EURORDIS Working paper

The impact of the economic crisis and cost-containment measures on European citizens' health

The case of rare diseases

In this document:

- *An introduction: the onset of the crisis in 2008 and how European States were hit, how they decided to reduce public spending on health to diminish their deficits;*
- *Facts that suggest or show an impact of the crisis and of the measures to control the public deficit in the general population (on mental health, suicides, communicable diseases);*
- *A special focus on the situation of patients in Greece and Ireland;*
- *An analysis of some medicines with diverging reimbursement opinions for some orphan products, as an illustration of HTA methods and conclusions that vary from one country to the other, with consequences on the access to treatments;*
- *Country cards, with:*
    - *Information on health expenditure, characteristics of some policies to contain pharmaceutical costs (external reference pricing, health-technology assessment, public tendering, generics, co-payment…),*
    - *Main measures adopted to contain these costs*
    - *Questions to National Alliances to document on the impact of the crisis and of the economic measures from the patients' perspective;*
- *All sources of information contained in this working document;*
- *A glossary of all terms used in this document.*

Introduction

The financial and economic crisis hit European countries starting 2008 but with different waves, depending on the level of connections with US banks and the domino effect.

Since the onset of the crisis in 2008, some countries have made considerable efforts to absorb health budget reductions by reducing the cost of publicly financed services (e.g. the price of pharmaceuticals and public sector salary levels), thereby protecting access to needed services. However, other policy changes such as the closure of facilities, reductions in staffing and reduced opening times, as well as higher user charges, can be expected to restrict access. By deterring access to timely and effective care, these changes are likely to incur greater financial and human costs, for example by increasing the risk of amputations, blindness or renal failure among people with diabetes or suicides among those with mental health problems (MCDAID D, forthcoming 2013).

Table 1 shows the reduction in public health expenditure per capita from 2008 to 2011 that highlights countries which had the most pronounced reduction.

Table 1: Countries with a reduction in per capita public spending on health (national currency units), 2008–2011 (Sarah Thomson, 2013). Source: Authors' calculations based on WHO National Health Accounts: http://www.who.int/nha/en. Note: Countries shown in bold experienced reduced spending in more than one year.

2008	2009	2010	2011
Andorra	**Andorra**	Albania	**Andorra**
France	Bulgaria	**Armenia**	**Armenia**
Luxembourg	**Croatia**	**Croatia**	**Czech Republic**
Malta	**Estonia**	**Czech Republic**	Germany
	Hungary	**Estonia**	**Greece**
	Ireland	Finland	**Ireland**
	Latvia	**Greece**	Netherlands
	Lithuania	Iceland	Portugal
	FYR Macedonia	**Ireland**	Slovakia
	Romania	**Latvia**	**Spain**
	San Marino	**Lithuania**	United Kingdom
		Montenegro	
		Slovenia	
		Spain	

Estonia, Latvia and Lithuania only experienced two years of lower spending, in contrast to three or more years in Greece, Ireland and Portugal. These countries were severely hit by the crisis, some requested assistance from the European Commission, European Central Bank and International Monetary Fund (see figure 1).

As a consequence, it is important to measure the impact of the measures adopted on the health of European citizens, and people living with a rare disease in particular. For example, financial pressures are reported to have increased waiting times in several countries (Estonia, Greece, Iceland, Ireland, Latvia, Romania, and United Kingdom).

This working paper summarises data that were published since 2010 on the health impact of the crisis and cost-containment measures by EU Member States and other European countries, for the whole population.

The European Organisation for Rare Diseases is collecting and analysing similar facts that document on new or increased difficulties people with a rare disease may be experiencing in this context.

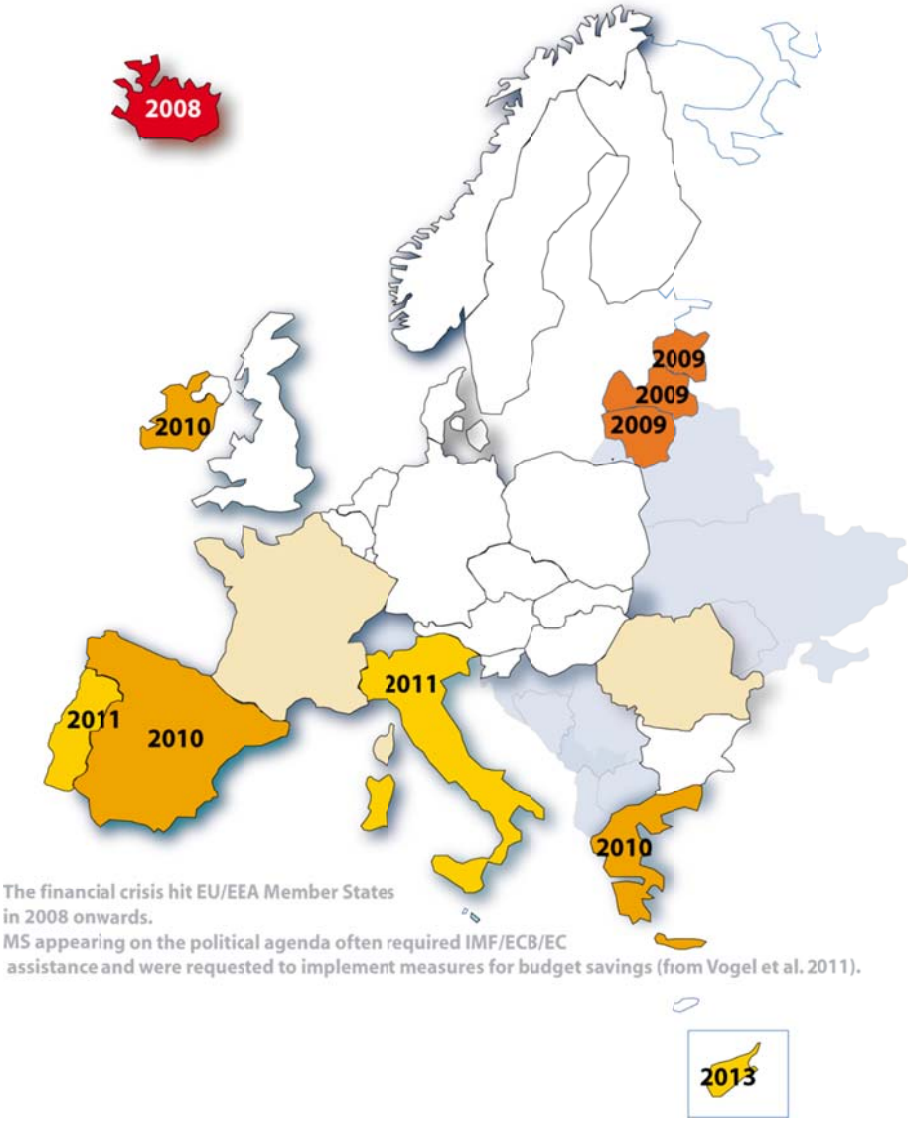


Figure 1: the impact of the financial and economic crisis hit European countries in 2008, some States appeared on the political agenda of the International Monetary Fund, European Commission and European Central Bank early in 2008 like Iceland, other in 2013 like Cyprus. France and Romania are currently under surveillance because of their debts and public deficits.

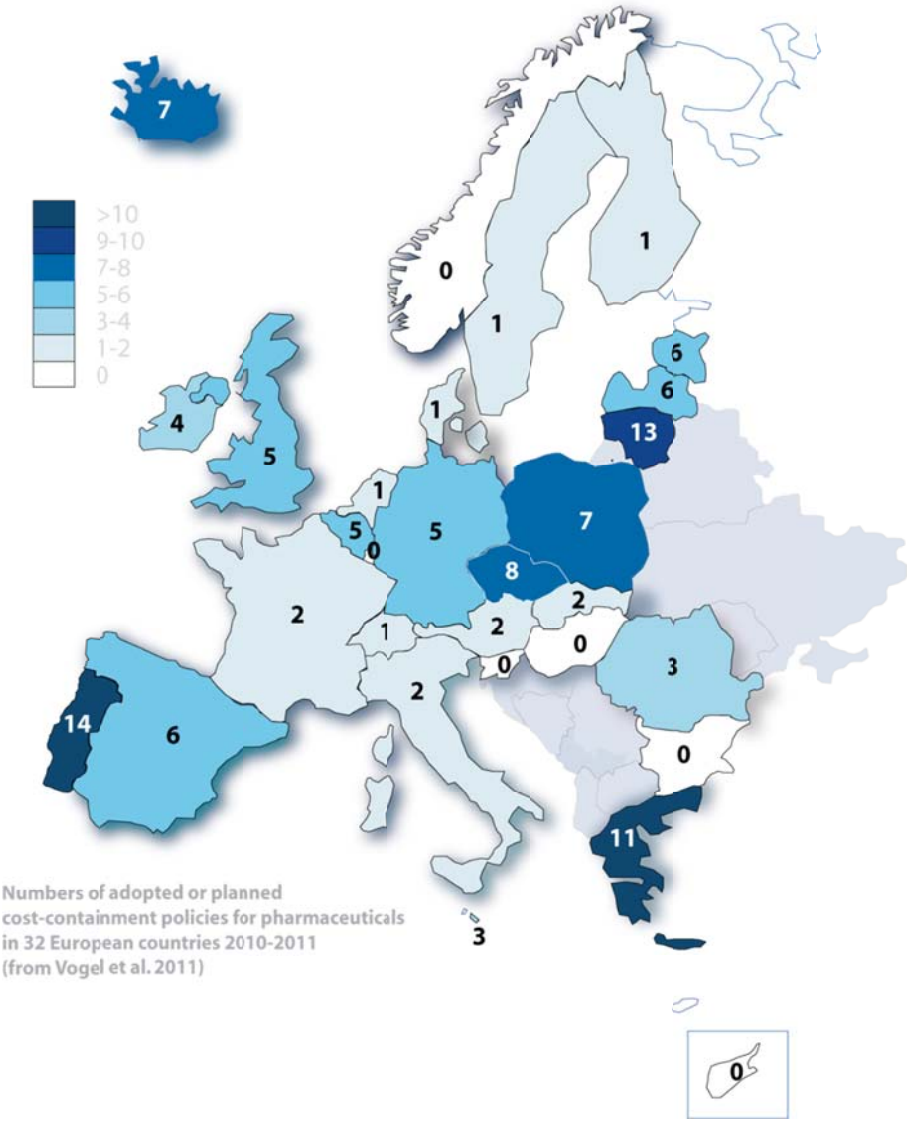


Figure 2: number of cost-containment policies for pharmaceuticals adopted in 32 European countries in 2010-2011 (Vogler S, 2011).

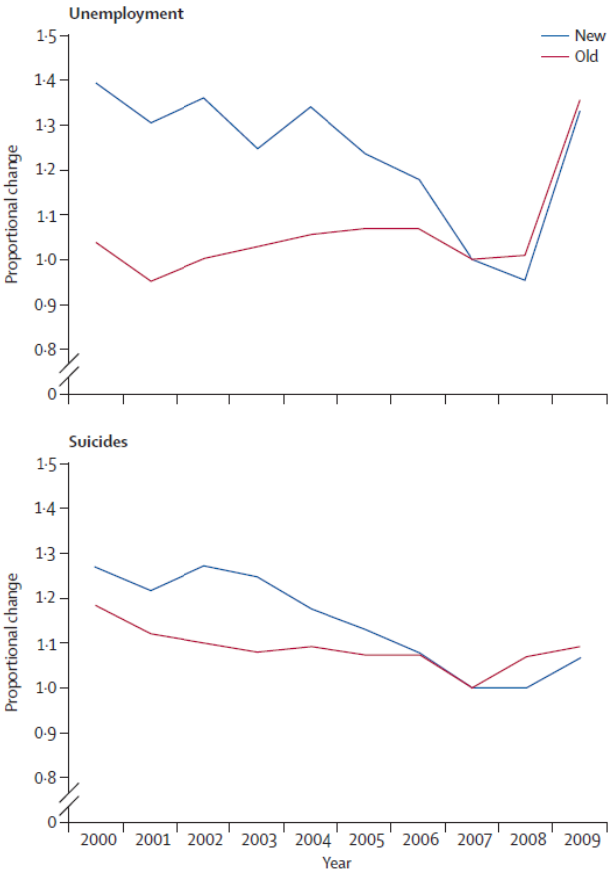
In the general population

Mental health

Mental health has been the area most sensitive to economic changes so far. A long-term decline in suicides in the European Union has been reversed (David Stuckler, 2011), with increases concentrated among men of working age. In the newest EU Member States suicides peaked in 2009 and remained high in 2010 (David Stuckler, 2011). In other Member States further increases were observed in 2010 Research in England has confirmed the close association with job losses (Barr B, 2012) with other research identifying an association with unemployment and the fear of unemployment (Slogett, 1998).

Impact on suicide rates

Stuckler et al. extracted mortality rate data by age-group and cause from the WHO European Health for All database (WHO, 2011), and adult unemployment trends from EUROSTAT (EUROSTAT, Unemployment rate, annual average, by sex and age groups (%), 2013). Unfortunately, complete data for the period 2000–09 are currently only available for 10 of the 27 European Union (EU) countries: six in the pre-2004 EU (Austria, Finland, Greece, Ireland, the Netherlands, and the UK) and four in the post-2004 EU (Czech Republic, Hungary, Lithuania, and Romania).



Greece and Ireland, had greater rises in suicides (17% and 13%, respectively) than did the other countries, and in Latvia suicides increased by more than 17% between 2007 and 2008.

In the UK, Barr B et al. found that "before the economic crisis in 2008, the rate of male suicides was declining in England by 57 suicides per year (95% confidence interval 56 to 58), from 2000 to 2007; female suicides decreased by 26 suicides per year (24 to 27) in the same period. They estimated 846 more suicides among men (818 to 877) and 155 more suicides among women (121 to 189) than would have been expected if these trends had continued in the period 2008-10. About two fifths of the recent increase in suicides among men (increase of 329 suicides, 126 to 532) during the 2008-10 recession could be attributed to rising unemployment".

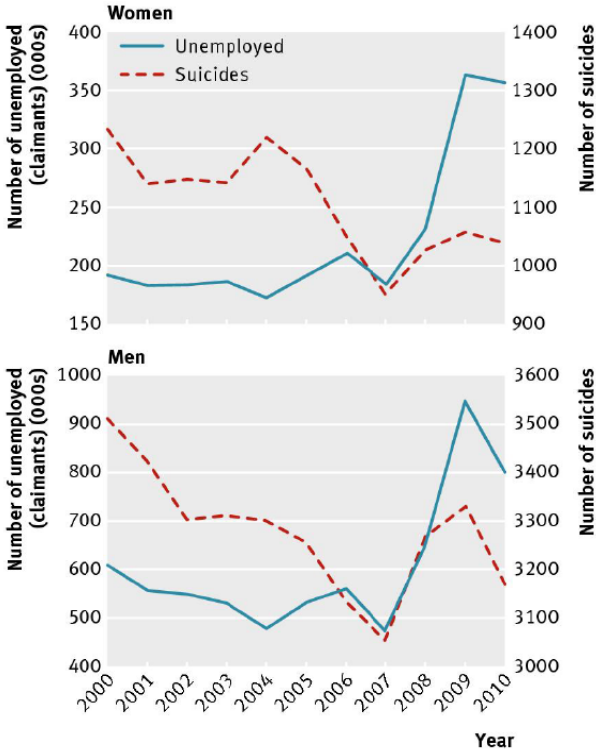


Figure 4: Trends in the numbers of suicides and unemployed in England, 2000-10, by sex (Barr B et al. 2012)

Communicable diseases

There are well documented outbreaks in some of the countries that have experienced the deepest austerity measures include, e.g. the re-emergence of malaria and transmission of dengue fever in Greece (Bonovas-Nikopoulos, 2012) and Portugal (Sousa C A, 2012).

Greece has seen a major upsurge in HIV infections among intravenous drug users, coinciding with substantial reductions in funding for needle exchange programmes (ECDC, 2012).

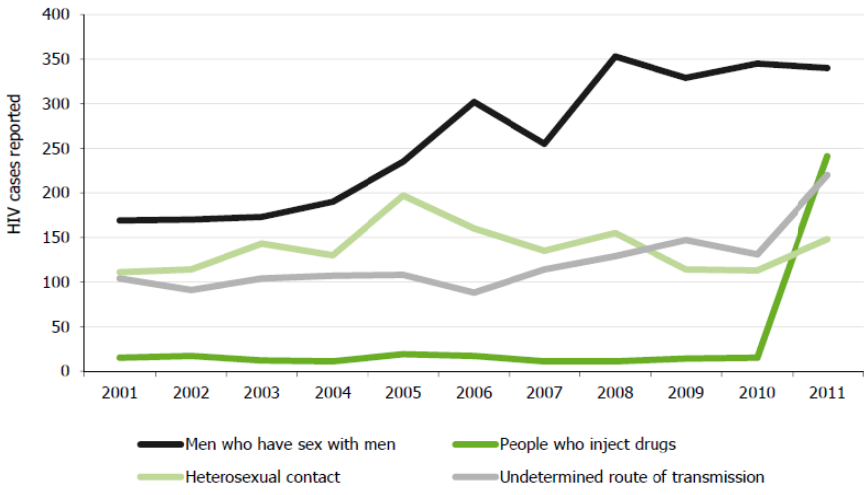


Figure 5: Number of HIV infections by route of transmission and year of report, Greece, 2001–2011 (ECDC 2012)

According to the ECDC report, "Worsened economic conditions tend to increase both the size and the vulnerability of some at-risk populations, such as people who inject drugs (PWID) and sex

workers. Increased levels of unemployment are documented to lead to higher levels of homelessness and, in turn, homelessness tends to increase the risk of PWID (Johnson TP, 2007). It is also known that homeless drug users are more likely to pursue high risk sexual activities (Kral AH, 2000). Indeed the evidence from past economic downturns demonstrates an increase in HIV incidence as well as risk-taking behaviour (Suhrcke M, 2011) (Friedman SR, 2009)."

Other indicators of crisis impact in Greece

A long-term decline in infant mortality has been reversed in Greece since 2008, with two consecutive years of increases (EUROSTAT, Statistics database. European Commission, 2013) in 2009 and 2010. Longer term data are needed to confirm the trend.

Figure 6: infant mortality in Greece, by year (Eurostat 2013)

At the same time there has been a 32% increase in the number of stillbirths (Vlachadis N, 2013). The authors are "worried that the stillbirth rate will continue to rise because an increasing number of pregnant women are unemployed and without insurance, and thereby excluded from the Greek National Healthcare System's obstetric care."

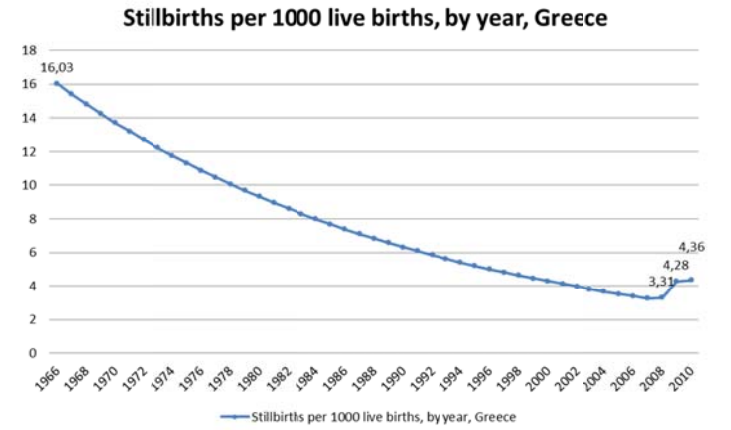


Figure 7: Increase in stillbirths in Greece (Vlachadis 2013)

The W.H.O report on the impact of the crisis on citizens' health (Sarah Thomson, 2013) concludes that "It is very likely that there will be effects on health that may not manifest themselves for some

time. These may arise from changes in population access to needed services, such as proper management of chronic disease with patient participation and adherence to treatment".

