mechanism to apply for an increase for a product that is no longer economically viable, this involves the submission of a full transparent and costed business case. There are no clear timelines for a decision and little or no communication on the progress towards decisions.
(19) Prices are never adjusted. Only prices for non-reimbursed medicines can be adjusted (increased) by the industry, specifically every 2 years in odd years. exceptions are cases in which the association requests a price increase for particular products. For what concerns reimbursed medicines prices tend to be aligned to the lowest priced generic medicine, so slowly tend to decrease over the years. For reimbursed medicines industries can ask for price adjustment, through a specific form
(20) If the price in Belgium of a reference changes (increase or decrease) then this needs to be applied in Luxembourg
(21) Not EU countries Norway and UK
(22) We have a big risk by the exchange rate of Norway and UK. the choice of price lists and by the method; not to choose the mediate price but the lowest prices in the reference country. NB due the method the prices of generic are more affected then the prices of specialty.
(23) Reimbursement for the drug is valid for 2 or 3 years after which the price is negotiated (downwards only). It is possible to apply for price increase during the decision but the process is demanding.
(24) During the external referencing there is no possibility to increase the price, even if the average of the 3 lowest prices is higher, than the drug price in the SR.
(25) This is the general annual review. The prices can be reviewed also when new MA enter into the market or any time on request by MAH
(26) In theory, prices can increase, but in practice, they rarely do (needs to go through extensive revision and approval process by FOPH).
(27) Price can go up or down in primary care. In hospital sales, the contract price stemming from tenders can be altered but this happens very rarely.

	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
4. Which criteria is used to set the prices																														
External reference pricing			✓	✓	✓	✓		✓				✓		✓		✓	✓	✓		✓		✓	✓	✓	✓	✓	✓			
Set % below originator price	✓	✓	✓	✓	✓			✓	✓	✓		✓	✓		✓	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓		
Percentage below originator price	50%	**(2)**	30%	30%	20%			30%	50%	60%		65%	40%		20%	30%	30%				70-90%	25%	50%	65%	49%	68%	40%	20%-70%		
Maximum price			✓	✓	✓						✓						✓				✓	✓				✓		✓	✓	
Negotiation				✓						✓											✓	✓				✓				
Other																														✓
Comments	**(1)**							**(3)**	**(4)**		**(5)**	**(6)**	**(7)**	**(8)**	**(9)**	**(10)**		**(11)**						**(12)**	**(13)**	**(14)**	**(15)**	(16)	**(17)**	**(18)**

(1) The first generic drug must be priced 50% below the original brand. The second generic drug must be 18% below the first, and the third generic drug must be 15% below the second. The original brand must reduce its price by 30% three months after the first generic enters the market. Three months after the third generic enters, all products must match the third generic's price. Subsequent generics must be slightly cheaper than the lowest-priced existing generic.
(2) -44,75 -> -68,49
(3) Generic product entry into reimbursement requires 30% lowering of price vs originator. Next entry -10%. In case of biosimilars first biosimilar entry is required -15% lower price, next biosimilar -10%.
Once Gx medicine is already reimbursed- if in list is two medicinal products, then reference price is based on the medicinal product the price of which is lower.
Once Gx medicine is already reimbursed- in the case reimb. list contain three or more same INN products, reference prices are calculated on the basis of the price of the medicinal product with the next lowest price after the product with the lowest price.
(4) To be eligible for reimbursement, a generic medicine must be 60% cheaper than the originator product (before the patent expires). If the medicine includes a delivery device, the generic must be 50% cheaper.
(5) - internal reference pricing (lowest third)- price freeze (maximum price could be exceeded, but then patients have to pay)
(6) Reference product is priced via ERP and the gx are priced at 65% of the reference product
(7) the price of the first product must be 40% lower than the original; the second by 20%, the third by another 10%, the fourth by 5%, and the sixth and seventh entrants must reduce the price by another 5%. After these, no further price reduction is necessary.
(8) External ref pricing for interchangeable products post Gx launch. At the time of launch GX products must be 60% below innovator. Hybrid products must be 50% below the innovator.
(9) Balduzzi Decree voluntary and automatic method to determine the price of a new generic.
(10) 30% for the first one, 10% for the next two and 5% for the following ones, if there are at least 5 drugs in the reference group the price for the next drug can be equal to the cheapest one
(11) In Luxembourg they use the same prices as defined in Belgium.The only difference is the % of VAT.
(12) Set 65 % Below originator price Minimum price or average of the lowest 3 prices in the basket for essential medicines
(13) Regulated price reduction -49% for entering to the market/Reimbursement list.External reference pricing valid for generics.
(14) France, Germany, Austria
(15) There is no specification in the law, so it is usually a 40% below the originator price, but in the last years we are seeing other criterias as other countries prices, market volume...
(16) In relation to the revenue of the original for initial reimbursement, later during every three years price review in relation to the revenue of the active substances. At market entry, the price reduction for generics ranges between 20% and 70% below the originator price. During the regular 3-year price review, the reduction ranges between 20% and 40%, based on the total revenue of the active substance (including the originator and all generics).
(17) When Generics enters the market, they can have the same price as the originator or lower. If price competition starts (prices dorps with more than 70% by competition) the originator must lower their price with approximately 65% 6 months after patent expiry (if they want to stay reimburesd - if they skip reimbursed). That price (-65%) will be the maximum price for generics (and originators). If you are not reimbursed, the pricing are free.
(18) Price can go up or down in primary care. In hospital sales, the contract price stemming from tenders can be altered but this happens very rarely.

	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
5. Countries using external reference pricing (ERP) to set prices: 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)																														
Bulgaria		✓								✓		✓			✓	✓	✓							✓	✓	✓	✓			
Croatia						✓				✓					✓											✓	✓			
Cyprus	✓	✓					✓			✓	✓	✓			✓												✓		✓	
Czech Republic		✓		✓			✓		✓	✓	✓		✓	✓	✓	✓	✓			✓		✓	✓		✓	✓	✓		✓	
Estonia	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	
Greece	✓	✓		✓	✓			✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓			✓		✓	✓	✓			
Ireland	✓			✓			✓			✓		✓	✓			✓			✓				✓			✓		✓	✓	
Latvia						✓	✓	✓					✓				✓		✓			✓		✓	✓					
Lithuania	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓		✓	
Netherlands		✓								✓											✓									✓
Poland	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	
Portugal		✓								✓					✓												✓			
Romania	✓	✓	✓		✓						✓	✓			✓		✓									✓		✓		
Slovakia	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓		✓	
Slovenia	✓									✓	✓																			
UK	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	
6. What is determined using external reference pricing (ERP)?																														
Price for originators (ERP is indirectly applied to generics as it is used to determine the price of originators, which ultimately influences the price of generics)				✓				✓				✓											✓			✓				
Price for generics (ERP is directly applied to generics)			✓	✓		✓											✓							✓		✓	✓			
Benchmarking with other countries					✓									✓		✓				✓		✓			✓					
Comments						(1)		(2)						(3)			(4)								(5)	(6)				

