



PPRI Report – Executive Summary

PPRI Secretariat

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Executive Summary

In the European Union, pricing and reimbursement of pharmaceuticals is primarily a national competence, and, as a result, 27 different pharmaceutical pricing and reimbursement systems are in place in the enlarged European Union.

The EU Member States have expressed an urgent need for information and data on the pharmaceutical systems in the fellow countries as well as a strong interest in learning about experiences with pricing and reimbursement strategies applied in other countries. Initiatives for overviews and data collections in the last years have often been confronted with problems of incomparable or out-dated information and/or have not exactly met the needs of policy makers.

PPRI network covering 52 institutions from the whole European Union and beyond

Therefore, the PPRI (Pharmaceutical Pricing and Reimbursement Information) project was launched under the framework of the Public Health Programme 2003–2008, Health information and knowledge 2004. PPRI is a research project commissioned by the European Commission, Health and Consumer Protection Directorate-General (DG SANCO) and co-funded by the Austrian Federal Ministry for Health, Family and Youth (BMGFJ).

The overall aim of the PPRI project is to improve information and knowledge on the pharmaceutical systems in the Member States of the enlarged EU, by strengthening the networking of the relevant national authorities and institutions in the field of pharmaceuticals in the EU.

In the initial stages of the project, which started in April 2005, the PPRI project management, consisting of the main partner Gesundheit Österreich GmbH (GÖG), Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen (ÖBIG) / Austrian Health Institute (short: GÖG/ÖBIG) and the associated partner World Health Organisation, Regional Office for Europe (WHO Europe) intended to build a network covering all EU Member States at that time, represented by one relevant authority. In fact, the PPRI network and its benefits for the participating countries became well-known, and in the course of the project several additional institutions joined. By the end of 2007, the PPRI network covered 52 institutions from a total of 31 countries (all EU Member States except Romania, plus Albania, Canada, Norway, Switzerland, and Turkey), of which 27 provided information for the PPRI analysis. The majority of the participating institutions are national authorities, mainly Ministries of Health, Medicines Agencies and third party payers. Additionally, international institutions (European Medicines Agency, OECD, WHO and World Bank) and representatives of related initiatives (e.g., Medicine Evaluation Committee) and projects (e.g., EUROMEDSTAT project, SOGETI Pharmaceutical Indicators project, Andalusian School of Public Health/EASP) joined the network.

Even after the end of the research project, the active communication and exchange of information between the network members continues in e-mail correspondence, responding to questions addressed to the whole group.

Over 20 PPRI Pharma Profiles

The increase in transparency on the pharmaceutical systems and the sharing of experiences was mainly achieved by the exchange of information at network meetings and by the compilation of in-depth country profiles, so-called PPRI Pharma Profiles.

In order to guarantee readability and comparability of the data and information, the PPRI Pharma Profiles follow a uniform, homogenous structure, the PPRI Pharma Profile Template in .dot format. For the development of the PPRI Pharma Profile Template, the outcome of a large-scale needs assessment process, involving 101 national stakeholders and 14 European and international institutions, was taken into consideration.

The PPRI Pharma Profiles were written by PPRI participants, who, as national officials and experts, are directly involved in the decision-making and administrative process of pharmaceutical pricing and/or reimbursement in their country. The reports were extensively reviewed by an editorial team, including researchers with country specific know-how.

At the end of the PPRI research project, 22 PPRI Pharma Profiles, offering in-depth information on the pharmaceutical pricing and reimbursement systems as of 2006/2007 (approximately 60 pages each), have been produced. The PPRI Pharma Profiles are included in Annex I of this PPRI Report and have been made accessible through the PPRI website (<http://ppri.oebig.at> → Publications).

Enhancing a common terminology via the PPRI Glossary

During the development of the PPRI Pharma Profile Template, misunderstandings and differences in the interpretation of technical terms between the national PPRI participants, who are all experts in their field, have become evident. Therefore, an additional deliverable, the PPRI Glossary covering key terminology regarding pharmaceutical pricing and reimbursement, was developed and considered as binding for the authors of the PPRI Pharma Profiles.