Difficulties patients are facing

Results of an IPSOS survey in Greece

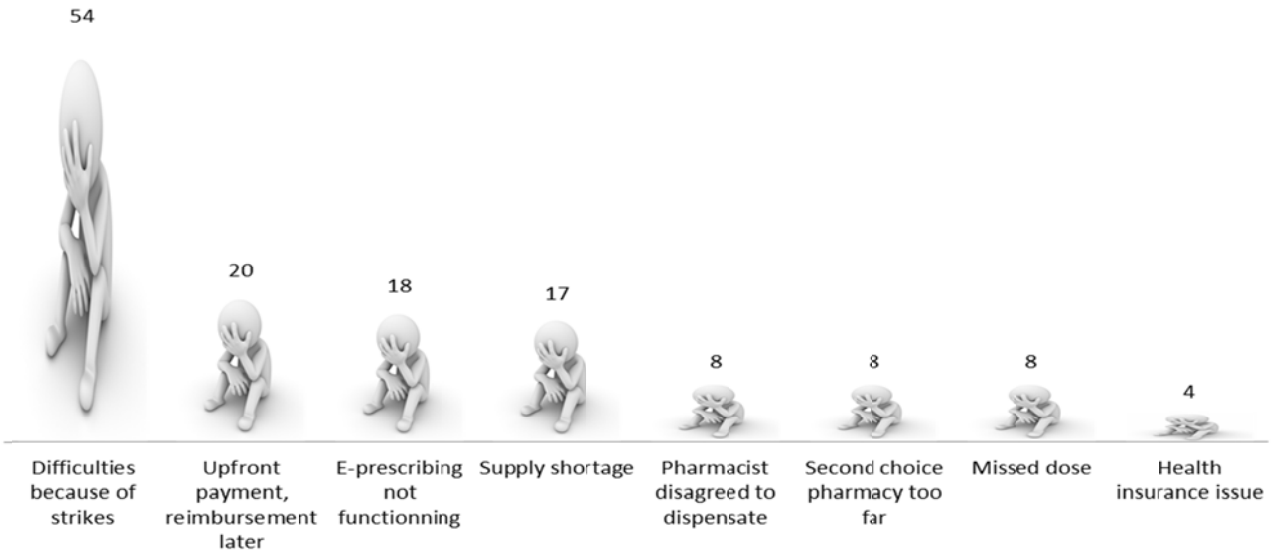
A survey investigating difficulties the Greek population was facing accessing healthcare services was conducted in September 2012 (Tripsa, 2013). Some 403 people (207 with a chronic disease[1], 96 with a rare and/or life-threatening disease[2] and 100 with an acute health problem were interviewed (age: 25 – 70 years, 323 (80%) in Athens-Attika and 80 (20%) in other urban areas: Salonica, Patra, Heraklio).

Of the 208 respondents who recently had to make an appointment in a hospital (only 34 (16.3%) reported no problem):

- 53 (25.5%) reported there were too few doctors and hence long waiting time to have an appointment / and 52 (25%) a long queue at the visit
- 37 (17.8%) missed the appointment because of a strike
- 35 (16.8%) could not visit the doctor they had chosen

For those who had specific problems concerning the dispensation of a medicine:

Figure 8: numbers of patients reporting difficulties in accessing medicines (base: 403 interviews). During the survey period, pharmacists had started a strike.



Patients with a **rare disease** (total number 96) who were prescribed an orphan medicine were 3.5 fold more likely to encounter a supply shortage than patients with non-rare chronic conditions (total number 206).

[1] Hypertension, hyperlipidaemia, diabetes, obstructive pulmonary disease, asthma, osteoporosis, etc.
[2] Multiple sclerosis, other autoimmune disease, orphan disease, cystic fibrosis, cancer, HIV infection, chronic kidney disease, etc.

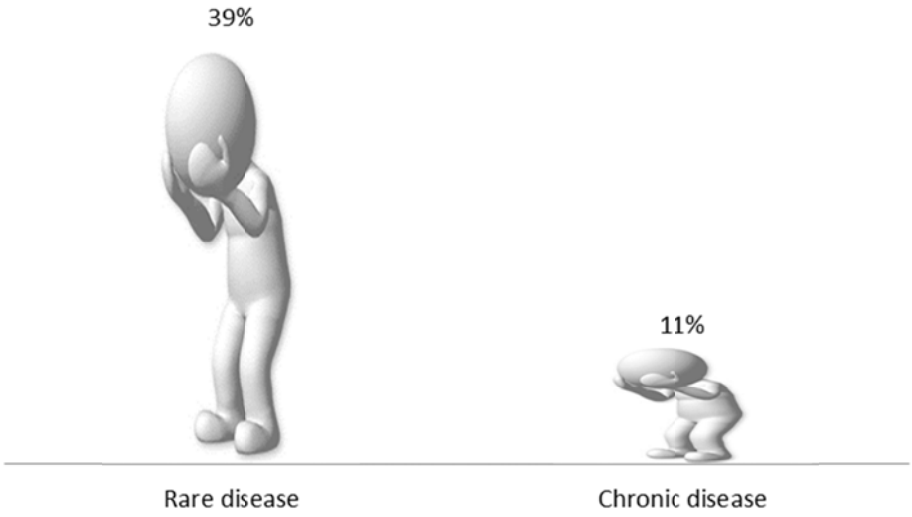


Figure 9: among respondents, people who were prescribed an orphan drug (indicated by "rare disease") were more frequently reporting supply shortages: 37/96 with a rare disease versus 23/207 with a chronic condition.

Health impact on the population in Ireland

In Ireland, growing unemployment and poverty had an immediate effect on the health system. As the share of the Irish population at risk of poverty has grown, so has the share eligible for access to publicly financed health care, which is subject to a means test. Between 2008 and 2012 the share of the population entitled to free primary care rose by more than 10 percentage points, from 32% to 43%. The Irish Department of Health has had to cover the cost of this extra demand for publicly financed health care with a budget that is now in its fourth year of cuts and may be cut again in 2014.

Variability of pricing/reimbursement decisions

(Paris, 2013)

In the recent years, the aspect of the economic value of medicines gave rise to the adoption of different methods to better inform decision makers when deciding the reimbursement of a medicine and/or negotiating its price. The idea is to favour treatment which are more effective than others (for the same cost, health gain may differ: if medicine A costs 10 000 € to gain one year of life and medicine B costs 20 000 € to gain one year of life, then medicine A should be favoured).

As this field is relatively new in medicine, we are still in an unstable environment, with various methods in place (for example some countries take the social and ethical value of a medicine into question, other don't) which may lead to diverging conclusions. In this chapter, some recent examples are described. A sample of products authorised between 2005 and 2011 were chosen by the authors. These products were chosen to illustrate differences across countries in how value is assessed and how this might affect reimbursement decisions and pricing outcomes (see Table).

In addition, similar information on Fabrazyme®, Replagal® and Myozyme®, three enzyme replacement therapies for rare diseases are provided (Source: CVZ, Netherlands).

Table 2

Active substance and trade names	Date of first Marketing authorisation	Indications	Criteria for selection
cetuximab, Erbitux®	2004	Metastatic cancer of the colon or rectum Squamous cell cancer of the head and neck (rare disease)	Disease severity Hospital settings
sunitinib, Sutent®	2007	Gastrointestinal stromal tumour (GIST), Metastatic renal cell carcinoma, Pancreatic neuro-endocrine tumours (2010)	Disease Severity, End of life treatment Hospital settings
ranibizumab, Lucentis®	2007	Neo-vascular (wet) age-related macular degeneration (AMD), Macular Oedema Following Retinal Vein Occlusion (RVO) The treatment of visual impairment due to diabetic macular oedema (DME)	Disease severity
eculizumab, Soliris®	2007	Paroxysmal nocturnal haemoglobinuria (PNH) Atypical haemolytic uremic syndrome (aHUS)	Orphan product
agalsidase beta, Fabrazyme®	2001	Fabry disease	Disease Severity Orphan product
agalsidase alfa, Replagal®	2001	Fabry disease	Disease Severity Orphan product
alglucosidase alfa, Myozyme®	2006	Glycogen Storage Disease Type II (Pompe's disease)	Disease Severity Orphan product

Cetuximab (Erbitux®)

Oncology

Different decisions in England, Scotland and Italy:

England (NICE[3]): Patient Access Scheme (PAS)[4] for first line treatment of metastatic colorectal cancer (MCC):

- 16% rebate on the amount cetuximab used on a per patient basis (NICE recommended the use of cetuximab in combination with radiotherapy for the treatment of locally advanced squamous cell cancer of the head and neck, without PAS, but did not recommend use in the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck).

Scotland (SMC[5]): PAS for the treatment of metastatic colorectal cancer in combination with chemotherapy for a selection of patients: undisclosed discount on acquisition costs.

Italy (AIFA[6]):

- Risk-Sharing for treatment of metastatic colorectal cancer (MCC): 50% reimbursement in case of therapeutic failure within 2 months/ 8 weeks of treatment;

[3] NICE National Institute for Health and Care Excellence

[4] Patient access schemes are special ways pharmaceutical companies can propose to enable patients to gain access to high costs drugs medicines. They are proposed by a pharmaceutical company and agreed between Health authorities and the pharmaceutical company.

[5] SMC Scottish Medicine Consortium

[6] AIFA Italian Medicines Agency

- Payment by results for the treatment of recurrent and/or metastatic squamous cell cancer of the head and neck: full reimbursement in case of therapeutic failure within 6 weeks of treatment.

Sunitinib (Sutent®)

Oncology

Same decisions in England, Scotland and Italy:

England (NICE): PAS for treatment of advanced or metastatic renal cell carcinoma (RCC) or gastro-intestinal stromal tumours (GIST), the manufacturer offers the first cycle of treatment with sunitinib free of charge to the NHS.

Scotland (SMC): PAS for treatment of gastrointestinal stromal tumour (GIST): Each patient receives one cycle of sunitinib free of charge.

Italy (AIFA) – Cost sharing for treatment of advanced or metastatic renal cell carcinoma (RCC): the company provides the first treatment cycle for free; -Sunitinib is recommended for the treatment of gastrointestinal stromal tumour (GIST)

Ranibizumab (Lucentis®)

(Age-related macular degeneration)

Different decisions in England, Scotland and Italy:

England (NICE): in a first PAS agreement signed in 2008, the cost of ranibizumab beyond 14 injections in each treated eye was met by the manufacturer. The most recent agreement proposed by the company and signed in 2012 consists in an undisclosed discount.

Scotland (SMC): PAS, simple discount, kept confidential.

Italy (AIFA): Payment by result, i.e. full reimbursement in case of therapeutic failure within 3 months of treatment (3 injections)

Eculizumab (Soliris®)

(Orphan drug)

Different decisions in France and Italy:

France (2008): budget ceiling beyond which the company agreed to provide the medicine free of charge

Italy (AIFA): the manufacturer pays for the two initial packages;

Egalsidase beta, Fabrazyme® and egalsidase alfa, Replagal®

(Fabry disease)

State	Agreements	Remarks
Spain	No rebates	Treatment and its potential continuation is decided based on discussions by an Expert Group
Italy	No rebates	Included in AIFA Monitoring Registry: this guarantees the use of the medicine when prescribed
Slovenia	100% reimbursed	
Poland	Not reimbursed	
Belgium	100% reimbursed	Joint decision-making college consisting of doctors and insurers
Latvia and Lithuania	No reimbursement	
Scotland	100% reimbursed	Mostly because registered at a time that the SMC did not yet exist
Malta	No reimbursement	
Germany	100% reimbursed	
Finland	100% reimbursed	Conditions: all adult men with Fabry disease and women and children with diagnosis Fabry disease if signs of developing cardiomyopathy, cerebral blood circulation disease or renal disease or neuropathic pain, which is not controlled with the regular treatment.
Czech Republic	No reimbursement limits, only fixed reimbursement price is set	Not fully reimbursed. However it is possible that the actual retail price is lower than the list retail price so that in reality the product could be fully reimbursed.
France	100% reimbursed	Reimbursed under a specific hospitall budget envelop called MIGAC (Missions for General Interest and Contractual support)
Sweden	100% reimbursed since introduced under old system	
United Kingdom	Left to the counties	NICE has never formally reported on Fabrazyme or Replagal

Alglucosidase alfa, Myozyme®

(Pompe's disease)

State	Agreements	Remarks
Spain	No rebates	Treatment and its potential continuation is decided based on discussions by an Expert Group
Italy	No rebates	Included in AIFA Monitoring Registry: this guarantees the use of the medicine when prescribed
Slovenia	Undisclosed complex risk sharing agreement	
Poland	Only classical form (in children) is reimbursed	Coordinating team of treating physicians
Belgium	100% reimbursed but exceptions in non-classical form: e.g. no reimbursement if no breathing problems or continuous oxygen treatment not needed	Joint decision-making college consisting of doctors and insurers

Latvia and Lithuania	No reimbursement	
Scotland	Formally can be reimbursed but "not recommended for reimbursement"	Reimbursed in some patients on the basis of "risk-sharing scheme 'in this case a central national fund
Malta	No reimbursement	
Germany	100% reimbursed	
Finland	A study is in progress to improve evidence	
Czech Republic	No reimbursement limits, only fixed reimbursement price is set	Not fully reimbursed. However it is possible that the actual retail price is lower than the list retail price so that in reality the product could be fully reimbursed.
France	In practice reimbursed	No price listed yet. The negotiation is still in progress. Yet, it is reimbursed under a specific hospital budget envelop called MIGAC (Missions for general interest and contractual)
Sweden	Not reimbursed, but official decision was never formally taken	
United Kingdom	Left to the counties	NICE has never formally reported on Myozyme®

Questions to National Alliances

Questions to all National Alliances

1. ***Do you have evidence of an impact of the economic and financial crisis that started in 2008 in the US on the health of citizens in your country, and in particular of people living with a rare disease?***

2. ***In particular, do you have facts or testimonies from patients who had to renounce to medical or social care they were receiving before? Or who could not access it and yet it was needed?***

Country cards

The information in the table for each country is explained in this chapter.

Total current expenditure on health

Belgium is taken as an example. The first information in the proportion of the gross domestic product (GDP) spent on health by decade from 1970 to 2000 and then yearly since 2006. It shows an important increase each decade until 2000, and then a stabilisation when governments started to adopt policies to control the health expenses. Since 2008, and when the information is available, countries which are facing severe financial difficulties and which are reducing their deficits have adopted measures that can translate into a decrease of the percentage of the GDP spent on health.

On the other hand, this ratio can also be impacted by the economic regression, and when GDP decreases, the ratio increases. "The ratio of health expenditure to GDP, which in macroeconomic terms is an indicator which summarises the financing needs of a national health system, is likely to rise in countries for which the GDP falls. Over the past four decades, health expenditure has risen in

most countries at a faster rate than GDP, leading to a rise in the expenditure ratio" (Devaux-Scherer, 2010).

This is what is happening in Greece, where the ratio of health expenditure to GDP is stable, not because of a better control of health expenses, but because of the marked decrease of the GDP since 2008.

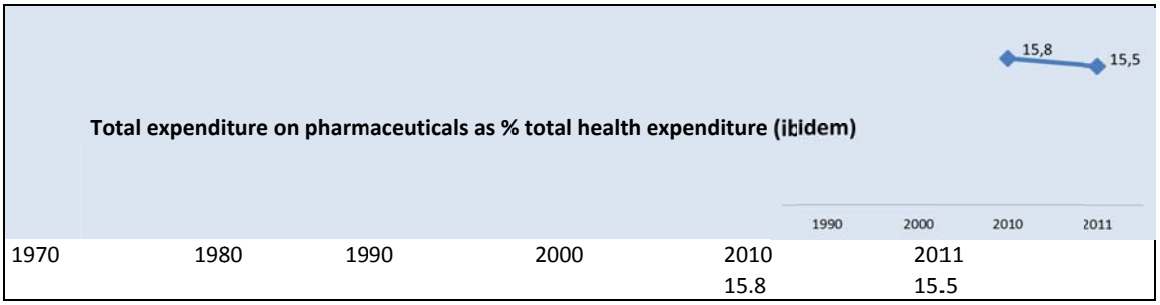
Total current expenditure on health (% GDP) (Eurostat, OECD Health Data 2013)										
1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
5.4	5.9	6.6	7.5	9.4	..	10.0	9.4	9.0	9.4	

Gross Domestic Product in Greece (billion €) (Eurostat, OECD Health Data 2013)						
2006	2007	2008	2009	2010	2011	2012
208,6	223,2	233,2	231,1	222,2	208,5	193,7

In Belgium, 10.5% of the GDP was spent on health in 2011, and this % is stable since 2009.

Total current expenditure on health (% GDP) (Eurostat, OECD Health Data 2013)										
1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
3.9	6.3	7.2	8.1	9.5	9.5	9.9	10.6	10.5	10.5	

Total expenditure on pharmaceuticals as % total health expenditure



1970	1980	1990	2000	2010	2011
				15.8	15.5

This information explains the proportion of the total health expenditure represented by pharmaceuticals and other medical non-durables. Other health expenses than pharmaceuticals include salaries of healthcare professionals, investments in hospital care etc.

In Belgium, 15.5% of the health expenditure was spent on pharmaceuticals in 2011, representing a slight decrease since 2010.

EU Member States implemented policies to contain the cost of pharmaceuticals at different times, and not all policies have reached their objectives so far, as shown in table below (in ten countries the pharmaceutical expenditure seems to be controlled, this is not the case in nine others).

Table 3: Year when the ratio between pharmaceuticals expenditure and total health expenditure started to decline. Sources: OECD Health Data 2013. Note: data were not availbale for Spain and United Kingdom. In Denmark, after a first declien in 2008, new measures adoptedin 2009-2010 further decreased the pharmaceutical expenditure in 2011.

2007	2008	2009	2010	2011	Objective not yet reached
Italy	Ireland	Austria	Belgium	Germany	France
	Portugal	Finland	Czech Republic	Slovak Republic	Iceland
	Denmark 1			Denmark 2	Netherlands
					Poland
					Slovenia
					Spain
					United Kingdom
					Sweden
					Hungary

There is a divide between Western-Northern Europe on one side and Eastern-Southern Europe on the other side in the proportion of the total health expenditure spent on pharmaceuticals. This proportion varies from 7% in Denmark to 32.9% in Hungary as shown below. The OECD average for European countries is 17.9%. As salaries are lower in Eastern-Southern Europe, and as the price of pharmaceuticals is not adapted to GDP per capita, the part of the health expenditure represented by pharmaceuticals is therefore higher.