(1) ERP is using for all price settings (originator and generics) and for reimbursement. Only for 1st generic - need of 40 % reduction from originator price
(2) The prices of pharmaceuticals with active ingredients that have a single manufacturer in Estonia are included in the external reference pricing scheme, including the host country of the manufacturer. External reference pricing is conducted using prices from EU, but mainly Latvia, Lithuania, and the Slovak Republic and an annual re-pricing system is in place.
(3) Euripid database is used by HSE to benchmark price for all reference priced products
(4) EU27
(5) Basket of all EU countries.
(6) Both, Ox and Gx

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7. What formula is applied when applying external reference pricing?																															
Lowest price in reference countries			✓					✓						✓						✓		✓		✓						
Average price of reference countries				✓	✓	✓											✓						✓				✓				
Other												✓				✓									✓	✓				
Comments				(1)	(2)	(3)		(4)				(5)		(6)		(7)	(7b)			(8)			(8b)	(9)	(10)	(11)				
8 .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					(12)	(13)		(14)			(15)			(16)			(16b)						(16c)	(17)						(17b)
9. 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	141	150	30	120	90	60		30	29	94	14	150	90	45	110	30-45	40	270		1	30	100	30	90	120	120-180	30	60	30	28
Comments																(18)								(19)				(19b)		(19c)
10. Is a marketing authorization necessary to apply for reimbursement of generic medicines?																															
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
No																					✓									
Comments					(20)	(21)		(22)	(23)		(24)								(25)											(26)

(1) Three countries prices are needed for the calculation and if one of them is 100% higher than other two countries prices, that highest one is excluded from the calculation.
(2) The ERP methodology involves comparing medicine prices in selected reference countries and Cyprus typically uses a basket comprising of one lowest price from high-price country, two lowest prices from medium-price countries and one lowest price from one low-price country. The average wholesale price from these countries serves as the basis for setting the Cypriot price, with an additional 3% markup to account for importation expenses.
(3) Average of the 3 lowest prices
(4) Average price of reference countries. But in practice usually, lowest price has been asked to be implemented by authorities.
(5) Average of the 2 different lowest prices at the Eurozone
(6) We believe the HSE use the lowest reimbursed price in reference countries - however the decision making process is not transparent.
(7) Price is set not higher than the 2nd lowest in the basket countries and not higher than in Estonia and Lithuania
(7b) Average of the 5 lowest prices **(8)** Problem is that you cannot compare prices. for example we, in the NL, pay a fee to the wholesalers. Which is component of the Dutch price.
(8) Problem is that you cannot compare prices. for example we, in the NL, pay a fee to the wholesalers. Which is component of the Dutch price.
(8b) If for hospital Price it is the lowest in external reference countries
(9) Lowest price in reference countries or the average of the lowest 3 in the basket for essential medicines
(10) The average of the three (3) lowest EU prices
(11) % of medicines of highest and lowest price in reference countries (FR, AT, DE).
(12) Price application is via Pharmaceutical Services of the MoH and reimbursement via the Health Insurance Organisation which manages the General Health System of the country
(13) 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 ask for price and reimbursement of already reimbursed product (with same active substance...)
(14) In case of entering into market, reimb and pricing are single process, once already in the market pricing becomes 4 times per year subject of scrutiny
(15) there is no application for pricing, internal reference pricing is a mathematical procedure. In Germany, everything is reimbursed
(16) For Gx products an application is made for pricing approval and once accepted a communication is send by the MAH to the reimbursement service to be added to the PCRS (Primary Care Reimbursement Service) list. In reality this is pretty seamless process.
(16b) In case a substance is in positive list
(16c) It is possible to do it in a single step,i.e., to apply for it as a single form
(17) Reimbursement is automatically granted after price is obtained if the INN is on the reimbursement list already. If the generic medicine brings new indication or new form/concentration, then an HTA process is required and reimbursement process is more complex, not longer automated.
(17b) For unbranded generics, there is freedom of pricing. For branded generics and biosimilars, the manufacturer needs to inform the Government what the maximum selling price will be prior to launch, and in some cases, the Government will seek an adjustment.
(18) decision not later than within 60 days after registration of the application
(19) 90 days for more 95% submissions (those having INN included in the List). When an HTA process is required timeline is prolonged to 1-2 years.
(19b) 60 days (from initial submission of the application to the FOPH until the approval of P&R)
(19c) A manufacturer must within at last 28 days of a new launch let the Government know of the planned launch and propose a maximum selling price limit.
(20) There are exceptions in case of long-term shortages and there is no other molecule to replace it for a specific use/therapy
(21) In general it´s neccesary. There are some exceptions in case of urgent need.
(22) To increase attractiveness of market and competition, authorities has set simplified MAH process to attract parallel trade import into country. Ordinary MAH is 210 days, while simplified MAH only 30 days. Prerequisite for submission of simplified MAH is already registered ordinary MAH in Estonia.
(23) A marketing authorization is a prerequisite for the general reimbursement of a medicine, but even if a medicine does not have a marketing authorization, it can still be reimbursed by Kela (the Social Insurance Institution of Finland) if Kela makes a separate decision on it. This requires that:
- The need for the medicine is medically justified.
- The treatment is essential, and no alternative authorized medicine is available.
- Kela approves the medicine for reimbursement based on an individual application.
(24) If there is marketing authorization the manufacturer can set the price (not apply)
(25) Not applicable. There is no reimbursement system in Malta.
(26) Not relevant. No reimbursement sought

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11. Is there an internal reference pricing reimbursement system (like jumbo groups) for generic medicines in your country?																														
Yes	✓	✓	✓	✓	✓	✓			✓		✓	✓	✓		✓	✓	✓			✓		✓	✓	✓	✓	✓	✓			
No							✓	✓		✓				✓				✓	✓		✓							✓	✓	✓
Comments		(1)			(2)	(3)		(4)				(5)		(6)		(7)			(8)					(9)					(10)	
12. How is the reference group established?																														
By active substance (ATC-5)	✓	✓	✓		✓				✓		✓		✓	✓	✓	✓	✓			✓			✓	✓	✓	✓	✓			
By pharmacological class (ATC-4)					✓						✓	✓	✓														✓			
By therapeutic class (ATC-3)				✓							✓																✓			
Other		✓			✓	✓																✓								
Comments		(11)			(12)	(13)			(14)			(15)										(16)								