Today, the PPRI Glossary, which is based on existing glossaries (e.g., of OECD and of WHO) and which has been regularly modified and enlarged, is intended to serve as a tool for promoting a common terminology in the field of pharmaceutical systems in the EU.

The PPRI Glossary is accessible through the PPRI website (<http://ppri.oebig.at> → Glossary).

Set of core PPRI indicators and comparative analysis

In order to compare the information on pharmaceutical systems, indicators were developed. The final set of PPRI indicators, which was approved by the PPRI group, contains 21 indicators for a comparison of both “hard” quantitative figures like pharmaceutical expenditure and prescriptions as well as qualitative information on pricing and reimbursement.

These indicators, as well as their methodological background, are discussed in a paper called “Set of Core PPRI Indicators”, which is available on the PPRI website and in Annex II of the report.

Table I: PPRI Executive Summary – Set of core PPRI indicators and results

No.	Indicator	Results	Year(s) ¹
Background			
1	Population age structure	Around 67% of the population in the PPRI countries is aged between 14–65 years. Concerning the elderly population above 65 years, there are differences between the countries, but a pattern regarding the group of the EU-15 (16%) and the EU-10 (15%) cannot be observed.	2005
2	Gross domestic product per capita in € PPPa	The average gross domestic product (GDP) per capita in the EU-25 amounts to € PPPa 22,800.-, with a huge difference between the EU-15 (average: € PPPa 27,900.-) and the EU-10 (average: € PPPa 14,200.-).	2004/2005
3	Public/private funding of health expenditure	The funding shares of health expenditure differ between the PPRI countries, varying from a public share of about 90% in the Netherlands (91.7%) and UK (87.4%) to about 50% in Latvia (52.7%) and Cyprus (47.6%).	2005
4	Total health expenditure per capita in € PPPa	In the EU-25, on average € PPPa 1,900.- per inhabitant were spent on health. Considerable differences are observed between the EU-15 (average: € PPPa 2,450.-) and the EU-10 (average: € PPPa 965.-).	2004/2005
Pharmaceutical system			
5	Regulatory framework for pharmaceutical policy	Pricing and reimbursement is a competence of the EU Member States. Complex statutory frameworks, usually including a Medicines Act, a Price Act and/or a Health Insurance Law, are in place in 26 of the 27 PPRI countries (exception: Ireland – agreements instead).	2006/2007
6	Key data on pharmaceutical industry	The new EU Member States in Central and Eastern Europe are still characterised by a strong locally-producing (generics) industry. Bio-tech industry is mainly situated in old EU Member States.	2006/2007
7	Inhabitants per POM dispensary	The ratio of inhabitants per POM dispensary differs between the new EU Member States (average: 3,260 inhabitants per POM dispensary) and the old Member States (average: 4,950 inhabitants per POM dispensary): Besides community pharmacies, POM dispensaries are mainly self-dispensing doctors (e.g., in Austria, Hungary, Ireland, Netherlands) or hospital pharmacies serving outpatients (e.g., in Norway).	2005
8	Total pharmaceutical expenditure as percentage of total health expenditure	In the EU-25, on average 19.6% of health expenditure is spent on pharmaceuticals. The new Member States (EU-10 average: 25.5%) spend comparably more of the health budget on pharmaceuticals than the old Member States (EU-15 average: 16.1%).	2005
9	Public/private funding of pharmaceutical expenditure	The ratios of public/private funding of pharmaceutical expenditure differ between the PPRI countries. The shares of publicly funded pharmaceutical expenditure vary from 90% or more in the Netherlands (98%, however only referring to the POM market) and UK (90%) to about 40% in Lithuania (43.0%) and Poland (35.0%).	2005