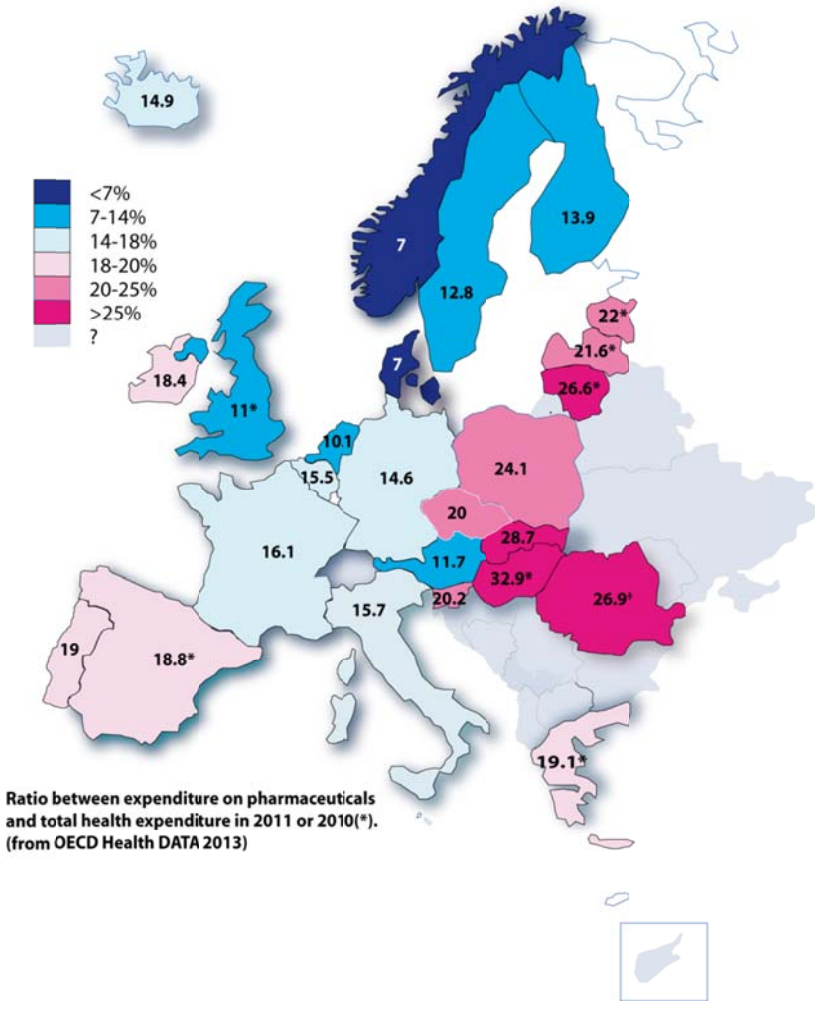
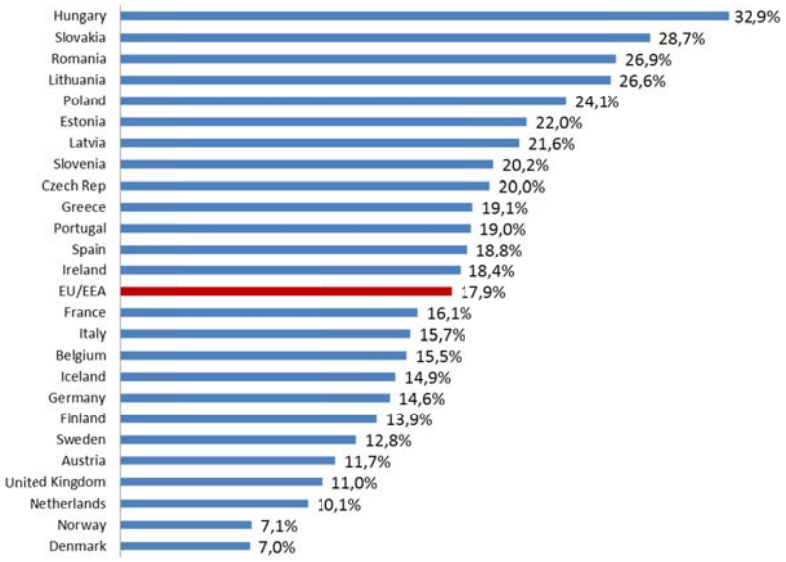


Figure 10: ratio between expenditure on pharmaceuticals and total health expenditure in OECD countries, in 2011 or 2010 (*). Dataa from Bulgaria, Cyprus and Croatia not available.



Total expenditure on pharmaceuticals (million €)

Total expenditure on pharmaceuticals (million €) (ibidem)		
2010	2011	2011 /2010
5926.0	6040.5	1.9%

This represents the budget spent in Belgium on pharmaceuticals, in million euros. Whilst attempting to contain the cost of medicines, this budget increased in 2011 compared to 2010 (+1.9%).

Price level index for pharmaceutical products

Price level index for pharmaceutical products in 2005, EU25=100
106

The prices of medicines vary by country. This information from 2005, so maybe a bit outdated, illustrates this variation: the index is the European average in 2005 and its value is 100. The difference with this value was calculated for a sample of medicines in each country.

In Belgium for example, this indices was 106: in other words, medicines are in average 6% more expensive in Belgium compared to the European average prices in 2005.

Globally, the differences ranged from 68 in Poland to 128 in Germany: this means medicines were 32% less expensive in Poland compared to the EU25 average, and 28% more expensive in Germany, in 2005. Figure 11 below shows the average in all EU Member States except Greece in 2005:

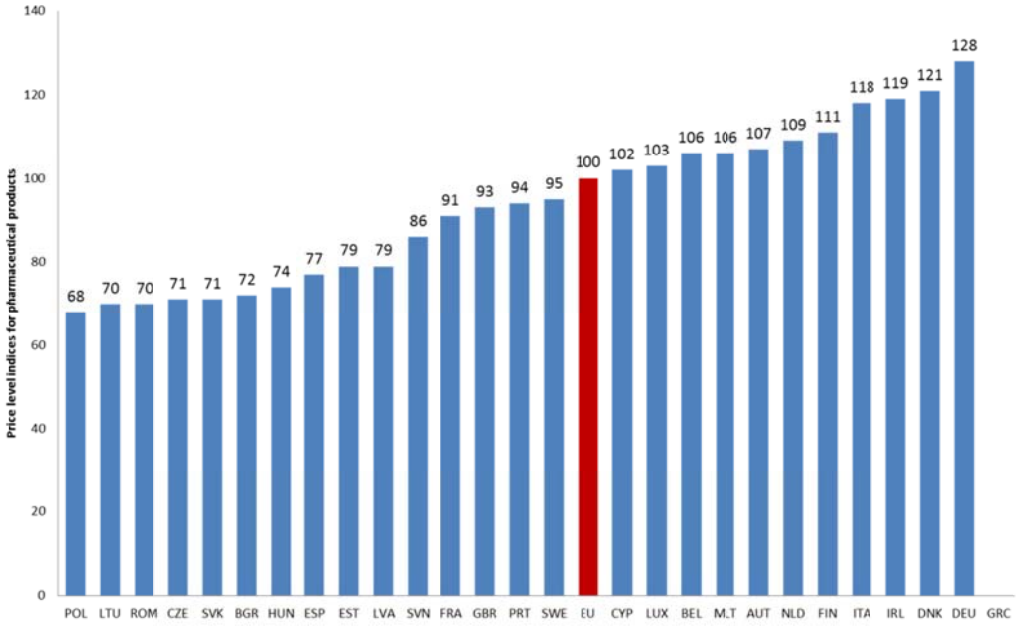


Figure 11: Price level indices for pharmaceutical products in 2005, EU25=100.
Source: Eurostat (2007); Commission services (DG ECFIN). Notes: Price level for EL not available

As a first view, it seems prices are adapted to the country' resources: prices seem to be lower in Eastern European countries than in Western or Northern European countries. When comparing the figures above to the actual gross domestic product per capita, it shows prices of medicines are in fact not adapted to the people resources. In figure 12 below, the effort to purchase medicines in Poland, Lithuania, Romania, Czech Republic, Slovakia, Bulgaria, Hungary, Estonia is much higher than in Western/Northern countries.

In other words, when the pharmaceutical industry is claiming the prices are adapted to each country' capability, this is only partly true, but globally it makes medicines far too expensive for patients living in poorer countries in Europe.

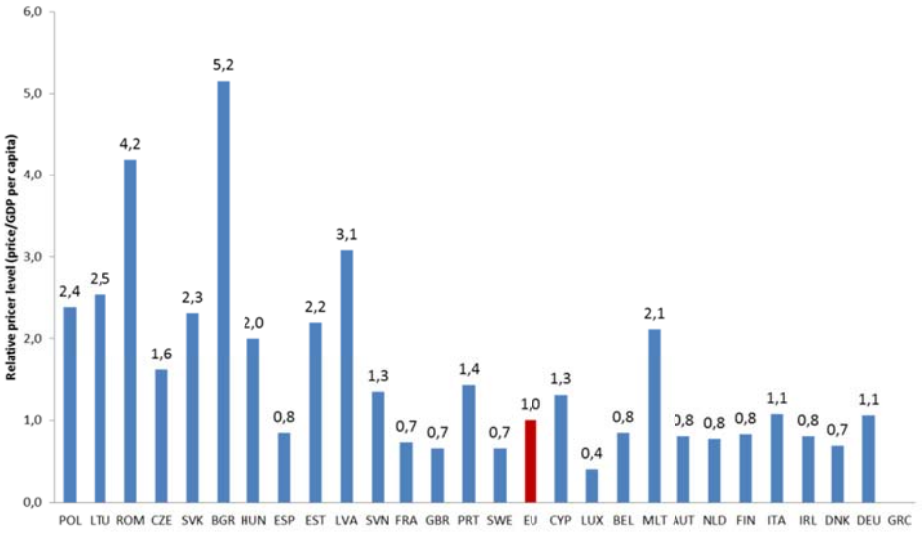


Figure 12: Relative price level (price/GDP per capita) for pharmaceutical products in 2005, EU25=100. Source: Eurostat (2007); Commission services (DG ECFIN). Notes: Price level for EL not available

The simulation in figure 13 shows the indices as calculated in figure 10 that would appear if the industry would adapt the prices of medicines to the purchasing power of the citizens, i.e. actually adjusting for the GDP per capita.

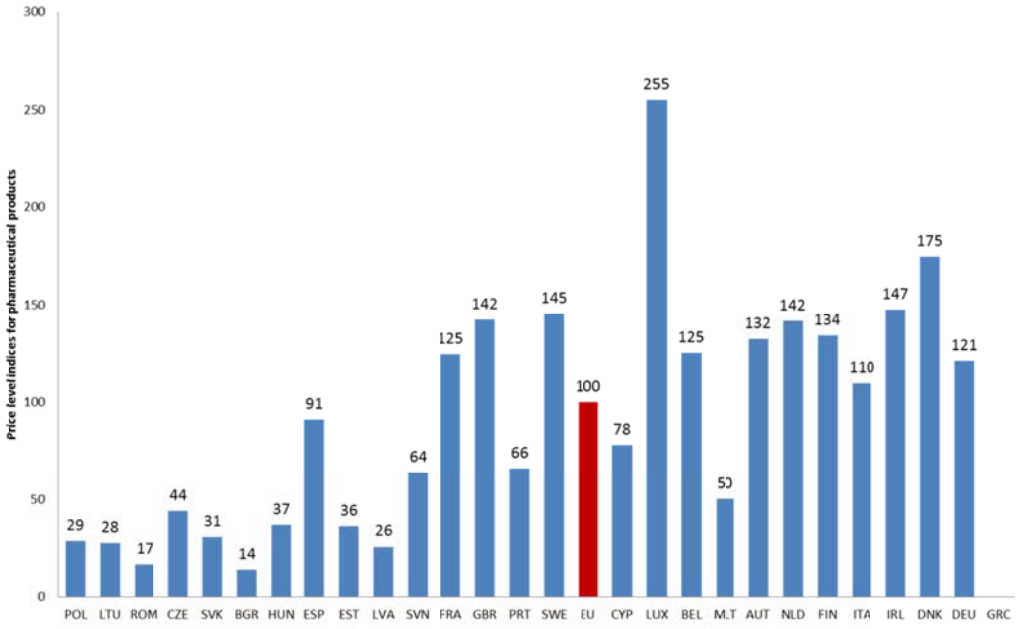


Figure 13: simulated indices considering the actual GDp per inhabitant.

In other words, only if prices would be 86% lower than the EU average in Bulgaria for example, then the efforts for Bulgarian patients would be the same as for all EU patients in average. Along this line, prices should be higher than the EU indices by 155% in Luxembourg, 25% in France and Belgium, 21% in Germany to account for growth product per capita when proposing prices with the objective of equity among EU citizens.

External reference pricing

In most EU Member States, prices of pharmaceuticals are set through external reference pricing (ERP). ERP establishes a price on the basis of prices of the same product in other countries. Mostly, price controls apply to reimbursable medicines, whereas non-reimbursable medicines are usually priced freely.

In this table, ERP in Belgium is used for all medicines (scope), based on the ex-factory prices (catalogue price). It refers to prices available in 24 countries, and Belgium calculates the average between all prices in the 24 countries. The 24 countries are indicated by a blue box and by a map.

Inversely, prices in Belgium are used by 10 other countries as a reference to estimate or negotiate their prices.

Characteristics of external reference pricing (Leopold C. S.-T., 2012)				
Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
All medicines	Ex-factory price	24	10	Average of all countries

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
■			■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	

Health-technology assessment (HTA)

This information is changing very rapidly, as many countries that did not assess the health-technologies before are now adopting methods to do so. Assessing a health technology, e.g. a medicine, means taking into consideration its efficacy, its toxicity, its quality, its economic impact in terms of cost-effectiveness, budget impact, budget savings etc. and also its social and ethical impact. In consists in providing an opinion on whether or not is it worth for society to cover the medicine in question.

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Allternatives	Budget impact
National Institute for Health and Disability Insurance (INAMI-RIZIV)	Coverage	Selected drugs based on health impact, disease burden, policy relevance	Yes	Yes	Yes	Yes

HTA is one of the elements and probably the most important, for deciding to reimburse a medicine and/or to negotiate the price.

In Belgium, the institution that reviews the HTA of medicines is INAMI-RIZIV. Its conclusions are used to decide to reimburse it or not, but are not used to negotiate prices. It is not used for all medicines but only for some, based on their potential health impact, burden of the disease and policy relevance. When an HTA is conducted, it takes into consideration the therapeutic benefit, the cost-effectiveness, in comparison with alternatives, and measures the budget impact.

Public tendering

Purchasers of medicines (hospitals, healthcare settings, insurance companies...) are using public procurement to decrease the prices of pharmaceuticals. Medicines purchased through tendering procedures are vaccines, pharmaceuticals in pandemic plans, but also branded pharmaceuticals and generics prescribed against non-communicable diseases. Price is the most important criterion for winning a tender. Other criteria include the availability of the medicine.

The table indicates a tendering procedure exists in Belgium, it applies to hospital care for medicines such as vaccines, or medicines defined in pandemic plans (communicable diseases). The award criterion is the best price for offer.

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital care	Vaccines, pharmaceuticals as defined in pandemic plans	Best price/offer

Positive/negative lists

Positive/negative lists: All EU Member States have positive lists specifying which specific pharmaceuticals are reimbursed. A few countries also have negative lists, excluding specific pharmaceuticals from reimbursement. In Belgium, there is a positive list and an HTA is often used to decide whether or not a medicine should be on the list of reimbursed medicines.

HTA, positive/negative lists (GÖG, 2010)	
Health technology assessment	Positive/negative lists
Yes	Positive

Generic substitution

The introduction of generic medicines on the market had a heterogeneous success in EU Member States. In some countries they are introduced immediately when they are authorised, at a very low price, while in other the price reduction compared to the originator product is not so important.

To favour the use of generic medicines, some States adopted measures to make the substitution of a branded product by a generic product mandatory: at the pharmacy, whenever a brand name appears on the prescription, the pharmacist has an obligation to substitute the medicine with a generic. In other countries, the pharmacist can indicate a generic product is available, but there is no obligation to substitute the brand name product.

Generic substitution (Vogler, 2012), (GÖG, 2010)
Partly obligatory (Obligatory substitution for antibiotics and anti-mycotics)

In Belgium, the substitution is partly mandatory (only for antibiotics and anti-mycotics).

Number of wholesalers and pharmacies and their average margins

This information indicates the number of pharmacies and retailers in each country, and the type of profits they can make on the medicines they sale.

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)							
#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler markup	Type of pharmacy markup	VAT	
4.8	15	8.5%	na	regressive	Regressive + dispensing fee	6.0%	21.0%
na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax							

This is important as economic competition exists among wholesalers and among pharmacies, and their respective margins as well as VAT that applies on the retailed prices of medicines have an impact on the total expenditures for pharmaceuticals.

In Belgium, there is an average of 4.8 pharmacies for 10 000 citizens, and an estimated number of 15 wholesalers. This can be compared to the EU average.

Cost-sharing policies

Cost-sharing requires patients covered by a health insurer to share the cost of the pharmaceutical product acquired. Cost-sharing may be applied as deductibles, co-insurance or co-payment. Co-insurance, whereby patients pay a percentage of the price of the medicine, is the most commonly used in the case of pharmaceuticals.

The rationale for using cost-sharing is to increase the price sensitivity of patients, reduce the unnecessary use of medicines and generate income for and reduce expenditure of public payers.

Cost-sharing policies (GÖG, 2010)
%

The co-payment can therefore be a% of the cost of the medicine (indicated by "%"), or a fixed amount. In Belgium, it is a %.

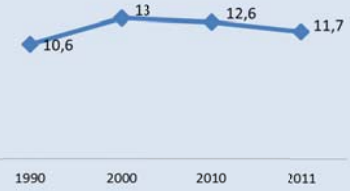
Specific questions to each one of the 26 National Alliances

Austria

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
4.9	7.1	7.8	9.4	9.7	9.7	9.9	10.5	10.4	10.2	

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)



1970	1980	1990	2000	2010	2011
		10.6	13.0	12.6	11.7

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
3761	3800	1.0%

Price level index for pharmaceutical products in 2005, EU25=100

106

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
All medicines	Ex-factory price	24	11	Average of all countries

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
■			■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
na	Na	na	na	na	na	Na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital care	Vaccines, pharmaceuticals as defined in pandemic plans	Best price/offer

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010): **Disallowed**

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler markup	Type of pharmacy markup	VAT	
1.5	10	10.0%	19.2%	regressive	Regressive + dispensing fee	10.0%	21.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010): **Fixed**

Recent measures

In a measure aiming to offer financial relief to socially vulnerable policy holders, as of 1 January 2008 a ceiling was set on prescription fees, targeted especially at people with high drug needs and low incomes. Under the new law, a cap is set at 2% of an insured person's annual net income spent on prescription drug costs, after which the insured person is exempt from all prescription drug charges for the remainder of the calendar year. Initial calculations by the Federation of Social Health Insurance Funds predicted that the new exemption would benefit approximately 300 000 people. Given the revenue losses for statutory health insurance there is uncertainty over the sustainability of the policy in light of the economic downturn. It also remains to be seen whether the government will compensate social insurance for the revenue losses and who will ultimately pay for the cap.

The Federation of Social Health Insurance Funds negotiated with pharmaceutical companies to lower pricing and reimbursement and to reduce the cost of drug prescribing by physicians. Cost savings of EUR 132 million in 2010 and projected EUR 222 million by 2013. (Philipa Mladovsky, 2012).

Questions

Co-payment for medicines

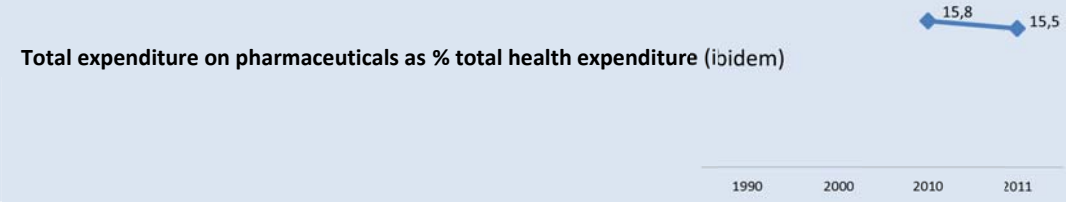
1. Did you notice an increase of the prescription fee? How much has it been increased?
2. Do you have examples of patients for whom 2% of the annual net income represents a too high burden?

Belgium

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
3.9	6.3	7.2	8.1	9.5	9.5	9.9	10.6	10.5	10.5	

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)



1970	1980	1990	2000	2010	2011
				15.8	15.5

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
5926.0	6040.5	1.9%

Price level index for pharmaceutical products in 2005, EU25=100

106

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
All medicines	Ex-factory price	24	10	Average of all countries

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria: Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
National Institute for Health and Disability Insurance (INAMI-RIZIV)	coverage	Selected drugs based on health impact, disease burden, policy relevance	Yes	Yes	Yes	Yes

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital and ambulatory care	Hospital care: Vaccines, pharmaceuticals as defined in pandemic plans and specific therapeutic groups of pharmaceuticals	Na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Partly obligatory (Obligatory substitution for antibiotics and antimycotics)

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler markup	Type of pharmacy markup	VAT	
4.8	15	8.5%	na	regressive	Regressive + dispensing fee	6.0%	21.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: %**

Recent measures

Given the current economic situation, there was a debate on whether to respect the annual growth norm of 4.5% that was established in 2004, the final decision taken was in favour of "protecting" the health care budget.