(1) We have clusters per INN, strength and comparable pack sizes
(2) Cyprus utilizes an IRP system for reimbursing generic medicines within its General Healthcare System (GHS). This system clusters medicines with the same active ingredient into reference groups, often based on the Anatomical Therapeutic Chemical (ATC) classification at level 4 or 5. Within each group, the lowest-priced medicine sets the reference price, which is fully reimbursed by the Health Insurance Organisation (HIO). If a patient opts for a more expensive alternative, they are responsible for paying the difference between the medicine's price and the reference price.
Additionally, generic substitution at the pharmacy level are permitted and pharmacists are encouraged to dispense the cheapest available medicine with the same active substance and pharmaceutical form.
(3) Jumbo group means therapeutically interchangeable medicines with similar clinical effect
(4) Internal referencing is based on INN purely, No jumbo groups with different INNs.
(5) ATC4 level
(6) not sure what is meant by this - there is an external reference price mechanism as outline on the earlier questions - there is no internal reference price for customers that is not aligned with the national reimbursement prices.
(7) Mandatory price reduction for generic vs originator (30% for the first one, 10% for the next two and 5% for the following ones, if there are at least 5 drugs in the reference group the price for the next drug can be equal to the cheapest one). Extra limitation for price increasing: price difference between cheapest and most expensive product in cluster cannot exceed 60%
(8) Not applicable. There is no reimbursement system in Malta.
(9) There are several reimbursement lists: A and B use a quartile system (jumbo groups) List C use only the lowest price within an INN who sets the reference price
(10) Depends on the definition of reference pricing . Sweden had a reference price system between 1994-2002. From Oct 2002 there is generic substitution but no longer reference price system . 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 .
(11) ATC5, strength, comparable packsize
(12) Cyprus utilizes an IRP system for reimbursing generic medicines within its General Healthcare System (GHS). This system clusters medicines with the same active ingredient into reference groups, often based on the Anatomical Therapeutic Chemical (ATC) classification at level 4 or 5. Within each group, the lowest-priced medicine sets the reference price, which is fully reimbursed by the Health Insurance Organisation (HIO). If a patient opts for a more expensive alternative, they are responsible for paying the difference between the medicine's price and the reference price.
Additionally, generic substitution at the pharmacy level are permitted and pharmacists are encouraged to dispense the cheapest available medicine with the same active substance and pharmaceutical form.
(13) Reference groups are based on therapeutical interchangeability medicines and similar clinical effect- there is MoH decree on reference groups (several ATC7 in one reference group).
(14) Medicines containing the same active ingredient and strength are grouped by package size.
(15) ATC-4 with many exceptions - ATC-4 according to the EDQM criteria (form, dosage, release, strength and indication). Generics of all high-cost medicines (Law 3816) are grouped in ATC-5 category.
(16) by create Limit Group (with the same international name or other international names but similar therapeutic eff ect and similar mechanism of action)13 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 ask for price and reimbursement of already reimbursed product (with same active substance...)

	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
13. 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											✓												(10)							
Comments				(2)	(3)	(4)			(5)		(6)	(8)								(9)				(12)	(13)					
OTHER (Comments)		(1)									(7)												(11)							
14. Are there positive or negative reimbursement lists for generic medicines in your country?																														
Positive list	✓	✓	✓	✓	✓		✓			✓		✓		✓	✓	✓	✓					✓				✓		✓	✓	
Negative List																														
No list						✓		✓	✓		✓		✓					✓	✓	✓	✓		✓	✓	✓		✓			✓
Comments								(14)				(15)		(16)					(17)									(18)		(19)

(1) lowest price per unit (+5%)
(2) The reference price is determined based on the lowest price of the original packaging of the medicine paid by the Insurance Fund, which achieved at least 10% volume share within the reference subgroup, if one has been determined, in a period of six months for which complete data are available. In case that the reference subgroup is not determined, the reference price is determined based on 5% volume share within the reference group.
(3) the reference price for medicines within the IRP system—used for reimbursement purposes—is established based on the lowest-priced medicine within a group of therapeutically equivalent products.
(4) Reference price is lowest price from ERP (all EU members states) of any medicine listed on the reference group.
(5) 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.
(6) complicated process with several sub-processes depending on the 3 groups
(7) average price of lowest third of medicines
(8) Average of the two lowest different prices in the Eurozone
(9) Average reference price
(10) Based on the average of the 5 lowest priced medicines of the same group of active substances
(12) For list C and quartile average for A and B lists
(13) Basket of all EU countries, the average of three (3) lowest EU prices.
(14) No separate positive, or negative lists. Basically Positive list is effective reimbursement list
(15) The vast majority of gx are in the positive lists. However, there are both Positive and Negative lists for all medicines (not only gx).
(16) Once reimbursement is applied for and granted all products appear on the list.
(17) Not applicable. There is no reimbursement system in Malta.
(18) all reimbursed drugs are listed in the specialty list: Spezialitätenliste (SL) - Präparate
(19) There are local formularies which guide prescribers in primary care on what to prescribe, but there are no positive or negative reimbursement lists.

Control of Excess Spending

	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
15. Is there any type of out-of-pocket (OOP) payment that patients must make for generic medicines?																														
Yes	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓				✓	✓	✓	✓			✓	✓	
No						✓				✓									✓	✓	✓					✓	✓			✓
Comments					(1)	(2)		(3)				(4)			(5)	(6)			(7)			(8)				(9)		(9b)		(9c)
16. What type of cost sharing or out-of-pocket payment by patients is used?																														
Fixed amount per prescription/pack (Co-payment)	✓			✓									✓		✓			✓				✓			✓			✓		✓
% Of cost of medicines is partially reimbursed (Co-insurance)		✓	✓						✓			✓				✓		✓					✓	✓						
Patient annual/monthly consumption (DDD)																														
Difference above reference price					✓			✓			✓					✓	✓						✓			✓				
Insurance takes effect when a certain threshold has been reached (deductible)																				✓								✓		
Other							✓				✓			✓															✓	
Comments								(11)	(12)			(13)				(15)						(16)		(17)	(18)					
OTHER (Comments)							(10)							(14)			(14b)												(19)	(20)
17. Do the out-of-pocket payment schemes for generic medicines differ from those for the reference originator medicines?																														
Yes												✓		✓	✓										✓					
No	✓	✓	✓	✓	✓		✓	✓	✓		✓		✓			✓	✓	✓				✓	✓	✓		✓		✓	✓	✓
Comments																														