No.	Indicator	Results	Year(s) ¹
Pricing			
10	Pricing policies at manufacturer level	<p>In 24 of the 27 PPRI countries prices are controlled for outpatient pharmaceuticals. In the majority of these countries, price control is limited to pharmaceuticals with reimbursement eligibility (= reimbursable pharmaceuticals), whereas for non-reimbursable pharmaceuticals, which are often OTC products, the manufacturer may freely set the price.</p> <p>The most common price control policy is statutory pricing, where authorities set the price on a regulatory, unilateral basis. In a few PPRI countries pharmaceutical prices are negotiated between the manufacturer (or wholesaler) and the government authority. UK has no direct price control, but the prices of NHS pharmaceuticals are indirectly controlled via a profit control scheme.</p> <p>22 PPRI countries apply external price referencing (international price benchmarking). Another common pricing procedure is the comparison with equivalent or similar products within the same country (internal price referencing).</p>	2007
11	Pricing policies at distribution level	<p>21 of the 27 PPRI countries have statutory wholesale mark-ups, in the form of either a linear mark-up or a regressive scheme; six countries maintain no statutory wholesale mark-up.</p> <p>Pharmacy margins are regulated in all 27 PPRI countries. Usually, they take the form of a regressive scheme or a linear mark-up, but they may also be a fixed fee (e.g., Netherlands) or a fee-for-service remuneration (Slovenia, UK).</p> <p>In several PPRI countries statutory wholesale and pharmacy mark-ups cover all pharmaceuticals whereas in others OTC are excluded from regulations.</p>	2007
12	Taxes on pharmaceuticals	<p>In most PPRI countries the value-added tax rate for pharmaceuticals is lower than the standard VAT rate. A few countries have split VAT rates on pharmaceuticals, with a lower or even 0% rate for a specific group of pharmaceuticals. Additional taxes include pharmacy fees (e.g., Finland).</p>	2007
Reimbursement			
13	Positive/negative list	<p>In all PPRI countries, reimbursement lists exist. Positive lists are in place in 24 PPRI countries. Three countries have introduced a negative list, and two countries provide the legal basis, but have not implemented the measure yet.</p>	2006/2007
14	Reference price system	<p>18 of the 27 PPRI countries have introduced a reference price system (in one country it still has to be implemented).</p>	2006/2007
15	Mechanisms for vulnerable groups	<p>Nearly all PPRI countries have introduced mechanisms to protect vulnerable groups from excessive out-of-pocket payments (e.g., a 100% reimbursement, a higher reimbursement rate than the standard rate, exemptions from prescription fees, limit on the co-payment amount).</p>	2006/2007

No.	Indicator	Results	Year(s) ¹
Rational use of pharmaceuticals			
16	Share of generics in volume and value as percentage of outpatient market	The average generics share in volume is 50% or more in EU-15 countries with a history of generic promotion (e.g., Germany, Netherlands) as well as in some of the new Member States with a tradition of generics production. In other old Member States which started later with generic promotion, the share in volume is below 20%. Expressed in value, the generics shares are usually lower, ranging from around 20%–30% in the “generics countries” and about 10% in the others, which is due to the relatively low prices of generics.	2005/2006
17	Prescription guidelines	The majority of the PPRI countries have introduced prescription guidelines, which are mostly indicative and usually refer to the outpatient sector.	2006/2007
18	Mandatory guidelines for decision makers / role of pharmaco-economics	De facto all PPRI countries consider pharmaco-economic aspects in pricing and reimbursement decisions. The extent of the application of pharmaco-economics differs between the countries.	2006/2007
19	Information to patients	Within the EU, advertising to the general public is not allowed for POM. Currently, under the Pharmaceutical Forum process, a Working Group is dedicated to the issue of patient information.	2006/2007
20	Monitoring of consumption	Several PPRI countries have established consumption monitoring systems. The data are usually provided by wholesalers and/or pharmacies. Consumption monitoring is, in general, only done for the outpatient market, and is often limited to the reimbursement segment.	2006/2007
21	Number of prescriptions per capita in volume and value	In the PPRI countries (where data are available), on average 11.8 prescriptions are delivered per inhabitant per year. The average value per prescription is € 21.30, amounting to an average annual expenditure for prescriptions of € 217.- per capita.	2006

EU = European Union; EU-10 = new EU Member States having acceded to the EU in May 2004; EU-15: old EU Member States, having acceded before May 2004; EU-25 = EU Member States having acceded before January 2007; NHS = National Health Service; OTC = Over-the-Counter; POM = prescription-only medicines; POM dispensaries = retail facilities that are allowed to sell prescription-only medicines to outpatients, for instance pharmacies; PPPa = Purchasing Power Parities, PPRI countries = 27 countries which have contributed to the PPRI comparative analysis, these are EU-25 Member States except Spain, plus Bulgaria, Norway and Turkey, VAT = value added tax

¹ This is the year(s) generally referred to. But in some cases earlier years were taken as latest available year.