Enlargement of the group entitled to increased reimbursement of health care expenses: from 2007, low income families (or individuals) are eligible. In 2011 the income ceiling was fixed at EUR 15 163.96 and increased by EUR 2807.26 for each additional family member. New reimbursements for patients with certain chronic conditions were also introduced.

In 2010, a new cost containment measure introduced a biannual application of a compulsory price reduction for "old" drugs: drugs reimbursed for over 12 years and less than 15 years had their ex-factory price and reimbursement basis reduced by 15%, and drugs reimbursed for over 15 years underwent a 17% reduction. New rules in place for reimbursement for implants and medical devices since 2008. Price reductions have occurred but the effect on volume is unclear. (Philipa Mladovsky, 2012).

Questions

Co-payment for medicines

1. Did you notice an increase of the co-payment for medicines? Do you have examples?
2. Do you have examples of families for whom a ceiling of 15 163.96 € plus 2 807.26 € for each additional family member represents a too high burden?

Bulgaria

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)

1970	1980	1990	2000	2010	2011

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010

Price level index for pharmaceutical products in 2005, EU25=100

72

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Prescription only	Ex-factory price	9	3	3 lowest prices

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
■				■					■			■								■	■	■				■		Russia

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
na	na	na	na	na	Na	na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
na	na	Na	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment	Positive/negative lists
	Positive

Generic substitution (Vogler, 2012), (GÖG, 2010)

Disallowed

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler markup	Type of pharmacy markup	VAT	
5.9	20	8.5%	20%	regressive	Regressive	20.0%	20.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)

%

Recent measures

The MofH budget reduced from BGN 713 million (2008) to BGN 537 M (2009) and BGN 570 M (2010). Planned National Health Insurance Fund revenues in 2009 were BGN 2, 47 M but only BGN 2, 21 M was collected. Planned expenditures were BGN 2, 07 M but real expenditures were BGN 1, 75 M.

In 2011 the government was planning to reform purchasing of medical devices by centralising certification of medical equipment, labs and highly specialised medical activities and introducing a positive list of medical devices.

The government was planning to decentralise funding for drugs for rare diseases and cancer from the Ministry of (Philipa Mladovsky, 2012).

Questions

Cutting staff in public services

1. To achieve short-term savings by lowering overhead costs, Bulgaria reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds. Do you have examples?

Croatia

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)

1970	1980	1990	2000	2010	2011

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010

Price level index for pharmaceutical products in 2005, EU25=100

Na

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Prescription only medicines	setting maximum wholesale prices	5	na	na

Countries in basket (Philipa Mladovsky, 2012)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
				■					■		■			■										■			

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
Na	Na	Na	na	na	na	Na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Na	Na	na	Na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment	Positive/negative lists
Na	Na

Generic substitution (Vogler, 2012), (GÖG, 2010)

Na

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler markup	Type of pharmacy markup	VAT	
na	na	na	na	na	na	na	na

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)

Na

Recent measures

Government debt for health expenditures amounted to HRK 4.8 billion in 2008; the goal thus became to reduce the deficit and ensure that spending is financed only from revenues, with new borrowing only to cover previous liabilities. By the end of 2010, the government had reduced the budget for health by HRK 1.5 billion (with unpaid debt reduced by almost 20%).

Office-holders from state level to local level in Croatia will have to offer their resignation if it is established that they have breached the fiscal accountability legislation. According to the legislation, the total expenditure of the general budget (the government's budget plus budgets of local self-government units and financial plans for extra budgetary users) is to be reduced annually by one percentage point of the projected GDP.

Co-payments have been reduced from HRK 15 in 2009 to HRK 10 for primary care visits and prescriptions. Supplementary health insurance premiums increased in 2010, depending on income: an insured person (employee) with a monthly salary or income of more than HRK 5108 pays HRK 130 per month instead of HRK 80; an insured person (pensioner) with a monthly pension or income of more than HRK 5108 pays HRK 80 per month instead of HRK 50. Certain categories of insurance are exempt from payment (depends on: health status, economic status, age, etc.).

In 2010 Croatia substantially reformed its pricing and reimbursement regulation for prescription medicines. The wholesale prices of all medicines are set through international price comparisons (based on France, Italy, Slovenia, Spain and Czech Republic) and internal reference pricing. International price comparisons are used for setting maximum wholesale prices.

Financing of drugs is regulated by cross product agreements and pay back agreements (i.e. defined maximum expenditure limits, overspends paid back by pharmaceutical companies or avoided by timely donations, strict penalties for deliberate shortages). These measures decreased drug expenditure by 7%. (Philipa Mladovsky, 2012).

Questions

Decreased user charges

Health authorities took the following steps to protect people from financial hardship when accessing health care:

1. Reducing user charges for primary care: do you have testimonies from patients with lower income who could access more easily to their doctors?
2. Reducing user charges for outpatient prescription drugs: do you have testimonies from patients with lower income who could purchase more easily their medicines?

Cutting staff in public services

To achieve short-term savings by lowering overhead costs, Croatia reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds.

3. Do you have examples?

Other measures

4. Increasing investment in e-health: do you have examples of new e-health instruments particularly useful in your country?

Cyprus

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)

1970	1980	1990	2000	2010	2011

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010

Price level index for pharmaceutical products in 2005, EU25=100

102

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Imported prescription only medicines and over-the-counter medicines	Pharmacy purchasing price	4	5	Avg. of the 4 lowest plus 3% to cover

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
■								■			■												■				

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
na	na	na	na	na	na	na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital and ambulatory care	na	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment — Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Obligatory in public sector

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler markup	Type of pharmacy markup	VAT	
5.6	na	na	na	Differs for locally manufactured versus imported drugs	Linear	5.0%	15.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: % (public sector)**

Recent measures

In 2011 the government made the decision to again postpone the implementation of the new National Health Insurance system. Cyprus, which does not have a health care system that offers

universal coverage, in 1991 voted for the law that would create a new National Health Insurance Scheme but this has not been implemented to date. According to Ministry of Health estimates, in 2007 83% of the population had comprehensive coverage free of charge at the point of service. The rest of the population has access to public health services either on reduced or full rates (2% and 15% of the population, respectively) (Philipa Mladovsky, 2012).

Questions

Increased user charges

1. User charges (charge for the use of a product or service) for ambulatory care were increased: do you have testimonies from patients renouncing to visiting their doctor due to too high user charges?
2. Prescription drugs co-payment was increased: do you have testimonies from patients renouncing to purchasing a medicine due to too high co-payments?
3. User charges (charge for the use of a product or service) for emergency departments were increased: do you have testimonies from patients renouncing to emergency care due to too high user charges?

Czech Republic

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
			6	6.5	6.3	6.7	7.7	7.2	7.4	

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)

1970	1980	1990	2000	2010	2011
					20.0%

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
2217	2223,05	0,3%

Price level index for pharmaceutical products in 2005, EU25=100

70

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
All medicines	Ex-factory prices	8	11	Avg. of all countries

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
na		Na	na	na	na	na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital and ambulatory care	Hospital care: Vaccines, pharmaceuticals as defined in pandemic plans; pharmaceuticals relevant for public hygiene in competence of MoH	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010): Indicative

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler markup	Type of pharmacy markup	VAT	
2.3	30	4.3%	na	Regressive	Regressive	10.0%	20.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010): %

Recent measures

Decrease in Ministry of Health budget by CZK 2 000 million (about 30% decrease) in 2010 compared to 2008. Increase of user charges for inpatient stay from CZK 60 to CZK 100 per day in hospital planned for 2012. A law is planned for 2012 which will introduce the possibility of charging co-payments for more "luxurious" care, which will be of the same quality as the standard care provided under SHI but with better (hotel-type) amenities. The Ministry of Health cut

reimbursement rate of drugs by insurance funds by 7% between 2009 and 2011. This can result in an increase of co-payments by patients if the importer/producer does not reduce the wholesale price. Mandatory use of positive lists of drugs for Ministry of Health providers (university hospitals, representing 50% of the market) introduced in 2011 (previously the list was voluntary). Further lists planned for 2012.

The basic benefit package and list of reimbursed services will be assessed from the perspective of health technology assessment (using evidence from abroad) in 2012/2013. Information to patients on which services are reimbursed will be improved in 2012. This may result in a reallocation of public and private expenditure.

Change of reimbursement mechanisms in hospitals from global budgets towards diagnosis related groups planned for 2012. Restructuring of inpatient beds is being considered (analysis being done in 2011) in order to decrease number of acute care beds and increase number of beds for follow-up care (Philipa Mladovsky, 2012).

Questions

Co-payment for medicines

1. Did you notice an increase of the co-payment for medicines? Do you have examples?

Reimbursement policy for medicines

2. A review of reimbursed medicines started in 2008.Do you have examples of medicines for rare diseases which are no longer reimbursed?

Increased user charges

3. Prescription drugs co-payment was increased: do you have testimonies from patients renouncing to purchasing a medicine due to too high co-payments?
4. Hospital care costs were increased: do you have testimonies from patients renouncing to hospital care a medicine due to too user charges?
5. Non-routine vaccines user charges were increased: do you have testimonies from patients renouncing to some specific vaccines due to too high user charges?
6. Medical devices charges were increased: do you have testimonies from patients renouncing to some medical devices due to too high user charges?

Cutting staff in public services and other measures

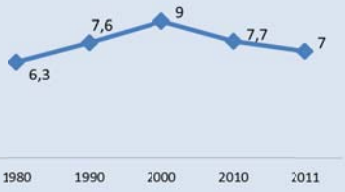
7. To achieve short-term savings by lowering overhead costs, Czech Republic reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and health insurance funds. Do you have examples?
8. Increasing investment in e-health: do you have examples of new e-health instruments particularly useful in your country?
9. Doctors may have to prescribe a medicine using the international non-commercial name and no longer a commercial name. Do you have examples where patients had to change a medicine they were used to for the same medicine but from a different manufacturer?

Denmark

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
3.9	6.3	7.2	8.1	9.5	9.6	9.8	11.0	10.7	10.5	

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)



1970	1980	1990	2000	2010	2011
	6.3	7.6	9.0	7.7	7.0

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
1942	1763	-9.2%

Price level index for pharmaceutical products in 2005, EU25=100

121

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Not applied	-	-	8	-

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
Reimbursement Committee of the Danish Medicines Agency (DKMA)	Coverage	Every new drug	Yes	Not clear when applied	No	No

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital care	Vaccines, pharmaceuticals against communicable diseases, pandemics	Na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010): **Obligatory**

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler markup	Type of pharmacy markup	VAT	
0.6	5	6.5%	19.3%	Negotiations with manufacturer	Linear and dispensing fee	25.0%	25.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010): **%**

Recent measures

Continued growth in health care budgets by DKK 5 billion through 2011–2013 financed in part through cross-subsidisation of the health budget from the education budget.

As part of on-going policies accelerated after 2008, efforts to improve rational pharmacotherapy (Philipa Mladovsky, 2012).

Questions

Co-payment for medicines

1. Did you notice an increase of the co-payment for medicines? Do you have examples?

Increased user charges

2. User charges (charge for the use of a product or service) for in vitro fecundation were increased: do you have testimonies from patients renouncing to in vitro fecundation due to too high user charges?

Cutting staff in public services

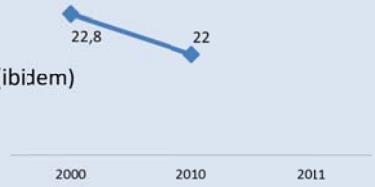
3. To achieve short-term savings by lowering overhead costs, Denmark reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds.
   Do you have examples?

Estonia

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
			5.2	5.0	5.1	5.8	6.8	6.3	5.8	

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)



1970	1980	1990	2000	2010	2011
			22.8	22.0	

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
198		

Price level index for pharmaceutical products in 2005, EU25=100

79

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Innovative reimb.	Ex-factory prices	4	7	Not defined

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
																											Country of origin

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
-	-	-	-	-	-	-

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital and ambulatory care	Hospital care: vaccines, pharmaceuticals against communicable diseases and drug addiction disorders	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Indicative

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler markup	Type of pharmacy markup	VAT	
2.3	50	na	19.0%	Regressive	Regressive	9.0%	20.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: Fixed, %**

Recent measures

The Ministry's health expenditure reduced by 24% in 2009 compared to 2008. Cuts focused on non-communicable diseases (NCDs) and programmes on communicable diseases were protected.

European Union (EU) social funds were used to compensate for the reduction in NCD budget but these funds will no longer be available from 2012.

Estonian Health Insurance Fund (EHIF) accumulated substantial reserves before the crisis. The government did not allow these reserves to be depleted during the initial period of the crisis, but later these reserves were gradually used to compensate for the decreasing revenues of the EHIF.

15% co-insurance rate for nursing inpatient care was introduced from 2010.

The Estonian Health Insurance Fund (EHIF) reduced the benefit package in two ways. First, the system for temporary sick leave benefits was reformed. From 1 July 2009 no benefit is paid during the first three days of sickness or injury (previously first day only), the employer pays the benefit from day 4 to day 8t and the EHIF starts to pay the benefit from day nine (and not from day two).

The rate of sickness benefit was reduced from 80% to 70% of the insured person's income. The rate of sickness benefit in the case of caring for a child less than 12 years of age was reduced from 100% to 80%.

The maximum length of maternity leave was reduced from 154 days to 140 days.

The Ministry of Social Affairs was developing a comprehensive health technology assessment system in 2011 with the help of Tartu University.

Maximum waiting times for outpatient specialists' visits increased in March 2009 by the decision of the EHIF supervisory board from four to six weeks.

In March 2010 the Ministry of Social Affairs (MOSA) initiated amendments to the ministerial decree on drug prescriptions to support active ingredient-based prescribing and dispensing. The amendment did not change prescribing rules, but does require pharmacies to provide patients with the drug with the lowest level of cost sharing and to note if patients refuse cheaper alternatives. In April 2010 the Health Insurance Act was amended to extend the application of price agreements and reference pricing to medicines in the lowest (50%) reimbursement category (some effective drugs and many less cost effective drugs). Price agreements previously only applied to drugs reimbursed at higher rates (100%, 90% and 75%).

At the beginning of 2010 EHIF and MOSA launched a new e-prescription system, which currently operates alongside paper prescribing. The new system makes active ingredient-based prescribing easier. (Philipa Mladovsky, 2012).

Questions

Increased user charges

1. User charges (charge for the use of a product or service) for ambulatory care were increased: do you have testimonies from patients renouncing to visiting their doctor due to too high user charges?
2. User charges (charge for the use of a product or service) for long term care were increased: do you have testimonies from patients renouncing to long term care?

Other measures

3. E-prescribing was introduced in 2010: do you have examples where this made care more complex?
4. Pharmacies are now obliged to provide the least expensive medicine to patients and to have it on stock: do you have examples which may have affected the patients (more difficult medicine to take, new adverse reactions, medication errors…)?

France

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
5.3	6.9	8.2	9.8	10.5	10.4	10.6	11.3	11.3	11.2	

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)

1970	1980	1990	2000	2010	2011
24.4	16.4	17.3	16.9	16.5	16.1%

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
36006	36146.6	0.6%

Price level index for pharmaceutical products in 2005, EU25=100

91

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Innovative reimbursed medicines	Ex-factory prices	4	13	Prices "similar" to those in the reference countries DE, ES, IT, UK)

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
					■				■					■												■	

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
Evaluation Committee for Medicines of the National Health Authority (HAS) and Economic Committee for Health Products (CEPS)	Coverage and pricing	Every new drug	Yes	Not clear when applied	No	Yes

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital care	na	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010): **Obligatory**

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
3.6	10	6.2%	na	Regressive	Regressive	5.0%	25.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010): **Fixed, %**

Recent measures

Since the economic crisis, the health budget has increased sharply and the deficit has risen from EUR 4.4 billion in 2008 to EUR 10.6 billion in 2009. In 2010 the total increase in health spending was 3.2% compared to 2009. The increase in the deficit is linked both with higher expenses and lower revenues from tax (e.g. General Social Contribution, the income tax earmarked for social security spending). In 2011 the planning budgetary assumption was that expenses for health would increase overall by 2.9% in comparison with 2010.

The social security budget of November 2010 included a number of measures to reduce costs and increase revenues. It was anticipated that savings in 2011 in health expenses would reach EUR 2 billion.

Since 2008 new co-payments for prescription drugs, doctor visits and ambulance transport are not reimbursable by private voluntary health insurance.

The social security budget of November 2010 included the following measures to increase revenues:

- A decrease from 35% to 30% of the rate of reimbursement of pharmaceuticals;
- A decrease from 65% to 60% for the rate of reimbursement of medical procedures;
- This comes in addition to the increase from EUR 16 to EUR 18 per day for the patient's contribution to a stay in hospital that was introduced in 2010.
- In addition, French statutory health insurance has applied a new rule since 2009 that penalises patients who do not follow the agreed medical pathway by increasing their co-payment contribution by 40%.

Le Revenu Minimum d'Insertion (RMI) or basic benefit was replaced in June 2009 by the Revenu de Solidarité Active (RSA), resulting in an increase in the number of overall recipients. With this change, beneficiaries of the new RSA automatically have the right to receive state-funded CMU (Couverture Maladie Universelle) – universal health insurance – and complementary insurance CMU-C.

Five-year hospital sector investment plan (2008– 2012) of EUR 16 billion of which only EUR 6 million is to be spent in 2010–2012 (Philipa Mladovsky, 2012).

Questions

Co-payment for medicines

1. Did you notice a decrease in the reimbursement of some medicines from 35% to 30%? Do you have examples for some rare diseases?

Increased user charges

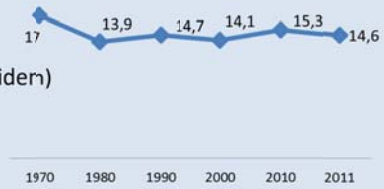
2. Prescription drugs co-payment was increased: do you have testimonies from patients renouncing to purchasing a medicine due to too high co-payments?
3. Hospital care costs were increased: do you have testimonies from patients renouncing to hospital care a medicine due to too user charges?

Germany

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
5.7	8.1	8.0	9.9	10.3	10.1	10.3	11.3	11.1	11.0	

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)



1970	1980	1990	2000	2010	2011
17.0	13.9	14.7	14.1	15.3	14.6%

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
42383	41352.0	-2.4%

Price level index for pharmaceutical products in 2005, EU25=100

128

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Specific reimb. medicines	na	15	11	Na

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
■	■			■		■		■	■	■	■		■	■					■	■			■	■		■	

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
Institute for Quality and Efficiency in Health Care (IQWiG)	Coverage	Selected drugs based on health/cost impact, drugs with inconclusive evidence	Yes	Yes	Yes	No

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Ambulatory care	Mostly generics (also biosimilars), some branded	Lowest price, product portfolio, supply

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Negative**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Obligatory

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
2.6	5	5.0%	24.0%	Regressive	Linear	19.0%	19.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: %**

Questions

Reimbursement policy for medicines

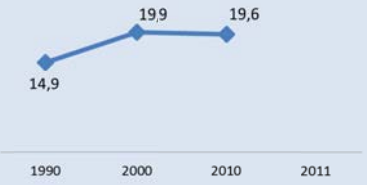
1. A new law on the reimbursement of medicines was adopted in 2011 with a value assessment. Do you have examples of medicines for rare diseases which are not or no longer reimbursed?

Greece

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
5.4	5.9	6.6	7.5	9.4	..	10.0	9.4	9.0	9.4	

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)



1970	1980	1990	2000	2010	2011
		14.9	19.9	19.6	-

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
4515	-	-

Price level index for pharmaceutical products in 2005, EU25=100

-

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
All excl. generics	Ex-factory prices	22	11	Avg. of the 3 lowest price

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
■	■	■	■	■	■				■	■	■	■	■	■	■	■	■		■	■	■	■		■	■	■	

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
-	-	-	-	-	-	-

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital care	-	-

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive/Negative**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Obligatory

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
8.3	160	4.0%	na	Regressive	Regressive	6.5%	23.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: %**

Recent measures

In May 2010, Greece was put under the supervision of European Commission, the European Central Bank (ECB) and the International Monetary Fund (IMF) due to the public deficit and debts as well as the credit crisis. The Memorandum that Greece signed dictates a series of measures referring to the health sector, focusing especially on reduction of public expenditure. In the context of the Memorandum, public health expenditure had to be reduced by 0.5% of GDP during 2011.