(1) OTC products are 100% OOP. Rx Gx which are within the list of GHS reimburses up to the reference price. If a patient chooses a higher-priced product (e.g., a brand-name version), they pay the difference out-of-pocket.
(2) There is no obligatory co-payment for any medicines (generic included). Co-payment is subject to the market behavior of MAHs.
(3) Every Rx medicine (applied for both- Gx and Originators) has copayment of 3.5eur as prescription cost, what does not depend on reimbursement level or price of medicine. Beside prescription cost additional co payment may apply based on reimbursement level- eg. 50% case co-payment 50% beside 3.5eur applies same way to Gx and originators, while in 100% reimbursement 3.5eur prescription cost is only co-pay for patient.
(4) Copayment is 10% or 25% depending on the indication. Starting from July 2023, additional co-payments will be put on generics with a retail price higher than the reference price. However the additional copayment for generics cannot exceed the amount of 3 EUR per package.
(5) Regions (21) are allowed to require the payment of a ticket on the medical prescription or pack. Actually 70% of the regions has a copayment ticket. 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
(6) Co-pay if products are not on reference
(7) The correct answer is Not Applicable, since there is no reimbursement system in Malta.
(8) out-of-pocket payment only for medicines in pharmacies; no payment for medicines in hospitals
(9) Only if company decides. Lowest is without co-payment.
(9b) In Switzerland, patients typically pay a 10% co-payment for reimbursed medicines which are listed on the speciality list. However, if they choose a more expensive medicine over a cheaper one without medical justification, the co-payment can rise up to 40%.
(9c) In England, people of working age who work must pay a contribution when they pick up their NHS prescribed medicine from a community pharmacy (around 12 Euros). In Scotland, Wales and Northern Ireland, no charges apply.
(10) Gradual reimbursement. Max yearly expense app. 600 Euro
(11) The patient always pays the part of the price of the drug that exceeds the limit of reference price. Besides 3.5 fixed prescription fee applies. Then in accordance of disease severity partial reimbursement can be applied and depending on that, the total out-of-pocket cost applies- eg. 50%, 75% or 100%
reimbursement with co pay of 50%, 25% and 0% accordingly.

(12) The reimbursement rates for medicines in Finland are based on the severity of the illness and the necessity of the medication. Higher reimbursement rates apply to essential and long-term treatments, while lower rates apply to less critical medications. There are three categories:
1. Basic rate of reimbursement 40%. 2. Lower special rate of reimbursement 65 %. 3. Higher special rate of reimbursement 100% (a copayment of EUR 4.50 per medicine is charged). Patients also have to pay the possible difference above the reference price.
In 2025 the annual maximum is set at EUR 633 after which copayment is EUR 2.50 for each reimbursable medicine.
(13) Three types of OOP are simultaneously applied: 1) 0% or 10% or 25% of the reimbursement price of the product. The reimbursement price is calculated at the positive list. 2) the difference between the product's retail price and the reimbursement price. For generics this amount cannot exceed 3 EUR. 3) The amount of 1 euro per prescription (applies to all reimbursed medicines at the retail channel)
(14) Monthly medicines threshold for all medicines for families that do not qualify for state provided healthcare. once threshold is meet all excess is state funded. For state funded patients (GMS card holders) then all medicines are free however patients pay a dispensing fee for each item dispensed.
(14b) Max copayment for medicines if there is 1 producer in the substance is 5.87 eur max copayment for medicines if there is 2 and more producers in the substance is 25 % of reference price
(15) 100%: chronic, life-threatening diseases or diseases causing irreversible disability where medicines ensure and maintain the patient's life functions. Medicines are fully reimbursed for in-patient care. 75%: chronic diseases or diseases causing disability where medicines maintain or improve the patient's health; 50%: chronic or acute diseases where medicines are necessary to improve the patient's health, vaccines
For children up to age 18 and low income persons the pharmaceuticals included in the Positive list are 100% reimbursed except when more expensive, not the reference (cheapest) product is prescribed, patient pays the price difference. Prescription-only medicines not included in the positive list are reimbursed for children aged up to 24 months (reimbursement rate 50%) and for pregnant women and women within 70 days of postnatal period (reimbursement rate 25%) + prescription fee
(16) Fixed amount per pack for medicines in the pharmacy; no payment for medicines in hospitals
(17) For A and B lists.There are 90% and 50% for the average quartile
Difference is covered by the patient as co-payment. For C list reimbursement level is up to 120 % for the lowest Price within INN.
(18) For drugs where fixed co-payment is not defined by rules, then ratio between reimbursement and co-payment should be kept.
(19) 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 months period this system starts all over again.
(20) This only applies in England to working age people who work and when picking up an NHS prescription from a community pharmacy.

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18. Which of the following measures are applied in your country in the case of excess spending in the pharmaceutical budget?																														
Mandatory price reductions and rebates											✓	✓		✓							✓									
Mandatory price reductions and rebates percentage:											(1)	(2)		(3)							90%									
Clawback/payback		✓	✓	✓	✓			✓		✓		✓	✓	✓	✓	✓	✓					✓		✓	✓		✓			✓
Generics are exempted											✓															✓				
Other: Please specify	✓	✓	✓	✓		✓	✓		✓							✓		✓	✓	✓			✓	✓					✓	
Comments	(4)							(11)	(12)			(15)		(16)					(19)		(21b)	(22)	(23)	(24)						
OTHER (Comments)	(5)	(6)	(7)	(8)		(9)	(10)		(13)		(14)					(17)	(17b)	(18)	(20)	(21)					(25)				(26)	(27)
19. If you mentioned that clawback/payback is applied, how is the target spending determined?																														
Global pharmaceutical target budget		✓			✓					✓												✓								
Segmented pharmaceutical target budget (e.g., hospital vs retail or innovator vs off-patent)												✓	✓		✓	✓														
Pharmaceutical expenditure growth rate			✓																											
Other				(28)				(29)			✓	(33)		✓			✓							✓	✓		✓			✓
Comments								(30)						(34)			(34b)													
OTHER (Comments)								(31)			(32)													(35)	(36)		(37)			(38)