Sources: Set of Core PPRI Indicators, PPRI Report, PPRI at a Glance, cf. PPRI website:
<http://ppri.oebig.at> → Publications

Based on the indicators, a comparative analysis was undertaken for, in total, 27 countries (short: PPRI countries), covering the current 27 EU Member States except Romania and Spain, plus Norway and Turkey. A brief overview on the pharmaceutical system in Canada, which is a PPRI participating country, was also included. The main information sources for the comparative analysis were the PPRI Pharma Profiles as well as contributions provided by those participants who had not submitted or finalised a Profile at the time of the analysis. Data and information to be presented in the comparative analysis have been carefully reviewed by the PPRI participants.

The comparative analysis is a major part of this PPRI Report and is displayed in chapter 3, which provides, moreover, country specific examples of pharmaceutical policies. The overview table “PPRI at a Glance” (cf. end of chapter 3) sums up the results of the comparative analysis per core PPRI indicator.

In the following paragraphs, the major outcomes with regard to pharmaceutical pricing and reimbursement in the outpatient sector of the 27 PPRI countries as of 2006/2007 will be presented. The results addressing all PPRI core indicators, beyond pricing and reimbursement, are listed in a concise manner in Table I.

Pharmaceutical pricing policies in the PPRI countries

At the manufacturer level, pharmaceutical prices are controlled in 24 of the 27 PPRI countries. No price control at manufacturer level is exercised in Denmark, Germany and Malta. The prices of reimbursable pharmaceuticals in Denmark and Germany are however indirectly influenced through the reimbursement system.

In most PPRI countries (e.g., France, Hungary, Slovakia), price control only pertains to pharmaceuticals which are eligible for reimbursement, whereas there is free pricing for non-reimbursable pharmaceuticals, which are often OTC (Over-the-Counter) products.

The most common pricing policy is statutory pricing, where the authorities set the price on a regulatory basis. In a few PPRI countries (e.g., Italy, France) pharmaceutical prices are negotiated between the manufacturer (or wholesaler) and the government authority. A special case is the UK, where there is no direct price control, but where the prices of NHS (National Health Service) pharmaceuticals are indirectly contained via the PPRS (Pharmaceutical Price Regulation Scheme), which allows companies a pre-determined maximum profit on their product portfolio.

Table II: PPRI Executive Summary – Pharmaceutical pricing in the outpatient sector in the PPRI countries, 2006/2007

C.	Price control	Pricing policy	Method.		Statutory mark-up		VAT on ph.
			Ext.	Int.	Wholesale	Pharmacy	
AT	Reimb. ph.	Statutory pricing	Y	Y	Y, all ph.	Y, all ph.	20%
BE	All ph.	Statutory pricing	Y	Y	Y, all ph.	Y, all ph.	6%
BG	All ph.	Statutory pricing	Y	Y	Y, POM	Y, POM	20%
CY	All ph.	Statutory pricing	Y	N	N, imported ¹	Y, all ph.	0% ¹
CZ	All ph.	Statutory pricing	Y	Y	Y, all ph.	Y, all ph.	5%
DE	No control	Price notification	–	– ²	Y, POM and reimb. OTC	Y, POM and reimb. OTC	16% ('06) 19% ('07)
DK	No control	Price notification	–	– ²	N	Y, all but some OTC ³	25%
EE	Reimb. ph.	Statutory pricing after negotiations	Y	Y	Y, all ph.	Y, all ph.	5%
EL	All ph.	Statutory pricing	Y	Y	Y, all ph.	Y, all ph.	9%