The health budget for 2011 decreased by EUR 1.4 billion, with EUR 568 million saved through measures dictated by the Memorandum related to salaries and benefits cuts and EUR 840 million saved through cuts in operating costs of hospitals.

From 2011, an increase in user charges from EUR 3 to EUR 5 in outpatient departments of public facilities; user charges in health centres removed for certain vulnerable groups.

From 2011, the poor and uninsured are only allowed to be treated in designated hospitals and prescribed generics. The Memorandum imposes a limit of no more than two months for submitting an invoice for reimbursement for hospital charges to social insurance funds in Greece as well as other EU Member States and private HICs for non-nationals and non-permanent residents.

The Memorandum aims at saving EUR 2 billion from pharmaceutical products – EUR 1 billion was to be saved in 2011 – reducing pharmaceutical expenditure by 1% of GDP. From 2011, positive list of medicines reintroduced (it was abolished in 2006), with a focus on generics. Reduction in VAT for medicines (11% to 6.5%); increased use of generics (50% of medicines in public hospitals should be generics); maximum generic price is 60% of branded drugs; centralised procurement of medical services and goods; private individuals are permitted to procure contracts; fines from EUR 500 to EUR 50 000 if there is deviation from the approved budget in a procurement contract.

From 2011, salary cuts (e.g. nurses' salary cut by 14% compared with 2009). Temporary staff employed under fixed term contracts removed. Reduction in the replacement of staff who are retiring (for five persons who are retiring only one is to be appointed).

From 2011, reduction in pharmacists' profit by 15–20%. Liberalisation of pharmacies: more than one pharmacist can work at the same pharmacy and pharmacies can be established in closer proximity to each other. Extension of hours, decrease in population threshold for setting up a pharmacy; rebates available.

Development of a pricing system for hospitals on basis of medical cases, which will be used for setting hospital budgets from 2013 (Philipa Mladovsky, 2012).

Questions

Reimbursement policy for medicines

1. Did you notice the re-introduction of a positive list (medicines that are reimbursed) and of a negative one (not reimbursed medicines? Do you have examples where a medicine for a rare disease is no longer reimbursed?
2. Did you notice an increase of the co-payment for medicines? Do you have examples?

Increased user charges

3. User charges (charge for the use of a product or service) for ambulatory care were increased: do you have testimonies from patients renouncing to visiting their doctor due to too high user charges?
4. Prescription drugs co-payment was increased: do you have testimonies from patients renouncing to purchasing a medicine due to too high co-payments?
5. Hospital care costs were increased: do you have testimonies from patients renouncing to hospital care a medicine due to too user charges?

Decreased user charges

On the other hand, health authorities took the following steps to protect people from financial hardship when accessing health care:

6. Abolishing user charges for diagnostic tests in public hospitals: do you have examples of diagnostic tests which became free in public hospitals (no co-payment)?
7. Abolishing user charges for organ transplants in public hospitals: do you have examples of patients who could receive an organ transplant at no cost for them?

Cutting staff in public services

8. To achieve short-term savings by lowering overhead costs, Greece reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds.
   Do you have examples?

Hungary

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
			6.8	8.0	7.4	7.3	7.6	7.8	7.7	7.6

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)

1970	1980	1990	2000	2010	2011
				34.6	34.4

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
2353.9	2461.2	4.6%

Price level index for pharmaceutical products in 2005, EU25=100

74

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Reimbursed medicines	Pharmacy purchasing price	14	11	Lowest price per basket

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
■	■			■	■			■	■		■		■	■						■	■			■	■		1 more

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic Benefit	Cost effectiveness	Alternatives	Budget impact
na	na	Na	Na	na	na	na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital and ambulatory care	Hospital care: Vaccines, pharmaceuticals against communicable diseases, pandemics	Lowest price, supply

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive & Negative**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Indicative

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
2.4	10	6.2	19.0	Regressive	Regressive	5.0%	25.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: Fixed, %**

Recent measures

The centrally set budget for the health insurance fund (HIF) did not change much nominally between 2008 and 2011, which implies that real expenditure on health decreased when adjusting for inflation. Overall, a slight reduction in government expenditure on health as a share of GDP.

From 2008 pharmaceutical and medical appliance companies were obliged to pay a fee to the government exchequer for the promotional activity of their medical sales representatives. This

amounts to around HUF 5 million per year (approx. EUR 20 000) for a sales representative of pharmaceuticals and HUF 1 million for one in the area of medical products.

In 2009 sick-pay benefits were reduced. Previously the HIF could provide sick-pay for up to one year for employees with valid insurance. Without insurance it was only 45 days. This changed to 30 days. With a minimum two-year period of insurance the amount was 70% of income. In case of a shorter insurance period or inpatient care it was 60%. After the modification these were decreased to 60% and 50%.

From 2010, financial rewards were introduced for the rational use of drugs. Doctors are rewarded for prescription of cheaper, but therapeutically equivalent substitutes and pharmacies may promote the use of these drugs by altering doctors' prescriptions.

In 2011 the government announced plans to reform the prescription drug subsidy system (Philipa Mladovsky, 2012).

Questions

Increased user charges

1. Insurance for sick-days was reduced from 70 or 60% of salary to 60 or50%. Do you know patients/families who are now financially challenged due to this modification?

Reimbursement policy for medicines

2. Doctors are encouraged to prescribe the cheapest therapeutically equivalent medicine available. Do you have examples of patients who may have difficulties with this policy?

Iceland

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
-	-	-	-	9.1	9.1	9.1	9.6	9.3	9.0	8.9

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)

1970	1980	1990	2000	2010	2011
	-	-	-	-	14.9%

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
140,6	141,2	0.4%

Price level index for pharmaceutical products in 2005, EU25=100

-

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
-	-	-	-	-

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
-	-	-	-	-	-	-

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
-	-	-	-

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment	Positive/negative lists
-	-

Generic substitution (Vogler, 2012), (GÖG, 2010)

-

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
-	-	-	-	-	-	-	-

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)

-

Recent measures

The national budget has been cut considerably post-crisis, including approximately 5% annual cuts to the health care and social security sectors. According to national statistics, per capita total health expenditure growth was -3.1% in 2009 and - 4.0% in 2010. As of March 2009, the Ministry of Health has reduced expenditures, including for equipment, drugs, operating expenses and patient transport. The budget of the National University Hospital has been reduced by approximately 18% from 2007 to 2010.

To minimize the effect of the crisis and cuts in expenditure on health services, a document was published in early 2009 focusing on public health, equity, and labour issues. A number of actions have been taken as a result, such as providing access to dental care free of charge for low-income families since 2009.

There has been increased emphasis on occupational rehabilitation by the Icelandic Rehabilitation Fund to systematically decrease the probability of employees losing their jobs due to incapacity and sickness. To this end, the Icelandic Rehabilitation Fund was established in 2008 to provide consulting services to employees who are on extended sick leave so they do not lose their jobs. Since the financial crisis, activity at the fund has increased.

As of March 2009, official prescription rules must now be followed (i.e. certain generics must be prescribed before trying costlier alternatives), otherwise patients must pay 100% of drug costs. As a result, applicable drug costs were reduced by 10.7% from 2009 to 2010.

Over 700 people have lost their jobs at the National University hospital in the period 2007–2010 (approximately 10% of total staff). According to surveys, these cuts have created negative attitudes among staff. Currently there are physician vacancies in many health care organisations around the country. In addition, the average age of medical doctors is increasing dramatically, as medical doctors choose not to return to the country after obtaining their specialisation abroad.

There have been a number of health centre mergers. For example there were around 20 rural health centres in 2007 but by 2011 there were only 12. (Philipa Mladovsky, 2012).

Questions

Co-payment for medicines

1. Did you notice an increase of the co-payment for medicines? Do you have examples?

Reimbursement policy for medicines

2. Did you notice changes in reimbursement policy, e.g. change from general to individual reimbursement?

Increased user charges

3. User charges (charge for the use of a product or service) for ambulatory care were increased: do you have testimonies from patients renouncing to visiting their doctor due to too high user charges?

Decreased user charges

On the other hand, health authorities took the following steps to protect low income patients from financial hardship when accessing health care:

4. Expanding exemption for dental care from user charges for low income patients: do you have examples of low income patients who had easier access to dental care?

Cutting staff in public services

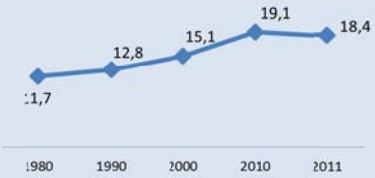
5. To achieve short-term savings by lowering overhead costs, Iceland reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds.
   Do you have examples?

Ireland

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
5.1	7.7	5.8	5.7	7.3	7.5	8.6	9.6	9.0	8.5	

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)



1970	1980	1990	2000	2010	2011
	11.7	12.8	15.1	19.1	18.4

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
2646	2478.7	-6.3%

Price level index for pharmaceutical products in 2005, EU25=100

119

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Prescription-only medicine incl. generics	Pharmacy purchasing price	9	8	Average of all countries

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
■	■				■	■			■	■	■								■							■	

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic Benefit	Cost effectiveness	Alternatives	Budget impact
-	-	-	-	-	-	-

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital and ambulatory care	Hospital care: Vaccines, pharmaceuticals against communicable diseases, pandemics	Most Economically Advantageous Tender

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Disallowed

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
3.4	5	na	na	na	Dispensing fee	0.0%	21.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: No**

Recent measures

Savings in the health budget of over EUR 1 billion announced in 2010 budget. In 2011, the overall budget for health was down by a further EUR 746 million. Increased funds to cover increasing numbers of people on low incomes eligible for medical cards (by September 2009, 1.4 million people were covered by medical cards, up by 4% year on year): increase in the 2009 medical card budget equivalent to a 1% real increase in funding per capita; supplementary budget in the 2011 budget: minor funding increases to cancer care (EUR 10 million), homecare packages (EUR 8 million) child protection (EUR 9 million) and the Fair Deal (EUR 6 million), which provides financial support for people assessed as needing long-term nursing home care.

From 2009, for the two-thirds of the population without medical cards (medical cards confer free access to GPs and waive hospital inpatient fees for those under certain income thresholds and some people over 70 years of age) user charges increased for public (17%) and private (20%) beds in public hospitals, use of the emergency department in public hospitals, emergency department charges, and deductibles for the drugs payment scheme (which reimburses nonmedical card holders for cost of drugs over a certain amount).

In the 2010 budget: introduction of a 50 cent charge for a prescription for all medical card holders up to a maximum of EUR 10 per family per month; increasing the drugs reimbursement threshold to EUR 120 (from EUR 100 in 2009) a month for the 70% of the population who pay for their own drugs.

From 2009, removal of medical cards for the 12 100 wealthiest (3.4%) people aged over 70. Medical cards confer free access to GPs and waive hospital inpatient fees for those under certain income thresholds.

Renegotiation of deals with pharmaceutical companies from 2010. From 2009, reduction of 8% on all professional fees and cut to pharmacy fees of 24–34%. Further cuts in fees of 5% for health professionals were introduced in 2010 and 2011. (Philipa Mladovsky, 2012).

Questions

Increased user charges

1. Prescription drugs co-payment was increased: do you have testimonies from patients renouncing to purchasing a medicine due to too high co-payments?
2. Hospital care costs were increased: do you have testimonies from patients renouncing to hospital care a medicine due to too user charges?
3. User charges (charge for the use of a product or service) for emergency departments were increased: do you have testimonies from patients renouncing to emergency care due to too high user charges?

Decreased user charges

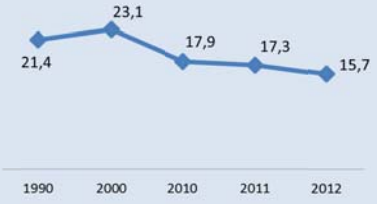
4. On the other hand, health authorities took the following steps to protect low income people from financial hardship when accessing health care:
   Expanding exemption for prescription drugs (for low income patients): do you have examples of low income patients who could purchase prescription medicines more easily?

Italy

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
		7.3	7.7	8.5	8.2	8.6	8.9	8.9	8.7	8.7

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)



1970	1980	1990	2000	2010	2011	2012
		21.4	23.1	17.9	17.3	15.7

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
24872	23562	-5.3%

Price level index for pharmaceutical products in 2005, EU25=100

118

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Reimbursed medicines	Ex-factory prices	Not defined	12	Average of all countries

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
																											Not defined

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
-	-	-	-	-	-	-

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
na	na	na	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment — Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Indicative

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
2.9	70	3.0	na	na	Linear	10.0%	20.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: Fixed**

Recent Measures

In 2011, investment in health care infrastructures was to be cut from over EUR 1 billion to EUR 236 million. Research funding for the public health care sector was to be cut from EUR 91.9 million to EUR 18.4 million. The fund for disease prevention and health promotion was to be cut from EUR 29.6 million to EUR 5.9 million. Palliative care was to be cut to only EUR 1 million.

From 2010 a tighter budget cap was fixed for regions' pharmaceutical expenditure. The budget for drugs has been reduced in absolute value by EUR 800 million starting from 2010, being fixed at

13.3% of total public health care expenditure. Consequently the level of financing by the state was reduced by EUR 800 million from the year 2010.

For 2010–2011, removed fee of EUR 10 for specialist and diagnostic services. The 2011 Financial Law introduces increases in co-payment fees for visits to doctors and analysis (EUR 10+) and for interventions in emergency wards not justified by urgent situations (EUR 25+).

From 2010, performance measurement introduced and linked to payment of providers as a cost containment measure. (Philipa Mladovsky, 2012).

Questions

Co-payment for medicines

1. Did you notice an increase of the co-payment for medicines? Do you have examples?

Increased user charges

2. User charges (charge for the use of a product or service) for ambulatory care were increased: do you have testimonies from patients renouncing to visiting their doctor due to too high user charges?

Latvia

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
	2.1	2.5	6.0					6.0		

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)

1970	1980	1990	2000	2010	2011
				21.6	

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
293		

Price level index for pharmaceutical products in 2005, EU25=100

79

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Reimbursed medicines	Ex-factory prices	2	7	Third lowest price and not higher than the price in LT+EE

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
																											Not defined

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
-	-	-	-	-	-	-

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital and ambulatory care	Hospital care: Vaccines, pharmaceuticals against communicable diseases, pandemics and oncology drugs	Lowest price

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012)**,** (GÖG, 2010)**: Indicative**

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
3.8	na	3.3	19	Regressive	Regressive	12.0%	22.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: %**

Recent measures

The following specific financial cuts in expenditure were made by the Ministry of Health in 2010 compared to 2008:

- treatment -40.4%
- public health -88.6%

- central administration - 58.6%
- medical and health education at university - 41.7%
- administration of health care financing - 67.7%

Funding in the budget for work of heart health cabinets and control and epidemiological surveillance decreased by 86.9% and funding for health statistics reduced by 74% in 2010 compared to 2008.

In 2009 the pharmaceutical reimbursement budget was decreased by 7.1% compared to 2008. Primary care was set as a priority, so cuts in the reimbursement of pharmaceuticals were proportionally smaller than cuts in the sector of inpatient health care.

Reimbursement of pharmaceuticals: measures that came into force in 2009 were the reduction of the percentage of reimbursement for certain diagnoses from 75% to 50% and from 90% to 75% for other diagnoses. Thus the financial burden was partially shifted to patients. Consequently, there was an increase in patient co-payment by 59% in 2009 compared to 2008. This resulted in an average level of patient co-payments in the reimbursement system of approximately 30% in 2009.

At the same time, 100% reimbursement was maintained for the most severe diagnoses, such as oncology and endocrinology. The reduction of the rate of reimbursement was a short-term measure to reduce costs; it was understood that it could seriously affect public health indicators in the longer term.

The Social Safety Net was introduced in Latvia at the end of 2009 and is financed by a loan from the World Bank. Most of the Social Safety Net spending on health care is intended to cover the co-payment of patients for health care services and to provide 100% reimbursement of medicinal products for the less well-off – those who receive less than LVL 120 per month, equivalent to EUR 170. It was planned that this measure will end on 31 December 2011.

Therapeutic reference groups were extended and more attention was given to the international comparison of pharmaceutical prices. The Centre of Health Economics re-evaluated the cost–effectiveness and prices for the treatment of HIV/AIDS in 2009 and specified recommendations for the prescribing of pharmaceuticals. Previously, the pharmaceuticals for HIV/AIDS were purchased centrally but have been included in the reimbursement system since 2010.

On the basis of an evaluation of cost–effectiveness and negotiations with companies on price reductions based on international comparisons, the Centre of Health Economics made significant price reductions – from 3% to 49% – compared to prices in 2009. This enabled treatment for an increasing number of patients for the same amount of money.

The Public Health Agency was closed in 2009. Many public health functions were distributed among other institutions and some were lost.

The number of publicly funded hospitals with inpatient care provision in Latvia decreased from 88 in 2008 to 72 in 2009 and 39 in 2010. The number of hospitals per 100 000 inhabitants in 2009 was 3.18, compared to 1.73 in 2010. The number of hospital beds decreased from 746/100 000 inhabitants in 2008 to 625 in 2009 and 493 in 2010. In 2009 compared with 2008 the number of hospital admissions and bed days in inpatient hospitals decreased by 27.1%. Average costs per

single hospital stay decreased by 1.2% but the cost of one inpatient day increased by 6.8% (Philipa Mladovsky, 2012).

Questions

Co-payment for medicines

1. Did you notice an increase of the co-payment for medicines? Do you have examples?

Increased user charges

2. User charges (charge for the use of a product or service) for ambulatory care were increased: do you have testimonies from patients renouncing to visiting their doctor due to too high user charges?
3. Prescription drugs co-payment was increased: do you have testimonies from patients renouncing to purchasing a medicine due to too high co-payments?

Cutting staff in public services

4. To achieve short-term savings by lowering overhead costs, Latvia reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds.
   Do you have examples?

Lithuania

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
		3.3	6.5					7.5		

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)

1970	1980	1990	2000	2010	2011
				26.6	

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
528		

Price level index for pharmaceutical products in 2005, EU25=100

70

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Prescription only medicines incl. generics	Ex-factory prices	6	10	Declared manufacturer price is compared with 95% of the average manufacturer prices in reference countries

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
				■			■					■								■						■		

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
-	-	-	-	-	-	-

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
na	na	na	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010): **Indicative**

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
4.5	na	8.5	na	Regressive	Regressive	5.0%	21.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010): **%**

Recent measures

In 2008 government expenditure on health was LTL 1000.7 million but it declined to LTL 854.4 million in 2009. In 2009 the budget of the Compulsory Health Insurance Fund (CHIF) remained at the same level as in 2008. However, in the year 2010 its budget decreased by 8% compared to years 2009 and 2008 (LTL 4.01 billion compared to LTL 4.39 billion).

State subsidies for people insured by the state more than doubled (from LTL 674 million in 2007 to LTL 781 million in 2008, LTL 1.1 billion in 2009 and LTL 1.5 billion in 2010). The subsidies for those insured by the state increased from LTL 353 in 2007 to LTL 428 in 2008, LTL 605 in 2009, and LTL 744 in 2010 per insured person per year.

For the year 2011 it was planned that the state would pay LTL 733 per insured person. According to health insurance legislation, in any given year, this amount is calculated as approximately one-third of the average gross salary in the country two years previously.

In 2009 some changes were implemented reducing payment of illness benefit, which is paid for socially insured temporarily sick people from the Social Insurance Fund. For example, previously illness benefit was 85% of the salary of a socially insured person in the majority of cases. After the changes were implemented, during the first seven days illness benefit is only 40% of salary and, after the eighth day, 80% of the salary.