(1) 6% und 10%
(2) 14- 30% of the ex-f at the reimbursement retail channel / 5% of the hosp.price for High Cost and hospital products
(3) no set percentage
(4) No respective measures applied.
(5) not applicable
(6) Saving measures (mandatory price decreases)
(7) 100% Clawback
(8) Therapeutic referencing and lowering the prices to the rule from by law.
(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´s on MAH and health insurance companies what is real form and amount of payback in these agreements.
(10) None
(11) Claw-back is based on contract with government and usually related to originators and bio products, not Gx Rx
(12) Several cost-saving measures have been implemented in the last 15 years (including e.g. mandatory price reductions)
(13) In Finland, there is no predefined budget for pharmaceutical expenses.
(14) Generics are partially exempted.
(15) Basic rebate range from 14 to 30% of the ex-factory price depending on the sales volume of each trimester. Additional rebates of 3% or 5% according to the product characteristics (e.g. High Cost Medicines, products in exclusive ATC-5 sub-clusters, products at the most costly ATC-4 categories. Note that products with DTC <0.2 EUR, and products in negotiation agreement are excluded from the additional rebates
(16) there is mandatory clawback on al branded innovative products - this is regardless of budgetary overrun
(17) There are budgets for the prescribing of reimbursable medical products allocated for physicians who have agreements with the NHS.
(17b) Claw-back is based on contract with government and usually related to originators.
(18) not applicable
(19) There are no such measures in Malta
(20) not applicable
(21) It never happens...
(21b) Payback/clawback policies require manufacturers to pay back a share of their revenue if a pre-specified budget ceiling for public pharmaceutical expenditures is exceeded.
(22) applies only to medicines in pharmacies
(23) Extraordinary Contribution for the Pharmaceutical Industry. 14,3% in hospital and 2,5% in retail. applies to all generic sales and it is not linked to an excess spending of the pharmaceutical budget.
(24) Clawback policies require manufacturers to pay back a share of their revenue if a pre-specified budget ceiling for public pharmaceutical expenditures is exceeded.
(25) Clawback/payback,Other (Please specify) - National legislation defines clawbacks for MEA, but it is not implemented successfully in practice.
(26) All pharmacies must dispense the substitutable product with the lowest price. This works very well and is an effective way to reduce cost. Budget restrictions is not necessary.
(27) A clawback exists for branded generics and biosimilars of 10%-35%, depending on the level of reduction in the sale price against the originator pre-loss of exclusivity.
(28) Spending in the respective therapeutic area and related to originators. Managed entry agreements with percentage of payback is from 5% to 25%.
(29) Yearly sales are determined in contract with government. It's not a specific percentage
(30) Its not specific % but amount what is exceeding determined turnover limit as set for yearly contract with government.
(31) Brand specific fixed turnover limit
(32) demand-driven system
(33) 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
(34) this is a set clawback rate on branded company medicines which increases over the life of the pricing and supply agreement - Gx companies do not have this clawback mechanism in our agreement
(34b) It's not a specific percentage, it's based on yearly sales.
(35) Clawback is capped and differentiated (25% innovative. 20% imported generics, 15% locally produced). It is applied on the quantities sold in the reimbursement system
(36) Base for payback is sum of sale of product for 12 month before observing period. MoH SR takes a budget on each product reimbursed over 1,5 mio EUR. All sales, over the budget are considered as paybacks to HICs.
(37) Contribution for sales volume
(38) In the UK, branded generic and biosimilar manufacturers now pay a fixed rate depending on the level of reduction they offer against the originator pre-LoE. Ultimately, this links into a wider pricing scheme for branded medicines where NHS drug spending growth is capped.

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NEW **20. If segmented pharmaceutical budget was chosen please specify:**																														
												(1)			**(2)**	**(3)**														**(3b)**
21. How is the clawback/payback calculated?																														
Based on market share					✓							✓			✓	✓								✓						
Based on revenue		✓						✓									✓								✓	✓				
Based on growth			✓																						✓					
Other				✓						✓	✓		✓	✓								✓					✓			✓
OTHER (Comments)				**(3c)**						**(4)**	**(5)**		**(6)**	**(7)**								**(8)**					**(9)**			
22. What is the percentage of the clawback/payback applied to the base selected above?																														
Percentage		6%	100 %	5 - 25%	3%			100 %		60%	6/16 %	25%	20%	9%	18%	1%						50%		15%	-	1%	1,5 % - 2%			
Comments															**(10)**										**(11)**					**(12)**
23. Is there a differentiated clawback/payback for generic medicines compared to the originator?																														
Yes											✓													✓						✓
No		✓	✓	✓	✓			✓		✓		✓	✓	✓	✓	✓	✓					✓			✓					
Comments								**(13)**			**(14)**	**(15)**		**(16)**	**(17)**		**(17b)**							**(18)**	**(19)**		**(20)**			
24. What percentage of the budget overrun is paid back by the pharmaceutical industry?																														
Percentage		100 %	100 %	-	3%			100 %		60%		100 %	100 %	1%	50%	1%	100 %					50%		15%	-		-			-
Comments				**(20b)**											**(21)**									**(22)**	**(23)**		**(24)**			**(25)**

(1) Different budgets for a) Hospital and b) EOPYY, the main SSF The EOPYY budget is further segmented into 2 different budgets i.e EOPYY retail (products from private pharmacies and EOPYY High Cost Medicine dispensed by EOPYYs 32 own pharmacies)
(2) Overrun budget is divided 50% for regions and 50% for industries, but just for hospital channel.
(3) Budget is specified for one active substance or group of active substance per dg
(3b) Yes, a clawback only applies to branded products.
(3c) It depends, in some cases it is a percantage of sales or the difference in price from the therapeutic equivalent on the CHIF list or both combined (mostly for retail products), while in other it is the difference between sales and alocated CHIF budget for a year (mostly for hospital products)
(4) Its calculated based on market share for 70% of the contribution and based on growth for the remaining 30% of the contribution.
(5) fixed clawback (Herstellerrabatt), if lowered by 10% → 6%
(6) based on the extra governmental spending on reimbursed pharmaceuticals compared to what budgeted for the calendar year on the Jan 1 of the respective year. Clawback is calculated based on the % of reimbursement share of MAH
(7) based on the reimbursement price of the medicine
(8) only for products in the pharmacy whose value for the limit group is increasing. The payback depends on the product's share in the limit group and amounts to 50% of the calculated value
(9) Sales volume. The % applied is 1,5% or 2% depending on sales volume (just retail) and it can be reduced by opting into Profarma project
(10) It is not determined, it depends on the overspending value, each year.
(11) % is not defined. National legislation defines clawback, but it is not implemented in practice.
(12) Based on the level of reduction in the sale price of the branded generic or biosimilar compared to the originator list price pre-LoE
(13) Gx medicine do not have claw-back, only originators have that due to budget impact.
(14) Gx: 6% and/or 10% Ox: 7% post AMNOG negotiation (German HTA)
(15) Retail : All products with DTC< 0.2 EUR have a clawback cap up to 10%. Hospital : All products with hosp. price up to 5 EUR are exempted from clawback. From 5.01 EUR to 15 EUR : max. clawback 40%, From 15.01 EUR to 30 EUR : max cb 60%
(16) no clawback on generics
(17) No, the only difference is that generic and off-patent medicines don't contribute for overspending of innovative products.
(17b) Gx medicine do not have claw-back, only originators.
(18) 25% for Ox and 15% for Gx
(19) there's no general clawback settings, but for expensive drugs (original, biologicals) volume agreement could be there.
(20) The difference came from the sales volumes
(20b) Not defined but close to 100%
(21) 50% for hospital channel – 100% for retail channel
(22) 15% for all generics 25% for innovative medicines
(23) not defined
(24) not defined
(25) In totality, suppliers of branded older medicines, including generic and biosimilars, paid back around 10% of the spend on these medicines in 2024. Some exemptions apply to small and mid-sized companies.