C.	Price control	Pricing policy	Method.		Statutory mark-up		VAT on ph.
			Ext.	Int.	Wholesale	Pharmacy	
FI	Reimb. ph.	Statutory pricing (pricing & reimbursement is combined)	Y	Y	N	Y, all ph. ⁴	8%
FR	Reimb. ph.	Price negotiations	Y	Y	Y, reimb. ph.	Y, reimb. ph.	2.1%/5.5%
HU	Reimb. ph.	Price negotiations, statutory pricing criteria	Y	Y	Y, all ph.	Y, all ph.	5%
IE	Reimb. ph.	Pricing based on agreement between state and industry	Y	N	Y, reimb. ph. (not statutory)	Y, reimb. ph. (not statutory)	0% / 21%
IT	Reimb. ph.	Price negotiations	Y	Y	Y, reimb. ph.	Y, reimb. ph.	10%
LT	Reimb. ph.	Statutory pricing	Y	Y	Y, reimb. ph.	Y, reimb. ph.	5%
LU	All ph.	Statutory pricing	Y	N	Y, all ph.	Y, all ph.	3%
LV	Reimb. ph.	Statutory pricing after negotiations	Y	Y	Y, all ph.	Y, all ph.	5%
MT	No control	–	–	–	Y, all ph.	Y, all ph.	0%
NL	POM	Statutory pricing	Y	(N) ²	N	Y, POM	6%
PL	Reimb. ph.	Statutory pricing after negotiations	Y	Y	Y, reimb. ph.	Y, reimb. ph.	7%
PT	POM	Statutory pricing	Y	Y	Y, POM	Y, POM	5%
SE	Reimb. ph.	Statutory pricing (pricing & reimbursement is combined)	N	(N) ⁵	N	Y, all ph.	0% / 25%
SI	Reimb. ph.	Statutory pricing	Y	Y	N (2006) Y, all ph. (2007)	Y, all ph.	8.5%
SK	Reimb. ph.	Statutory pricing	Y	Y	Y, all ph.	Y, all ph.	19% ('06) 10% ('07)
UK	NHS ph.	Indirect price control through profit control (PPRS)	N	Y	Y, reimb. ph.	Y, reimb. ph.	0% / 17.5%
NO	POM	Statutory pricing	Y	Y	N	Y, all ph.	25%
TR	All ph.	Statutory pricing	Y	Y	Y, all ph.	Y, all ph.	8%

C. = Countries, Ext. = external price referencing (international price benchmarking), int. = internal pricing referencing, method. = methodology, N = no, NHS = National Health Service, ph. = pharmaceuticals, OTC = Over-the-Counter, POM = prescription-only medicines, PPRS = Pharmaceutical Price Regulation Scheme, reimb. = reimbursable, VAT = value-added tax, Y = yes

¹ No statutory wholesale mark-up for imported pharmaceuticals, and a statutory linear wholesale mark-up for locally-produced pharmaceuticals. No VAT rate, except on diagnostic agents (VAT of 15%)

² Germany, Denmark and the Netherlands have a reference price system, which is not applied as a tool for price regulation, but as method to set reimbursement limits

³ OTC products available for sale at other dispensaries than pharmacies are exempted

⁴ For all pharmaceuticals except NRT (nicotine replacement therapy) products if they can be sold outside the pharmacy

⁵ Within the system for generic substitution substitutable pharmaceuticals are grouped together. A price which is lower or the same as the highest price within a substitution group is accepted without further investigation.

Sources: Set of Core PPRI Indicators, PPRI Report, PPRI at a Glance, cf. PPRI website:
<http://ppri.oebig.at> → Publications

22 of the 27 PPRI countries apply external price referencing (international price comparisons or price benchmarking), comparing their prices to those of the same products in other countries as a basis for their own pricing or reimbursement decisions. The reference countries are normally chosen due to their geo-strategic position (neighbouring countries, historic links) and to the price level (either a mix of high and low price countries or a focus on low price countries). Most PPRI countries use a basket with a maximum of five to seven reference countries.

Another commonly applied comparison tool is internal price referencing, comparing the prices of products to those of their equivalents (e.g., generics) and/or similar products within the same country and using this as basis for a pricing or reimbursement decision.

In 16 of the 27 PPRI countries (year 2007) the controlled price type is the ex-factory price (manufacturer price). Nine PPRI countries (year 2007) fix pharmaceutical prices at the pharmacy purchasing price (wholesale) level, whereas two countries determine the pharmacy retail price.