The Plan for the Improvement of Pharmaceutical Accessibility and Price Reduction was approved in July 2009. From 2010 there were new requirements for generic pricing, e.g. the first generic has to be priced 30% below the originator, while the second and third generics must be priced at least 10% less than the first generic to be reimbursed.

A newly priced catalogue of medicines which are reimbursed from the CHIF was enacted. Medicines started to be reimbursed according to active substance (INN) of the product and patient has the right to choose medicine for which co-payment is smallest. The base price of more than 1000 medicines was reduced. (Philipa Mladovsky, 2012).

Questions

Co-payment for medicines

1. Did you notice an increase of the co-payment for medicines? Do you have examples?

Cutting staff in public services

2. To achieve short-term savings by lowering overhead costs, Lithuania reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds.
   Do you have examples?

Other measures

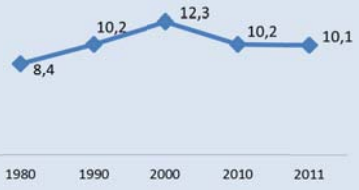
3. Pharmacies are now obliged to provide the least expensive medicine to patients and to have it on stock: do you have examples which may have affected the patients (more difficult medicine to take, new adverse reactions, medication errors…)?
4. Since 2010 doctors are obliged to prescribe a medicine using the international non-commercial name. Do you have examples where patients had to change a medicine they were used to for the same medicine but from a different manufacturer?
5. Which medicines?

Netherlands

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
	7.0	7.5	7.6.	10.0	10.0	10.2	11.0	11.2	11.1	11.6

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)



1970	1980	1990	2000	2010	2011
	8.4	10.2	12.3	10.2	10.1

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
6715.0	6755.0	0.6%

Price level index for pharmaceutical products in 2005, EU25=100

109

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Prescription only medicines	Pharmacy retail price	4	8	Avg. of all countries

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
	■				■						■															■	

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
Health Care Insurance Board, Committee for Pharmaceutical Aid (CHF)	Coverage and pricing	Drugs not classifiable under reference pricing system	Yes	Yes	Yes	Yes

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Ambulatory care	Several products	Lowest price

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Indicative

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
1.2	10	18	Na	Negotiations with manufacturer	Dispensing fee	6.0%	19.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: Yes**

Recent measures

Co-payments were to be increased for certain services from 2010, as a result of restrictions in the benefit package.

From 2010, limited reimbursement for physiotherapy sessions; coverage of care outside the EU removed and requires bilateral adjustments with certain countries; mental health services restricted and psychological care reimbursement reduced from eight to five sessions.

From 2010, policies allowing Health Insurance Funds to have a greater role in purchasing care accelerated, playing an important role in the reduction of prices of, for example, medicines and executing a "preferential policy" to keep drug prices under control.

From 2010, as part of the changes to purchasing by social health insurance funds, pharmacists receive a pre-defined fee for each service and bonuses are removed.

From 2010, greater integration of primary care at the community level to reduce use of hospital care and promotion of e-mental health to increase self-management (Philipa Mladovsky, 2012).

Questions

Reducing access to care

1. Health authorities reduced access to some mental health services: do you have examples of patients who could not access mental health services they needed?

Responses

Ellen van Veldhuizen

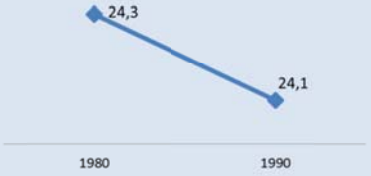
- In fact access to psychological care is becoming easier.
- In 2013, patients could benefit from 5 reimbursed consultations to a primary care psychologist (reimbursed by their health insurance). In 2014, this limitation of 5 consultations expires.
- All treatments within the basic mental healthcare are covered by the health insurance. From 2014 onwards, there is no co-payment anymore.
- At the end of the treatment, the practitioner submits the costs to the health insurance.
- http://www.rijksoverheid.nl/onderwerpen/geestelijke-gezondheidszorg/basiszorg-ggz-en-zorg-dichtbij-huis

Poland

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
		4.4	5.3	5.9	5.9	6.4	6.7	6.5	6.4	

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)



1970	1980	1990	2000	2010	2011
				24.3	24.1

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
5613.0	5557.7	-1%

Price level index for pharmaceutical products in 2005, EU25=100

68

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Reimbursed medicines	Ex-factory Prices	17	9	Lowest price per basket

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
	■			■	■	■		■	■		■	■	■	■	■	■			■		■		■			■	Switzerland

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
na	na	na	na	na	na	na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
na	na	na	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Indicative

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
2.8	na	9.8	na	Regressive	Regressive	8.0%	23.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: %**

Recent measures

In 2009, the government cut its investment expenditures in health care infrastructure by half. The lower expenditures were continued in subsequent state budgets.

A new law was presented by the government in 2011, to regulate the reimbursed drugs market. The key elements of the regulations are as follows: maximum limit of National Health Fund expenditures for drugs reimbursement was established at the level of 17% of total expenditures – when the limit is exceeded, producers of pharmaceuticals included in the reimbursement system will be obliged to pay back certain amounts; maximum margin on drugs sold by wholesalers and pharmacies; prices of reimbursed drugs in pharmacies will be fixed; no discounts are allowed between wholesalers and pharmacies. The law is very much criticised by the pharmaceutical industry, pharmacies and other interested parties, but has a strong support from the government and the Parliament.

New law introduced in 2011 to allow hospitals to be corporatized. They will continue to be publicly owned but will be subject to bankruptcy laws. This is intended to improve financial management (Philipa Mladovsky, 2012).

Questions

Co-payment for medicines

1. Did you notice an increase of the co-payment for medicines? Do you have examples?

Reimbursement policy for medicines

2. Did you notice the effect of the new reimbursement law adopted in 2012? Do you think reimbursement decisions are faster?
3. Or do you have examples of issues with the reimbursement of medicines for rare diseases?

Other measures

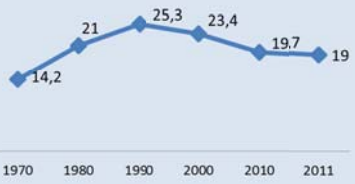
4. New reimbursement law valid from 2012 on: information duties of pharmacies about least expensive equivalent medicines and having them on stock. Do you have examples of patients who were informed about a less expensive medicine and who accepted to be provided with this one? For which medicines?

Portugal

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
2.4	5.0	5.8	8.5	9.4	9.4	9.7	10.2	10.2	9.7	9.4

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)



1970	1980	1990	2000	2010	2011
14.2	21.0	25.3	23.4	19.7	19.0

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
3450.0	3135,6	-9.1%

Price level index for pharmaceutical products in 2005, EU25=100

94

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Prescription only medicines and reimbursed Over the counter (excl. generics)	Ex-factory Prices and Pharmacy retail price	3	11	Average of all countries

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
									■					■										■			

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
na	na	na	na	na	na	na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital and ambulatory care	Na	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Yes**

Generic substitution (Vogler, 2012)**,** (GÖG, 2010)

Obligatory

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
2.6	10	6.9	18	Regressive	Regressive	6.0%	23.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: %**

Recent measures

The government has initiated a comprehensive reform package to improve efficiency and to reduce significantly the costs of the health care sector. Authorities expected the package to yield savings worth EUR 700 million in 2011. The government is committed to achieve further cost savings of EUR 200 million in 2012 by cutting operational costs by 10%.

Through the Fundação para a Ciência e a Tecnologia (FCT), the state subsidises research and development (R&D), grants higher education research scholarships and awards funding to research units. In 2011, some R&D units were informed that a large part of the predicted funding would not be available and many research scholarships are also being eliminated.

From 2011: increase in charges applied to some vaccines, such as yellow fever, Japanese encephalitis, typhoid, meningitis and rabies tetravalent. These charges of less than EUR 1 per vaccine increased to EUR 50– 100 per vaccine. And also:

- Increase in charges asked for doctor declarations by a health authority or a public health professional from less than EUR 1 to EUR 20;
- doctor declarations attesting to the incapacity of a patient for health reasons by a medical board to EUR 50;
- doctor declarations of appeal by a medical board to EUR 100. This means that a disabled person who wants to access fiscal benefits (paying less income tax, for instance, or paying less taxes when buying a car adapted for disabled people), and for whom asking for a doctor's declaration of appeal by a medical board is mandatory to access these benefits, now has to pay much more than before.
- State subsidy for some pharmaceutical drugs was cancelled, totally or partially: In 2010, a law which granted 100% state subsidy for some antidepressants, antipsychotic and other drugs associated with the treatment of a few serious mental illnesses (such as schizophrenia, dementia, autism, bipolar disorder) was revoked. Those patients now have to pay 5–10% of the cost of treatment. From January 2011, 16 types of pharmaceutical drugs (for which medical prescription was not mandatory) were no longer subsidised, including paracetamol, anti-acids and antivirals.

From 2011, centralised procurement of medicines and diagnostic tests; reductions in pricing and reimbursement; faster availability of generics, prescribing by active ingredient, prescribing guidelines, e-prescribing.

Measures included in the 2011 national budget: (1) Price reduction on generic drugs that have high prices compared with international ones, starting with the most sold generics omeprazole and simvastatin: prices should be at least 35% lower than the brand pharmaceutical drug. (2) Price reduction of 7.5% on biological pharmaceutical drugs. (3) Price reduction on supplementary diagnostic and therapeutic procedures: 5% on clinical diagnostic tests and 3% on medical imaging. (4) Decrease the price of pharmaceutical goods subsidised by state by 6%.

From December 2010: disciplining consumption in ambulatory hospital; charging a financial penalty in case of inappropriate use of pharmaceutical drugs.

Data regarding beds per 100 000 inhabitants show a decrease from 336.7 beds in hospitals in 2008 to 334.8 in 2009 and from 5.5 beds in primary health centres in 2008 to 4.6 in 2009. Regarding the number of primary health centres, more recently there has been a slight decrease of primary health centres (for example 377 in 2008 to 375 in 2009), but a very strong decrease in primary health centre outposts or peripheral units (1778 in 2008 to 1318 in 2009). (Philipa Mladovsky, 2012).

Questions

Reimbursement policy for medicines

1. Did you notice changes in reimbursement policy, e.g. more rapid reimbursement decision for generics? Or Over-the-counter products which are not reimbursed anymore?
2. Did you notice an increase of the co-payment for medicines? Do you have examples?

Increased user charges

3. User charges (charge for the use of a product or service) for ambulatory care were increased: do you have testimonies from patients renouncing to visiting their doctor due to too high user charges?
4. Prescription drugs co-payment was increased: do you have testimonies from patients renouncing to purchasing a medicine due to too high co-payments?
5. Hospital care costs were increased: do you have testimonies from patients renouncing to hospital care a medicine due to too user charges?
6. User charges (charge for the use of a product or service) for emergency departments were increased: do you have testimonies from patients renouncing to emergency care due to too high user charges?
7. Non-routine vaccines user charges were increased: do you have testimonies from patients renouncing to some specific vaccines due to too high user charges?

Decreased user charges

On the other hand, health authorities took the following steps to protect low income people from financial hardship when accessing health care:

8. Expanding exemption for prescription drugs (for low income patients): do you have examples of low income patients who could purchase prescription medicines more easily?

Cutting staff in public services

9. To achieve short-term savings by lowering overhead costs, Portugal reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds.
   Do you have examples?

Other measures

10. E-prescribing was introduced or reinforced: do you have examples where this made care more complex?

Romania

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
		2.9	5.2					5.6		

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)

1970	1980	1990	2000	2010	2011
				26.9	

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
1816.0		

Price level index for pharmaceutical products in 2005, EU25=100

70

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Prescription only	Ex-factory Prices	12	3	Lowest price per basket

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
■	■	■		■	■			■	■			■		■	■					■					■		

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
na	na	na	na	na	na	na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital and ambulatory care	Hospital care: Vaccines and pharmaceuticals as defined in pandemic plans	Lowest price

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment — Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010): **obligatory**

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
2.3	40	12.0	17.0	Regressive	Regressive	9.0%	24.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010): **%**

Recent measures

Ministry of Health budget reduced from RON 4,969 million in 2008 to RON 4,417 million in 2011. The health sector was protected in comparison to other public sectors in terms of budgetary cuts. New user charges to be implemented during 2011 included the following co-payments:

- RON 5 for a visit to a GP, RON 15 for a home visit by a GP,
- RON 10 for one day in hospital,

- RON 50 for continuous hospitalization for several days.
- The maximum level of co-payment will not exceed RON 600 per individual per year.

The law on co-payments also stipulates exceptions, such as veterans, retired persons with less than RON 700 income per month, children, etc.

In 2010 a limit on the number of reimbursed visits to a GP and specialist physician for the same condition was introduced for the first time: a maximum of five visits. In 2011 the maximum number of visits decreased to three. If a patient wants to use more than the stated number of visits s/he has to pay out of pocket.

Under pressure from pharmaceutical companies and wholesalers, the Ministry of Health updated prices of pharmaceuticals to reflect the new exchange rate (it had worsened due to inflation) causing an increase in prices in 2009.

In 2011 the National Health Insurance Fund changed the reference price system for reimbursed drugs in order to contain costs by stimulating the prescription of medicines with prices below the reference price.

A claw-back mechanism for pharmaceutical companies was introduced in 2010 (after VAT deduction a percentage from the total sales of reimbursed drugs has to be paid back to Ministry of Health; the claw-back rate is on a sliding scale depending on value of total sales).

At the beginning of 2011 Ministry of Health announced the merger of 111 hospitals; 71 hospitals will be converted into nursing homes for the elderly (Philipa Mladovsky, 2012).

Questions

Reducing access to care

1. Health authorities reduced the number of publicly covered doctor visits for the same condition in a year (five visits per year in 2010, reduced to three in 2011): do you have examples of patients who complained they could not see their doctors as needed?

Cutting staff in public services

2. To achieve short-term savings by lowering overhead costs, Romania reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds.
   Do you have examples?

Other measures

3. Increasing investment in e-health: do you have examples of new e-health instruments particularly useful in your country?

Slovenia

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
			8.2	7.8	7.5	7.9	8.6	8.6	8.5	8.5

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)

1970	1980	1990	2000	2010	2011
				20.3	20.2

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
621.0	623,4	0.4%

Price level index for pharmaceutical products in 2005, EU25=100

86

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Reimbursed medicines	Ex-factory Prices	3	8	95% of the average of the 3 countries

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
■						■					■																

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
na	na	Na	na	na	na	na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital and ambulatory care	na	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment — Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Indicative

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
1.5	10	8.5	2.10€	Regressive	Regressive + dispensing fee	8.5%	20.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: %**

Recent measures

In 2009 the NHIF introduced changes treatment, certain medicines, non-urgent ambulance services, dental prosthesis, and certain ophthalmological appliances). As a result, a higher percentage of costs is paid by patients (most of whom are subsequently reimbursed by voluntary health insurance).

In 2009 the National Health Insurance Fund (NHIF) revised lists of medicines; reduced prices of medicines through negotiation with suppliers; provided information to the public regarding proper use of medicines; provided training in rational prescribing for physicians; and reduced the price of dialysis due to lower prices of erythropoietin.

In 2009 the NHIF reduced the price of health services (generally) by 2.5% and implemented penalties for health care providers related to the breach of the contract between the fund and the provider. (Philipa Mladovsky, 2012).

Questions

Increased user charges

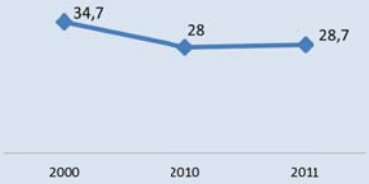
1. Prescription drugs co-payment was increased: do you have testimonies from patients renouncing to purchasing a medicine due to too high co-payments?
2. Dental prosthesis user charges were increased: do you have testimonies from patients renouncing to dental prosthesis due to too high user charges?

Slovakia

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
			5.4	7.0	7.4	7.6	8.6	8.5	7.6	

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)



1970	1980	1990	2000	2010	2011
			34.7	28.0	28.7

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
1567.0	1504.7	-4.0%

Price level index for pharmaceutical products in 2005, EU25=100

71

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Reimbursed medicines	Ex-factory Prices	26	8	Avg. of the 6 lowest countries in the basket

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic Benefit	Cost effectiveness	Alternatives	Budget impact
na	na	Na	Na	na	na	na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
na	na	na	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Obligatory

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
3.6	10	na	21.0	Regressive	Regressive + dispensing fee	10.0%	20.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: Fixed, %**

Questions

Decreased user charges

1. Health authorities took the following steps to protect low income people from financial hardship when accessing health care:
   Expanding exemption for prescription drugs (for low income patients): do you have examples of low income patients who could purchase prescription medicines more easily?

Cutting staff in public services

2. To achieve short-term savings by lowering overhead costs, Slovakia reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds. Do you have examples?

Other measures

3. Doctors may have to prescribe a medicine using the international non-commercial name and no longer a commercial name. Do you have examples where patients had to change a medicine they were used to for the same medicine but from a different manufacturer?
4. Which medicines?

Spain

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
3.2	5.1	6.3	7.0	8.1	8.2	8.6	9.3	9.4	9.1	

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)

1970	1980	1990	2000	2010	2011
	21.8	18.6	22.0	18.8	

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
18500.0		

Price level index for pharmaceutical products in 2005, EU25=100

77

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Innovative reimb.	Ex-factory Prices	Not defined	14	na

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other
																											Euro zone countries

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic Benefit	Cost effectiveness	Alternatives	Budget impact
na	na	Na	Na	na	na	na

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
na	Na	na	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Negative**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Obligatory

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
4.5	60	3.5	na	Regressive	Regressive	4.0%	18.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: %**

Recent measures

The health system is decentralised to the level of autonomous regions. The regions have responsibility for budgets and applying cost-containment measures. To date the only region that has drafted an Action Plan for building sustainability of the health system is Catalonia (April 2011). Under the plan, the 2011 health budget is 10% lower compared to 2010 (and, in nominal terms, is equal to the 2007 budget). The measures are justified based on the following initial financial situation of the Catalan health system: between 2003 and 2010 the Catalan health budget

increased by 76.5% and the deficit was reduced by EUR 2.61 million. Nevertheless, 2010 ended with a deficit of EUR 850 million.

Catalonia demanded compensation for treating patients residing in other autonomous regions from 2011.

Since 2011, Catalan applies a waiting list management system and makes changes in waiting list prioritisation criteria. From April 2010 reduction in non-urgent care (eye surgeries, hip and knee replacement).

National level: attempts to reduce pharmaceutical expenditures (through more favourable negotiation with the pharmaceutical providers, but not through more efficient use of medicines).

Catalan plan: from 2011, develop efficient prescribing strategies based on cost effectiveness, co-responsibility among providers and patients, use of generics or lower cost alternative (Philipa Mladovsky, 2012).

Questions

Increased user charges

1. Co-payment for medicines sold in both hospitals and community pharmacies is now applied to 34 active substances whereas before, they were only applied when the medicines were sold in community pharmacies. Do you have the list of the 34 medicines in question?
2. Introduced compulsory generic substitution by pharmacies at the cheapest available medicine: the least expensive active ingredient may vary every month, as the buying procedure is negotiated monthly. This result in patients having to change medication due to the current lowest price: burdensome for patients with chronic diseases. Do you have testimonies from patients making mistakes, finding it too complex, or missing doses due to this?

Decreased user charges

3. Health authorities took the following steps to protect low income people from financial hardship when accessing health care:
   Expanding exemption for prescription drugs (for low income patients): do you have examples of low income patients who could purchase prescription medicines more easily?

Cutting staff in public services

4. To achieve short-term savings by lowering overhead costs, Spain reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds.
   Do you have examples?

Other measures

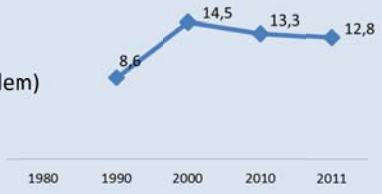
5. E-prescribing was introduced or reinforced: do you have examples where this made care more complex?