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NEW **25. Has the budget overrun increased, decreased, or remained the same over the past few years?**																														
Increased			✓		✓									✓	✓						✓	✓	✓	✓	✓	✓	✓		✓	✓
Decreased		✓																		✓										
Remained the same																														
Don't know				✓		✓				✓			✓			✓		✓												
Other (Please specify)	✓						✓	✓	✓		✓						✓													
	(1)						(2)	(3)	(4)		(5)					(6)	(6b)		(7)											(7b)
NEW **26. Do you have any opportunities to give feedback on governmental decisions concerning the pharmaceutical budget?**																														
Public consultations	✓				✓								✓					✓		✓	✓								✓	✓
Advisory boards or committees		✓			✓			✓				✓						✓		✓	✓								✓	
Industry feedback sessions	✓	✓	✓		✓			✓						✓				✓		✓	✓								✓	✓
Healthcare provider consultations																		✓			✓									
No formal feedback mechanisms				✓		✓			✓	✓		✓				✓	✓		✓			✓	✓			✓	✓			
Other (Please specify)							✓				✓				✓		✓		✓	✓				✓	✓					
OTHER (Comments)							(9)				(10)				(11)		(11b)		(12)	(13)				(14)	(15)					

(1) not applicable
(2) No budget
(3) Budget overrun is only brand related, not as industry, therefore not known to others
(4) Pharmaceutical reimbursement expenses have been increasing over the past seven years.
(5) demand-driven system
(6) Differs from new product entries, price decrease and patient increase
(6b) Budget overrun is only brand related.
(7) Not applicable. There is no such system in Malta. The tendering system is used to keep the prices as low as possible by stimulating very aggressive competition.
(7b) The budget overrun has increased in recent years, because of the growth of patented medicines. Off-patent branded medicine clawbacks have now been delinked from the growth in patented medicines.
(8) As we have no targeted the question is not applicable. Of course, as everywhere, healthcare costs are increasing which is a big concern
(9) No budget
(10) Demand-driven system
(11) As a national association we give feedback on governmental decisions, proposing new mechanisms to improve our position in the pharmaceutical sector. This happens through appointments with parliamentarians or participation in technical round tables
(11b) Provide feedback through meetings and roundtables with parlimentarians.
(12) No. The Health Department Budget is allocated by the Central Government and covers the purchase of medicines and medical devices.
(13) we have a lot of working groups
(14) No formal public consultation, but with every stakeholders meeting and media events we make comments re budget
(15) In general, the official comments might be provided via Association level.
(16) Once again, we have no fixed budget target therefore the question is no applicable

Hospital tendering

	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
27. Is there a tendering system in place for generic medicines in the hospital market?																														
Yes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
No																														
Comments								(1)						(2)						(3)				(4)						
28. What is the scope of the tenders?																														
National			✓	✓	✓		✓	✓		✓		✓	✓			✓	✓	✓	✓		✓	✓	✓	✓						✓
Regional	✓								✓	✓		✓			✓												✓		✓	
Hospital (individual or group)	✓	✓	✓	✓		✓		✓		✓	✓		✓	✓	✓	✓	✓			✓		✓	✓	✓	✓	✓	✓	✓		
Other																														
29. Which body is in charge of the tendering system?																														
National government			✓	✓	✓			✓		✓			✓			✓	✓	✓	✓		✓	✓	✓	✓		✓				✓
Regional government							✓					✓			✓												✓		✓	
Health insurance funds								✓					✓																	
Group of hospitals	✓	✓				✓			✓	✓	✓							✓		✓		✓		✓	✓		✓	✓		
Individual hospitals	✓	✓	✓	✓		✓		✓		✓	✓		✓	✓		✓	✓			✓		✓	✓	✓	✓		✓	✓		
Other							✓						✓												✓					
Comments																														
OTHER (Comments)							(5)					(6)	(7)												(8)					
30. To whom are the tenders applied?																														
All pharmaceuticals			✓	✓	✓	✓	✓	✓	✓		✓		✓			✓	✓	✓	✓	✓		✓	✓	✓		✓	✓	✓	✓	✓
Off-patent pharmaceuticals	✓	✓								✓		✓		✓	✓						✓				✓					
Other																														
Comments						(9)								(10)		(11)													(12)	

(1) Hospitals run their tenders and State sick fund also run tender for hospital usage for Gx medicine
(2) Adhoc - not national
(3) We have 105 hospitals and they tender in 7 hospital groups. But there is no obligation to buy the medicines that won the tender....
(4) Yes, however it is not tailored for generics only.
(5) Amgros
(6) EKAPY which is the National Authority for Health Care Procurement, a body under the supervision of the MoH
(7) University clinics
(8) General HIC has central purchasing in place but only for selected molecules.
(9) But we know that no hospital in the Czech Republic is not able to tender all medicines.
The average of pharmaceuticals bought in tenders is between 50-75 % and cheap medicines and medicines for public part of hospital pharmacy are often bought directly without tender.

(10) adhoc - not all hospitals and not all products
(11) Centralised procurement is organised by the NHS for the purchase of the following pharmaceuticals and medical devices: (1) peritoneal dialysis, (2) vaccines, standard tuberculin and syringes (3) parenteral chemotherapy medicines (4) and the treatment of phenylketonuria and other genetically- determined diseases. Health care institutions themselves organise the procurement of pharmaceuticals and medical devices that are not purchased centrally.
Hospital pharmaceuticals are purchased according to the Public Procurement Law. Procurement is the sole pricing policy for pharmaceuticals and medical devices used in hospitals. Procurement is mainly organised by using open tendering procedures. Minor purchases are made after requesting quotes.
(12) All pharmaceuticals that are often used. There are no tenders on low volume products.

	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
31.How are tendering contracts awarded?																														
By active substance	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
By therapeutic indications							✓									✓														
Other						✓															✓									
Comments						(1)													(2)	(3)	(3b)	(4)								(4b)
32. What is the average contract duration of the tender?																														
Most common period is ___ months	12	24	24	6-12	24	36	12	12	24	12	12	24	12	24	36	12	12	24	24	24	36	24	12	12-48	12	12	12	12	24	18-24
Comments																								(5)						
33. Does a single tender contract allow for more than one winner?																														
Yes							✓			✓	✓	✓	✓								✓	✓	✓					✓		✓
No	✓	✓	✓	✓	✓	✓		✓	✓					✓	✓	✓	✓	✓	✓	✓				✓	✓	✓	✓		✓	
Comments																			(11)											
YES (Comments)					(6)		(7)	(8)				(9)	(10)								(11b)	(12)	(13)							
34. Is there an agreed minimum or maximum volume as a result of winning the tender?																														
Minimum volume		✓	✓					✓									✓	✓	✓		✓			✓						
Maximum volume					✓							✓											✓	✓						
None	✓			✓		✓	✓		✓	✓	✓		✓	✓	✓	✓				✓		✓			✓	✓	✓	✓	✓	
Comments		(15)						(16)					(17)			(18)	(18b)	(19)	(20)			(21)		(22)	(23)	(24)				(25)