At distribution level, 21 PPRI countries (year 2007) have statutory wholesale mark-ups, either in form of a linear mark-up or a regressive scheme. Cyprus (for imported pharmaceuticals), Denmark, Finland, Netherlands, Norway and Sweden apply no statutory wholesale mark-up, and since the controlled price type is the pharmacy purchasing price, the ex-factory price is an outcome of negotiations between the manufacturer and the wholesaler.

Pharmacy margins are regulated in all 27 PPRI countries. Usually, they obtain the form of a regressive scheme or a linear mark-up. Pharmacy remuneration occurs via a fixed fee per prescription in the Netherlands and in Germany (together with a linear mark-up), and pharmacists in Slovenia and the UK receive a fee-for-service remuneration.

In several PPRI countries, statutory wholesale and pharmacy mark-ups cover all pharmaceuticals. A few countries apply the distribution regulation only to reimbursable pharmaceuticals (e.g., Lithuania, Poland) or to prescription-only medicines (e.g., Bulgaria, Portugal).

In most PPRI countries the value-added tax (VAT) rate for pharmaceuticals is lower than the standard VAT rate. Exceptions are Austria, Bulgaria, Denmark, Germany and Norway, where the VAT rate on pharmaceuticals is the same as for other goods. A few countries have split VAT rates, with no VAT or a lower rate for a specific group of pharmaceuticals (e.g., for POM in Sweden or NHS pharmaceuticals in the UK).

Table II provides country specific information on core pricing-related PPRI indicators.

Reimbursement strategies in the PPRI countries

In most PPRI countries the eligibility for reimbursement and the reimbursement rates depend on the product. A pharmaceutical may be considered reimbursable (i.e. the purchasing cost are fully or partially covered by a third party payer) or non-reimbursable, and different reimbursement rates may apply for different products. This product-specific approach (i.e. eligibi-

lity for reimbursement is determined on product level) is applied in 18 of the PPRI countries (e.g., Czech Republic, Germany, Greece, Italy, Luxembourg, Slovenia, and Slovakia).

Further eligibility criteria can be the disease (e.g., in the Baltic States) and the population groups concerned (e.g., Ireland, Turkey). In Denmark and Sweden, reimbursement coverage increases with rising pharmaceutical consumption (i.e. pharmaceutical expenditure within a year). This implies that in the beginning the patients have to pay 100% of their medication themselves, but after they have passed respective spending thresholds their medication is reimbursed at rising rates.

In most PPRI countries, not all reimbursable pharmaceuticals are fully reimbursed, since some products are partially reimbursed at specific percentage rates. In seven of the 27 PPRI countries (e.g., Austria, Italy) reimbursement means a coverage of 100% (no percentage reimbursement rates), irrespective of any further out-of pocket payments, such as prescription fees or co-payments due to a reference price system.

In all PPRI countries, reimbursement lists are in place. Positive lists, which include pharmaceuticals that may be prescribed at the expense of a third party payer, are applied in 24 PPRI countries (exceptions: Germany, Greece and UK). Three countries (Germany, Hungary, and UK) use negative lists, and two further countries (Greece, Finland) have provided the legal basis for the introduction of a negative list, but have not implemented the measure yet.

Table III provides country specific information on the reimbursement-related PPRI indicators.

Table III: PPRI Executive Summary – Pharmaceutical reimbursement in the outpatient sector in the PPRI countries, 2006/2007

C.	Lists		Reference price system	Out-of pocket payment			Key mechanisms for vulnerable groups
	Pos.	Neg.		Fixed	%	Deduct.	
AT	Y	N	N	Y	N	N	Exemptions from prescription fee
BE	Y	N	Y, since 2001	N	Y	N	Reduced co-payment rates, annual co-payment ceiling
BG	Y	N	Y	N	Y	N	N.a.
CY	Y	N	N	N	Y	N	Access to health care of the public sector
CZ	Y	N	Y, since 1995	N	Y	N	-
DE	N	Y	Y, since 1989	N	Y ¹	N	Exemptions from co-payment, annual co-payment ceiling
DK	Y	N	Y, since 1993	N	Y	Y	Exemptions from co-payment, annual co-payment ceiling
EE	Y	N	Y, since 2003	Y	Y	N	Reduced co-payment rates
EL	N	(Y) ²	Y, since 2006	N	Y	N	Reduced co-payment rates
FI	Y	(Y) ²	N	Y	Y	N	Annual co-payment ceiling
FR	Y	N	Y, since 2003	N	Y	N	Exemptions from co-payment
HU	Y	Y	Y, since 1991	N	Y	N	Exemptions from co-payment
IE	Y	N	N	N	N	Y	Exemptions from co-payment