Sweden

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
6.8	8.9	7.7	7.8	8.6	8.5	8.8	9.5	9.0	8.9	

Total expenditure on pharmaceuticals as % total health expenditure (ibidem)



1970	1980	1990	2000	2010	2011
		8.6	14.5	13.3	12.8

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
4534.8	4600.4	1.4%

Price level index for pharmaceutical products in 2005, EU25=100

95

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Not applied			7	

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic Benefit	Cost effectiveness	Alternatives	Budget impact
Dental and Pharmaceutical Benefits Board (TLV)	Coverage and pricing	Every new drug	Yes	Yes	Yes	No

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital care	na	na

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Positive**

Generic substitution (Vogler, 2012), (GÖG, 2010)

Obligatory

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
1	10	2.5	21.0	Negotiations with manufacturer	Regressive	0.0%	25.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010)**: %, deductible**

Recent measures

No measures reported in the recent years.

Questions

See questions to all alliances.

United Kingdom

Total current expenditure on health (% GDP)
(Eurostat, OECD Health Data 2013)

1970	1980	1990	2000	2006	2007	2008	2009	2010	2011	2012
4.2	5.3	5.5	6.7	8.0	8.1	8.4	9.3	9.1	9.1	

Total expenditure on pharmaceuticals as % total health expenditure
(ibidem)

1970	1980	1990	2000	2010	2011
15.8	13.5	14.5	14.8	11.0	

Total expenditure on pharmaceuticals (million €) (ibidem)

2010	2011	2011 /2010
18154.0		

Price level index for pharmaceutical products in 2005, EU25=100

93

Characteristics of external reference pricing (Leopold C. S.-T., 2012)

Scope	Price level	# of countries in basket	# of countries using this country as a reference	Calculation of reference price
Not applied			11	

Countries in basket (ibidem)

AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK	Other

Characteristics of health-technology assessment (Sorenson, 2010, July)

Review body	Function	Scope	Key decision criteria			
			Therapeutic benefit	Cost effectiveness	Alternatives	Budget impact
National Institute of Health and Clinical Excellence (NICE)	Coverage and pricing**	Selected drugs based on health impact, disease burden, policy relevance	Yes	Yes	Yes	Yes

**Starting in 2014, the UK will launch an obligatory value-based pricing on all medicines

Characteristics of public tendering (Leopold C. H.), (Kanavos, 2009)

Tendering in place	Applied to	Pharmaceuticals procured	Criteria
Yes	Hospital care	Vaccines, pharmaceuticals against communicable diseases, pandemics	Most economically advantageous tender

HTA, positive/negative lists (GÖG, 2010)

Health technology assessment: **Yes** Positive/negative lists: **Negative**

Generic substitution (Vogler, 2012), (GÖG, 2010): **Disallowed**

Number of wholesalers and pharmacies and their average margins (ABDA, 2011) (Kanavos P, 2011)

#pharmacies per 10,000 population	#wholesalers	Avg. wholesaler margin (%PPP)	Avg. pharmacy margin (%PRP)	Type of wholesaler Markup	Type of pharmacy markup	VAT	
2.1	10	12.5	Na	Negotiations with manufacturer	Linear + dispensing fee	0.0%	20.0%

na = not available; PPP = pharmacy purchase price; PRP = pharmacy retail price; VAT = value-added tax

Cost-sharing policies (GÖG, 2010): **Fixed**

Recent measures

After years of unprecedented budget growth (6.6% per year in 1999–2007), the NHS has entered a new era of austerity. In October 2010 the Department of Health published the Spending Review settlement for the NHS which involves an average 0.1% real terms increase over the next four years

and a requirement to find up to GBP 5 billion productivity improvements a year through to 2014/2015 to meet increased demand and improve the quality of its services.

To meet the rising costs of health care and increasing demand on its services, the NHS will have to release up to GBP 20 billion of annual efficiency savings over the next four years, all of which will be reinvested to meet rising levels of demand and to support improvements in quality and outcomes.

A programme to expand the range of long-term conditions that benefit from free prescriptions was announced by the previous government but not implemented; this will now no longer be taken forward.

A programme of one-to-one nursing for cancer patients and a one-week wait for cancer diagnostics was announced by the previous government but not implemented; it will now not be taken forward.

Various reports of cuts in services are emerging, probably due to less spending power resulting in some form of rationing or restriction in services in the NHS, although more evidence is needed to confirm this (Philipa Mladovsky, 2012).

Questions

Cutting staff in public services

1. To achieve short-term savings by lowering overhead costs, United Kingdom/Scotland reported closing, merging, centralising or cutting staff in non-provider organisations such as the health ministry, public health agencies and, less frequently, health insurance funds. Do you have examples?
2. There are discussions to introduce value-based pricing in 2013. Do you have examples where value-based pricing has already been applied?
3. With which consequences for the patients?

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Glossary

ACCESS (ACCESSIBILITY)

The patient's ability to obtain medical care and a measure of the proportion of a population that reaches appropriate health services. The ease of access is determined by such components as the availability of medical services and their acceptability to the patient, the location of health care facilities, transportation, hours of operation and cost of care. Barriers to access can be financial (insufficient monetary resources), geographic (distance to providers), organisational (lack of available providers) and sociological (e.g., discrimination, language barriers). Efforts to improve access often focus on providing/improving health coverage. [Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

ACCESS WITH EVIDENCE DEVELOPMENT (AED)

Initiative in which a payer provides temporary or interim funding for a particular technology or service to facilitate the collection of information needed to reduce specific uncertainties around a coverage decision. [Source: Stafinski T, McCabe C, Menon D: Funding the unfundable – mechanisms for managing uncertainty in decisions on the introduction o new and innovative technologies into healthcare systems. Pharmacoeconomics 2010; 28:113-42.] See also: managed entry agreements

AFFORDABILITY

The extent to which medicines and further health care products are available to the people who need them at a price they / their health system can pay. [Source: adapted from WHO. A model quality assurance system for procurement agencies]

BRAND NAME (INNOVATOR`S NAME, PROPRIETARY PRODUCT NAME, MEDICINE SPECIALITY PRODUCT NAME, MEDICINAL SPECIALITY PRODUCT NAME)

Name given for marketing purposes to any ready-prepared medicine placed on the market under a special name and in a special pack. A brand name may be a protected trademark.

BUDGET IMPACT

A budget is an estimate of revenue and expenditure for a specified period. Budget impact refers to the total costs that pharmaceutical reimbursement and use entail with respect to one part of the health care system, pharmaceutical care, or to the entire health care system, taking into account the possible reallocation of resources across budgets or sectors of the health care system.

BUDGET IMPACT ANALYSIS (BIA)

Budget Impact Analysis is an essential part of a comprehensive economic assessment of a health care technology and is increasingly required, along with cost-effectiveness analysis (CEA), prior to

formulary approval or reimbursement. The purpose of a BIA is to estimate the financial consequences of adoption and diffusion of a new health care intervention within a specific health care setting or system context given inevitable resource constraints. In particular, a BIA predicts how a change in the mix of medicines and other therapies used to treat a particular health condition will impact the trajectory of spending on that condition. Users of BIA include those who manage and plan for health care budgets such as administrators of national or regional health care programs, administrators of private insurance plans, administrators of health care delivery organisations and employers who pay for employee health benefits. BIA should be viewed as complementary to cost-effectiveness analysis (CEA), not as a variant or replacement. Whereas, CEA evaluates the costs and outcomes of alternative technologies over a specified time horizon to estimate their economic efficiency, BIA addresses the financial stream of consequences related to the uptake and diffusion of technologies to assess their affordability. [Source: Report of the ISPOR Task Force on Good Research Practices – Budget Impact Analysis]

CLAW-BACK

A system allowing third party payers to recoup (part of the) discounts/rebates granted in a reimbursement system between various stakeholders, e.g. wholesalers and pharmacists. [Source: PPRI Glossary]

CO-PAYMENT

Insured patient's contribution towards the cost of a medical service covered by the insurer. Can be expressed as a percentage of the total cost of the service or as a fixed amount. [Source: OECD – Pharmaceutical Pricing Policies in a Global Market] See also: out-of pocket payments

COMMUNITY PHARMACY

Health care facility dispensing medicines (POM and OTC, reimbursable and non-reimbursable medicines) to out-patients. Pharmacies are subject to pharmacy legislation (e.g. national legislation regarding establishment and ownership of pharmacies). In many countries, community pharmacies are private facilities, but public pharmacies (i.e. in public ownership) also exist. Pharmaceutical provision for inpatients is provided for by hospital pharmacies or pharmaceutical depots; in some cases hospital pharmacies also act as community pharmacies. [Source: adapted from PPRI Glossary] See also: hospital pharmacy

CONDITIONAL COVERAGE

Schemes where coverage is granted conditional on the initiation of a program of data collection. [Source: Carlson JJ , Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy. 2010 Aug. 96(3):179-90.] See also: managed entry agreements

COST-BENEFIT ANALYSIS

Compares the cost of a medicinal intervention to its benefit. Both costs and benefits must be measured in the same monetary units (e.g. euro, dollars) [Source: Strom, Kimmel. Textbook of pharmaco-epidemiology]

COST-CONTAINMENT

Measures taken to reduce expenditure or the growth rate of expenditure, or the unit cost of services. Cost-containment measures may be targeted to control inefficiencies in consumption, allocation, or production of health care services that contribute to higher than necessary costs. Cost-containment is a word used freely in health care to describe most cost reduction activities by providers. This includes a broad range of cost control mechanisms e.g. limiting budgets, cost-sharing, regulation of supply of services and staff, patients' waiting lists, exclusion of certain groups from entitlement to services, privatisation, and managed competition. Regarding medicines, it may concern the framework of the pricing and reimbursement systems (e.g. price control, reimbursement lists) and subsequent changes (e.g. price freeze/cuts, de-listings). [Source: adapted from PPRI Glossary]

COST-EFFECTIVENESS

Value for money. A specific health care treatment is said to be "cost-effective" if it gives a greater health gain than could be achieved by using the resources in other ways. [Source: NICE Glossary]

COST-EFFECTIVENESS ANALYSIS (CEA)

Cost-effectiveness analysis (CEA) is an economic analysis that assesses both the costs and the effects of a health intervention. Costs are measured in monetary units. Effects are measured in units of outcomes experienced such as life year gained (LYG), quality adjusted life of years (QALY) or cases of disease prevented. Whether the outcome of an analysis is cost-effective depends on the cost-effectiveness threshold value. CEA can identify the alternative that, for a given output level, minimises the actual value of costs, or, alternatively, for a given cost, maximises the outcome level.

COST-FREE MEDICINES

Cost free medicines are products which are given to hospitals/hospital pharmacies in the course of the delivery without need for payment (e.g. from wholesaler to hospitals/hospital pharmacies or pharmaceutical company to hospitals/hospital pharmacies).

COST-PLUS PRICING

Pricing procedure which calculates a "reasonable" price for a product based on the production costs, promotional expenses, research and development, administration costs, overheads and profit [Source: adapted from PPRI Glossary]

COST-SHARING

A provision of health insurance or third party payment that requires the individual who is covered to pay part of the cost of health care received. This is distinct from the payment of a health insurance premium, contribution or tax which is paid whether health care is received or not. [Source: OECD – A System of Health Accounts] See also: out-of pocket payments

COVERAGE

A measure of the extent to which the services rendered cover the potential need for those services in the community [Source: WHO. A Glossary of Terms for Community Health Care and Services for Older Persons]

COVERAGE WITH EVIDENCE DEVELOPMENT (CED)

A binary coverage decision is conditioned upon the collection of additional population level evidence to support continues, expanded, or withdrawal of coverage [Source: Carlson JJ , Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy 2010 Aug. 96(3):179-90.] See also: managed entry agreements

DE-LISTING

Exclusion of a medicine from a medicine list (e.g. positive list), often resulting in exclusion from reimbursement [Source: PPRI Glossary]

DISCOUNT

A price reduction granted to specified purchasers of a pharmaceutical product under specific conditions. [Source: OECD. Pharmaceutical Pricing Policies in a Global Market]

DISEASE-SPECIFIC REIMBURSEMENT

Eligibility for reimbursement is linked to the underlying disease which shall be treated. [Source: PPRI Glossary]

DISPENSING FEE

Normally a fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up. The fee more accurately reflects the work involved in dispensing a prescription; a percentage mark-up makes profit dependent on the sale of expensive medicines.

EFFECTIVENESS

Effectiveness is the extent to which an intervention does more good than harm when provided under the usual circumstances of health care practice. Relative effectiveness can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice. [Source: European Union Pharmaceutical Forum. Core principles on relative effectiveness]

EFFICACY

Efficacy is the extent to which an intervention does more good than harm under ideal circumstances. Relative efficacy: can be defined as the extent to which an intervention does more good than harm, under ideal circumstances, compared to one or more alternative interventions. [Source: European Union Pharmaceutical Forum. Core principles on relative effectiveness]

EFFICIENCY

An ability to perform well or achieve a result without wasted energy, resources, effort, time or money thus the extent to which objectives are achieved by minimising the use of resources (i.e. obtaining the best possible value for the resources used). Greater efficiency is achieved where the same amount and standard of services are produced for a lower cost, if a more useful activity is substituted for a less useful one at the same cost or if needless activities are eliminated. Efficiency can be measured in physical terms (technical efficiency) or terms of cost (economic efficiency). Technical efficiency means producing the maximum possible sustained output from a given set of inputs. Allocative efficiency is when resources are allocated in such a way that any change to the

amounts or types of outputs currently being produced (which might make someone better off) would make someone worse off. [Source: World Bank]

END USERS OF PHARMACEUTICAL (END USERS)

End users can be patients, consumers, or professional who directly use the pharmaceutical product on patients/consumers. [Source: WHO. IMPACT. Principles and elements for national legislation against counterfeit medical product]

ESSENTIAL MEDICINES

Essential medicines are those that satisfy the priority health care needs of the population. Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. The concept of essential medicines is forward-looking. It incorporates the need to regularly update medicines selections to reflect new therapeutic options and changing therapeutic needs; the need to ensure medicine quality; and the need for continued development of better medicines, medicines for emerging diseases, and medicines to meet changing resistance patterns. [Source: WHO. Essential medicines]

EX-FACTORY PRICE

The manufacturer's posted price. Discounts or other incentives offered by manufacturers result in an effective price that is lower than the ex-factory price. [Source: OECD. Pharmaceutical Pricing Policies in a Global Market]

EXTERNAL PRICE REFERENCING (INTERNATIONAL PRICE COMPARISON)

The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country. [Source: adapted from PPRI Glossary]

FIXED CO-PAYMENT

An out-of-pocket payment in the form of a fixed amount (like for example a prescription fee) to be paid for a service, a medicine or a medical device. [Source: PPRI Glossary] See also: deductible and percentage co-payment.

GENERIC SUBSTITUTION

Practice of substituting a pharmaceutical, whether marketed under a trade name or generic name (branded or unbranded generic), by a pharmaceutical, often a cheaper one, containing the same active ingredient(s) [Source WHO A model quality assurance system for procurement agencies]

GROSS DOMESTIC PRODUCT (GDP)

The gross domestic product (GDP) is defined as the gross expenditure on the final uses of the domestic supply of goods and services valued at purchasers values less imports of goods and services. Comparisons of gross domestic products are arguably best based on purchasing power parities (PPP) and not on market exchange rates. [Source: OECD. Society at a glance, 2001]

GROUP PURCHASING

Formation of an alliance of several purchasers to negotiate product price based on increased volume. This includes bulk procurement through a tender system, at a national or regional level. [Source: Global Conference on the Future of Hospital Pharmacy]

HEALTH EXPENDITURE (HE, TOTAL HEALTH EXPENDITURE, THE)

Health expenditure is defined as the sum of expenditure on activities that – through application of medical, paramedical, and nursing knowledge and technology – has the goals of: - Promoting health and preventing disease; - Curing illness and reducing premature mortality; - Caring for persons affected by chronic illness who require nursing care; - Caring for persons with health-related impairments, disability, and handicaps who require nursing care; - Assisting patients to die with dignity; - Providing and administering public health; - Providing and administering health programmes, health insurance and other funding arrangements. Health expenditure includes expenditure on: Personal health (curative care, rehabilitative care, long term nursing care, ancillary services to health care, medical goods dispensed to out-patients) and expenditure on Collective health (prevention and public health, administration and insurance). Health expenditure can be separated in: Public expenditure: health expenditure incurred by public funds (state, regional and local government bodies and social security schemes). Private expenditure: privately funded part of total health expenditure. Private sources of funds include out-of-pocket payments (both over-the-counter and cost-sharing), private insurance programmes, charities and occupational health care. [Source: OECD. A System of Health Accounts]

HEALTH TECHNOLOGY

Health technologies include medicines, medical devices such as artificial hip joints, diagnostic techniques, surgical procedures, health promotion activities (e.g. the role of diet versus medicines in disease management) and other therapeutic interventions. [Source: NICE Glossary]

HEALTH TECHNOLOGY ASSESSMENT (HTA)

Health technology is the application of scientific knowledge in health care and prevention. Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. [Source: EUnetHTA]

HIGH-COST PATIENT

A patient whose condition requires large financial expenditures or significant human and technological resources

HOSPITAL PHARMACY

Hospital pharmacy is the health care service, which comprises the art, practice, and profession of choosing, preparing, storing, compounding, and dispensing pharmaceuticals and medical devices, advising health care professionals and patients on their safe, effective and efficient use. Hospital pharmacy is a specialised field of pharmacy which forms an integrated part of patient health care in a health facility. Hospital pharmacy is the profession that strives to continuously maintain and

improve the medication management and pharmaceutical care of patients to the highest standards in a hospital setting. [Source: European Association of Hospital Pharmacists]

HOSPITAL PRICE (AVERAGE SELLING PRICE TO HOSPITALS)

The price or amount paid by a hospital (or hospital pharmacy) in order to take delivery of certain unit of medicines. Often the hospital price corresponds to the pharmacy purchasing price. It may or may not include VAT.

HOSPITAL-ONLY MEDICINES (HOM)

Medicines that may only be administered in hospitals [Source: PPRI Glossary]

INFORMAL PAYMENTS

Informal payments are payments to health care professionals in cash or in kind made outside official remuneration for these services by third party payers. They are usually provided by patients.

INTERNAL PRICE REFERENCING

The practice of using the price(s) of identical medicines (ATC 5 level) or similar products (ATC 4 level) or even with therapeutic equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country. [Source: adapted from PPRI Glossary]

LIST PRICE

The prices that purchasers display as the prices at which they are prepared to sell their products and/or regulated by legislation. The prices of products as quoted in the purchaser's price list, catalogue, internet site, advertisements, in a national price list/formulary etc. They are not necessarily actual transaction prices. Depending on the country and/or the product, they may or may not include delivery and installation costs, VAT and other indirect taxes on products, discounts, surcharges and rebates, invoiced service charges and voluntary gratuities. Certain pharmaceutical transactions, such as setting payment rates to pharmacies, may be based on list prices [Source: EUROSTAT-OECD. Methodological manual on purchasing power parities (PPPs)]

MANAGED ENTRY AGREEMENTS

An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize their effective use, or limit their budget impact. [Source: Klemp, M Frønsdal KB, Facey K. What principles should govern the use of Managed Entry Agreements? International Journal of Technology Assessment in Health Care. 2011 Jan;27(1):77-83.] Types of managed entry agreements: • Access with evidence development (AED) • Conditional coverage • Coverage with evidence development (CED) • Patient access scheme (PAS) • Performance based agreement • Performance based health outcome reimbursement schemes • Performance-linked reimbursement • Price volume agreements • Risk sharing schemes.