(1) Inpatient care - MoH and antimonopol body prefer to tender by active substance and this process is increasingly used (but some hospitals prefer to tender by specific brand, especially in biological treatment). Outpatient care (public part of hospital pharmacy) - mainly tender by specific brands.
(2) Mainly by active substance. In selected cases only, by therapeutic indications.
(3) Lowest price only
(3b) Price 25%. Environment 30%. Other 4 %.
(4) For some products, it is possible to vary the indications between products. In such cases, the tender conditions may also specify an indication
(4b) By active substance, then lines on the basis of strength, pack size and form are awarded within that active substance
(5) It is dependent on the therapeutic area. Longer contracts are usually the ones organised by hospitals and not the Ministry of Health, and they can be a barrier for entry to market for biosimilar medicines
(6) Not for the same substance but in case there are more than one substance in the same announcement of the tender.
(7) Very seldom
(8) There can be rare cases separate lines for originator and Gx product. Mostly used in specialty care and bio field.
(9) three lowest bidders are awarded with percentages of 50%, 30% and 20% respectively of the tender volume
(10) Yes - in case of common Gx products. No- in case of molecules in national tenders (e.g. some of biosimilars)
(11) No unless the tender is split into lots - In that case, each lot is treated like a small tender and each lot is awarded separately and may or may not be awarded to the same supplier. Tenders with lots are not very common (< 10% of tenders). However, each lot is a different dose so there is only 1 winner per molecule/dose combination.
(11b) When the market is huge
(12) There are tenders where the contract is divided into packages. Then there is one winner for each package.
(13) Usually 2 or 3
(14) Normally not
(15) In theory, both max and minimum volume, but in reality these are not always taken into account and often not met
(16) Its set as desired volume, but not limited to this number only and hospitals have right to exceed this volume
(17) in case of hospital tender, no maximum; there is maximum volume in case of national tenders
(18) Not sure
(18b) In theory both but in practice often not met.
(19) Min volume of 70%
(20) Minimum volume 80%, maximum volume up to 200%. Percentages are related to the published tender quantities. The Government is bound to purchase at least 80% of the published quantity. If there is an increase in demand, the Government has the right to purchase up to double quantity.
(21) contracts define delivery quantities in accordance with demand
(22) Minimum and maximum volumes are stipulated in the contract, however hospitals order based on their needs and there is no enforcement of these limits. If lower volumes or no volume is requested there is no way for companies to request compensation
(23) No volume guarantee
(24) Volumes based on PY usage +- 30%
(25) There is an estimated volume, but contractors suppliers must fulfil the reasonable demand that occurs over the contract, or face penalties

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NEW **35. If there is an agreed minimum or maximum volume as a result of winning the tender, is there flexibility to adjust this volume during the contract period?**																														
Yes		✓			✓		✓										✓	✓			✓					✓		✓		
No	✓		✓					✓					✓	✓	✓								✓		✓				✓	
Not sure											✓	✓				✓				✓										
Comments					(1)		(2)												(3)						(4)					✓
36. After granting the tender, are prices subject to change before the next tender?																														
Yes			✓	✓	✓			✓		✓					✓					✓		✓	✓			✓				
No	✓	✓				✓	✓		✓		✓	✓	✓	✓		✓	✓	✓	✓		✓				✓		✓	✓	✓	✓
Comments		(5)		(6)	(7)	(8)		(9)														(10)				(11)			(12)	
37. Is the winning price from the tender transparent to other competitors?																														
Yes		✓	✓		✓	✓	✓	✓	✓		✓	✓	✓		✓		✓	✓	✓			✓	✓		✓	✓			✓	
No	✓			✓						✓				✓		✓				✓	✓						✓	✓		✓
Comments					(13)	(14)		(15)	(16)							(17)									(18)					(18b)
38. Are factors other than the lowest price considered when determining the winner of the tender?																														
Yes				✓			✓		✓	✓	✓	✓						✓	✓		✓	✓					✓	✓	✓	
In specific circumstances	✓	✓												✓						✓										
No			✓		✓	✓		✓					✓		✓	✓	✓						✓	✓	✓	✓	✓			✓
Comments	(19)	(20)		(21)		(22)	(23)		(24)			(25)		(26)				(27)	(28)	(29)	(29b)	(30)		(31)			(32)		(33)	(34)

(1) The flexibility is for the government to buy less but not more from the awarded volume since is a non-binding contract
(2) But only by the procurer
(3) The flexibility is only from the buyer's end
(4) No volume guarantee
(5) In case of mandatory price decreases, some hospitals demand a further reduction in price
(6) Only if reimbursed (or maximum approved) price drops below tender price for the concerned product.
(7) only in the case that the w/s price will decrease below the awarded price
(8) It depends on contract conditions - it´s on contract parties. (we are not sure about meaning of question)
(9) For that so called mini tenders can be announced, to check if prices are lower or new competitors enter
(10) a change in price may result from a change in the financing limit
(11) They can change based on reference pricing.
(12) Ok to lower the price but not ok to increase the price during a tender period.
(13) in case a company loses the tender, government informs the participants for the price and name of the winner
(14) Generally yes - Contract should be published in contract register. In reality contract parties can agree that specific price is subject to trade secret and will not be publicly available.
(15) Only after opening envelopes winning price becomes known to other bidders. But bidders are wholesalers, not pharma company's themselves
(16) Concealing prices is rare, but there have been some isolated cases.
(17) Not sure
(18) Only applies to General Health Insurance Company (owned by state)
(18b) No. Though losing bidders do get feedback as to how far they are away from the winning bid as a range.
(19) Other criteria were applied only in very few cases. E.g. a plan to ensure availability was required.
(20) Price is almost always the main criteria, but points are also awarded to handling and other MEAT-criteria. For tenders in biologicals, there is a royal decree that forbids anti-competitive elements in the determination of other elements than price
(21) Qualitative criteria: delivery time, environmental ISO.
(22) We are working on changing this practice (MEAT criteria).
There is methodology for directly managed hospitals (the biggest one) that also other factors should be involved in tenders but reality is still not very favorable to other factors
(23) Sometimes availability or green criteria. Varies
(24) In addition to the lowest price, factors such as quality and patient safety may be considered. Essential differences between the compared products in terms of ease and speed of preparation and use are also taken into account.
(25) he 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
(26) supply constraints
(27) Some product characteristics, quality, supply.
(28) Tender specifications are given priority. For example, if they ask for a scored tablet and the cheapest product is not scored, it is disqualified. Nature of pack – blister packs are given priority over HDPE bottles.
(29) Availability, ESG but no transparency in weighing
(29b) Environment. Supply and other soft factors
(30) Price may not be the only factor, which is determined by law. The most common other criterion is payment terms.
(31) Generally minimum prices is considered, however there are hospitals who organize tenders for innovation only (although with patent lost)
(32) There are other valuable factors as some characteristics or features, logistic points (aggregation)... However, price is the most valuable factor
(33) Environmental criteria
(34) No. But this will change for new tenders let from over the course of 2025.