C.	Lists		Reference price system	Out-of pocket payment			Key mechanisms for vulnerable groups
	Pos.	Neg.		Fixed	%	Deduct.	
IT	Y	N	Y, since 2001	Y ³	N	N	Exemptions from co-payment
LT	Y	N	Y, since 2003	N	Y	N	Access to a specific positive lists
LU	Y	N	N	N	Y	N	Annual co-payment ceiling
LV	Y	N	Y, since 2005	N	Y	N	N.a.
MT	Y	N	N	N	N	N	Not applicable
NL	Y	N	Y, since 1991	N	N	N	Fiscal arrangements
PL	Y	N	Y, since 1998	Y	Y	N	Reduced co-payment rates
PT	Y	N	Y, since 2003	N	Y	N	Reduced co-payment rates, exemption from co-payment
SE	Y	N	N (it existed from 1993 to 2002)	N	Y	Y	Annual co-payment ceiling
SI	Y	N	Y, since 2003	N	Y	N	Exemptions from co-payment
SK	Y	N	Y, since 1995	Y	Y	N	Annual co-payment ceiling
UK	N	Y	N	Y	N	N	Exemptions from co-payment
NO	Y	N	N	N	Y	N	Annual co-payment ceiling
TR	Y	N	Y, since 2004	N	Y	N	Exemptions from co-payment

C. = countries, Deduct. = deductible, Neg. = negative list, N = no, n.a. = not available, Pos. = positive list, Y = yes, % = percentage co-payment

Definitions: cf. PPRI Glossary, <http://ppri.oebig.at> → Glossary

Out-of pocket payments: The amount a person has to pay for all covered healthcare services for a defined period

Fixed out-of pocket payment, e.g. prescription fee: The patient has to pay a fixed fee for each prescription item dispensed at the expense of a third party payer, i.e. a form of a fixed co-payment

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 social health insurance / national health service paying the remaining proportion.

Deductible: Out-of pocket payments in the form of a fixed amount which must be paid for a service or of total cost incurred over a defined period by a covered person beforehand, then all or a percentage of the rest of the cost is covered by a social health insurance / national health service.

¹ Prescription fee as percentage of price, with absolute minimum and maximum

² Legal basis for negative list, not yet implemented

³ Prescription fees in some regions

Sources: Set of Core PPRI Indicators, PPRI Report, PPRI at a Glance, cf. PPRI website: <http://ppri.oebig.at> → Publications

A reference price system is in place in 18 PPRI countries. Ten of these countries (e.g., Denmark, Italy, Portugal) base their reference groups (i.e. groups of interchangeable pharmaceuticals) on substance (ATC 5) level, whereas seven other countries (among those, Czech Republic, Germany, the Netherlands) also consider therapeutically similar pharmaceuticals as interchangeable (ATC 4 level or even broader therapeutic groups). Greece, which introduced the reference price system in 2006, is still in the process of fine-tuning the methodology used.

On buying a pharmaceutical under a reference price system, the patient has to pay the difference between the reference price (= maximum reimbursement amount) and the actual pharmacy retail price, in addition to any fixed co-payments or percentage co-payment rates.

Further out-of pocket payments are prescription fees (in seven PPRI countries) and deductibles (in three countries). The most common form of out-of pocket payments are percentage co-payments for pharmaceuticals which are partially reimbursed. Percentage co-payments are applied in 21 PPRI countries.

Nearly all PPRI countries have introduced mechanisms to protect vulnerable groups from excessive out-of pocket payments. Specific population groups are granted a 100% reimbursement (e.g., in Hungary, Portugal), a higher reimbursement rate than the standard one (e.g., in Belgium, Estonia) or exemptions from the prescription fee (e.g., in Austria). The total amount of co-payment may be limited (e.g. a maximum co-payment per prescription like in Belgium, or annual ceilings of private expenses on pharmaceuticals and/or on health care in Germany and Luxembourg).