MARGIN (DISTRIBUTION MARGIN)

The percentage margin is the percentage of the selling price that is profit. The wholesale margin is the gross profit of wholesalers, expressed as a percentage of the wholesale price. The pharmacy

margin is the gross profit of pharmacies expressed as a percentage of the pharmacy retail price. [Source: adapted from PPRI Glossary]

MAXIMUM PRICE

This term is used in a different way in different countries: e.g. in some countries it is the maximum amount which is reimbursed (cf. reference price system), in others it is the maximum share that is refunded by third party payers expressed as percentage of the reimbursement basis. [Source: PPRI Glossary]

NEGATIVE LIST

List of medicines which cannot be prescribed at the expense of the third party payer [Source: PPRI Glossary

ORDER ENTRY

Process by which a medication order is reviewed and processed in preparation for dispensing; may include manual or electronic processes [Source: Global Conference on the Future of Hospital Pharmacy]

OUT-OF POCKET MAXIMUM (ANNUAL CEILING)

The maximum amount (e.g. a certain percentage of income) that an insured person has to pay for all covered health care services for a defined period (often a year) [Source: PPRI Glossary]

OUT-OF POCKET PAYMENTS (OPP)

Payments made by a health care consumer that are not reimbursed by a third party payer. They include cost-sharing and informal payments to health care providers. Cost-sharing: a provision of health insurance or third party payment that requires the individual who is covered to pay part of the cost of health care received. This is distinct from the payment of a health insurance premium, contribution or tax which is paid whether health care is received or not. Cost-sharing can be in the form of deductibles, co-insurance or co-payments: Deductibles: Amounts required to be paid by the insured under a health insurance contract, before any payment of benefits can take place. Usually expressed in terms of an "annual" amount. Once the deductible is reached, the insurers then pays up to 100% of approved amounts for covered services provided during the remainder of that benefit year. Co-payment: cost-sharing in the form of a fixed amount to be paid for a service. Co-insurance: cost-sharing in the form of a set proportion of the cost of a service. [Source: OECD. A System of Health Accounts]

OVER PRESCRIBING

If a physician prescribes more medicines than comparable physicians (e.g. with similar patient groups or in the same region). The measurement of over prescribing is of particular importance if the doctor has been approved a pharmaceutical budget. [Source: PPRI Glossary]

OVER-THE-COUNTER (OTC) MEDICINE (OVER-THE-COUNTER PRODUCT)

Medicines which may be dispensed without a prescription and which are in some countries available via self-service in pharmacies a/o other retail outlets (e.g. drug stores). Selected OTC products may be reimbursed for certain indications in some countries. [Source: PPRI Glossary]

PARALLEL TRADE

Parallel trade in medicines within the EU is a form of arbitrage in which medicinal products are purchased in one Member State, typically where income levels are relatively low, and sold into other Member States, where income levels and hence prices are higher (although there are exceptions to this, when high prices are being charged in lower income Member States). About 100 parallel trade enterprises are involved, between them employing about 12,000 people (5,000 in the UK), some on a part-time or casual basis. The major companies are represented at EU level by the trade association European Association of Euro-Pharmaceutical Companies (EAEPC), but there are a relatively large number of others holding licences about whom less is known. [Source: Europe Economics. Safe Medicines Through Parallel Trade Contribution to an Impact Assessment]

PATIENT ACCESS SCHEME (PAS)

Patient access schemes are special ways Pharmaceutical companies can propose to enable patients to gain access to high costs drugs medicines. They are proposed by a pharmaceutical company and agreed between the Department of Health and the pharmaceutical company. [Source: Patient Access Scheme Liaison Unit at NICE, adapted] See also: managed entry agreements

PAY-BACK

A cost-containment measure; a financial mechanism that requires manufacturers to refund a part of their revenue to a payer (i.e. third party payer) if sales exceed a previously determined or agreed target-budget [Source: PPRI Glossary]

PERCENTAGE CO-PAYMENT

Cost-sharing in the form of a set proportion of the cost of a service or product. The patient pays a certain fixed proportion of the cost of a service or product, with the third party payer paying the remaining proportion. [Source: PPRI Glossary]

PERFORMANCE BASED AGREEMENT

Agreement between a payer and a pharmaceutical, device or diagnostic manufacturer where the price level and/or revenue received is related to the future performance of the product in either a research or a real world environment. [Source: Towse A, Garrison L. Can't get no satisfaction? Will pay for performance help? Toward an economic framework for understanding performance-based risk sharing agreements for innovative medical products. Pharmacoeconomics 2010, 28:93-102.] See also: managed entry agreements

PERFORMANCE BASED HEALTH OUTCOME REIMBURSEMENT SCHEMES

Schemes between healthcare payers and medical product manufacturers in which the price, level, or nature of reimbursement are tied to future measures of clinical or intermediate endpoints ultimately related to patient quality or quantity of life, appear to have arisen out of a desire to provide patients with access to novel and potentially beneficial healthcare technologies under conditions of significant uncertainty and cost pressures. [Source: Carlson JJ , Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy. 2010 Aug. 96(3):179-90.] See also: managed entry agreements

PERFORMANCE-LINKED REIMBURSEMENT

Schemes where the reimbursement level for covered products is tied to the measure of clinical outcomes in the real world. [Source: Carlson JJ , Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health Policy. 2010 Aug. 96(3):179-90.] See also: managed entry agreements

PHARMACEUTICAL BUDGET

Pharmaceutical budgets are a cost-containment measure of third party payers. The maximum amount of money to be spent on medicines in a specific region or period of time is fixed ex-ante. [Source: PPRI Glossary]

PHARMACEUTICAL EXPENDITURE (PE, TOTAL PHARMACEUTICAL EXPENDITURE, TPE)

It is defined as total expenditure on pharmaceutical and other medical nondurables. This comprises medicinal preparations, branded and generic medicines, drugs, patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives. Other medical nondurables comprise wide range of medical nondurables such as bandages, elastic stockings, incontinence articles, condoms and other mechanical contraceptive devices

PHARMACY PURCHASING PRICE

The price charged by wholesalers to the retailers (usually pharmacies). It includes any wholesale mark-up. [Source: OECD. A System of Health Accounts]

PHARMACY RETAIL PRICE (PRP)

The price charged by retail pharmacist to the general public. It includes any pharmacy mark-up or dispensing fee. It can be a Gross PRP (including VAT) or a Net PRP (excluding VAT). [Source: adapted from PPRI Glossary]

PHARMACY TAX

A tax - other than VAT - levied by a state or city on the pharmacy retail price of an item, collected by the retailer [Source: PPRI Glossary]

POPULATION-GROUP-SPECIFIC REIMBURSEMENT

Specific population groups (e.g. children, old-age pensioners) are eligible for medicines, while others are not. [Source: PPRI Glossary]

POSITIVE LIST (FORMULARY)

List of medicines that may be prescribed at the expense of the third party payer [Source: PPRI Glossary]

PRESCRIPTION ONLY MEDICINES

Products that can be dispensed only on a health professional prescription. Products are subject to medical prescription where they: — are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision, or — are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation, or — are normally prescribed by a doctor to be administered parenterally. — the medicinal product is intended for out-patients but its use may produce very

serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment. [Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

PRICE CAP (PRICE CEILING)

A cost-containment measure which fixes ex-ante the maximum price of medicine, e.g. taking into consideration inflation rates and production cost. Companies are allowed to choose any price below this threshold and in exchange authorities refrain from further control of company data (profit margins, sales etc.). [Source: PPRI Glossary]

PRICE CONTROL

Pricing policies where government authorities set the price of a medicine and/or indirectly influence it (e.g. statutory pricing, price negotiations, public procurement). Contrary to free pricing. The bases on which regulated prices are set vary. These may be on costs, return on investment, mark-ups, etc. [Source: PPRI Glossary and OECD. Glossary of statistical terms]

PRICE CUT

A cost-containment measure where the set price of a medicine is reduced by the authorities.

PRICE FREEZE

A common cost-containment method. The price of a medicine is fixed at a given level, mostly for a predetermined period of time. Price freezes are sometimes based on agreements between pharmaceutical industry and authorities but in most cases it is done by law. [Source: PPRI Glossary]

PRICE NEGOTIATION

A form of pricing procedure, where medicine prices are discussed/negotiated (e.g. between manufacturer and third party payer) [Source: PPRI Glossary]

PRICE NOTIFICATION

A form of pricing procedure where pharmaceutical companies officially inform the authorities about the price of the medicine

PRICE TYPE

The level at which the price of a medicine is set. The following price types exist: ex-factory price, pharmacy purchasing price, pharmacy retail price

PRICE VOLUME AGREEMENTS

Agreements which focus on controlling financial expenditure with pharmaceutical companies refunding over budget situations. [Source: Adamski J. Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers. BMC Health Services Research 2010, 10:153.] See also: managed entry agreements

PRICE-VOLUME AGREEMENT

Like a framework agreement, a volume control tool. The price of a medicine is agreed between public authorities and a manufacturer on the basis of a forecast volume of sales. If the actual sales volume exceeds the forecast, the price of the medicine is usually reviewed downwards. [Source: PPRI Glossary]

PROCUREMENT

The act of purchasing a pharmaceutical by a public authority. [Source: OECD. A System of Health Accounts] Pharmaceutical procurement is a complex process that involves many steps and many stakeholders. It is also conducted within national and institutional policies, rules, regulations, and structures that may hinder or support the overall efficiency of the procurement process. An effective procurement process at any level must ensure that four strategic objectives are achieved: the procurement of the most cost effective medicines in the right qualities, the selection of reliable suppliers of high-quality products, procurement and distribution systems that ensure timely and undisturbed deliveries, processes that ensure the lowest possible total costs. [Source: WHO. Operational principles for good pharmaceutical procurement]

PURCHASER'S PRICE

The amount paid by the purchaser in order to take delivery of a unit of a good or service at the time and place required by the purchaser. It excludes any VAT (or similar deductible tax on products) which the purchaser can deduct from his own VAT liability in respect of VAT invoiced to his customers. It includes supplier's retail and wholesale margins, separately invoiced transport and insurance charges and any VAT (or similar deductible tax on products) which the purchaser cannot deduct from his own VAT liability. In the case of equipment goods it will also include installation costs if applicable. Purchasers' prices are the prices most relevant for decision-making by buyers. [Source: EUROSTAT-OECD. Methodological manual on purchasing power parities (PPPs)] See also: list price

PURCHASING POWER PARITIES (PPP)

Spatial deflators and currency converters, which eliminate the effects of the differences in price levels between countries, thus allowing volume comparisons of Gross Domestic Product (GDP) components and comparisons of price levels. PPPs are calculated in three stages: first for individual products, then for groups of products or basic headings and, finally, for groups of basic headings or aggregates. The PPPs for basic headings are unweight averages of the PPPs for individual products. The PPPs for aggregates are weighted averages of the PPPs for basic headings. The weights used are the expenditure on the basic headings. PPPs at all stages are price relatives. They show how many units of currency A need to be spent in country A to obtain the same volume of a product or a basic heading or an aggregate that X units of currency B purchases in country B. In the case of a single product, the "same volume" means "identical volume". But in the case of the complex assortment of goods and services that make up an aggregate such as GDP, the "same volume" does not mean an "identical basket of goods and services". The composition of the basket will vary between countries according to their economic, social and cultural differences, but each basket will provide equivalent satisfaction or utility. Also referred to as "parity" or "parities". [Source: EUROSTAT-OECD. Methodological manual on purchasing power parities (PPPs)]

RATIONAL USE OF MEDICINES

Rational use of medicines requires that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community." Such a definition covers the good-quality (i.e. proper and appropriate) use of pharmaceuticals by providers and consumers, including adherence to treatment. [Source: WHO. The rational use of medicines]

REBATE

A discount paid to the purchaser after the transaction has occurred. Pharmacies may receive a bulk refund from a wholesaler, based on sales of a particular product or total purchases from that wholesaler over a particular period of time. It does not affect the price the patient pays, but the retailer's profits will be higher. [Source: EUROSTAT-OECD. Methodological manual on purchasing power parities (PPPs)]

REFERENCE PRICE SYSTEM

The third party payer determines a maximum price (= reference price) to be reimbursed for certain medicines. On buying a medicine for which a fixed price / amount (~ the so-called reimbursement price) has been determined, the insured person must pay the difference between the fixed price / amount and the actual pharmacy retail price of the medicine in question, in addition to any fixed co-payment or percentage co-payment rates. Usually the reference price is the same for all medicines in a given ATC 4 level and/or ATC 5 level group. [Source: PPRI Glossary]

REIMBURSEMENT

Reimbursement is the percentage of the reimbursement price (for a service or a medicine) which a third party payer pays. So 100% reimbursement means that the third party payer covers 100% of the reimbursement price / amount of a medicine or service except a possible prescription fee

REIMBURSEMENT CATEGORY (REIMBURSEMENT GROUP)

Medicines eligible for reimbursement are often grouped according to selected characteristics, e.g. route of administration (oral, etc.), main indication (oncology, paediatric, etc.), ATC level, classification (hospital-only, etc.). In many countries different reimbursement rates are determined for different reimbursement categories. [Source: PPRI Glossary]

REIMBURSEMENT MARKET

The reimbursement market is the sub-market in which a third party payer reimburses medicines.

REIMBURSEMENT PRICE

This price is the basis for reimbursement of medicines in a health care system, i.e. the maximum amount paid for by a third party payer. The reimbursed amount can either be the full reimbursement price (like e.g. Austria) or a percentage share of the reimbursement price (e.g. in Denmark). In a reference price system the reimbursement price is lower than the full price of the medicine, leaving the patient to pay the difference privately (or through complementary voluntary health insurance). [Source: PPRI Glossary]

REIMBURSEMENT RATE

The percentage share of the price of a medicine or medicinal service, which is reimbursed/subsidised by a third party payer. The difference to the full price of the medicine or medicinal service is paid by the patients. [Source: PPRI Glossary]

REIMBURSEMENT SCHEME

The reimbursement system which covers the majority of residents in a country, in some countries also referred to as "general" reimbursement. [Source: PPRI Glossary]

RETAILER (DISPENSARY)

A company that sells goods to consumers. In the pharmaceutical sector, the retailer is the pharmacy or any other dispensary of medicines. Umbrella term for facilities that dispense/sell medicines (POM and OTC) to out-patients, e.g. community pharmacies, POM dispensaries, dispensing doctors, hospital pharmacies, pharmacy outlets, medicine chests, drugstores, supermarkets etc. In most countries the dispensation of medicines is regulated by law, e.g. stating that supermarkets or drug stores may only sell a limited range of OTC. [Source: WHO and HAI. Measuring medicine prices, availability, affordability and price components and PPRI Glossary]

RISK SHARING SCHEMES

Agreements concluded by payers and pharmaceutical companies to diminish the impact on the payer's budget of new and existing medicines brought about by either the uncertainty of the value of the medicine and/or the need to work within finite budgets. [Source: Adamski J. Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers. BMC Health Services Research 2010, 10:153.] See also: managed entry agreements A contract between two parties who agree to engage in a transaction in which there are uncertainties regardless concerning its final value. Nevertheless, one party, the company, has sufficient confidence in its claims of either effectiveness or efficiency that it is ready to accept a reward or a penalty depending on the observed performance of its product. [Source: de Pourville G.Risk-sharing arrangements for innovative drugs. A new solution to old problems. Eur J Health Econ 2006, 7:155-7.] See also: managed entry agreements

RISK-BENEFIT BALANCE

An evaluation of the positive therapeutic effects of the medicinal product in relation to its risks (any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health and any risk of undesirable effects on the environment.) [Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use]

RISK-SHARING AGREEMENT

An agreement between public authorities and one manufacturer which links the price of a medicine to a defined risk. The risk can be a risk of inappropriate use (over prescribing compared to targeted population or prescription of inappropriate dosages) or can be related to the cost-effectiveness claimed by the manufacturer. [Source: PPRI Glossary]

SICKNESS FUND (SOCIAL INSURANCE INSTITUTION)

A single social health insurance institution. In some countries there are several sickness funds operating (Austria) or even competing each other (Germany). Some sickness funds are operating on a regional basis whereas others are limited to specific professional groups like farmers or self-employed persons. [Source: PPRI Glossary]

SOCIAL HEALTH INSURANCE (SHI)

Social health insurance is a type of health care provision, often funded through insurance contributions by employers and employees as well as state subsidies. In many countries there are obligatory schemes for (employed) persons whose income does not exceed a certain amount/limit (= insurance obligation) in place. Social health insurance is often organised in different sickness funds - in some countries allowing the patient to select a sickness fund (Germany) whereas in

others the membership is determined mandatory, e.g. depending on the type of occupation (e.g. Poland, Austria). In some social health insurance countries persons with higher income as well as self-employed persons may opt for substitutive private health insurance. In addition to social health insurance in some countries voluntary health insurance, covering e.g. out-of pocket payments or allowing for free choice of doctors, is very popular. [Source: PPRI Glossary]

STATUTORY PRICING

Pricing system, where medicine prices are set on a regulatory basis (e.g. law, enactment, decree) [Source: PPRI Glossary]

TENDER

Any formal and competitive procurement procedure through which tenders/offers are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous. [Source: African Development Bank Group – Glossary of procurement terms] See also: procurement methods

THERAPEUTIC BENEFIT (THERAPEUTIC VALUE)

The effect conveyed on a patient following administration of a pharmaceutical which restores, corrects or modifies a physiological function(s) for that patient. [Source: PPRI Glossary]

THERAPEUTIC REFERENCING

The practice of using the price(s) of similar products (ATC 4 level) or with therapeutic equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country. [Source: adapted from PPRI Glossary]

THIRD PARTY PAYER (PAYER, INSURER, PURCHASER)

Public or private organisation that pays or insures health or medical expenses on behalf of beneficiaries or recipients. Recipients pay a premium for this coverage in all private and some public programs of social insurance, while the system is supported by general taxation in the National Health Services. The payer then pays bills on behalf of covered individuals, which are called third party payments. They are distinguished by the separation among the individual receiving the service (the first party), the individual or institution providing it (the second party), and the organisation paying for it (third party).

TRANSPARENCY DIRECTIVE

Directive 89/105/EEC (of 21 December 1988) relates to the transparency of measures regulating the pricing of medicines for human use and their inclusion in the scope of national third party payers. [Source: PPRI Glossary]

VALUE ADDED TAX (VAT)

A sales-tax on products collected in stages by enterprises. It is a wide-ranging tax usually designed to cover most or all goods and services, including pharmaceutical products. The VAT rate of pharmaceuticals in the EU is often lower than the standard VAT rate. Deductible VAT is the value added tax payable on purchases of goods and services intended for intermediate consumption, gross fixed capital formation or for resale which producers are permitted to deduct from their own

VAT liability to the government in respect of VAT invoiced to their customers. Non-deductible VAT is the value added tax payable by purchasers that is not deductible from their own VAT liability, if any. [Source: adapted from EUROSTAT-OECD. Methodological manual on purchasing power parities (PPPs)]

VOLUME CONTROL

Measures applied by authorities (e.g. state, third party payers) or actors (e.g. hospitals) in order to affect and limit the amount of medicines prescribed and/or dispensed (e.g. pharmaceutical budgets).

VOLUNTARY HEALTH INSURANCE (VHI)

Health insurance that is taken up and paid for at the discretion of individuals or employers on behalf of individuals. VHI can be offered by public or quasi-public bodies and by for-profit (commercial) and non-profit private organisations. In the European context, VHI can be classified in three different ways: Substitutive Private Health Insurance provides cover that would otherwise be available provided by state. In a social health insurance system people who have no insurance obligation (in some countries e.g. self-employed) may opt for substitutive private health Insurance. Complementary VHI provides cover for services excluded or not fully covered by the state (e.g. dental care), including cover for co-payments imposed by the statutory health care system. Supplementary VHI provides cover for faster access and increased consumer choice. [Source: PPRI Glossary]

WHOLESALE

All activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in the Member State concerned. Wholesalers have a "public service obligation": the obligation to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question. [Source: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use] Full-liner: The activity of pharmaceutical full-line wholesaling consists of the purchase and sale, warehousing, order preparation and delivery / distribution of the full assortment of medicines (in range and depth) on a defined market) Short-liner: The activity of pharmaceutical short-line wholesaling consists of the delivery and distribution of a selected assortment of medicines on a defined market. [Source: adapted from GIRP website]

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