	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
NEW **39. What is the lead time from the contract being signed until the first supply of medicine is expected?**																														
	2	3	3	7	3	3	1	6	1	1	2	100	1	1	1	1	1	1	16	4	9	1	15		6	45	3	3	4	16
Comments				**(1)**					**(2)**															**(3)**						**(4)**
NEW **40. Do you have any opportunities to give feedback when the tender is being designed?**																														
Yes				✓			✓		✓						✓			✓		✓	✓	✓		✓		✓			✓	✓
Other stakeholders are consulted but not industry								✓						✓																
No	✓	✓	✓		✓	✓				✓	✓	✓	✓			✓	✓		✓				✓		✓		✓	✓		
Comments					**(5)**	**(6)**		**(7)**								**(8)**			**(9)**			**(10)**								

(1) In average 3 months, but the time period can vary from 2 months to 1 year as the tender clients initiate procurement procedures in different periods during the year.
(2) Lead times vary, but the delivery must usually begin very soon after the decisions are announced.
(3) Few days
(4) 16 weeks stated, but can often be less.
(5) But in some case that there are challenges in supply chain and/or production and there is only one company that has the specific substance
(6) The association does not comment on the tenders. But MAHs can provide comments after the tender is publicly available.
(7) As wholesalers can enter tenders by law, then these are counterparts
(8) not sure
(9) Comments related to the previous question (Q38): 16 weeks from date of the first order. This can be placed on the date of signing or at a later date according to the needs of the customer. Subsequent orders have a 10 week lead time.
(10) the tender procedure includes a consultative stage and may change the terms of the tender

Retail tendering

	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
41. Is there a tendering system in place for generic medicines in the retail market?																														
Yes					✓	✓					✓									✓										
No	✓	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Comments						(1)																							(2)	
42. What is the geographical scope of the retail tenders?																														
National					✓						✓									✓										
Regional											✓																			
Hospital (individual or group)																														
Other						✓																								
Comments						(3)																								
43. Which body is in charge of the retail tendering system?																														
National government					✓																									
Regional government																														
Health insurance funds											✓									✓										
Group of hospitals																														
Individual hospitals																														
Other					✓	✓																								
Comments					(4)																									
44. How are retail tendering contracts awarded?																														
By active substance					✓						✓									✓										
By therapeutic indications																														
Other						✓																								
Comments																														
45. What is the average contract duration of the tender? (in months)																														
Months					24	12					24									24										
46. Does a single contract tender allow more than one winner?																														
Yes											✓																			
No					✓															✓									

(1) In Czech Republic we have specific situation in retail market - several pharmacy chains have 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) In other countries some people call the Swedish and Danish system for tender like system . We do not.

(3) based on the owner of pharmacy (pharmacy chains)
(4) Health Insurance Organisation that runs the GHS

	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
47. Is there an agreed minimum or maximum volume as a result of winning the tender?																														
Minimum volume																														
Maximum volume					✓																									
None											✓									✓										
NEW **48. If there is an agreed minimum or maximum volume as a result of winning the tender, is there flexibility to adjust this volume during the contract period?**																														
Yes																														
No					✓						✓																			
Not sure																														
Comments																														
49. After granting the tender, are prices subject to change before the next tender?																														
Yes					✓															✓									
No											✓																			
50. Is the winning price from the tender transparent to other competitors?																														
Yes					✓																									
No						✓					✓									✓										
51. Are factors other than the lowest price considered when determining the winner of the tender?																														
Yes																														
No					✓	✓														✓										
In specific circumstances											✓																			
Comments											(1)																			
NEW **52. What is the lead time from the contract being signed until the first supply of medicine is expected?**																														
					1	1					6									6										
NEW **53. Do you have any opportunities to give feedback when the tender is being designed?**																														
Yes											✓																			
Other stakeholders are consulted but not industry					✓																									
No						✓														✓								✓		
Comments											(2)									(3)										

(1) Brand new: only for Antibiotics and few selected Oncologics there is one EU-slot and two Rest-of-world slots, allowing for less rebates when producing in EU
(2) Only companies, not the associations
(3) All insurers work does it different, no regulation...

Pharmacists' incentives

	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Switzerland	Sweden	United Kingdom
54. Is generic medicines substitution legally allowed?																														
Yes			✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
No	✓	✓		✓																										
Comments		(1)	(2)	(3)				(4)				(5)			(6)									(7)					(8)	(8b)
55. Are there recommendations to substitute generic medicines?																														
Yes					✓	✓	✓	✓		✓		✓			✓		✓	✓		✓		✓	✓		✓			✓		
No			✓																✓					✓		✓	✓			✓
There is an obligation to substitute with economic most advantageous medicine									✓		✓		✓	✓		✓					✓								✓	
Comments						(9)					(10)					(11)						(12)		(13)						(13b)
NEW **56. Which statement describes pharmaceutical 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																✓								✓					✓	✓
Comments								(14)	(15)	(16)						(17)					(17b)	(18)		(19)	(20)		(21)		(22)	(23)

(1) Only in case of medicine shortage or in emergency situations
(2) With the doctor's permission
(3) Only in cases where there is shortage of concerned medicine in place, pharmacist is allowed to substitute the product for the other with the same or lower price.
(4) Legally its INN based e prescription
(5) unless the physician states differently
(6) ticking the box non substitutable but they have to motivate it among a restricted number of choices defined by the guidelines of the MOH
(7) No specific recommendation but they can be substituted.
(8) ...and mandatory
(8b) Yes, for unbranded medicines prescibed. Where a doctor makes a choice of a specific product, the pharmacist must dispense this version.
(9) If there are more medicines in same ATC7 group, then pharmacist has to offer the medicine with the lowest co payment.
(10) obligation to dispense one of the four cheapest Gx
(11) community pharmacists are obliged to dispense lowest price's medicines of equivalent therapeutic efficacy to patients
(12) There is an obligation to inform patients of the possibility of substitution with a more economic generic
(13) No specific recommendation but they can be substituted.
(13b) Pharmasists are free to choose the version to dispense if the GP prescribes in the generic / INN name. But no recommendations as such.
(14) Physicians can also write the brand, but then need to give explanation into patient story, why substitution isn't allowed
(15) Patients that refuse substitution will have to pay the difference to reference price.
(16) if patients refuse, they pay the difference
(17) Medical doctors must prescribe just indicating the INN name of the active ingredient instead of the brand name; community pharmacists are obliged to dispense lowest price's medicines of equivalent therapeutic efficacy to patients. Doctors are left a 30% free choice to prescribe branded pharmaceutical products, provided they justify it from the medical point of view.
(17b) Patients can refuse, but must pay price differences
(18) Physicians can prevent this, but they must note the reason in the documentation
(19) Pharmacists and patient agree on the product
(20) Rules defined by national Drug Law 362/2011
(21) Patients can refuse
(22) Pharmacists can also refuse (but only for medical reasons).
(23) Pharmacists are financially incentivised to dispense the most affordable version where the doctor prescribes generically and doesn't state a particular brand.

generic medicines

better access. better health.

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