Cost-containment and rational use

In the PPRI project, 27 different pharmaceutical pricing and reimbursement systems have been analysed. Each system has its characteristics resulting from the traditional culture of policy making in a country. Nevertheless, some key instruments which form a pharmaceutical system (e.g., national formularies) are found in virtually all PPRI countries, and specific tools are quite common. For instance, external price referencing has been applied by an increasing number of PPRI countries, and several countries have introduced a reference price system.

In terms of pharmaceutical expenditure expressed in Purchasing Power Parities (PPP), the EU-25 countries spend on average € PPPa 320.- per inhabitant per year (year 2005). There appears to be a difference in spending between the more wealthy EU-15 Member States (average of € PPPa 360.- per capita) and the new Member States (EU-10 average: € PPPa 254.- per inhabitant). The same pattern can be observed regarding health expenditure: The new EU Member States spent on average € PPPa 965.- per inhabitant in 2004, whereas in EU-15 countries the average total health expenditure per inhabitant amounted to about € PPPa 2,450.-. However, the percentage of health expenditure spent on pharmaceuticals tends to be higher in those countries having a lower gross domestic product per inhabitant.

Due to limited financial resources and restricted pharmaceutical budgets, cost-containment has been a necessity for de facto all PPRI countries. The most common pricing related cost-containment measures have been price cuts, margins cuts or changes in the mark-up schemes, and statutory discounts to be granted by manufacturers and/or distribution actors to third party payers. Widely-used measures in the reimbursement segment include modifications of the reimbursement lists (listing and delisting of pharmaceuticals), the launch of systematic reimbursement reviews, and the introduction of reference price systems.

In fact, a few countries (e.g. Sweden) of the EU-15 group have succeeded in keeping the growth in pharmaceutical expenditure at relatively moderate rates of four to five percent annually. These countries have continuously undertaken a range of measures, targeting both at pricing and at reimbursement.

In general, the rationale of reforms in the last years was not limited on cost-containment only, but also aimed at promoting a more rational use of pharmaceuticals, i.e. guaranteeing the correct provision of pharmaceuticals to the individual patient (neither over-supply nor under-supply). The increasing importance of rational use has also had an impact on containing pharmaceutical expenditure, since rational use of pharmaceuticals goes, to a great extent, hand in hand with cost-containment. In particular, a policy of generic promotion appears to be an effective tool for both cost-containment and a more rational use of pharmaceuticals.

The growth in public pharmaceutical expenditure has, in general, been higher than that in private expenditure. In some countries, in particular those with comparably lower growth rates for total pharmaceutical expenditure, the shares of private pharmaceutical expenditure have even decreased in the last decade. On an overall level, two thirds of pharmaceutical expenditure are covered by public payers, but quite considerable differences between the PPRI countries exist, in that wealthier countries tend to have higher shares of public funding.

Challenges

The PPRI analysis has achieved its goal to provide in-depth information on pharmaceutical pricing and reimbursement processes in the outpatient sector of the 27 PPRI countries, and has disclosed gaps in the availability of data, which were classified as core indicators (e.g., the shares of public/private funding of pharmaceutical expenditure). Together with the non-availability of data, major problems of data comparability due to different definitions and counting methods, with regard to key indicators such as pharmaceutical expenditure, the number of issued prescriptions or even the number of pharmaceuticals, have been revealed.

Besides closing the remaining data availability gaps, another challenge for the future is to get a complete picture of the pharmaceutical systems. PPRI has contributed to increasing knowledge on outpatient pharmaceutical systems in Europe, as this was the objective of the project. However, additional attention need to be given to the hospital sector, since the inpatient pharmaceutical service and provision influences the outpatient organisation and funding of pharmaceuticals.

In order to guarantee relevant and valid information, the findings of the PPRI project, in particular the Pharma Profiles, need to be kept up-to-date, as pharmaceutical systems are changing rapidly. The PPRI participants intend to up-date their Pharma Profiles in regular, annual intervals.

Furthermore, it is planned to retain the PPRI network of currently 52 institutions, and the participating countries have expressed their interest to continue sharing information and meeting each other. In fact, in November 2007, after the official end of the PPRI research project, a meeting of the PPRI network took place.